ঔষধ নিয়ন্ত্রণ কমিটির ২৭ফেব্রুয়ারী, ২০২০ তারিখে অনুষ্ঠিত ২৫১ তম সভার কার্যবিবরণী

স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়ের স্বাস্থ্য সেবা বিভাগের সচিব জনাব মোঃ আসাদুল ইসলাম এর সভাপতিত্বে ঔষধ নিয়ন্ত্রণ কমিটির ২৫১ তম সভা বিগত ২৭ফেব্রুয়ারী ২০২০ তারিখ সকাল১০.৩০ ঘটিকায় মন্ত্রণালয়ের সভা কক্ষে অনুষ্ঠিত হয়।

সভায় কমিটির নিম্নবর্ণিত সদস্যগণ উপস্থিত ছিলেন (জেষ্ঠ্যতার ক্রমানুসারে নয়)ঃ

১. মেজর জেনারেল মোঃ মাহবুবুর রহমান, মহাপরিচালক, ঔষধ প্রশাসন অধিদপ্তর।
২. জনাবমোঃ ইসমাইল হোসেন, অতিরিক্ত সচিব, স্বাস্থ্য সেবা বিভাগ, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়, বাংলাদেশ সচিবালয়, ঢাকা।
৩. অধ্যাপক ডাঃ মোঃ ইসমাইল খান, উপাচার্য, চট্টগ্রাম মেডিকেল বিশ্ববিদ্যালয়, চট্টগ্রাম।
৪. ব্রিঃ জেঃ মোঃ কুদরত-ই-ইলাহী, উপদেষ্টা চিকিৎসা বিশেষজ্ঞ এবং মেডিক্যাল অনকোলজিস্ট, সি এম এইচ, ঢাকা।
৫. অধ্যাপক ড. এস. এম. আবদুর রহমান, ডীন, ফার্মেসী অনুষদ, ঢাকা বিশ্ববিদ্যালয়।
৬. অধ্যাপক ডাঃ জাকির হোসাইন গালিব, চর্ম ও যৌন রোগ বিভাগ, স্যার সলিমুল্লাহ্ মেডিকেল কলেজ, ঢাকা।
৭. ডাঃ এস, এম, নজরুল ইসলাম, পরিচালক, প্রশিক্ষণ ও মূল্যায়ণ, LBI, DLS, প্রাণি সম্পদ গবেষণা প্রতিষ্ঠান।
৮. জনাব মুহাম্মদ মাহবুবুল হক, সচিব, বাংলাদেশ ফার্মেসী কাউন্সিল।
৯. ডাঃ ইশরাত জাহান, সহকারী অধ্যাপক, গাইনী এন্ড অবসটেট্রিক্স বিভাগ, স্যার সলিমুল্লাহ্ মেডিকেল কলেজ, ঢাকা।
১০. অধ্যাপক ড. মোঃ হাসান কাউসার, বিশেষজ্ঞ প্রতিনিধি, বাংলাদেশ ফার্মাসিউটিক্যাল সোসাইটি, ঢাকা।

পর্যবেক্ষক ঃ

১. ডাঃ মোমেনুল হক, বিশেষজ্ঞ প্রতিনিধি, উপদেষ্টা, বাংলাদেশ ঔষধ শিল্প সমিতি, ঢাকা এবং ব্যবস্থাপনা পরিচালক, মেসার্স জেনারেল ফার্মাসিউটিক্যালস্ লিঃ।
২. জনাব রাব্বুর রেজা, বিশেষজ্ঞ প্রতিনিধি, বাংলাদেশ ঔষধ শিল্প সমিতি এবং সিওও, মেসার্স বেক্সিমকো ফার্মাসিউটিক্যালস লিঃ।
৩. জনাব এম, মোসাদ্দেক হোসেন, বিশেষজ্ঞ প্রতিনিধি, বাংলাদেশ ঔষধ শিল্প সমিতি এবং ব্যবস্থাপনা পরিচালক, মেসার্স ইউনিমেড ইউনিহেলথ লিঃ।
৪. জনাব মোঃ আবদুর রাজ্জাক, বাংলাদেশ ঔষধ শিল্প সমিতি কর্তৃক মনোনীত মেডিকেল ডিভাইস বিশেষজ্ঞ এবংব্যবস্থাপনা পরিচালক, জেএমআই সিরিঞ্জেস এন্ড মেডিকেল ডিভাইসেস লিঃ, কুমিল্লা ।
৫. জনাবমোঃ শাহজালাল, বিশেষজ্ঞ প্রতিনিধি, বাংলাদেশ ফার্মাসিউটিক্যাল ইম্পোটার্স এসোসিয়েশন।

সভায় আলোচ্য বিষয়সমূহ :

১. ঔষধ নিয়ন্ত্রণ কমিটির ৩০ এপ্রিল ২০১৯ তারিখে অনুষ্ঠিত ২৫০ তম সভার কার্যবিবরণী নিশ্চিতকরণ প্রসঙ্গে ।
২. স্থানীয়ভাবে উৎপাদনের জন্য ৩৬১ টি হিউম্যান ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের উপর আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে ।
৩. আমদানীর জন্য ৩৫ টি হিউম্যান ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের উপর আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।
৪. স্থানীয়ভাবে উৎপাদনের জন্য ৩৫ টি ভেটেরিনারি ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের উপর আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে।
৫. আমদানীর জন্য ৪০টি ভেটেরিনারি ঔষধের বিষয়ে টেকনিক্যাল সাব-কমিটির সুপারিশের উপর আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে ।
৬. স্থানীয়ভাবে উৎপাদনের জন্য ১১৩ টি হারবাল ঔষধের বিষয়ে টেকনিক্যাল সাব-কমিটির সুপারিশের উপর আলোচনা ও সিদ্ধান্ত গ্রহণ প্রসঙ্গে ।
৭. বিবিধ আলোচনা।

সভার আলোচনা ও সিদ্ধান্ত ঃ

সভাপতি উপস্থিত সকলকে স্বাগত জানিয়ে সভার কার্যক্রম শুরু করেন। তিনি ঔষধ প্রশাসন অধিদপ্তরের মহাপরিচালক মেজর জেনারেল মোঃ মাহবুবুর রহমানকে সভার আলোচ্যসূচী উপস্থাপনের জন্যঅনুরোধ করেন। তিনি সভার আলোচ্যসূচী উপস্থাপন করেন। অতঃপর তিনি ঔষধ প্রশাসন অধিদপ্তরের পরিচালক জনাব মোঃ রুহুল আমিন-কে আলোচ্যসূচী অনুযায়ী বিষয়সমূহ উপস্থাপন করার জন্য আহবান করেন।

জনাব মোঃ রুহুল আমিন আলোচ্যসূচী অনুযায়ী বিষয়সমূহ পর্যায়ক্রমে উপস্থাপন করেন। তিনি উল্লেখ করেন যে, ইতোমধ্যে ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব-কমিটির নিম্নবর্ণিত দু'টি সভা অনুষ্ঠিত হয়েছে।

টেকনিক্যাল সাব-কমিটির সভা ঃ

ক) বিগত ১৪ জানুয়ারী, ২০২০ তারিখে সকাল ১১.০০ ঘটিকায় হিউম্যান ও ভেটেরিনারি মেডিসিনের আবেদন মূল্যায়নের নিমিত্তে ঔষধ প্রশাসন অধিদপ্তরের সভা কক্ষে ড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব-কমিটিরএকটি সভা অনুষ্ঠিত হয়।

খ) বিগত ২০জানুয়ারী, ২০২০ তারিখে সকাল ১১.০০ ঘটিকায় হারবাল ঔষধের আবেদন মূল্যায়নের নিমিত্তে ঔষধ প্রশাসন অধিদপ্তরের সভা কক্ষে হার্বাল ঔষধ এডভাইজরী কমিটি (ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব কমিটি)- এর একটি সভা অনুষ্ঠিত হয়।

১। ঔষধ নিয়ন্ত্রণ কমিটির ২৫০ তম সভার কার্যবিবরণী নিশ্চিতকরণ প্রসঙ্গে।

বিগত৩০ এপ্রিল ২০১৯ তারিখে অনুষ্ঠিত ঔষধ নিয়ন্ত্রণ কমিটির ২৫০ তম সভার কার্যবিবরণী সভায় উপস্থাপন করা হয়।

জনাব মোঃ রুহুল আমিন সভাকে অবহিত করেন, ড্রাগ কন্ট্রোল কমিটির ২৫০ তম সভায় ইতঃপূর্বে অনুমোদিত ১০৭ টি ভিটামিন ও মিনারেল কম্বিনেশন প্রডাক্ট এর মধ্যে রেজিস্ট্রেশন বহাল রাখা হয় ৪৫ টির এবং রেজিস্ট্রেশন বাতিল করা হয় ৬২ টির। ১৭ জুলাই ২০১৯ তারিখে বাংলাদেশ ঔষধ শিল্প সমিতি একটি পত্রের মাধ্যমে ঔষধ নিয়ন্ত্রণ কমিটির ২৫০তম সভায় বাতিলকৃত ভিটামিন ও মিনারেল জাতীয় ঔষধের প্রয়োজনীয়তা থাকায় তারা এ সিদ্ধান্ত পূণঃমূল্যায়নের জন্য অনুরোধ করেন। উক্ত আবেদনের পরিপ্রেক্ষিতে ঔষধ নিয়ন্ত্রণ কমিটির ২৫০তম সভায় বাতিলকৃত ৬২ টি ভিটামিন ও মিনারেল জাতীয় ঔষধের উৎপাদন ও বাজারজাতকরণের প্রয়োজনীয়তা পূণঃমূল্যায়নের জন্য ইতঃপূর্বে গঠিত কমিটির নিকট প্রেরণ করা হয়।উক্ত কমিটি ১০৭টি ভিটামিন কম্বিনেশনের মধ্যে ৬০ টি ভিটামিন ও মিনারেল কম্বিনেশন প্রয়োজন নেই এবং ৪৬ টি ভিটামিন মিনারেল কম্বিনেশন বহাল রাখার বিষয়ে সুপারিশ করেন এবং উক্ত কম্বিনেশন পদসমূহের একটি তালিকা প্রণয়ন করেন।উল্লেখ্য যে, কমিটি কর্তৃক প্রয়োজন নেই মর্মে সুপারিশকৃত ৬১ টি পদের তালিকায় উল্লিখিত ক্রমিক নং ৩২ ও ৩৩ পদ দু'টি একই পদ। মোট ভিটামিন ও মিনারেলের কম্বিনেশন পদের সংখ্যা ১০৬ টি।

টেকনিক্যাল সাব-কমিটির সিদ্ধান্ত ঃ

ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব-কমিটির সভায় উক্তকমিটির মতামত মোতাবেক ১০৬ টি ভিটামিন ও মিনারেল কম্বিনেশন প্রডাক্ট এর মধ্যে ৬০ টি ভিটামিন ও মিনারেল কম্বিনেশন প্রডাক্টের রেজিস্ট্রেশন বাতিল এবং ৪৬ টি ভিটামিন ও মিনারেল কম্বিনেশন প্রডাক্ট এর নিবন্ধন বহাল রাখা যেতে পারে মর্মে মতামত প্রদান করেন।

- পরবর্তীতে জাতীয় পুষ্টি সেবা, জনস্বাস্থ্য পুষ্টি প্রতিষ্ঠান, মেসার্স রেনাটা লিঃএবং মেসার্স এসএমসি মার্কেটিং কোম্পানি মহাপরিচালক, ঔষধ প্রশাসন অধিদপ্তর বরাবর লিখিত আবেদনে বাতিলের জন্য সুপারিশকৃত Ascorbic Acid 30 mg + Folic Acid 0.16 mg + Iron 12.5 mg + Vitamin A 0.3 mg + Zinc (As Gluconate) 5 mg Sachetপদটির রেজিস্ট্রেশন বহাল রাখার জন্য অনুরোধ করেন ।
- মেসার্স রেনাটা লিঃ মহাপরিচালক, ঔষধ প্রশাসন অধিদপ্তর বরাবর লিখিত আবেদনে বাতিলের জন্য সুপারিশকৃত Copper 0.56 mg + Folic Acid 0.15 mg + Iodine 0.09 mg + Iron 10 mg + Niacin 6 mg +Pyridoxine 0.5 mg + Riboflavin 0.5 mg + Selenium 0.017 mg + Vitamin A 0.4 mg + Vitamin B_1 0.5 mg + Vitamin B_{12} 0.0009 mg + Vitamin C 30 mg + Vitamin D 0.005 mg +Vitamin E 5 mg + Zinc 4.1 mg Sachet পদটির রেজিস্ট্রেশন বহাল রাখার জন্য অনুরোধ করেন।

তারা আবেদনে উল্লেখ করেছেন,৬ মাস থেকে ৫ বছর বয়সি শিশুদের অপুষ্টি জনিত সমস্যায় বাংলাদেশ সরকারের Multiple Micronutrient Powder (MNP) ব্যবহারের National Strategy এর আওতায় Directorate General of Family Planning এবং Directorate General of Health Services টেন্ডারের মাধ্যমে MNP ক্রয় করে থাকে।সরকারী কর্মসূচির সাথে সংগতি রেখে বিভিন্ন দেশীয় এবং আন্তর্জাতিক উন্নয়ন সংস্থা যেমন, ব্রাক, ইউনিসেফ, ওয়ার্ল্ড ভিশন ও সূর্যের হাসি নেটওয়ার্ক এই MNP কর্মসূচী বাস্তবায়ন করছে।UNICEF বর্তমানে বিশ্বব্যাপী ৫০টির বেশী দেশে National, Sub-National এবং Pilot পর্যায়ে ৬ মাস থেকে ৫ বছর বয়সি শিশুদের অপুষ্টি জনিত সমস্যা দূর করতে Complementary Feeding এর সাথে Multiple Micronutrient Powder (MNP) ব্যবহারে Commnunity Level-এ কার্যক্রম পরিচালনা করছে।

এ বিষয়ে সভাপতি মহোদয় অধ্যাপক ডাঃ মোঃ ইসমাইল খান এর নিকট মতামত জানতে চাইলে তিনি পদদুটি বহাল রাখার বিষয়ে মতামত প্রদান করেন।কমিটির সদস্যগণ উক্ত মতামতের সাথে একমত পোষণ করেন।

ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত ঃ

১০৬ টি ভিটামিন ও মিনারেল কম্বিনেশন প্রডাক্টের মধ্যেড্রাগ কন্ট্রোল কমিটির টেকনিক্যাল সাব-কমিটিরসুপারিশকৃত বাতিলের তালিকায় অন্তর্ভূক্ত ভিটামিন ও মিনারেল কম্বিনেশন প্রডাক্ট এর মধ্যে Ascorbic Acid 30 mg + Folic Acid 0.16 mg + Iron 12.5 mg + Vitamin A 0.3 mg + Zinc (As Gluconate) 5 mg Sachet এবং Copper 0.56 mg + Folic Acid 0.15 mg + Iodine 0.09 mg + Iron 10 mg + Niacin 6 mg +Pyridoxine 0.5 mg + Riboflavin 0.5 mg + Selenium 0.017 mg + Vitamin A 0.4 mg + Vitamin B_1 0.5 mg + Vitamin B_{12} 0.0009 mg + Vitamin C 30 mg + Vitamin D 0.005 mg +Vitamin E 5 mg + Zinc 4.1 mg Sachetপদ দুটি সহ মোট৪৮ টি ভিটামিন ও মিনারেল কম্বিনেশন প্রডাক্ট এর নিবন্ধন বহাল রাখার সিদ্ধান্ত গৃহীত হয়। ৫৮ টি ভিটামিন ও মিনারেল কম্বিনেশন প্রডাক্টের রেজিস্ট্রেশন বাতিল করার সিদ্ধান্ত গৃহীত হয় (Annexure-A)।

ড্রাগ কন্ট্রোল কমিটির ২৫০ তম সভার ভিটামিন ও মিনারেল জাতীয়কম্বিনেশন পদের রেজিস্ট্রেশন বাতিল এবং বহালরাখার বিষয়ক গৃহীত সিদ্ধান্ত বাতিল করা হয় এবং গৃহীত সংশোধনীসহ সর্বসম্মতিক্রতে ২৫০তম সভার কার্যবিবরণী নিশ্চিত করা হয়।

২। স্থানীয়ভাবে উৎপাদনের জন্য আবেদিত ৩৬১টি হিউম্যান ঔষধের রেজিস্ট্রেশন অনুমোদন বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের আলোকে সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

টেকনিক্যাল সাব কমিটির সিদ্ধান্ত ঃ

২.১ স্থানীয়ভাবে উৎপাদনের জন্য নতুন ঔষধ এবং প্রচলিত ঔষধের নতুন আকার ও মাত্রার হিউম্যান ঔষধের রেজিস্ট্রেশনের নিমিত্তে দাখিলকৃত৩৬১ টি পদের আবেদনের মধ্যে টেকনিক্যাল সাব কমিটি কর্তৃক ১৬৭ টি পদের আবেদন অনুমোদনের সুপারিশ করা হয় এবং ১৯১ টি পদের আবেদননামঞ্জুরের সুপারিশ করা হয়।

ঔষধ নিয়ন্ত্রণ কমিটির আলোচনা ও সিদ্ধান্তঃ

ক) ১৬৫ টি পদের আবেদন অনুমোদন করা হয়;
খ) ১৯২ টি পদের আবেদন নামঞ্জুর করা হয়;

২.২ টেকনিক্যাল সাব কমিটি কর্তৃক নিম্নবর্ণিত দুইটি পদের বিষয়ে সাইক্রিয়াটিস্ট এর মতামত গ্রহন করার সুপারিশ করা হয় ঃ

পদসমূহঃ

(a) Pitolisant hydrochloride equivalent to Pitolisant 4.45 mg Tablet,

(b) Pitolisant hydrochloride equivalent to Pitolisant 17.8 mg Tablet

ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত ঃউক্ত দুটি পদের বিষয়ে সাইক্রিয়াটিস্ট এর মতামত গ্রহন করতে হবে।

২.৩ টেকনিক্যাল সাব কমিটি কর্তৃক নিম্নবর্ণিত একটি পদেরবিষয়ে ইউরোলজিস্ট এর মতামত গ্রহন করার সুপারিশ করা হয় ঃ

পদটিঃ

(a) Tiopronin 100 mg delayed release tablet

ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত ঃ উক্ত পদের বিষয়েইউরোলজিস্ট এর মতামত গ্রহন করতে হবে।

Bilastine INN 10 mg Orodispersible Tablet অনুমোদন প্রসঙ্গেঃ

ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব-কমিটির সভার কার্যবিবরণীতেBilastine INN 10 mg OrodispersibleTablet ক্রমিক নং -১২৭ ও ২১২ তে দু'বার উপস্থাপিত হয়েছে। পদটি UKMHRA কর্তৃক অনুমোদিত। আবেদনকারী প্রতিষ্ঠান মেসার্স এস কে এফ ফার্মাসিউটিক্যালস লিঃ রেফারেন্স দাখিল না করায় ক্রমিক নং -২১২ তে প্রয়োজনীয় রেফারেন্স নেই বিধায় নামঞ্জুরের জন্য সুপারিশ করা হয়েছে,কিন্তুক্রমিক নং - ১২৭ এ উল্লেখিত একই পদের আবেদনকারী প্রতিষ্ঠান মেসার্স পপুলার ফার্মাসিউটিক্যালস লিঃUKMHRA এর রেফারেন্স দাখিল করায় অনুমোদনের সুপারিশ করা হয়েছে।

ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্তঃক্রমিক নং-১২৭ ও ২১২ এ উল্লিখিতBilastine INN 10 mg OrodispersibleTabletপদটিমেসার্স পপুলার ফার্মাসিউটিক্যালস লিঃ এবং মেসার্স এস কে এফ ফার্মাসিউটিক্যালস লিঃএর অনুকূলে অনুমোদন করা হয়।

Mosquito repellent জাতীয় প্রডাক্ট অনুমোদন প্রসঙ্গেঃ

সভায় জনাব রাব্বুর রেজা, পর্যবেক্ষক, বাংলাদেশ ঔষধ শিল্প সমিতি এবং সিওও, বেক্সিমকো ফার্মাসিউটিক্যালস লিঃ বলেন, mosquito repellentজাতীয় দুটি পদ টেকনিক্যাল সাব কমিটির সভায় N, N-Diethylbenzamide INN 12%এবং Citronella Oil INN 22.375 gm/100 ml eq.to Citronella Oil 25 ml/100 ml + Eucalyptus Oil USP 23.1750 gm/100 ml eq.to. Eucalyptus Oil 25 ml/100 ml solutionঅনুমোদনের জন্য সুপারিশ করা হয়েছে। এ পদগুলো পরিবেশ অধিদপ্তরের অনুমোদনের ভিত্তিতে বাজারজাত করা যেতে পারে, ঔষধ প্রশাসন অধিদপ্তরের অনুমোদনের প্রয়োজন নেই বলে তিনি মতামত প্রদান করেন। এ বিষয়ে সভাপতি মহোদয় বলেন, mosquito repellentজাতীয় প্রডাক্ট ঔষধ হিসেবে ঔষধ প্রশাসন অধিদপ্তর কর্তৃক অনুমোদনের প্রয়োজন নেই। পরিবেশ অধিদপ্তরের অনুমোদ গ্রহণ করেই বাজারজাত করা যেতে পারে।

ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্ত ঃMosquito repellent জাতীয় প্রডাক্ট ঔষধ হিসেবে অনুমোদনের প্রয়োজন নেই।(**Annex-B**)

৩। আমদানীর জন্য আবেদিত ৩৫টি হিউম্যান ঔষধের রেজিস্ট্রেশন অনুমোদন বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের আলোকে সিদ্ধান্ত গ্রহণ প্রসঙ্গে ঃ

টেকনিক্যাল সাব কমিটির সিদ্ধান্ত ঃ

আমদানীর জন্য রেজিস্ট্রেশনের নিমিত্তে দাখিলকৃত ৩৫ টি নতুন ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটি কর্তৃক ১৬ টি পদের আবেদন অনুমোদনের সুপারিশ করা হয় এবং ১৯ টি পদের আবেদননামঞ্জুরের সুপারিশ করা হয়।

ঔষধ নিয়ন্ত্রণ কমিটির আলোচনা ও সিদ্ধান্তঃ

নিম্নবর্ণিত পদসমূহ আইসিইউ, ক্যান্সার এবং বার্ণ ইউনিটের রোগীদের উন্নত চিকিৎসার জন্য প্রয়োজন রয়েছে বিধায় রেজিস্ট্রেশনের অনুমোদন প্রদানের বিষয়ে মেসার্স রেডিয়েন্ট এক্সপোর্ট ইমপোর্ট এন্টারপ্রাইজ এর পক্ষ হতে লিখিত আকারে আবেদন করা হয়। এ বিষয়ে বিস্তারিত আলোচনা হয়। পদগুলোর বিষয়ে মতামত গ্রহণের জন্য সংশ্লিষ্ট বিশেষজ্ঞদের সমন্বয়ে একটি কমিটি গঠণের সিদ্ধান্ত গৃহীত হয় এবং কমিটির মতামত প্রাপ্তির পর টেকনিক্যাল সাবকমিটিতে উপস্থাপনের সিদ্ধান্ত গৃহীত হয়।

১. Omegaven "Fresenius" emulsion for infusion, 100ml,
২. SmofKabiven emulsion for infusion, 986ml (Three Chamber Bag),
৩. SmofKabiven emulsion for infusion, 1477ml (Three Chamber Bag) ও
৪. SmofKabiven Perifer emulsion for infusion, 1206ml (Three Chamber Bag)

ক) ১৬ টি পদের আবেদন অনুমোদন করা হয়;
খ) ১৫ টি পদের আবেদন নামঞ্জুর করা হয়;(**Annex-C**)

৪। স্থানীয়ভাবে উৎপাদনের জন্য আবেদিত ৩৫ (পঁয়ত্রিশ)টি ভেটেরিনারী ঔষধের রেজিস্ট্রেশন অনুমোদন বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের আলোকে সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

টেকনিক্যাল সাব কমিটির সিদ্ধান্ত ঃ

স্থানীয় উৎপাদনের জন্য রেজিস্ট্রেশনের নিমিত্তে দাখিলকৃত ৩৫ টি নতুন ভেটেরিনারি ঔষধের আবেদনের বিষয়ে টেকনিক্যাল সাব কমিটি কর্তৃক ২১ টি পদের আবেদন অনুমোদনের সুপারিশ করা হয় এবং ১০ টি পদের আবেদননামঞ্জুরের সুপারিশ করা হয় এবং ০৪ টি ভ্যাকসিন জাতীয় পদের বাংলাদেশে ফিল্ড ট্রায়ালের মাধ্যমে কার্যকারিতা প্রমাণ সাপেক্ষে অনুমোদন করা যেতে পারে বলে মতামত প্রদান করা হয়।

ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্তঃ

ক) ২১ টি পদের আবেদন অনুমোদন করা হয়;
খ) ১০ টি পদের আবেদন নামঞ্জুর করা হয়;
গ) নিম্নোক্ত ৪ টি পদেরবাংলাদেশে ফিল্ড ট্রায়ালের মাধ্যমে কার্যকারিতা প্রমাণ সাপেক্ষে অনুমোদন করার সিদ্ধান্ত গৃহীত হয় ঃ

পদসমূহঃ-

1. Avian Influenza Type A Virus Strain H9N2 (Inactivated) NLT 10^{7} EID_{50} + Newcastle disease virus (Inactivated) NLT 10^{8} EID_{50} 250 ml, 500 doses Emulsion (Injection) (Vet)
2. Avian Influenza Type A Virus Strain H9N2 (Inactivated) NLT 10^{7} EID_{50} + Newcastle disease virus (Inactivated) NLT 10^{8} EID_{50} 500 ml, 1000 doses Emulsion(Injection)(Vet)
3. Avian Influenza Type A Virus Strain H9N2 (Inactivated) NLT 10^{7} EID_{50} 500 ml, 1000 doses Emulsion(Injection)(Vet)
4. Avian Influenza Type A Virus Strain H9N2 (Inactivated) NLT 10^{7} EID_{50} 250 ml, 500 doses Emulsion(Injection)

(**Annex-D**)

৫।আমদানীর জন্য আবেদিত ৪০ (চল্লিশ)টি ভেটেরিনারী ঔষধের রেজিস্ট্রেশন অনুমোদন বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের আলোকে সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

টেকনিক্যাল সাব কমিটির সিদ্ধান্ত ঃ

আমদানীর জন্য রেজিস্ট্রেশনের নিমিত্তে দাখিলকৃত ৪০ টি নতুন ভেটেরিনারি ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটি কর্তৃক ২৫ টি পদের আবেদন অনুমোদনের সুপারিশ করা হয় এবং ১৫ টি পদের আবেদননামঞ্জুরের সুপারিশ করা হয়।

ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্তঃ

ক) ২৫ টি পদের আবেদন অনুমোদন করা হয়;
খ) ১৫ টি পদের আবেদন নামঞ্জুর করা হয়;(**Annex-E**)

৬।(ক)টেকনিক্যাল সাব কমিটির বিবিধ আলোচনার পরিপ্রেক্ষিতে ঔষধ নিয়ন্ত্রণ কমিটি কর্তৃক গৃহীত সিদ্ধান্ত ঃ

সভায় নিম্নবর্ণিত প্রডাক্টগুলোর বিষয়ে বিস্তারিত আলোচনা হয়। প্রডাক্টগুলোর মধ্যে ক্রমিক নং-১, ২,৩,৪ ও ৬ এর আবেদন অনুমোদন করা যেতে পারে বলে মতামত প্রদান করা হয় এবং ক্রমিক নং- ৫ নং প্রডাক্টটিরআবেদন নামঞ্জুর করা হয়(Annex-F)।

SI.NO	Name of the Medicine with dosage form	Generic Name with Strength	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ঔষধ নিয়ন্ত্রণ কমিটির ২৫১ তম সভার সিদ্ধান্ত
1	Chloral Hydrate 143.3mg/5ml Oral Solution	Chloral Hydrate BP 143.3mg/5ml	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	অনুমোদন করা হল।
2	Posaconazole 300 mg/ 16.7 mL injection	Posaconazole INN 300 mg/ 16.7 mL	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
3	Baricitinib 2 mg Tablet	Baricitinib INN 2 mg	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
4	Empagliflozin 5 mg + Metformin Hydrochloride 500 mg Tablet	Empagliflozin INN 5 mg + Metformin Hydrochloride USP 500 mg	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
5	Jardiance Met 5mg/500mg film-coated tablets (Imported)	Empagliflozin5mg + Metformin HCl Ph. Eur500mg.	ক্রমিক নং-৪ এ পদটি স্থানীয়ভাবে উৎপাদনের জন্য অনুমোদন করা যেতে পারে মর্মে মতামত প্রদান করা হয়েছে । এমতাবস্থায় আমদানির জন্য রেজিস্ট্রেশনের প্রয়োজন নাই বিধায়আবেদন নামঞ্জুরের সুপারিশ করা হয়েছে।	***আমদানির জন্য রেজিস্ট্রেশনের আবেদন নামঞ্জুর করা হল।***
6	n-alkyl dimethyl benzyl ammonium chloride BP 40mg with Urea 60mg BP/1gm Granules (Veterinary) (post approval এর জন্য আবেদিত)	n-alkyl dimethyl benzyl ammonium chloride BP 40mg with Urea 60mg BP/1gm Granules	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

(খ)বিবিধ আলোচনা ও সিদ্ধান্ত ঃ

১. মেসার্স ডেল্টা ফার্মাসিউটিক্যালস Baricitinib 2 mg Tablet ডিসিসিতে অনুমোদনের জন্য ১১/০২/২০২০ তারিখে আবেদন করেছে। ডিসিসি-২৫০ তম সভায় ডেল্টা ফার্মার উক্ত পদটির আবেদন নামঞ্জুর করা হয়। পদটি M/SSquare Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, GazipurএবংM/SIncepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhakaপ্রতিষ্ঠানের অনুকূলেAnnex-F এর ক্রমিক নং ৩ এ আবেদন টেকনিক্যাল সাব কমিটি কর্তৃক আবেদন মঞ্জুরের সুপারিশ করা হয়।এ বিষয়ে আলোচনাক্রমেAnnex-F এর ক্রমিক নং ৩ এ মেসার্স ডেল্টা ফার্মাসিউটিক্যালস এর অনুকূলে পদটির আবেদন মঞ্জুরের বিষয়ে সিদ্ধান্ত গৃহীত হয়।

ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্তঃBaricitinib 2 mg Tabletনামীয় পদটিM/SSquare Pharmaceuticals Ltd., (Dhaka Unit), Kaliakoir, Gazipur,M/SIncepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhakaএবংমেসার্স ডেল্টা ফার্মাসিউটিক্যালস এর অনুকূলে আবেদন মঞ্জুরের বিষয়ে সিদ্ধান্ত গৃহীত হয়।

২.অধ্যাপক এ কে আজাদ খান, সভাপতি, বাংলাদেশ ডায়াবেটিক সমিতি নিম্নোক্ত ৪ টি পদের অনুমোদনের জন্য লিখিতভাবে অনুরোধ করেন।

1. Empagliflozin 5 mg + Metformin Hydrochloride 1000 mg
2. Empagliflozin 10 mg + Metformin Hydrochloride 1000 mg
3. Empagliflozin 12.5 mg + Metformin Hydrochloride 1000 mg
4. Empagliflozin 25 mg + Metformin Hydrochloride 1000 mg

পদসমূহ অধ্যাপক এ কে আজাদ খান ২৩.০২.২০ তারিখে অনুমোদনের বিষয়ে লিখিতভাবে মহাপরিচালক, ঔষধ প্রশাসন অধিদপ্তর বরাবর সুপারিশ করেন বিধায় টেকনিক্যাল সাব কমিটিতে উপস্থাপিত হয়নি। উক্ত৪ টি পদ USFDA কর্তৃক অনুমোদিত। কিন্তু প্রয়োজন নেই বিধায় ডিসিসি-২৫০ তম সভায় নামঞ্জুর করা হয়।

সভাপতি মহোদয় ঔষধ নিয়ন্ত্রণ কমিটির টেকনিক্যাল সাব কমিটির পরবর্তী সভায় উক্ত পদগুলো উপস্থাপন করার পরামর্শ প্রদান করেন।

ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্তঃপদসমূহ টেকনিক্যাল সাব কমিটির পরবর্তী সভায় উপস্থাপনের সিদ্ধান্ত গৃহীত হয়।

৩.Clobetasol Propionate BP 0.05% + Salicylic Acid BP 6%অয়েন্টমেন্টনামীয় পদটি ঔষধ নিয়ন্ত্রণ কমিটির ২৪৩ এবং ২৫০ তম সভায় নামঞ্জুর করা হয়। কিন্তু পদটি মেসার্স এস কে এইফ ফার্মাসিউটিক্যালস লিঃ, মিরপুর, ঢাকা এর অনুকূলে ২২.১২.২০১৬ তারিখে ভুল বসতঃ রেজিস্ট্রেশন প্রদান করা হয়েছে। পদটি post approval এর জন্য উপস্থাপন করা হয়।

এ বিষয়ে, সভাপতি মহোদয় বলেন, এ ধরনের ভুল কেন হয়েছেতাঅনুসন্ধান করে দেখা যেতে পারে এবং পরবর্তীতে টেকনিক্যাল সাব কমিটিতে উপস্থাপন করা যেতে পারে।

ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্তঃমহাপরিচালক, ঔষধ প্রশাসন অধিদপ্তর মেসার্স এস কে এইফ ফার্মাসিউটিক্যালস লিঃ, মিরপুর, ঢাকা এর অনুকূলে পদটির রেজিস্ট্রেশনের বিষয়ে অনুসন্ধানপূর্বক টেকনিক্যাল সাব কমিটির পরবর্তী সভায় উপস্থাপনের ব্যবস্থা গ্রহণ করবেন।

৪. (Sodium Alginate USP 5gm + Sodium Bicarbonate USP 2.67 gm + Calcium Carbonate BP 1.6gm)/100ml oral suspension নামীয় পদটিM/S Reckitt Benckiser Healthcare (UK) Ltd, M/S Ibnsina Pharmaceuticals Ltd, M/S Incepta Pharmaceuticals Ltd, M/S Beacon Pharmaceuticals Ltd, M/S Benham Pharmaceuticals Ltd, M/S Unimed & Unihealth Ltd, M/S Advanced Chemical Industries Ltd এর অনুকূলে রেজিস্ট্রেশন প্রদান করা হয়েছে।

কিন্তু ড্রাগ কন্ট্রোল কমিটির ২১১ তম সভায় মেসার্স রেকিট এন্ড কোল্ডম্যান (বাংলাদেশ) লিঃ এর অনুকূলে Gaviscon (Sodium Alginate 500mg/10 ml) অনুমোদন করা হয়।M/S Reckitt Benckiser Healthcare (UK) Ltd এবং M/S Unimed & Unihealth Ltd নামীয় প্রতিষ্ঠান দুটি তাদেরঅনুমোদিত Annexure এ API হিসেবে Sodium Alginate USP 5gm + Sodium Bicarbonate USP 2.67 gm + Calcium Carbonate BP 1.6gm উল্লেখ করেছে এবংM/S Ibnsina Pharmaceuticals

Ltd, M/S Incepta Pharmaceuticals Ltd, M/S Beacon Pharmaceuticals Ltd, M/S Benham Pharmaceuticals Ltd, ও M/S Advanced Chemical Industries Ltd নামীয় প্রতিষ্ঠানসমূহ তাদের Annexure এ API হিসেবে Sodium Alginate USP 5gm এবং Excipient হিসেবে Sodium Bicarbonate USP 2.67 gm ও Calcium Carbonate BP 1.6gm উল্লেখ করেছে।

এ বিষয়ে, সভাপতি মহোদয় বলেন, পদটির ফর্মুলেশন পরীক্ষা করে দেখা যেতে পারে এবং পরবর্তীতে টেকনিক্যাল সাব কমিটিতে উপস্থাপন করা যেতে পারে ।

ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্তঃমহাপরিচালক, ঔষধ প্রশাসন অধিদপ্তর পদটির ফর্মুলেশন পরীক্ষাপূর্বক টেকনিক্যাল সাব কমিটির পরবর্তী সভায় উপস্থাপনের ব্যবস্থা গ্রহণ করবেন।

৬। স্থানীয়ভাবে উৎপাদনের জন্য ১১৩ (একশত তেরো) টি হারবাল ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটির সুপারিশের আলোকে সিদ্ধান্ত গ্রহণ প্রসঙ্গে।

টেকনিক্যাল সাব কমিটির সিদ্ধান্ত ঃ

স্থানীয়ভাবে উৎপাদনের জন্য রেজিস্ট্রেশনের নিমিত্তে দাখিলকৃত ১১৩ টি নতুন হারবাল ঔষধের বিষয়ে টেকনিক্যাল সাব কমিটি কর্তৃক ৮১ টি পদের আবেদন অনুমোদনের সুপারিশ করা হয় এবং ৩২ টি পদের আবেদননামঞ্জুরের সুপারিশ করা হয়।

ঔষধ নিয়ন্ত্রণ কমিটির সিদ্ধান্তঃ

ক) ৮১ টি পদের আবেদন অনুমোদন করা হয়;
খ) ৩২ টি পদের আবেদন নামঞ্জুর করা হয়।(Annex-G)

অন্য কোন আলোচ্য বিষয় না থাকায় সভাপতি মহোদয় উপস্থিত সকলকে ধন্যবাদ জ্ঞাপন করে সভার সমাপ্তি ঘোষণা করেন।

মেজর জেনারেল মোঃ মাহবুবুর রহমান
মহাপরিচালক
ঔষধ প্রশাসন অধিদপ্তর
ও
সদস্য সচিব
ঔষধ নিয়ন্ত্রণ কমিটি

মোঃ আসাদুল ইসলাম
সচিব, স্বাস্থ্য সেবা বিভাগ
স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়
ও
সভাপতি
ঔষধ নিয়ন্ত্রণ কমিটি

Annex:-B: Proposed Product list for Locally Manufacture (Human)

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
1.	Pharmasia Limited, Gojariapara, Bhawal Mirzapur, Gazipur.	Sucralose 25% w/v Solution	Sucralose BP 25%	Other Classification	Sucralose is a non-nutritive artificial sweetener, 600 times sweeter than sucrose. Sucralose can be used as sweetener in different foods like pudding, milk products, jelly, fruit juices, tea, coffee, desserts, hot and cold beverage etc. Due to zero calorie sweetener, it is a nice preparation for the health conscious people. Sucralose can be a unique choice for the diabetic patients who have excess amount of glucose in blood.	**Contra-indication:** No known contraindications are found. **Side-effect:** No known side effects are found.	Sucralose 8 mg,12mg Tablet, 6.5 gm sachet.	Sucralose was approved by the USFDA, in 1999, to be utilized in foods, beverages, pharmaceutical products, diets and vitamin supplements.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
2.	Pharmasia Limited, Gojariapara, Bhawal Mirzapur, Gazipur. M/S Ziska Pharma Ltd, Kaliakoir, Sofipur, Gazipur. Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna. Somatec pharmaceuticals LTD., SARULIA, DEMRA, DHAKA BANGLADESH. Drug International Ltd (Unit-3) 31/1, Satrong Road, Gopalpur, Tongi Industrial Area Gazipur, Bangladesh **Orion Pharma Ltd, Siddhirganj, Narayangang.**	Lefamulin 600 mg Tablet	Lefamulin Acetate INN 671.00 mg eq. to Lefamulin 600 mg.	Anti-Infective	Lefamulin is a pleuromutilin antibacterial indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by susceptible microorganisms. To reduce the development of drug resistant bacteria and maintain the effectiveness of Lefamulin and other antibacterial drugs, Lefamulin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	**Contra-indication:** Lefamulin Acetate is contraindicated in patients with known hypersensitivity to lefamulin, pleuromutilin class drugs, or any of the components of Lefamulin Acetate. Concomitant use of Lefamulin Acetate tablets with CYP3A substrates that prolong the QT interval is contraindicated. **Side-effect:** diarrhea, nausea, vomiting, hepatic enzyme elevation **WARNINGS AND PRECAUTIONS:** **QT Prolongation:** Avoid use in patients with known QT prolongation, ventricular arrhythmias including torsades de pointes, and patients receiving drugs that prolong the QT interval such as antiarrhythmic agents. **Embryo-Fetal Toxicity:** May cause fetal harm. Advise	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						females of reproductive potential of the potential risk to the fetus and to use effective contraception. **Clostridium difficile-associated Diarrhea (CDAD):** Evaluate patients who develop diarrhea.				
3.	Pharmasia Limited, Gojariapara, Bhawal Mirzapur, Gazipur.	Sodium Bicarbonate 2.32 g + Citric Acid 2.18 g + Sodium Carbonate Anhydrous 0.50 g Powder Sachet	Sodium Bicarbonate BP 2.32 g + Citric Acid BP 2.18 g + Sodium Carbonate Anhydrous BP 0.50 g / 5 gm powder	Antacid	The symptomatic relief of indigestion, flatulence and nausea.	**Contra-indication:** Persons on a restricted sodium diet e.g. those suffering from hypertension or congestive heart failure, should not use this product unless directed by a doctor. Patients with impaired hepatic and renal function. Sodium Carbonate + Sodium Bicarbonate + Citric Acid is contraindicated in patients with a prior hypersensitivity reaction to Sodium Carbonate + Sodium Bicarbonate + Citric Acid or any other ingredient of the preparation. **Side-effect:** Minor gastrointestinal irritations, including belching, flatulence, and abdonminal distention.	New	UKMHRA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
4.	Pharmasia Limited, Gojariapara, Bhawal Mirzapur, Gazipur. Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Pitolisant hydrochloride equivalent to Pitolisant 4.45 mg Tablet	Pitolisant hydrochloride INN equivalent to Pitolisant 4.45 mg Tablet	Anxiolytic	Pitolisant hydrochloride is a histamine-3 (H3) receptor antagonist/inverse agonist indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.	**Contra-indication:** Pitolisant hydrochloride is contraindicated in patients with severe hepatic impairment. **Side-effect:** The most common adverse reactions are insomnia, nausea, and anxiety. **WARNINGS AND PRECAUTIONS:** QT Interval Prolongation: Increases in QT interval. Avoid use with drugs that	New	USFDA	ঔষধটির বিষয়ে সাইক্রিয়াটিস্ট এর মতামত নেওয়া যেতে পারে।	সাইক্রিয়াটিস্ট এর মতামত গ্রহন করতে হবে।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						also increase the QT interval and in patients with risk factors for prolonged QT interval. Monitor patients with hepatic or renal impairment for increased QTc.				
5.	Pharmasia Limited, Gojariapara, Bhawal Mirzapur, Gazipur. Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Pitolisant hydrochloride equivalent to Pitolisant 17.8 mg Tablet	Pitolisant hydrochloride INN equivalent to Pitolisant 17.8 mg Tablet	Anxiolytic	Pitolisant hydrochloride is a histamine-3 (H3) receptor antagonist/inverse agonist indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.	**Contra-indication:** Pitolisant hydrochloride is contraindicated in patients with severe hepatic impairment. **Side-effect:** The most common adverse reactions are insomnia, nausea, and anxiety **WARNINGS AND PRECAUTIONS:** QT Interval Prolongation: Increases in QT interval. Avoid use with drugs that also increase the QT interval and in patients with risk factors for prolonged QT interval. Monitor patients with hepatic or renal impairment for increased QTc.	New	USFDA	ঔষধটির বিষয়ে সাইক্রিয়াটিস্ট এর মতামত নেওয়া যেতে পারে।	সাইক্রিয়াটিস্ট এর মতামত গ্রহন করতে হবে।
6.	Pharmasia Limited, Gojariapara, Bhawal Mirzapur, Gazipur. M/S Ziska Pharma Ltd, Kaliakoir, Sofipur, Gazipur. Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Acme Laboratories Ltd., Dhamrai, Dhaka	Baloxavir Marboxil 20 mg tablet	Baloxavir Marboxil INN 20 mg tablet	Antiviral	Baloxavir Marboxil is a polymerase acidic (PA) endonuclease inhibitor indicated for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours. **Limitations of Use:** Influenza viruses change over time, and factors such as the virus type or subtype, emergence of resistance, or changes in viral virulence could diminish the clinical benefit of antiviral drugs. Consider available information on drug susceptibility patterns for circulating influenza virus strains when deciding whether to use Baloxavir Marboxil.	**Contra-indication:** Baloxavir Marboxil is contraindicated in patients with a history of hypersensitivity to baloxavir marboxil or any of its ingredients. **Side-effect:** Adverse events reported in at least 1% of adult and adolescent subjects treated with Baloxavir Marboxil included diarrhea (3%), bronchitis (2%), nasopharyngitis (1%),	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						headache (1%) and nausea (1%). **WARNINGS AND PRECAUTIONS:** Risk of Bacterial Infection: Serious bacterial infections may begin with influenza-like symptoms, may coexist with, or occur as a complication of influenza. Baloxavir Marboxil has not been shown to prevent such complications. Prescribers should be alert to potential secondary bacterial infections and treat them as appropriate.				
7.	Pharmasia Limited, Gojariapara, Bhawal Mirzapur, Gazipur. M/S Ziska Pharma Ltd, Kaliakoir, Sofipur, Gazipur. Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Acme Laboratories Ltd., Dhamrai, Dhaka	Baloxavir Marboxil 40 mg tablet	Baloxavir Marboxil INN 40 mg tablet	Antiviral	Baloxavir Marboxil is a polymerase acidic (PA) endonuclease inhibitor indicated for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours. **Limitations of Use:** Influenza viruses change over time, and factors such as the virus type or subtype, emergence of resistance, or changes in viral virulence could diminish the clinical benefit of antiviral drugs. Consider available information on drug susceptibility patterns for circulating influenza virus strains when deciding whether to use Baloxavir Marboxil.	**Contra-indication:** Baloxavir Marboxil is contraindicated in patients with a history of hypersensitivity to baloxavir marboxil or any of its ingredients. **Side-effect:** Adverse events reported in at least 1% of adult and adolescent subjects treated with Baloxavir Marboxil included diarrhea (3%), bronchitis (2%), nasopharyngitis (1%), headache (1%) and nausea (1%). **WARNINGS AND PRECAUTIONS:** Risk of Bacterial Infection: Serious bacterial infections may begin with influenza-like symptoms, may coexist with, or occur as a complication of influenza. Baloxavir Marboxil has not been shown to prevent such complications. Prescribers	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						should be alert to potential secondary bacterial infections and treat them as appropriate.				
8.	Pharmasia Limited, Gojariapara, Bhawal Mirzapur, Gazipur. Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh.	Solriamfetol 75 mg Tablet	Solriamfetol Hydrochloride INN equivalent to Solriamfetol 75 mg tablet	Antidepressants	Solriamfetol is a dopamine and norepinephrine reuptake inhibitor (DNRI) indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).	**Contra-indication:** Concurrent treatment with a monoamine oxidase inhibitor (MAOI) or use of an MAOI within the preceding 14 days. **Side-effect:** headache, nausea, decreased appetite, insomnia, and anxiety. **WARNINGS AND PRECAUTIONS:** **Blood Pressure and Heart Rate Increases:** Measure heart rate and blood pressure prior to initiating and periodically throughout treatment. Control hypertension before and during therapy. Avoid use in patients with unstable cardiovascular disease, serious heart arrhythmias, or other serious heart problems. **Psychiatric Symptoms:** Use caution in treating patients with a history of psychosis or bipolar disorders. Consider dose reduction or discontinuation of Solriamfetol if psychiatric symptoms develop.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*
9.	Pharmasia Limited, Gojariapara, Bhawal Mirzapur, Gazipur. Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh.	Solriamfetol 150 mg Tablet	Solriamfetol Hydrochloride INN equivalent to Solriamfetol 150 mg tablet.	Antidepressants	Solriamfetol is a dopamine and norepinephrine reuptake inhibitor (DNRI) indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).	**Contra-indication:** Concurrent treatment with a monoamine oxidase inhibitor (MAOI) or use of an MAOI within the preceding 14 days. **Side-effect:** headache, nausea, decreased appetite, insomnia, and	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						anxiety. **WARNINGS AND PRECAUTIONS:** **Blood Pressure and Heart Rate Increases:** Measure heart rate and blood pressure prior to initiating and periodically throughout treatment. Control hypertension before and during therapy. Avoid use in patients with unstable cardiovascular disease, serious heart arrhythmias, or other serious heart problems. **Psychiatric Symptoms:** Use caution in treating patients with a history of psychosis or bipolar disorders. Consider dose reduction or discontinuation of Solriamfetol if psychiatric symptoms develop.				
10.	Pharmasia Limited, Gojariapara, Bhawal Mirzapur, Gazipur.	Dextrose Monohydrate 40% Oral Gel	Dextrose Monohydrate USP 40% Oral Gel	Caloric Agents	Glucose pharmaceutical formulations are indicated for caloric supply and carbohydrate supplementation in case of nutrient deprivation. It is also used in metabolic disorders such as hypoglycemia.	**Contra-indication:** Contraindicated in patients with a known hypersensitivity to Dextrose or Glucose. **Side-effect:** Chills, electrolyte imbalance, fever, fluid imbalance, hypersensitivity, local reaction, localized pain, polyuria, rash, venous thrombosis.	New	BNF 76 Page-1009	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
11.	Pharmasia Limited, Gojariapara, Bhawal Mirzapur, Gazipur. Beacon Pharmaceuticals Ltd, Kathali, Bhaluka,	Iron 30mg Capsule	Ferric Maltol INN 231.500mg eq. to Iron 30mg	DRUG used in Anemia and other Blood disorder	Ferric Maltol is an iron replacement product indicated for the treatment of iron deficiency in adults.	**Contra-indication:** • Hypersensitivity to the active substance or any excipient • Hemochromatosis and other iron overload syndromes	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
	Mymensingh. **Delta Pharma Ltd, Pakundia, Kishorganj.** Team Pharmaceuticals Ltd. BSCIC, Rajshahi. Opsonin Pharma Ltd, Rupatali, Barishal. Somatec Pharmaceuticals ltd, Demra, Dhaka. **Advanced Chemical Industries Limited, 07 Hajeeganj, Godnayl, Narayanganj.** EVEREST Pharmaceuticals Ltd. Kanchpur BSCIC, Soanragon, Narayanagnj BANGLADESH					• Patients receiving repeated blood transfusions **Side-effect:** Most common adverse reactions (incidence > 1%) are flatulence, diarrhea, constipation, feces discolored, abdominal pain, nausea, vomiting and abdominal discomfort/distension. **WARNINGS AND PRECAUTIONS:** **IBD flare:** Avoid use in patients with IBD flare **Iron overload:** Accidental overdose of iron products is a leading cause of fatal poisoning in children under 6. Keep out of reach of children.				
12.	Pharmasia Limited, Gojariapara, Bhawal Mirzapur, Gazipur.	Dolutegravir 50 mg Tablet	Dolutegravir 50 mg Tablet	Antiviral	Dolutegravir is a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI) indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and children aged 12 years and older and weighing at least 40 kg.	**Contraindication:** Coadministration of Dolutegravir with dofetilide is contraindicated due to the potential for increased dofetilide plasma concentrations and the risk for serious and/or life-threatening events. **Side-effect:** The most common adverse reactions of moderate to severe intensity and incidence ≥2% (in those receiving Dolutegravir in any one adult trial) are insomnia and headache. **Warnings and precautions:** • Hypersensitivity reactions characterized by rash,	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						constitutional findings, and sometimes organ dysfunction, including liver injury, have been reported. Discontinue Dolutegravir and other suspect agents immediately if signs or symptoms of hypersensitivity reactions develop, as a delay in stopping treatment may result in a life-threatening reaction. Dolutegravir should not be used in patients who have experienced a previous hypersensitivity reaction to Dolutegravir. • Patients with underlying hepatitis B or C may be at increased risk for worsening or development of transaminase elevations with use of Dolutegravir. Appropriate laboratory testing prior to initiating therapy and monitoring for hepatotoxicity during therapy with Dolutegravir is recommended in patients with underlying hepatic disease such as hepatitis B or C. • Redistribution/accumulation of body fat and immune reconstitution syndrome have been reported in patients treated with combination antiretroviral therapy.				
13.	Navana Pharmaceuticals Limited, Rupshi, Rupganj, Narayangonj.	Itraconazole 200 mg Capsule	Itraconazole Pellets 40% w/w Ph.gr. 500 mg (As Itraconazole USP 200 mg) Capsule	Antifungal Agent	Itraconazole Capsules are indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised patients: 1. Blastomycosis, pulmonary and extrapulmonary 2. Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis, and	**Contraindication :** Itraconazole Capsules should not be administered for the treatment of onychomycosis in patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF.	Itraconazole 100 mg Capsule	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					3. Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy.	**Side-effect:** It has been associated with rare cases of serious hepatotoxicity, including liver failure and death. Some of these cases had neither pre-existing liver disease nor a serious underlying medical condition. If clinical signs or symptoms develop that are consistent with liver disease, treatment should be discontinued and liver function testing performed. **<u>Warnings and precautions:</u>** Itraconazole Capsule has been associated with rare cases of serious hepatotoxicity, including liver failure and death. Some of these cases had neither pre-existing liver disease nor a serious underlying medical condition, and some of these cases developed within the first week of treatment. If clinical signs or symptoms develop that are consistent with liver disease, treatment should be discontinued and liver function testing performed. Continued Itraconazole use or reinstitution of treatment with Itraconazole is strongly discouraged unless there is a serious or life-threatening situation where the expected benefit exceeds the risk.				
14.	Navana Pharmaceuticals Limited, Rupshi, Rupganj, Narayangonj.	Calcitriol 3mcg/g Ointment	Calcitriol USP 3mcg/g Ointment	Vitamins and Combinations	Calcitriol Ointment is a vitamin D analog indicated for the topical treatment of mild to moderate plaque psoriasis in adults 18 years and older.	**Contraindication :** None **Side-effect:** Most common side effects (incidence >3%) were lab test abnormality, urine	Existing: calcitriol injection 1 mcg/ml	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						abnormality, psoriasis, hypercalciuria, and pruritus. **<u>Warnings and precautions:</u>** If aberrations in parameters of calcium metabolism are noted discontinue Calcitriol Ointment until these normalize. • Avoid excessive exposure of Calcitriol Ointment treated areas to either natural or artificial sunlight.				
15.	Navana Pharmaceuticals Limited, Rupshi, Rupganj, Narayangonj. Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Naproxen 220mg + Diphenhydramine 25 mg Tablet	Naproxen Sodium BP 220 mg + Diphenhydramine Hydrochloride BP 25mg Tablets	Nonsteroidal antiinflamatory and drugs used in arthritis	It is Indicated for Occasional use, for a limited period of time (five days or less), for fast and effective relief of acute nighttime pain and accompanying sleeplessness caused by aches and pains associated with arthritis, joints, muscles, backache, headache, migraine pain and toothache and, in these circumstances, for increased duration of sleep uninterrupted by pain • Helps you fall asleep and stay asleep.	**Contraindication:** It is contraindicated in patients: • who have previously exhibited allergy or with known hypersensitivity to the active substances naproxen or diphenhydramine hydrochloride or any of the excipients in the tablet. • with a history of asthma, urticaria, or allergic-type reactions after taking acetylsalicylic acid (ASA) or other NSAIDs (i.e. complete or partial syndrome of ASA-intolerance - rhinosinusitis, urticaria/angioedema, nasal polyps, asthma). Fatal anaphylactoid reactions have occurred in such individuals. Individuals with the above medical problems are at risk of a severe reaction even if they have taken NSAIDs in the past without any adverse reaction. • with active peptic ulcers, a history of	**New** Naproxen 250 mg Tablet Esomeprazole 20 mg + Naproxen 500 mg Tablet Diphenhydramine Hydrochloride 50 mg Tablet	USFDA কর্তৃক OTC হিসেবে অনুমোদিত।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						recurrent ulceration, or active gastrointestinal bleeding • with inflammatory bowel disease. • with severe liver impairment or active liver disease • with severe renal impairment (creatinine clearance <30 mL/min or 0.5 mL/sec) or deteriorating renal disease (individuals with lesser degrees of renal impairment are at risk of deterioration of their renal function when prescribed NSAIDs and must be monitored) • in women in their third trimester of pregnancy because of risk of premature closure of the ductus arteriosus and prolonged parturition. **Side-effects:** Stop use and contact a doctor if you experience: heartburn, nausea, vomiting, ringing or buzzing in the ears, bloating,redness or swelling is present in the painful area, choking sensation,diarrhea or constipation.				
16.	Navana Pharmaceuticals Limited, Rupshi, Rupganj, Narayangonj.	Amorolfine 0.25% Cream	Amorolfine BP 0.25% w/w Cream	Anti-Fungal Agent	Dermatomycoses caused by dermatophytes: tinea pedis (athlete's foot), tinea cruris, tinea inguinalis, tinea corporis, tinea manuum, pityriasis versicolor.	**Contraindications:** Amorolfine cream must not be reused by patients who have shown hypersensitivity to the active substance or to any of the excipients. No experience exists of use during pregnancy and nursing, therefore, the use of	Amorolfine Hydrochloride 50 mg/ml Solution.	UKMHRA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						amorolfine cream should be avoided during pregnancy and lactation. **Adverse Reactions:** Adverse reactions are rare and mostly mild in nature. Most common adverse reactions are Immune system disorders, Skin and subcutaneous tissue disorders. **Warnings and precautions:** Avoid contact of the lacquer with eyes, ears and mucous membranes. Patients with underlying conditions predisposing to fungal nail infections should be referred to a doctor. Such conditions include peripheral circulatory disorders, diabetes mellitus, and immunosuppression. Patients with nail dystrophy and destroyed nail plate should be referred to their doctor.				
17.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Melphalan 2mg Tablet	Melphalan USP 2mg	Anti-cancer	This Tablets are indicated for the palliative treatment of multiple myeloma and for the palliation of non-resectable epithelial carcinoma of the ovary. Neuroblastoma, Breast Cancer, Malignant Melanoma.	**Contra-indication:** Melphalan should not be used in patients whose disease has demonstrated a prior resistance to this agent. Patients who have demonstrated hypersensitivity to melphalan should not be given the drug. **Side-effect:** Hematologic: The most common side effect is bone marrow suppression leading to leukopenia, thrombocytopenia, and anemia. Although bone marrow suppression frequently occurs, it is usually reversible if melphalan is withdrawn early enough. However, irreversible bone marrow failure has been	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						reported. Gastrointestinal: Nausea, vomiting, diarrhea, and oral ulceration occur. Hepatic disorders ranging from abnormal liver function tests to clinical manifestations such as hepatitis and jaundice have been reported. Miscellaneous: Other reported adverse reactions include: pulmonary fibrosis (including fatal outcomes) and interstitial pneumonitis, skin hypersensitivity, maculopapular rashes, vasculitis, alopecia, and hemolytic anemia. Allergic reactions, including urticaria, edema, skin rashes, and rare anaphylaxis, have occurred after multiple courses of treatment. Cardiac arrest has also been reported rarely in association with such reports. **Warnings and precautions:** Melphalan should be administered in carefully adjusted dosage by or under the supervision of experienced physicians who are familiar with the drug's actions and the possible complications of its use.				
18.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Melphalan 50mg/vial Injection (Lyophilized powder)	Melphalan Hydrochloride INN 56.00mg eq. to Melphalan 50mg/vial	Anti-cancer	Melphalan for Injection is indicated for the palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate.	**Contra-indication:** History of serious allergic reaction to melphalan. **Side-effect:** Most common adverse reactions observed in at least 50% of patients treated with Melphalan are neutrophil count decreased, white blood cell count decreased, lymphocyte count	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						decreased, platelet count decreased, diarrhea, nausea, fatigue, hypokalemia, anemia, and vomiting. **<u>Warnings and precautions:</u>** Gastrointestinal toxicity: Nausea, vomiting, diarrhea or oral mucositis may occur; provide supportive care using antiemetic and antidiarrheal medications as needed. • Embryo-fetal toxicity: Can cause fetal harm. Advise of potential risk to fetus and to avoid pregnancy. • Infertility: Melphalan may cause ovarian function suppression or testicular suppression.				
19.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Brexanolone 100mg/20ml (5mg/ml) Injection	Brexanolone INN 100mg/20ml	Antidepressants	It is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression (PPD) in adult.	**Contra-indication: None** **Side-effect:** Most common adverse reactions (incidence ≥5% and at least twice the rate of placebo) were sedation/somnolence, dry mouth, loss of consciousness, and flushing/hot flush. **<u>Warnings and precautions:</u>** **Suicidal Thoughts and Behaviors:** Consider changing the therapeutic regimen, including discontinuing Brexanolone, in patients whose PPD becomes worse or who experience emergent suicidal thoughts and behaviors.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
20.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh. Incepta Pharmaceuticals	Sufentanil 30 mcg Sublingual Tablet	Sufentanil Citrate USP 45 mcg eq. to Sufentanil 30 mcg	opioid analgesic	Sufentanil, an opioid agonist, and is indicated for use in adults in a certified medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic and for which	**Contra-indication:** • Significant Respiratory Depression. • Acute or severe bronchial	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
	Ltd.; Zirabo, Savar, Dhaka. SOMATEC PHARMACEUTICALS LTD., SARULIA, DEMRA, DHAKA BANGLADESH Eskayef Pharmaceuticals Limited, Tongi, Gazipur.				alternative treatments are inadequate. **Limitations of Use:** • Not for home use or for use in children. Discontinue treatment with Sufentanil before patients leave the certified medically supervised healthcare setting. • Not for use for more than 72 hours. • Only to be administered by a healthcare provider. • Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Sufentanil for use in patients for whom alternative treatment options [e.g., non-opioid analgesics or opioid combination products]: - Have not been tolerated, or are not expected to be tolerated, - Have not provided adequate analgesia, or are not expected to provide adequate analgesia.	asthma in an unmonitored setting or in the absence of resuscitative equipment. • Known or suspected gastrointestinal obstruction, including paralytic ileus. • Known hypersensitivity to sufentanil or components of sufentanil. **Side-effect**: The most commonly reported adverse reactions (≥ 2%) were nausea, headache, vomiting, dizziness and hypotension. **Warnings and precautions:** Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely, particularly during initiation and titration. • Serotonin Syndrome: Potentially life-threatening condition could result from concomitant serotonergic drug administration. Discontinue Sufentanil if serotonin syndrome is suspected. • Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid. • Severe Hypotension: Monitor during dosage initiation and titration. Avoid use of Sufentanil in patients with circulatory shock. • Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness: Monitor for sedation and respiratory depression. Avoid				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						use of Sufentanil in patients with impaired consciousness or coma.				
21.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Sufentanil 100 mcg/ 2 ml Ampoule injection	Sufentanil Citrate USP 149.631mcg eq. to Sufentanil 100 mcg / 2 ml Ampoule	opioid analgesic	Sufentanil Citrate Injection is an opioid agonist indicated: • as an analgesic adjunct in the maintenance of balanced general anesthesia in patients who are intubated and ventilated. • as a primary anesthetic agent for the induction and maintenance of anesthesia with 100% oxygen in patients undergoing major surgical procedures, in patients who are intubated and ventilated, such as cardiovascular surgery or neurosurgical procedures in the sitting position, to provide favorable myocardial and cerebral oxygen balance or when extended postoperative ventilation is anticipated. • for epidural administration as an analgesic combined with low dose (usually 12.5 mg per administration) bupivacaine usually during labor and vaginal delivery.	**Contra-indication:** Hypersensitivity to sufentanil **Side-effect:** Most common adverse reactions were apnea, rigidity, and bradycardia. **<u>Warnings and precautions:</u>** • Risks of Skeletal Muscle Rigidity and Skeletal Muscle Movement: Manage with neuromuscular blocking agent. See full prescribing information for more detail on managing these risks. • Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or • Debilitated Patients: Monitor closely, particularly during initiation and titration. • Severe Cardiovascular Depression: Monitor during dosage initiation and titration. • Serotonin Syndrome: Potentially life-threatening condition could result from concomitant serotonergic drug administration. Discontinue Sufentanil Citrate Injection if serotonin syndrome is suspected. • Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, or Head Injury: Monitor for sedation and respiratory depression.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
22.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh.	Istradefylline 20mg Tablet	Istradefylline INN 20mg	Neuropsychiatric agent	It is an adenosine receptor antagonist indicated as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes.	**Contra-indication:** None **Side-effect:** The most common adverse reactions (at least 5%	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka					and more frequent than placebo) were dyskinesia, dizziness, constipation, nausea, hallucination, and insomnia. **Warnings and precautions:** • Dyskinesia: Monitor patients for dyskinesia or exacerbation of existing dyskinesia. • Hallucinations / Psychotic Behavior: Consider dosage reduction or stopping Istradefylline if occurs. • Impulse Control / Compulsive Behaviors: Consider dosage reduction or stopping Istradefylline if occurs.				
23.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Istradefylline 40mg Tablet	Istradefylline INN 40mg	Neuropsychiatric agent	It is an adenosine receptor antagonist indicated as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes.	**Contra-indication:** None **Side-effect:** The most common adverse reactions (at least 5% and more frequent than placebo) were dyskinesia, dizziness, constipation, nausea, hallucination, and insomnia. **Warnings and precautions:** • Dyskinesia: Monitor patients for dyskinesia or exacerbation of existing dyskinesia. • Hallucinations / Psychotic Behavior: Consider dosage reduction or stopping Istradefylline if occurs. • Impulse Control / Compulsive Behaviors: Consider dosage reduction or stopping Istradefylline if occurs.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
24.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh. M/S Ziska Pharma Ltd, Kaliakoir, Sofipur, Gazipur.	Upadacitinib 15mg ER Tablet	Upadacitinib INN 15mg	Antirheumatic Drugs	It is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with moderately to severely active rheumatoid arthritiswho have had an inadequate response or intolerance to methotrexate. **Limitation of Use:** Use of Upadacitinib in combination with other JAK inhibitors, biologic DMARDs, or with potent	**Contra-indication**: None **Side-effect:** Adverse reactions (greater than or equal to 1%) are: upper respiratory tract infections, nausea, cough, and pyrexia.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
	Advanced Chemical Industries Limited, 07 Hajeeganj, Godnayl, Narayanganj. **Delta Pharma Ltd, Pakundia, Kishorganj.** Eskayef Pharmaceuticals Limited, Tongi, Gazipur SOMATEC PHARMACEUTICALS LTD., SARULIA, DEMRA, DHAKA BANGLADESH Drug International Ltd (Unit-3) 31/1, Satrong Road, Gopalpur, Tongi Industrial Area Gazipur, Bangladesh. **Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka**				immunosuppressants such as azathioprine and cyclosporine is not recommended.	**Warnings and precautions:** • Serious Infections: Avoid use of Upadacitinib in patients with active, serious infection, including localized infections. • Malignancy: Consider the risks and benefits of Upadacitinib treatment prior to initiating therapy in patients with a known malignancy. • Thrombosis: Consider the risks and benefits prior to treating patients who may be at increased risk of thrombosis. Promptly evaluate patients with symptoms of thrombosis and treat appropriately. • Gastrointestinal Perforations: Use with caution in patients who may be at increased risk. • Laboratory Monitoring: Recommended due to potential changes in lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids. • Embryo-Fetal Toxicity: Upadacitinib may cause fetal harm based on animal studies. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception. • Vaccinations: Avoid use of Upadacitinib with live vaccines.				
25.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Bremelanotide 1.75mg/0.3ml Pre-filled syringe	Bremelanotide Acetate INN 1.890mg eq. to Bremelanotide 1.75mg/0.3ml	Antipsychotic	It is a melanocortin receptor agonist indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to: • A co-existing medical or psychiatric condition, • Problems with the relationship, or •The effects of a medication or drug substance **Limitations of Use:** • Not indicated for treatment of HSDD in postmenopausal women or in men. • Not indicated to enhance sexual performance.	**Contra-indication:** Uncontrolled hypertension or known cardiovascular disease **Side-effect:** Most common adverse reactions (incidence > 4%) are nausea, flushing, injection site reactions, headache, and vomiting. **Warnings and precautions:** • Transient increase in blood pressure and decrease in heart	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						rate: Occurs after each dose and usually resolves within 12 hours. Consider the patient's cardiovascular risk before initiating Bremelanotide injection and periodically during. treatment and ensure blood pressure is well-controlled. Bremelanotide injection is not recommended in patients at high risk for cardiovascular disease. •Focal hyperpigmentation: Reported by 1% of patients who received up to 8 doses per month, including involvement of the face, gingiva and breasts. Higher risk in patients with darker skin and with daily dosing. Resolution was not confirmed in some patients. Consider discontinuing Bremelanotide injection if hyperpigmentation develops. • Nausea: Reported by 40% of patients who received up to 8 monthly doses, requiring anti-emetic therapy in 13% of patients and leading to premature discontinuation for 8% of patients. Improved for most patients with the second dose. Consider discontinuing Bremelanotide injection or initiating anti-emetic therapy for persistent or severe nausea.				
26.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Pomalidomide 1mg Capsule	Pomalidomide INN 1mg	Anti-cancer	It is a thalidomide analogue indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified	**Contra-indication:** It can cause fetal harm when administered to a pregnant female. It is contraindicated in females who are pregnant. Pomalidomide is a thalidomide analogue, and is teratogenic in both rats and rabbits when administered during the period of organogenesis. If this drug is used during pregnancy or if the patient becomes pregnant while	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						taking this drug, the patient should be apprised of the potential hazard to a fetus. **Side-effect:** Most common adverse reactions (≥30%) included fatigue and asthenia, neutropenia, anemia, constipation, nausea, diarrhea, dyspnea, upperrespiratory tract infections, back pain and pyrexia. **Warnings and precautions:** **Hematologic Toxicity:** Neutropenia was the most frequently reported Grade 3/4 adverse event. Monitor patients for hematologic toxicities, especially neutropenia.				
27.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Pomalidomide 2mg Capsule	Pomalidomide INN 2mg	Anti-cancer	It is a thalidomide analogue indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified	**Contra-indication:** It can cause fetal harm when administered to a pregnant female. It is contraindicated in females who are pregnant. Pomalidomide is a thalidomide analogue, and is teratogenic in both rats and rabbits when administered during the period of organogenesis. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus. **Side-effect:** Most common adverse reactions (≥30%) included fatigue and asthenia, neutropenia, anemia, constipation, nausea, diarrhea, dyspnea, upperrespiratory tract infections, back pain and pyrexia. **Warnings and precautions:** **Hematologic Toxicity:** Neutropenia was the most	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						frequently reported Grade 3/4 adverse event. Monitor patients for hematologic toxicities, especially neutropenia				
28.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Pomalidomide 3mg Capsule	Pomalidomide INN 3mg	Anti-cancer	It is a thalidomide analogue indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified	**Contra-indication:** It can cause fetal harm when administered to a pregnant female. It is contraindicated in females who are pregnant. Pomalidomide is a thalidomide analogue, and is teratogenic in both rats and rabbits when administered during the period of organogenesis. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus. **Side-effect:** Most common adverse reactions (≥30%) included fatigue and asthenia, neutropenia, anemia, constipation, nausea, diarrhea, dyspnea, upperrespiratory tract infections, back pain and pyrexia. **Warnings and precautions:** **Hematologic Toxicity:** Neutropenia was the most frequently reported Grade 3/4 adverse event. Monitor patients for hematologic toxicities, especially neutropenia	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
29.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh. Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka **Opsonin Pharma Limited,** Rupatali, Barishal.	Rifamycin 194 mg DR Tablet	Rifamycin Sodium BP 200mg eq. to Rifamycin 194mg	Antitubercular	It is a rifamycin antibacterial indicated for the treatment of travelers' diarrhea caused by noninvasive strains of Escherichia coli in adults. **Limitations of Use:** It is not recommended for use in patients with diarrhea complicated by fever and/or bloody stool or due to pathogens other than noninvasive strains of E. coli. To reduce the development of drug-resistant bacteria and	**Contra-indication:** Rifamycin is contraindicated in patients with a known hypersensitivity to rifamycin, any of the other rifamycin class antimicrobial agents (e.g. rifaximin), or any of the components in Rifamycin. **Side-effect:** Most common adverse reactions	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					maintain the effectiveness of Rifamycin and other antibacterial drugs, Rifamycin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	(incidence > 2%) are headache and constipation. **Warnings and precautions:** Risk of Persistent or Worsening Diarrhea Complicated by Fever and/or Bloody Stool: Rifamycin was not shown to be effective in patients with diarrhea complicated by fever and/or bloody stool or diarrhea due to pathogens other than noninvasive strains of E. coli and is not recommended for use in such patients. Discontinue use if diarrhea gets worse or persists more than 48 hours, and consider alternative antibacterial therapy. • Clostridium difficile-associated Diarrhea: Evaluate if diarrhea occurs after therapy or does not improve or worsens during therapy.				
30.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Azacitidine 100mg/vial Injection.	Azacitidine INN 100mg/vial	Anti-cancer	It is indicated for treatment of patients with the following myelodysplastic syndrome subtypes: refractory anemia or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia.	**Contra-indication:** Azacitidine is contraindicated in patients with a known hypersensitivity to azacitidine or mannitol. Azacitidine is also contraindicated in patients with advanced malignant hepatic tumors **Side-effect:** Most common adverse reactions (>30%) by SC route are: nausea, anemia, thrombocytopenia, vomiting, pyrexia, leukopenia, diarrhea, injection site erythema, constipation, neutropenia and ecchymosis. Most common adverse reactions by IV route also included petechiae, rigors, weakness and hypokalemia. **Warnings and precautions:** Anemia, neutropenia and	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						thrombocytopenia. Perform complete blood counts (CBC) prior to each treatment cycle and as needed to monitor response and toxicity. Hepatotoxicity: Use with caution in patients with severe preexisting liver impairment. Renal abnormalities. Monitor patients with renal impairment for toxicity since azacitidine and its metabolites are primarily excreted by the kidneys . Monitor liver chemistries and serum creatinine prior to initiation of therapy and with each cycle. Azacitidine may cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be apprised of the potential hazard to a fetus. Men should be advised not to father a child while receiving Azacitidine.				
31.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Primidone 50mg Tablet	Primidone USP 50mg	Anti-convulsants	Primidone used alone or concomitantly with other anticonvulsants, is indicated in the control of grand mal, psychomotor, and focal epileptic seizures. It may control grand mal seizures refractory to other anticonvulsant therapy.	**Contra-indication:** Primidone is contraindicated in: 1) patients with porphyria and 2) patients who are hypersensitive to phenobarbital. **Side-effect:** The most frequently occurring early side effects are ataxia and vertigo. These tend to disappear with continued therapy, or with reduction of initial dosage. Occasionally, the following have been reported: nausea, anorexia, vomiting, fatigue, hyperirritability, emotional disturbances, sexual impotency, diplopia, nystagmus, drowsiness, and morbilliform skin eruptions. Granulocytopenia,	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						agranulocytosis, and red-cell hypoplasia and aplasia, have been reported rarely. These and, occasionally, other persistant or severe side effects may necessitate withdrawal of the drug. Megaloblastic anemia may occur as a rare idiosyncrasy to Primidone and to other anticonvulsants. The anemia responds to folic acid without necessity of discontinuing medication. **Warnings and precautions:** The abrupt withdrawal of antiepileptic medication may precipitate status epilepticus. The therapeutic efficacy of a dosage regimen takes several weeks before it can be assessed.				
32.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Carfilzomib 10mg/vial (Lyophilized powder)	Carfilzomib INN 10mg/vial	Anti-cancer	It is a proteasome inhibitor that is indicated: • as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.	**Contra-indication:** None **Side-effect:** The most common adverse reactions occurring in at least 20% of patients treated with Carfilzomib in monotherapy trials: anemia, fatigue, thrombocytopenia, nausea, pyrexia, dyspnea, diarrhea, headache, cough, edema peripheral. The most common adverse reactions occurring in at least 20% of patients treated with Carfilzomib in the combination therapy trials: anemia, neutropenia, diarrhea, dyspnea, fatigue, thrombocytopenia, pyrexia, insomnia, muscle spasm, cough, upper respiratory tract infection, hypokalemia. **Warnings and precautions:** Cardiac Toxicities: Monitor for signs and symptoms of cardiac failure or ischemia. Withhold	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Carfilzomib and evaluate promptly. • Acute Renal Failure: Monitor serum creatinine regularly. • Tumor Lysis Syndrome (TLS): Administer pre-treatment hydration. Monitor for TLS, including uric acid levels and treat promptly. • Pulmonary Toxicity, including Acute Respiratory Distress Syndrome, Acute Respiratory Failure, and Acute Diffuse Infiltrative Pulmonary Disease: Withhold Carfilzomiband evaluate promptly. • Pulmonary Hypertension: Withhold Carfilzomiband evaluate. Dyspnea: For severe or life-threatening dyspnea, withhold Carfilzomiband evaluate. • Hypertension, including Hypertensive Crisis: Monitor blood pressure regularly. If hypertension cannot be controlled, interrupt treatment with Kyprolis. • Venous Thrombosis: Thromboprophylaxis is recommended. • Infusion Reactions: Premedicate with dexamethasone. • Hemorrhage: Fatal or serious cases of hemorrhage may occur, including gastrointestinal, pulmonary, and intracranial hemorrhage. Promptly evaluate signs and symptoms of blood loss. • Thrombocytopenia: Monitor platelet counts; interrupt or reduce Carfilzomibdosing as clinically indicated. • Hepatic Toxicity and Hepatic				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Failure: Monitor liver enzymes regularly. Withhold Carfilzomibif suspected. • Thrombotic Microangiopathy: Monitor for signs and symptoms. Discontinue Carfilzomibif suspected. • Posterior Reversible Encephalopathy Syndrome (PRES): Consider neuro-radiological imaging (MRI) for onset of visual or neurological symptoms; discontinue Carfilzomibif suspected. • Increased Fatal and Serious Toxicities in Combination with Melphalan and Prednisone in Newly Diagnosed Transplant-Ineligible Patients • Embryo-Fetal Toxicity: Carfilzomibcan cause fetal harm. Females of reproductive potential should avoid becoming pregnant while being treated.				
33.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Carfilzomib 30mg/vial (Lyophilized powder)	Carfilzomib INN 30mg/vial	Anti-cancer	It is a proteasome inhibitor that is indicated: • as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.	**Contra-indication:** None **Side-effect:** The most common adverse reactions occurring in at least 20% of patients treated with Carfilzomib in monotherapy trials: anemia, fatigue, thrombocytopenia, nausea, pyrexia, dyspnea, diarrhea, headache, cough, edema peripheral. The most common adverse reactions occurring in at least 20% of patients treated with Carfilzomib in the combination therapy trials: anemia, neutropenia, diarrhea, dyspnea, fatigue, thrombocytopenia, pyrexia, insomnia, muscle spasm, cough, upper respiratory	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						tract infection, hypokalemia. **<u>Warnings and precautions:</u>** Cardiac Toxicities: Monitor for signs and symptoms of cardiac failure or ischemia. Withhold Carfilzomib and evaluate promptly. • Acute Renal Failure: Monitor serum creatinine regularly. • Tumor Lysis Syndrome (TLS): Administer pre-treatment hydration. Monitor for TLS, including uric acid levels and treat promptly. • Pulmonary Toxicity, including Acute Respiratory Distress Syndrome, Acute Respiratory Failure, and Acute Diffuse Infiltrative Pulmonary Disease: Withhold Carfilzomiband evaluate promptly. • Pulmonary Hypertension: Withhold Carfilzomiband evaluate. Dyspnea: For severe or life-threatening dyspnea, withhold Carfilzomiband evaluate. • Hypertension, including Hypertensive Crisis: Monitor blood pressure regularly. If hypertension cannot be controlled, interrupt treatment with Kyprolis. • Venous Thrombosis: Thromboprophylaxis is recommended. • Infusion Reactions: Premedicate with dexamethasone. • Hemorrhage: Fatal or serious cases of hemorrhage may occur, including gastrointestinal, pulmonary, and intracranial hemorrhage. Promptly evaluate signs and symptoms of blood				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						loss. • Thrombocytopenia: Monitor platelet counts; interrupt or reduce Carfilzomibdosing as clinically indicated. • Hepatic Toxicity and Hepatic Failure: Monitor liver enzymes regularly. Withhold Carfilzomibif suspected. • Thrombotic Microangiopathy: Monitor for signs and symptoms. Discontinue Carfilzomibif suspected. • Posterior Reversible Encephalopathy Syndrome (PRES): Consider neuro-radiological imaging (MRI) for onset of visual or neurological symptoms; discontinue Carfilzomibif suspected. • Increased Fatal and Serious Toxicities in Combination with Melphalan and Prednisone in Newly Diagnosed Transplant-Ineligible Patients • Embryo-Fetal Toxicity: Carfilzomibcan cause fetal harm. Females of reproductive potential should avoid becoming pregnant while being treated.				
34.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Carfilzomib 60mg/vial (Lyophilized powder)	Carfilzomib INN 60mg/vial	Anti-cancer	It is a proteasome inhibitor that is indicated: • as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.	**Contra-indication:** None **Side-effect:** The most common adverse reactions occurring in at least 20% of patients treated with Carfilzomib in monotherapy trials: anemia, fatigue, thrombocytopenia, nausea, pyrexia, dyspnea, diarrhea, headache, cough, edema peripheral. The most common adverse reactions occurring in at least 20% of patients treated with	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Carfilzomib in the combination therapy trials: anemia, neutropenia, diarrhea, dyspnea, fatigue, thrombocytopenia, pyrexia, insomnia, muscle spasm, cough, upper respiratory tract infection, hypokalemia. **<u>Warnings and precautions:</u>** Cardiac Toxicities: Monitor for signs and symptoms of cardiac failure or ischemia. Withhold Carfilzomib and evaluate promptly. • Acute Renal Failure: Monitor serum creatinine regularly. • Tumor Lysis Syndrome (TLS): Administer pre-treatment hydration. Monitor for TLS, including uric acid levels and treat promptly. • Pulmonary Toxicity, including Acute Respiratory Distress Syndrome, Acute Respiratory Failure, and Acute Diffuse Infiltrative Pulmonary Disease: Withhold Carfilzomiband evaluate promptly. • Pulmonary Hypertension: Withhold Carfilzomiband evaluate. Dyspnea: For severe or life-threatening dyspnea, withhold Carfilzomiband evaluate. • Hypertension, including Hypertensive Crisis: Monitor blood pressure regularly. If hypertension cannot be controlled, interrupt treatment with Kyprolis. • Venous Thrombosis: Thromboprophylaxis is recommended. • Infusion Reactions:				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Premedicate with dexamethasone. • Hemorrhage: Fatal or serious cases of hemorrhage may occur, including gastrointestinal, pulmonary, and intracranial hemorrhage. Promptly evaluate signs and symptoms of blood loss. • Thrombocytopenia: Monitor platelet counts; interrupt or reduce Carfilzomibdosing as clinically indicated. • Hepatic Toxicity and Hepatic Failure: Monitor liver enzymes regularly. Withhold Carfilzomibif suspected. • Thrombotic Microangiopathy: Monitor for signs and symptoms. Discontinue Carfilzomibif suspected. • Posterior Reversible Encephalopathy Syndrome (PRES): Consider neuro-radiological imaging (MRI) for onset of visual or neurological symptoms; discontinue Carfilzomibif suspected. • Increased Fatal and Serious Toxicities in Combination with Melphalan and Prednisone in Newly Diagnosed Transplant-Ineligible Patients • Embryo-Fetal Toxicity: Carfilzomibcan cause fetal harm. Females of reproductive potential should avoid becoming pregnant while being treated.				
35.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Atezolizumab 840mg/14ml injection	Atezolizumab INN 840mg/14ml	Anti-cancer	Atezolizumab is a programmed death-ligand 1 (PD-L1) blocking antibody indicated for the treatment of patients with: • Locally advanced or metastatic urothelial carcinoma who: • are not eligible for cisplatin-containing chemotherapy, and whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 5% of the tumor	**Contra-indication:** None **Side-effect:** Most common adverse reactions (≥ 20%) in patients with locally advanced or metastatic urothelial carcinoma were fatigue,	Atezolizumab INN 1200mg/20ml	রেফারেন্স নাই	ঔষধটির প্রয়োজন রয়েছে বিধায় আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					area), or • are not eligible for any platinum-containing chemotherapy regardless of level of tumor PD-L1 expression, or • have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. • Metastatic non-small cell lung cancer who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDAapproved therapy for these aberrations prior to receiving atezolizumab .	decreased appetite, nausea, constipation, urinary tract infection, diarrhea, and pyrexia. Most common adverse reactions (≥ 20%) in patients with metastatic non-small cell lung cancer were fatigue, decreased appetite, dyspnea, and cough. **Warnings and precautions:** Immune-Mediated Pneumonitis: Withhold or permanently discontinue based on severity of pneumonitis. • Immune-Mediated Hepatitis: Monitor for changes in liver function. Withhold or permanently discontinue based on severity of transaminase or total bilirubin elevation. • Immune-Mediated Colitis: Withhold or permanently discontinue based on severity of colitis. • Immune-Mediated Endocrinopathies -Hypophysitis: Withhold based on severity of hypophysitis. -Thyroid Disorders: Monitor for changes in thyroid function. Withhold based on severity of hyperthyroidism. -Adrenal Insufficiency: Withhold based on severity of adrenal insufficiency. -Type 1 Diabetes Mellitus: Withhold based on severity of hyperglycemia. • Infections: Withhold for severe or life-threatening infection. • Infusion-Related Reactions: Interrupt, slow the rate of infusion, or permanently discontinue based on severity of infusion reactions. • Embryo-Fetal Toxicity: Can				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and use of effective contraception.				
36.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Pexidartinib 200mg Capsule	Pexidartinib Hydrochloride INN 217.5mg eq to Pexidartinib 200 mg	Anti-cancer	Pexidartinib is a kinase inhibitor indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.	**Contra-indication: None** **Side-effect:** Most common adverse reactions (>20%) were increased lactate dehydrogenase, increased aspartate aminotransferase, hair color changes, fatigue, increased alanine aminotransferase, decreased neutrophils, increased cholesterol, increased alkaline phosphatase, decreased lymphocytes, eye edema, decreased hemoglobin, rash, dysgeusia, and decreased phosphate. **Warnings and precautions:** Embryo-Fetal Toxicity: May cause fetal harm. Advise patients of reproductive potential of the potential risk to a fetus and to use an effective method of contraception.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
37.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Fedratinib 100mg Capsule	Fedratinib Dihydrochloride Monohydrate INN 117.3mg eq. to Fedratinib 100mg	Anti-cancer	It is a kinase inhibitor indicated for the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis.	**Contra-indication:** None **Side-effect:** The most common adverse reactions (≥20%) are diarrhea, nausea, anemia, and vomiting. **Warnings and precautions:** Anemia and Thrombocytopenia: Manage by dose reduction, interruption, or transfusion. • Gastrointestinal Toxicity: Manage by dose reduction or interruption if patient develops severe diarrhea, nausea, or vomiting. Prophylaxis with anti-	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						emetics and treatment with anti-diarrhea medications are recommended. • Hepatic Toxicity: Manage by dose reduction or interruption. • Amylase and Lipase Elevation: Manage by dose reduction or interruption.				
38.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Doxophylline 100mg/10ml Ampoule	Doxophylline INN 100mg/10ml	Antiasthmatic	Doxophylline is used for the treatment of acute phase of Bronchial Asthma, Chronic obstructive pulmonary Diseases and pulmonary disease associated with bronchospasm.	**Contra-indication:** Doxophylline in contraindicated in acute myocardial infarction. It is also contraindicated in patients with hypotension, in lactating women & patients who have shown hypersensitivity to its components. **Side-effect:** Doxophylline rarely causes serious side effects, however possible side effects are similar for taking excess amount of caffeine. These include nausea, vomiting, headaches, upset stomach and heartburn.	Doxophylline 200mg, 400mg tablet 100 mg/5 ml Syrup	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
39.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Amifostine Trihydrate USP	Amifostine Trihydrate USP 626 mg eqv. to Amifostine 500mg/vial (as Lyophilized Powder)	Anti-cancer	Amifostine is indicated to reduce the cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced ovarian cancer. Amifostine is indicated to reduce the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancer, where the radiation port includes a substantial portion of the parotid glands.	**Contra-indication:** Amifostine Trihydrate is contraindicated in patients with known hypersensitivity to aminothiol compounds. **Side-effect:** Most Common Side Effects are hypotension, nausea and vomiting.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
40.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Entrectinib 100mg capsule	Entrectinib INN 100mg	Anti-cancer	It is a kinase inhibitor indicated for the treatment of: • Adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive. • Adult and pediatric patients 12 years of age and older with solid tumors that: - have a neurotrophic tyrosine receptor kinase (NTRK)	**Contra-indication:** none. **Side-effect:** The most common adverse reactions (≥ 20%) were fatigue, constipation, dysgeusia, edema,	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					gene fusion without a known acquired resistance mutation, - are metastatic or where surgical resection is likely to result in severe morbidity, and - have progressed following treatment or have no satisfactory alternative therapy.	dizziness, diarrhea, nausea, dysesthesia, dyspnea, myalgia, cognitive impairment, increased weight, cough, vomiting, pyrexia, arthralgia, and vision disorders. **Warnings and precautions:** **Congestive Heart Failure:** Assess left ventricular ejection fraction prior to initiation of entrectinib in patients with symptoms or known risk factors for CHF. Monitor patients for clinical signs and symptoms of congestive heart failure (CHF). For patients with myocarditis, with or without a decreased ejection fraction, MRI or cardiac biopsy may be required to make the diagnosis. For new onset or worsening CHF, withhold entrectinib, reassess LVEF and institute appropriate medical management. Reduce dose or permanently discontinue entrectinib based on severity of CHF or worsening LVEF. **Central Nervous System (CNS) Effects:** CNS adverse reactions including cognitive impairment, mood disorders, dizziness, and sleep disturbances can occur with entrectinib. Withhold and then resume at same or reduced dose upon improvement or permanently discontinue entrectinib based on severity. **Skeletal Fractures:** entrectinib increases the risk of fractures. Promptly evaluate patients with signs or symptoms of fractures. **Hepatotoxicity:** Monitor liver tests, including ALT and AST, every 2 weeks during the first month of treatment, then monthly thereafter, and as clinically				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						indicated. Withhold or permanently discontinue entrectinib based on severity. If withheld, resume entrectinib at same or reduced dose based on severity. **Hyperuricemia:** Assess serum uric acid levels prior to initiation and periodically during treatment with entrectinib. Monitor patients for signs and symptoms of hyperuricemia. Initiate treatment with uratelowering medications as clinically indicated and withhold entrectinib for signs and symptoms of hyperuricemia. Resume at same or reduced dose upon improvement based on severity. **QT Interval Prolongation:** Monitor patients who have or who are at risk for QTc interval prolongation. Assess QT interval and electrolytes at baseline and periodically during treatment. Withhold and then resume at same or reduced dose, or permanently discontinue entrectinib based on severity. **Vision Disorders:** Withhold for new visual changes or changes that interfere with activities of daily living until improvement or stabilization. Conduct an ophthalmological evaluation as appropriate. Resume at same or reduced dose upon improvement or stabilization. **Embryo-Fetal Toxicity:** Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and use of effective contraception.				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
41.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh. Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka. Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Entrectinib 200 mg Capsule	Entrectinib immediate release pellets (50%w/w) INN 400 mg eq. to Entrectinib 200 mg	Anti-cancer	It is a kinase inhibitor indicated for the treatment of: • Adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive. • Adult and pediatric patients 12 years of age and older with solid tumors that: - have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, - are metastatic or where surgical resection is likely to result in severe morbidity, and - have progressed following treatment or have no satisfactory alternative therapy.	**Contra-indication:** none. **Side-effect:** The most common adverse reactions (≥ 20%) were fatigue, constipation, dysgeusia, edema, dizziness, diarrhea, nausea, dysesthesia, dyspnea, myalgia, cognitive impairment, increased weight, cough, vomiting, pyrexia, arthralgia, and vision disorders. **Warnings and precautions:** **Congestive Heart Failure:** Assess left ventricular ejection fraction prior to initiation of entrectinib in patients with symptoms or known risk factors for CHF. Monitor patients for clinical signs and symptoms of congestive heart failure (CHF). For patients with myocarditis, with or without a decreased ejection fraction, MRI or cardiac biopsy may be required to make the diagnosis. For new onset or worsening CHF, withhold entrectinib, reassess LVEF and institute appropriate medical management. Reduce dose or permanently discontinue entrectinib based on severity of CHF or worsening LVEF. **Central Nervous System (CNS) Effects:** CNS adverse reactions including cognitive impairment, mood disorders, dizziness, and sleep disturbances can occur with entrectinib. Withhold and then resume at same or reduced dose upon improvement or permanently discontinue entrectinib based on severity. **Skeletal Fractures:** entrectinib increases the risk of fractures. Promptly evaluate patients with	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						signs or symptoms of fractures. **Hepatotoxicity:** Monitor liver tests, including ALT and AST, every 2 weeks during the first month of treatment, then monthly thereafter, and as clinically indicated. Withhold or permanently discontinue entrectinib based on severity. If withheld, resume entrectinib at same or reduced dose based on severity. **Hyperuricemia:** Assess serum uric acid levels prior to initiation and periodically during treatment with entrectinib. Monitor patients for signs and symptoms of hyperuricemia. Initiate treatment with uratelowering medications as clinically indicated and withhold entrectinib for signs and symptoms of hyperuricemia. Resume at same or reduced dose upon improvement based on severity. **QT Interval Prolongation:** Monitor patients who have or who are at risk for QTc interval prolongation. Assess QT interval and electrolytes at baseline and periodically during treatment. Withhold and then resume at same or reduced dose, or permanently discontinue entrectinib based on severity. **Vision Disorders:** Withhold for new visual changes or changes that interfere with activities of daily living until improvement or stabilization. Conduct an ophthalmological evaluation as appropriate. Resume at same or reduced dose upon improvement or stabilization. **Embryo-Fetal Toxicity:** Can cause fetal harm. Advise females of reproductive potential				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						of the potential risk to a fetus and use of effective contraception.				
42.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh.	Tecovirimat 200mg Capsule	Tecovirimat Monohydrate INN 209.566 mg eq. to Tecovirimat 200mg	Anti-Viral	Tecovirimat is an inhibitor of the orthopoxvirus VP37 envelope wrapping protein and is indicated for the treatment of human smallpox disease in adults and pediatric patients weighing at least 13 kg. **Limitations of Use:** • The effectiveness of tecovirimat for treatment of smallpox disease has not been determined in humans because adequate and well-controlled field trials have not been feasible, and inducing smallpox disease in humans to study the drug's efficacy is not ethical. • tecovirimat efficacy may be reduced in immunocompromised patients based on studies demonstrating reduced efficacy in immunocompromised animal models.	**Contra-indication:** none. **Side-effect:** Common adverse reactions in healthy adult subjects (≥ 2%) were headache, nausea, abdominal pain, and vomiting. **Warnings and precautions:** Hypoglycemia: Co-administration with repaglinide may cause hypoglycemia. Monitor blood glucose and monitor for hypoglycemic symptoms during coadministration.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*
43.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur. **Acme Laboratories Ltd., Dhamrai, Dhaka**	Levodopa 50 mg + Benserazide 12.5 mg capsule	Levodopa BP 50 mg + Benserazide BP 12.5 mg	Antiparkinsonian	It is indicated for the treatment of all forms of Parkinson's syndrome with the exception of medicine-induced parkinsonism.	**Contraindications:** patients with known hypersensitivity to levodopa or benserazide or any of the excipients. • patients receiving non-selective monoamine oxidase (MAO) inhibitors due to the risk of hypertensive crisis. However, selective MAO-B inhibitors, such as selegiline and rasagiline, or selective MAO-A inhibitors, such as moclobemide, are not contraindicated. Combination of MAO-A and MAO-B inhibitors is equivalent to non-selective MAO inhibition, and hence this combination should not be given concomitantly with it. • patients with decompensated endocrine, renal or hepatic function, cardiac disorders, psychiatric diseases with a psychotic component or closed angle glaucoma. Because levodopa may activate a malignant melanoma, It should not be used in patients with suspicious, undiagnosed lesions	Carbidopa 10mg + Levodopa 100 mg Tablet Carbidopa 25mg + Levodopa 250 mg Tablet	BNF 77 Page 410	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						or a history of melanoma. • the management of patients with intention tremor and Huntington's chorea. • patients less than 30 years old. **Side effects:** Complications to long-term levodopa and benserazide combination therapy appear commonly and include motor fluctuations, dyskinesias, neuropsychiatric problems, and cardiovascular effects. Involuntary movements (e.g., choreiform or dystonic movements) are associated with levodopa and benserazide combination therapy. Muscle twitching may signify early signs of overdosage.				
44.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur. **Acme Laboratories Ltd., Dhamrai, Dhaka**	Levodopa 100 mg + Benserazide 25 mg capsule	Levodopa BP 100 mg + Benserazide BP 25 mg	Antiparkinsonism	It is indicated for the treatment of all forms of Parkinson's syndrome with the exception of medicine-induced parkinsonism.	**Contraindications:** patients with known hypersensitivity to levodopa or benserazide or any of the excipients. • patients receiving non-selective monoamine oxidase (MAO) inhibitors due to the risk of hypertensive crisis. However, selective MAO-B inhibitors, such as selegiline and rasagiline, or selective MAO-A inhibitors, such as moclobemide, are not contraindicated. Combination of MAO-A and MAO-B inhibitors is equivalent to non-selective MAO inhibition, and hence this combination should not be given concomitantly with it. • patients with decompensated endocrine, renal or hepatic function, cardiac disorders, psychiatric diseases with a psychotic component or closed angle glaucoma. Because levodopa may activate a malignant melanoma, It should	Carbidopa 10mg + Levodopa 100 mg Tablet Carbidopa 25mg + Levodopa 250 mg Tablet	BNF 77 Page 410	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						not be used in patients with suspicious, undiagnosed lesions or a history of melanoma. • the management of patients with intention tremor and Huntington's chorea. • patients less than 30 years old. **Side effects:** Complications to long-term levodopa and benserazide combination therapy appear commonly and include motor fluctuations, dyskinesias, neuropsychiatric problems, and cardiovascular effects. Involuntary movements (e.g., choreiform or dystonic movements) are associated with levodopa and benserazide combination therapy. Muscle twitching may signify early signs of overdosage.				
45.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur.	Levodopa 200 mg + Benserazide 50 mg capsule	Levodopa BP 200 mg + Benserazide BP 50 mg	Antiparkinsonism	It is indicated for the treatment of all forms of Parkinson's syndrome with the exception of medicine-induced parkinsonism.	**Contraindications:** patients with known hypersensitivity to levodopa or benserazide or any of the excipients. • patients receiving non-selective monoamine oxidase (MAO) inhibitors due to the risk of hypertensive crisis. However, selective MAO-B inhibitors, such as selegiline and rasagiline, or selective MAO-A inhibitors, such as moclobemide, are not contraindicated. Combination of MAO-A and MAO-B inhibitors is equivalent to non-selective MAO inhibition, and hence this combination should not be given concomitantly with it. • patients with decompensated endocrine, renal or hepatic function, cardiac disorders, psychiatric diseases with a psychotic component or closed angle glaucoma. Because levodopa may activate a	Carbidopa 10mg + Levodopa 100 mg Tablet Carbidopa 25mg + Levodopa 250 mg Tablet	BNF 77 Page 410	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						malignant melanoma, It should not be used in patients with suspicious, undiagnosed lesions or a history of melanoma. • the management of patients with intention tremor and Huntington's chorea. • patients less than 30 years old. **Side effects:** Complications to long-term levodopa and benserazide combination therapy appear commonly and include motor fluctuations, dyskinesias, neuropsychiatric problems, and cardiovascular effects. Involuntary movements (e.g., choreiform or dystonic movements) are associated with levodopa and benserazide combination therapy. Muscle twitching may signify early signs of overdosage.				
46.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur.	Levodopa 100 mg + Benserazide 25 mg CR capsule	Levodopa BP 100 mg + Benserazide BP 25 mg	Antiparkinsonism	It is indicated for the treatment of all forms of Parkinson's syndrome with the exception of medicine-induced parkinsonism.	**Contraindications:** • patients with known hypersensitivity to levodopa or benserazide or any of the excipients. • patients receiving non-selective monoamine oxidase (MAO) inhibitors due to the risk of hypertensive crisis. However, selective MAO-B inhibitors, such as selegiline and rasagiline, or selective MAO-A inhibitors, such as moclobemide, are not contraindicated. Combination of MAO-A and MAO-B inhibitors is equivalent to non-selective MAO inhibition, and hence this combination should not be given concomitantly with it. • patients with decompensated endocrine, renal or hepatic function, cardiac disorders, psychiatric diseases with a psychotic component or closed angle glaucoma. Because levodopa may activate a	Carbidopa 10mg + Levodopa 100 mg Tablet Carbidopa 25mg + Levodopa 250 mg Tablet	BNF 77 Page 410	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						malignant melanoma, It should not be used in patients with suspicious, undiagnosed lesions or a history of melanoma. • the management of patients with intention tremor and Huntington's chorea. • patients less than 30 years old. **Side effects:** Complications to long-term levodopa and benserazide combination therapy appear commonly and include motor fluctuations, dyskinesias, neuropsychiatric problems, and cardiovascular effects. Involuntary movements (e.g., choreiform or dystonic movements) are associated with levodopa and benserazide combination therapy. Muscle twitching may signify early signs of overdosage.				
47.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur.	Naftidrofuryl oxalate 100 mg capsule	Naftidrofuryl oxalate BP 100 mg	Blood Coagulating	It is indicated for Peripheral vascular disease & Cerebral vascular disease	**Contraindications:** • Patients who are allergic (hypersensitive) to naftidrofuryl oxalate or any of the other ingredients of this medicine • People with a history of hyperoxaluria or recurrent calcium-containing stones. **Side effects:** Uncommon: Diarrhoea, epigastric pain, nausea, rash, vomiting. Rare: Liver injury, oxalate nephrolithiasis Frequently not known: oesophagitis.	New	BNF 77 Page 233	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
48.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur.	Hydrocortisone butyrate 0.1% Cream	Hydrocortisone butyrate USP 0.1%	Steroidal Anti Inflammatory	Hydrocortisone butyrate Cream 0.1% is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.	**Contraindications:** None. **Side-effects:** The following local adverse reactions are reported infrequently with topical corticosteroids but may occur more frequently with the use of	Hydrocortisone 1 gm/100 gm cream	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria. **Warnings and Precautions** : Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression may occur, with the potential for glucocorticosteroid insufficiency. Consider periodic evaluations for HPA axis suppression if Hydrocortisone butyrate 0.1% Cream is applied to large surface areas or used under occlusion. If HPA axis suppression is noted, reduce the application frequency, discontinue use, or switch to a lower potency corticosteroid. -Systemic effects of topical corticosteroids may also include manifestations of of Cushing's syndrome, hyperglycemia, and glucosuria. -Pediatric patients may be more susceptible to systemic toxicity due to their larger skin surface-to-body-mass ratios. -Initiate appropriate therapy if concomitant skin infections develop.				
49.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur. Acme Laboratories Ltd., Dhamrai, Dhaka	Fluocinolone acetonide 0.025% & Clioquinol 3% Cream	Fluocinolone acetonide USP 0.025% & Clioquinol USP 3%	Steroidal Anti Inflammatory	Inflammatory skin disorders such as eczemas associated with infection, Psoriasis associated with infection	**Contraindications:** Acne, Allergy to iodine, Bacterial, viral or fungal skin infection that is not secondary to another disease state (primary skin infections, eg impetigo, chickenpox, ringworm), Children less than 1 year of age,	Fluocinolone Acetonide 25 mg/100 gm Cream/ Ointment	BNF 77 Page 1223	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Chronic inflammatory disorder of the facial skin (acne rosacea), Inflammatory rash around the mouth (perioral dermatitis) & Nappy rash **Side-effects:** The following side effects have also been reported but how often they occur is unknown: • an allergic (itchy) reaction to the cream. • irritation where the cream has been applied. • a worsening of acne, rosacea and dermatitis around the mouth (see section 2). • patches of pale skin (depigmentation). • localised increased hair growth.				
50.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur. Acme Laboratories Ltd., Dhamrai, Dhaka. Opsonin Pharma Limited, Rupatali, Barishal.	Bismuth Subsalicylate 262.50 mg Tablet	Bismuth Subsalicylate BP 262.50 mg	Antacid	Bismuth subsalicylate is indicated for • Treating heartburn, • upset stomach, • indigestion, • nausea, gas, • diarrhea, • symptoms associated with eating or drinking too much. • decrease the number of bowel movements and make the stool firmer.	**Contraindications:** If any contain aspirin or other salicylates, be especially careful. Using other salicylate-containing products while taking this medicine may lead to overdose. **Side effects:** The most common side effects are: Constipation, Temporary and harmless darkening of the tongue or stool, Nausea.	Bismuth Subsalicylate 17.5 mg/ml Suspension	রেফারেন্স নাই DCC এর 243 তম সভায় প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
51.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur. Acme Laboratories Ltd., Dhamrai, Dhaka Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka. **Delta Pharma Ltd, Pakundia, Kishorganj.**	Omadacycline Tosylate 150 mg Tablet	Omadacycline Tosylate 196 mg eqv. to Omadacycline INN 150 mg.	Anti-infective	Omadacycline is a tetracycline class antibacterial indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms: Community-acquired bacterial pneumonia (CABP) • Acute bacterial skin and skin structure infections (ABSSSI) • To reduce the development of drug-resistant bacteria and maintain the effectiveness of Omadacycline and other antibacterial drugs, Omadacycline should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.	**Contraindications:** Known hypersensitivity to omadacycline, tetracycline-class antibacterial drugs or any of the excipients in Omadacycline. **Side effects:** The most common adverse reactions (incidence ≥2%) are nausea, vomiting, infusion site reactions, alanine aminotransferase increased, aspartate aminotransferase	New	US FDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
	Team Pharmaceuticals Ltd. BSCIC, Rajshahi. **Opsonin Pharma Limited,** Rupatali, Barishal. Somatec pharmaceuticals ltd., Sarulia, demra, dhaka Bangladesh. One Pharma Ltd, Bogura. Orion Pharma Ltd, Siddhirganj, Narayangang.					increased, gamma-glutamyl transferase increased, hypertension, headache, diarrhea, insomnia, and constipation. **Warnings and Precautions** : Mortality Imbalance in Patients with CABP: In the CABP trial, mortality rate of 2% was observed in Omadacycline Tosylate 150 mg Tablet -treated patients compared to 1% in moxifloxacin-treated patients. The cause of the mortality imbalance has not been established. Closely monitor clinical response to therapy in CABP patients, particularly in those at higher risk for mortality.-Tooth Discoloration and Enamel Hypoplasia: The use of Omadacycline Tosylate 150 mg Tablet during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown) and enamel hypoplasia.-Inhibition of Bone Growth: The use of Omadacycline Tosylate 150 mg Tablet during the second and third trimester of pregnancy, infancy and childhood up to the age of 8 years may cause reversible inhibition of bone growth. -Clostridium difficile-associated diarrhea: Evaluate if diarrhea occurs.				
52.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur. Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Omadacycline Tosylate 100 mg/vial Injection	Omadacycline Tosylate 131 mg eqv. to Omadacycline INN 100 mg/vial.	Anti-infective	Omadacycline is a tetracycline class antibacterial indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms: Community-acquired bacterial pneumonia (CABP) • Acute bacterial skin and skin structure infections (ABSSSI)	**Contraindications:** Known hypersensitivity to omadacycline, tetracycline-class antibacterial drugs or any of the excipients in Omadacycline. **Side effects:** The most common	New	US FDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
	Acme Laboratories Ltd., Dhamrai, Dhaka. **Opsonin Pharma Limited,** Rupatali, Barishal.				• To reduce the development of drug-resistant bacteria and maintain the effectiveness of Omadacycline and other antibacterial drugs, Omadacycline should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.	adverse reactions (incidence ≥2%) are nausea, vomiting, infusion site reactions, alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyl transferase increased, hypertension, headache, diarrhea, insomnia, and constipation. **Warnings and Precautions** : -Mortality Imbalance in Patients with CABP: In the CABP trial, mortality rate of 2% was observed in Omadacycline Tosylate 100 mg Injection treated patients compared to 1% in moxifloxacin treated patients. The cause of the mortality imbalance has not been established. Closely monitor clinical response to therapy in CABP patients, particularly in those at higher risk for mortality.-Tooth Discoloration and Enamel Hypoplasia: The use of Omadacycline Tosylate 100 mg Injection during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown) and enamel hypoplasia.-Inhibition of Bone Growth: The use of Omadacycline Tosylate 100 mg Injection during the second and third trimester of pregnancy, infancy and childhood up to the age of 8 years may cause reversible inhibition of bone growth. -Clostridium difficile-associated diarrhea: Evaluate if diarrhea occurs.				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
53.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur. Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Fostamatinib Disodium Hexahydrate 100 mg Tablet	Fostamatinib Disodium Hexahydrate INN 100 mg	DRUG used in Anemia and other Blood disorder	Fostamatinib is a kinase inhibitor indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.	**Contraindications:** None. **Side effects:** The most common adverse reactions (≥5% and more than placebo) are diarrhea, hypertension, nausea, respiratory infection, dizziness, ALT/AST increased, rash, abdominal pain, fatigue, chest pain and neutropenia. **Warnings and Precautions** : **Hypertension:** Monitor blood pressure every 2 weeks until stable, then monthly. Manage hypertension using standard antihypertensive treatment and, if needed, interrupt, reduce or discontinue Fostamatinib Disodium Hexahydrate 100 mg Tablet. **Hepatotoxicity:** Monitor LFTs monthly. If LFT levels are elevated, interrupt, reduce or discontinue Fostamatinib Disodium Hexahydrate 100 mg Tablet. - Diarrhea: Manage diarrhea with supportive measures. If diarrhea becomes severe, interrupt, reduce or discontinue Fostamatinib Disodium Hexahydrate 100 mg Tablet. - Neutropenia: Monitor ANC monthly, and for infection. If neutrophil count decreases below 1.0 x 109 /L, interrupt, reduce or discontinue Fostamatinib Disodium Hexahydrate 100 mg Tablet. **Embryo-Fetal Toxicity:** Fostamatinib Disodium Hexahydrate 100 mg Tablet can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception.	New	US FDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
54.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur.	Fostamatinib Disodium Hexahydrate 150 mg Tablet	Fostamatinib Disodium Hexahydrate INN 150 mg	DRUG used in Anemia and other Blood disorder	Fostamatinib is a kinase inhibitor indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.	**Contraindications:** None. **Side effects:** The most common adverse reactions (≥5% and more than placebo) are diarrhea, hypertension, nausea, respiratory infection, dizziness, ALT/AST increased, rash, abdominal pain, fatigue, chest pain and neutropenia. **Warnings and Precautions** : -Hypertension: Monitor blood pressure every 2 weeks until stable, then monthly. Manage hypertension using standard antihypertensive treatment and, if needed, interrupt, reduce or discontinue Fostamatinib Disodium Hexahydrate 150 mg Tablet.- Hepatotoxicity: Monitor LFTs monthly. If LFT levels are elevated, interrupt, reduce or discontinue Fostamatinib Disodium Hexahydrate 150 mg Tablet. - Diarrhea: Manage diarrhea with supportive measures. If diarrhea becomes severe, interrupt, reduce or discontinue Fostamatinib Disodium Hexahydrate 150 mg Tablet. - Neutropenia: Monitor ANC monthly, and for infection. If neutrophil count decreases below 1.0 x 109 /L, interrupt, reduce or discontinue Fostamatinib Disodium Hexahydrate 150 mg Tablet.- Embryo-Fetal Toxicity: Fostamatinib Disodium Hexahydrate 150 mg Tablet can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception.	New	US FDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
55.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur. Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Drug International Ltd 252, Tongi I/A Tongi, Gazipur.	Lefamulin 150 mg/vial injection	Lefamulin Acetate INN 168.00 mg eq. to Lefamulin 150 mg/15 ml vial.	Anti-infective	Lefamulin is a pleuromutilin antibacterial indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by susceptible microorganisms. To reduce the development of drug resistant bacteria and maintain the effectiveness of Lefamulin and other antibacterial drugs, Lefamulin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	**Contraindications:** Lefamulin is contraindicated in patients with known hypersensitivity to lefamulin, pleuromutilin class drugs, or any of the components of Lefamulin. • Concomitant use of Lefamulin tablets with CYP3A substrates that prolong the QT interval is contraindicated. **Side effects:** Most common adverse reactions (incidence ≥2%) are: • Lefamulin Injection: administration site reactions, hepatic enzyme elevation, nausea, hypokalemia, insomnia, and headache. **Warnings and Precautions** : **QT Prolongation:** Avoid use in patients with known QT prolongation, ventricular arrhythmias including torsades de pointes, and patients receiving drugs that prolong the QT interval such as antiarrhythmic agents. **Embryo-Fetal Toxicity:** May cause fetal harm. Advise females of reproductive potential of the potential risk to the fetus and to use effective contraception. **Clostridium difficile-associated Diarrhea (CDAD):** Evaluate patients who develop diarrhea.	New	US FDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
56.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur. Acme Laboratories Ltd., Dhamrai, Dhaka	Cholecalciferol 400 IU Chewable Gummy	Cholecalciferol USP 400 IU	Vitamin	Treatment and prevention of vitamin D deficiency	**Contraindications:** Hypersensitivity to vitamin D or any of the excipients in the product, Hypervitaminosis D, Nephrolithiasis, Diseases or conditions resulting in hypercalcaemia and/or hypercalciuria & Severe renal impairment.	Cholecalciferol 200 IU/ ml Oral Solution, 800 IU Soft Gelatin Capsule, 1000 IU Tablet, 2000 IU Capsule, 20000 IU Capsule & 200000 IU Injection.	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Side effects: Allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue, bone pain, increased thirst, increased urination, irregular heartbeat, high blood pressure, seizures, unexpected weight loss & unusually weak or tired.				
57.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur. Acme Laboratories Ltd., Dhamrai, Dhaka	Cholecalciferol 2000 IU Chewable Gummy	Cholecalciferol USP 2000 IU	Vitamin	Treatment and prevention of vitamin D deficiency	**Contraindications:** Hypersensitivity to vitamin D or any of the excipients in the product, Hypervitaminosis D, Nephrolithiasis, Diseases or conditions resulting in hypercalcaemia and/or hypercalciuria & Severe renal impairment. **Side effects:** Allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue, bone pain, increased thirst, increased urination, irregular heartbeat, high blood pressure, seizures, unexpected weight loss & unusually weak or tired.	Cholecalciferol 200 IU/ ml Oral Solution, 800 IU Soft Gelatin Capsule, 1000 IU Tablet, 2000 IU Capsule, 20000 IU Capsule & 200000 IU Injection	Reference নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।*
58.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur. General Pharmaceutical Ltd., Gazipur	Vortioxetine Hydrobromide 5 mg Immediate Release Tablet	Vortioxetine Hydrobromide INN 6.355 mg eq. to Vortioxetine 5 mg.	Antidepressant	It is indicated for the treatment of major depressive disorder (MDD).	**Contraindications:** Hypersensitivity to vortioxetine or any components of the vortioxetine formulation. **Monoamine Oxidase Inhibitors (MAOIs):** Do not use MAOIs intended to treat psychiatric disorders with vortioxetine or within 21 days of stopping treatment with vortioxetine. Do not use vortioxetine within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start vortioxetine	New	US FDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						in a patient who is being treated with linezolid or intravenous methylene blue. **Side effects:** Most common adverse reactions (incidence ≥5% and at least twice the rate of placebo) were: nausea, constipation and vomiting. **Warnings and Precautions** : - Serotonin Syndrome has been reported with serotonergic antidepressants (SSRIs, SNRIs, and others), including with Vortioxetine 5 mg Immediate Release Tablet, both when taken alone, but especially when coadministered with other serotonergic agents (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort). If such symptoms occur, discontinue Vortioxetine 5 mg Immediate Release Tablet and initiate supportive treatment. If concomitant use of Vortioxetine 5 mg Immediate Release Tablet with other serotonergic drugs is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increases . Treatment with serotonergic antidepressants (SSRIs, SNRIs, and others) may increase the risk of abnormal bleeding. Patients should be cautioned about the increased risk of bleeding when Vortioxetine 5 mg Immediate Release Tablet is coadministered with nonsteroidal antiinflammatory drugs				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						(NSAIDs), aspirin, or other drugs that affect coagulation. - Activation of Mania/Hypomania can occur with antidepressant treatment. Screen patients for bipolar disorder .- Hyponatremia can occur in association with the syndrome of inappropriate antidiuretic hormone secretion (SIADH) .				
59.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur. Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka General Pharmaceutical Ltd., Gazipur	Vortioxetine 10 mg Immediate Release Tablet	Vortioxetine Hydrobromide INN 12.71 mg eq. to Vortioxetine 10 mg	Antipsychotic	It is indicated for the treatment of major depressive disorder (MDD).	**Contraindications:** Hypersensitivity to vortioxetine or any components of the vortioxetine formulation. • Monoamine Oxidase Inhibitors (MAOIs): Do not use MAOIs intended to treat psychiatric disorders with vortioxetine or within 21 days of stopping treatment with vortioxetine. Do not use vortioxetine within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start vortioxetine in a patient who is being treated with linezolid or intravenous methylene blue. **Side effects:** Most common adverse reactions (incidence ≥5% and at least twice the rate of placebo) were: nausea, constipation and vomiting. **Warnings and Precautions** : - Serotonin Syndrome has been reported with serotonergic antidepressants (SSRIs, SNRIs, and others), including with Vortioxetine 10 mg Immediate Release Tablet, both when taken alone, but especially when coadministered with other serotonergic agents (including	New	US FDA DCC এর ২৪৩ তম সভায় Vortioxetine 10 mg ও Vortioxetine 20 mg প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়েছে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort). If such symptoms occur, discontinue Vortioxetine 10 mg Immediate Release Tablet and initiate supportive treatment. If concomitant use of Vortioxetine 10 mg Immediate Release Tablet with other serotonergic drugs is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increases . Treatment with serotonergic antidepressants (SSRIs, SNRIs, and others) may increase the risk of abnormal bleeding. Patients should be cautioned about the increased risk of bleeding when Vortioxetine 10 mg Immediate Release Tablet is coadministered with nonsteroidal antiinflammatory drugs (NSAIDs), aspirin, or other drugs that affect coagulation. - Activation of Mania/Hypomania can occur with antidepressant treatment. Screen patients for bipolar disorder .- Hyponatremia can occur in association with the syndrome of inappropriate antidiuretic hormone secretion (SIADH) .				
60.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur. Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka General Pharmaceutical Ltd., Gazipur	Vortioxetine 20 mg Tablet Immediate Release Tablet	Vortioxetine Hydrobromide INN 25.42 mg eq. to Vortioxetine 20 mg	Antipsychotic	It is indicated for the treatment of major depressive disorder (MDD).	**Contraindications:** Hypersensitivity to vortioxetine or any components of the vortioxetine formulation. • Monoamine Oxidase Inhibitors (MAOIs): Do not use MAOIs intended to treat psychiatric disorders with vortioxetine or within 21 days of stopping	New	US FDA DCC এর ২৪৩ তম সভায় Vortioxetine 10 mg ও Vortioxetine 20 mg প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়েছে।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						treatment with vortioxetine. Do not use vortioxetine within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start vortioxetine in a patient who is being treated with linezolid or intravenous methylene blue. **Side effects:** Most common adverse reactions (incidence ≥5% and at least twice the rate of placebo) were: nausea, constipation and vomiting. **Warnings and Precautions** : - Serotonin Syndrome has been reported with serotonergic antidepressants (SSRIs, SNRIs, and others), including with Vortioxetine 20 mg Immediate Release Tablet, both when taken alone, but especially when coadministered with other serotonergic agents (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort). If such symptoms occur, discontinue Vortioxetine 20 mg Immediate Release Tablet and initiate supportive treatment. If concomitant use of Vortioxetine 20 mg Immediate Release Tablet with other serotonergic drugs is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increases . Treatment with serotonergic antidepressants (SSRIs, SNRIs, and others) may increase the risk of abnormal bleeding. Patients should be cautioned about the increased				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						risk of bleeding when Vortioxetine 20 mg Immediate Release Tablet is coadministered with nonsteroidal antiinflammatory drugs (NSAIDs), aspirin, or other drugs that affect coagulation. - Activation of Mania/Hypomania can occur with antidepressant treatment. Screen patients for bipolar disorder .- Hyponatremia can occur in association with the syndrome of inappropriate antidiuretic hormone secretion (SIADH) .				
61.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur.	Loxapine 10 mg Capsule	Loxapine Succinate 13.6 mg eq to.Loxapine USP 10 mg	Antipsychotic	It is an antipsychotic medication used to treat psychosis and disorganized thinking associated with schizophrenia.	**Contraindications:** Loxapine is contraindicated in patients known to be hypersensitive to it. Comatose or severe drug induced depressed states. Patients with circulatory collapse. **Side effects:** Most common adverse reactions (incidence ≥ 2% and greater than placebo) were dysgeusia, sedation, and throat irritation. **Warning & Precaution:** • Neuroleptic Malignant Syndrome: May develop in patients treated with antipsychotic drugs. Discontinue treatment • Hypotension and Syncope: Use with caution in patients with known cardiovascular or cerebrovascular disease • Seizure: Use with caution in patients with a history of seizures or with conditions that lower the seizure threshold • Potential for Cognitive and Motor Impairment: Use caution when driving or operating machinery •	New	US FDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Cerebrovascular Adverse Reactions: Increased incidence of stroke and transient ischemic attack in elderly patients with dementia-related psychosis treated with antipsychotic drugs				
62.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur.	Loxapine 25 mg Capsule	Loxapine Succinate 34 mg eq to Loxapine USP 25 mg	Antipsychotic	It is an antipsychotic medication used to treat psychosis and disorganized thinking associated with schizophrenia.	**Contraindications:** Loxapine is contraindicated in patients known to be hypersensitive to it. Comatose or severe drug induced depressed states. Patients with circulatory collapse. **Side effects:** Most common adverse reactions (incidence ≥ 2% and greater than placebo) were dysgeusia, sedation, and throat irritation. **Warning & Precaution:** • Neuroleptic Malignant Syndrome: May develop in patients treated with antipsychotic drugs. Discontinue treatment. • Hypotension and Syncope: Use with caution in patients with known cardiovascular or cerebrovascular disease • Seizure: Use with caution in patients with a history of seizures or with conditions that lower the seizure threshold. • Potential for Cognitive and Motor Impairment: Use caution when driving or operating machinery. • Cerebrovascular Adverse Reactions: Increased incidence of stroke and transient ischemic attack in elderly patients with dementia-related psychosis treated with antipsychotic drugs.	New	US FDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
63.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur.	Loxapine 50 mg Capsule	Loxapine Succinate 68.1 mg eq to Loxapine USP 50 mg	Antipsychotic	It is an antipsychotic medication used to treat psychosis and disorganized thinking associated with schizophrenia.	**Contraindications:** Loxapine is contraindicated in patients known to be hypersensitive to it. Comatose or severe drug induced depressed states. Patients with circulatory collapse. **Side effects:** Most common adverse reactions (incidence ≥ 2% and greater than placebo) were dysgeusia, sedation, and throat irritation. **Warning & Precaution:** • Neuroleptic Malignant Syndrome: May develop in patients treated with antipsychotic drugs. Discontinue treatment • Hypotension and Syncope: Use with caution in patients with known cardiovascular or cerebrovascular disease • Seizure: Use with caution in patients with a history of seizures or with conditions that lower the seizure threshold • Potential for Cognitive and Motor Impairment: Use caution when driving or operating machinery • Cerebrovascular Adverse Reactions: Increased incidence of stroke and transient ischemic attack in elderly patients with dementia-related psychosis treated with antipsychotic drugs.	New	US FDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
64.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur. Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Aclidinium Bromide 400 mcg and Formoterol Fumarate 12 mcg Hard Gelatin	Aclidinium Bromide INN 400 mcg and Formoterol Fumarate USP 12 mcg	Drug used in Bronchial Asthma, Chronic Obstructive Pulmonary Disease (COPD)	It is a combination product containing a anticholinergic with long acting beta2-adrenergic agonist bronchodilator indicated for: • Maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).	**Contraindications:** Use of long acting beta2-adrenergic agonist (LABA), including formoterol fumarate, without an inhaled corticosteroid is contraindicated in patients with asthma. Hypersensitivity to aclidinium	New Formoterol Fumarate USP 12 mcg Inhalation capsule.	US FDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		Capsule.				bromide or formoterol fumarate or to any component of this product. **Side effects:** Most common adverse reactions (incidence ≥3% and more common than with placebo) include: upper respiratory tract infection and headache. **Warning & Precaution:** • Asthma-related death: Long-acting beta2-adrenergic agonists as monotherapy (without an inhaled corticosteroid) for asthma increase the risk of serious asthma-related events • Do not initiate in acutely deteriorating COPD or to treat acute symptoms Do not use in combination with an additional medicine containing a LABA because of risk of overdose • If paradoxical bronchospasm occurs, discontinue Aclidinium Bromide & Formoterol Fumarate and institute alternative therapy • Use with caution in patients with cardiovascular disorders • Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus and ketoacidosis • Be alert to hypokalemia and hyperglycemia • Worsening of narrow-angle glaucoma may occur. Use with caution in patients with narrow-angle glaucoma and instruct patients to contact a physician immediately if symptoms occur • Worsening urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						obstruction and instruct patients to consult a physician immediately if symptoms occur.				
65.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur.	Trazodone Hydrochloride 50 mg Immediate Release Tablet	Trazodone Hydrochloride USP 50 mg	Antidepressant	Trazodone is a selective serotonin reuptake inhibitor indicated for the treatment of major depressive disorder (MDD).	**Contraindications:** Concomitant use of monoamine oxidase inhibitors (MAOIs), or use within 14 days of stopping MAOIs. **Side effects:** Most common adverse reactions (incidence ≥5% and twice that of placebo) are: edema, blurred vision, syncope, drowsiness, fatigue, diarrhea, nasal congestion, weight loss. **Warning & Precaution:** • Serotonin Syndrome: Increased risk when co-administered with other serotonergic agents (e.g., SSRI, SNRI, triptans), but also when taken alone. If it occurs, discontinue Trazodone and initiate supportive treatment • Cardiac Arrhythmias: Increases the QT interval. Avoid use with drugs that also increase the QT interval and in patients with risk factors for prolonged QT interval • Orthostatic Hypotension and Syncope: Warn patients of risk and symptoms of hypotension • Increased Risk of Bleeding: Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), other antiplatelet drugs, warfarin, and other anticoagulants may increase this risk • Priapism: Cases of painful and prolonged penile erections and priapism have been reported. Immediate medical attention should be sought if signs and symptoms of prolonged penile erections or priapism are observed	New	US FDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						• Activation of Mania or Hypomania: Screen for bipolar disorder and monitor for mania or hypomania • Potential for Cognitive and Motor Impairment: Has potential to impair judgment, thinking, and motor skills. Advise patients to use caution when operating machinery • Angle-Closure Glaucoma: Avoid use of antidepressants, including Trazodone, in patients with untreated anatomically narrow angles.				
66.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur.	Trazodone Hydrochloride 100 mg Immediate Release Tablet	Trazodone Hydrochloride USP 100 mg	Antidepressant	Trazodone is a selective serotonin reuptake inhibitor indicated for the treatment of major depressive disorder (MDD).	**Contraindications:** Concomitant use of monoamine oxidase inhibitors (MAOIs), or use within 14 days of stopping MAOIs. **Side effects:** Most common adverse reactions (incidence ≥5% and twice that of placebo) are: edema, blurred vision, syncope, drowsiness, fatigue, diarrhea, nasal congestion, weight loss. **Warning & Precaution:** • Serotonin Syndrome: Increased risk when co-administered with other serotonergic agents (e.g., SSRI, SNRI, triptans), but also when taken alone. If it occurs, discontinue Trazodone and initiate supportive treatment • Cardiac Arrhythmias: Increases the QT interval. Avoid use with drugs that also increase the QT interval and in patients with risk factors for prolonged QT interval • Orthostatic Hypotension and Syncope: Warn patients of risk	New	US FDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						and symptoms of hypotension • Increased Risk of Bleeding: Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), other antiplatelet drugs, warfarin, and other anticoagulants may increase this risk • Priapism: Cases of painful and prolonged penile erections and priapism have been reported. Immediate medical attention should be sought if signs and symptoms of prolonged penile erections or priapism are observed • Activation of Mania or Hypomania: Screen for bipolar disorder and monitor for mania or hypomania • Potential for Cognitive and Motor Impairment: Has potential to impair judgment, thinking, and motor skills. Advise patients to use caution when operating machinery • Angle-Closure Glaucoma: Avoid use of antidepressants, including Trazodone, in patients with untreated anatomically narrow angles.				
67.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur.	Trazodone Hydrochloride 150 mg Extended Release Tablet	Trazodone Hydrochloride USP 150 mg	Antidepressant	Trazodone is a selective serotonin reuptake inhibitor indicated for the treatment of major depressive disorder (MDD).	**Contraindications:** Concomitant use of monoamine oxidase inhibitors (MAOIs), or use within 14 days of stopping MAOIs. **Side effects:** Most common adverse reactions (incidence ≥5% and twice that of placebo) are: somnolence/sedation, dizziness, constipation, vision blurred. **Warning & Precaution:** • Serotonin Syndrome: Increased risk when co-administered with other serotonergic agents (e.g.,	New	US FDA DCC এর ২৪৪ তম সভায় Trazodone Hydrochloride 150 mg প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হয়।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						SSRI, SNRI, triptans), but also when taken alone. If it occurs, discontinue Trazodone and initiate supportive treatment • Cardiac Arrhythmias: Increases the QT interval. Avoid use with drugs that also increase the QT interval and in patients with risk factors for prolonged QT interval • Orthostatic Hypotension and Syncope: Warn patients of risk and symptoms of hypotension • Increased Risk of Bleeding: Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), other antiplatelet drugs, warfarin, and other anticoagulants may increase this risk • Priapism: Cases of painful and prolonged penile erections and priapism have been reported. Immediate medical attention should be sought if signs and symptoms of prolonged penile erections or priapism are observed • Activation of Mania or Hypomania: Screen for bipolar disorder and monitor for mania or hypomania • Potential for Cognitive and Motor Impairment: Has potential to impair judgment, thinking, and motor skills. Advise patients to use caution when operating machinery • Angle-Closure Glaucoma: Avoid use of antidepressants, including Trazodone, in patients with untreated anatomically narrow angles				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
68.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur.	Trazodone Hydrochloride 300 mg Extended Release Tablet	Trazodone Hydrochloride USP 300 mg	Antidepressant	Trazodone is a selective serotonin reuptake inhibitor indicated for the treatment of major depressive disorder (MDD).	**Contraindications:** Concomitant use of monoamine oxidase inhibitors (MAOIs), or use within 14 days of stopping MAOIs. **Side effects:** Most common adverse reactions (incidence ≥5% and twice that of placebo) are: somnolence/sedation, dizziness, constipation, vision blurred. **Warning & Precaution:** • Serotonin Syndrome: Increased risk when co-administered with other serotonergic agents (e.g., SSRI, SNRI, triptans), but also when taken alone. If it occurs, discontinue Trazodone and initiate supportive treatment • Cardiac Arrhythmias: Increases the QT interval. Avoid use with drugs that also increase the QT interval and in patients with risk factors for prolonged QT interval • Orthostatic Hypotension and Syncope: Warn patients of risk and symptoms of hypotension • Increased Risk of Bleeding: Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), other antiplatelet drugs, warfarin, and other anticoagulants may increase this risk • Priapism: Cases of painful and prolonged penile erections and priapism have been reported. Immediate medical attention should be sought if signs and symptoms of prolonged penile erections or priapism are observed • Activation of Mania or Hypomania: Screen for bipolar disorder and monitor for mania	New	US FDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						or hypomania • Potential for Cognitive and Motor Impairment: Has potential to impair judgment, thinking, and motor skills. Advise patients to use caution when operating machinery • Angle-Closure Glaucoma: Avoid use of antidepressants, including Trazodone, in patients with untreated anatomically narrow angles.				
69.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur. Incepta Pharmaceuticals Ltd (Dhamrai Unit). Acme Laboratories Ltd., Dhamrai, Dhaka SOMATEC PHARMACEUTICALS LTD., SARULIA, DEMRA, DHAKA BANGLADESH	Elagolix Sodium 200 mg Tablet	Elagolix Sodium USP 207 mg eqv. to Elagolix 200 mg	Hormone	Elagolix is a gonadotropin releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis.	**Contraindications:** Pregnancy, Known osteoporosis, Severe hepatic impairment, Strong organic anion transporting polypeptide (OATP) 1B1 inhibitors. **Side effects:** Most common adverse reactions (>5%) in clinical trials included: hot flushes and night sweats, headache, nausea, insomnia, amenorrhea, anxiety, arthralgia, depression-related adverse reactions and mood changes. **Warnig & Precaution:** • Bone Loss: Dose- and duration-dependent decreases in bone mineral density (BMD) that may not be completely reversible. Assess BMD in women with additional risk factors for bone loss • Reduced Ability to Recognize Pregnancy: Elagolix may alter menstrual bleeding, which may reduce the ability to recognize pregnancy. Perform testing if pregnancy is suspected. Discontinue if pregnancy is confirmed • Suicidal Ideation and Mood Disorders: Advise patients to seek medical attention for	New Elagolix 150 mg Tablet	US FDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						suicidal ideation, suicidal behavior, new onset or worsening depression, anxiety, or other mood changes • Hepatic Transaminase Elevations: Dose-dependent elevations in serum alanine aminotransferase (ALT). Counsel patients on signs and symptoms of liver injury • Potential for Reduced Efficacy with Estrogen-Containing Contraceptives: Use non-hormonal contraception during treatment and for one week after discontinuing Elagolix.				
70.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur.	Elemental Iron 60 mg (as Ferrous Fumarate) and Folic Acid 2800 mcg film coated Tablet.	Elemental Iron BP 60 mg (as Ferrous Fumarate) and Folic Acid USP 2800 mcg	Drugs used in Anemia & Other Blood Disorder.	Weekly iron and folic acid supplementation to prevent maternal anemia, puerperal sepsis, low birth weight, and preterm birth in pregnant women and adolescent girls. For the prevention of neural tube defects and other congenital malformations in the foetus.	**Contraindications:** The following conditions are contraindicated with this drug: iron metabolism disorder causing increased iron storage, increased bodily iron from high red blood cell destruction, hemolytic anemia, ulcer from stomach acid, burning stomach, ulcerated colon, several blood transfusions and diverticular disease. **Side effects:** Iron preparations with ordinary doses of each component are usually nontoxic. Rarely Gastrointestinal irritation, Constipation & diarrhea may occur.	New	রেফারেন্স নাই (UNICEF এ সাপ্লাই এর জন্য রেজিস্ট্রেশনের আবেদন করেছেন)	প্রয়োজনীয় রেফারেন্স নাই বিধায় স্থানীয় বাজারে সরবরাহের ক্ষেত্রে আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নাই বিধায় স্থানীয় বাজারে সরবরাহের ক্ষেত্রে আবেদন নামঞ্জুর করা হল।***
71.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur.	Methylprednisolone Acetate 2.5 mg, Neomycin Sulfate 2.5 mg, Aluminum Chlorhydroxide Complex 100 mg and Colloidal Sulfur 50 mg Lotion	Methylprednisolone Acetate USP 2.5 mg, Neomycin Sulfate USP 2.5 mg, Aluminum Chlorhydroxide Complex USP 100 mg and Colloidal Sulfur USP 50 mg / 25 ml	Anti-infective	For control of acne vulgaris in the adolescent and young adult. Also in some cases of acne rosacea and seborrheic dermatitis.	**Contraindications:** In tuberculosis of the skin, herpes simplex, vaccinia, varicella and in other cutaneous infections which do not respond to neomycin. Known hypersensitivity to any of the components. **Side effects:** The following local adverse reactions have been reported with topical corticosteroids, either with or without occlusive dressings:	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						burning sensation, itching, irritation, dryness, folliculitis, secondary infection, skin atrophy, striae, hypertrichosis, acneiform, eruptions, allergic contact dermatitis, laceration of the skin and hypopigmentation.				
72.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur. Square Pharmaceuticals Ltd (Pabna Unit), Salgaria, Pabna.	N, N-Diethylbenzamide 12% Cream	N, N-Diethylbenzamide INN 12%	Other Classification	N, N-Diethylbenzamide is an insect repellent that is used in products to prevent bites from insects such as mosquitoes, biting flies, fleas and small flying insects.	**Contraindications:** People who are hypersensitive against N, N-Diethylbenzamide. **Side effects:** Using insect repellents containing N, N-Diethylbenzamide should not be harmful if label directions are followed and the product is used safely. Some persons who used products containing a high concentration of N, N-Diethylbenzamide or who were exposed to excessive amounts of N, N-Diethylbenzamide have experienced skin rashes, irritation, pain, watery eyes, blisters, and skin and mucous membrane irritation. Very rarely, exposure to N, N-Diethylbenzamide has been associated with seizures in people.	New	রেফারেন্স নাই	বর্ণিত ইন্ডিকেশনে ব্যবহারের জন্য ঔষধটির প্রয়োজন রয়েছে বিধায় আবেদন অনুমোদন করা যেতে পারে।	***Mosquito repellent*** ***জাতীয় প্রজাঙ্ক ঔষধ হিসেবে অনুমোদনের প্রয়োজন নেই।***
73.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Roxadustat 100mg Tablet	Roxadustat INN 100mg	Drug used in Anemia and other blood disorder	Renal anemia in patients on dialysis Patients not on erythropoiesis-stimulating agent treatment	**Contra-indication: None** **Side-effect:** No severe side effects had been reported in clinical trials	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
74.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Roxadustat 60mg Tablet	Roxadustat INN 60mg	Drug used in Anemia and other blood disorder	Renal anemia in patients on dialysis Patients not on erythropoiesis-stimulating agent treatment	**Contra-indication: None** **Side-effect:** No severe side effects had been reported in clinical trials		রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
75.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Arabinoxylan Compound 250mg	Arabinoxylan Compound INN 250mg	Anti-cancer	**Chronic fatigue syndrome (CFS).** Early research suggested that rice bran arabinoxylan compound might improve symptoms and immune function in people with CFS. But more recent evidence shows that rice bran	**Contra-indication: None** **Side-effect:**	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		Tablet			arabinoxylan compound does not improve symptoms of CFS including fatigue. All of the studies to date have been small and/or low quality, so more high quality research is needed **Swelling (inflammation) of the liver caused by the hepatitis C virus (hepatitis C).** Early research suggests that taking rice bran arabinoxylan compound helps to clear hepatitis C virus from the bloodstream in people with a certain type of hepatitis C. It seems to work as well as pegylated interferon plus ribavirin **Liver cancer.** Early research shows that taking rice bran arabinoxylan compound in combination with standard therapy might help people with liver cancer live longer compared to standard therapy alone. It might also help prevent liver cancer from returning after treatment. • **Boosting immune function.** • **Diabetes.** • **HIV/AIDS.** • **Preventing and treating cancer.** • **Other conditions.**					
76.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Arabinoxylan Compound 1000mg / sachet	Arabinoxylan Compound INN 1000mg / sachet	Anti-cancer	**Chronic fatigue syndrome (CFS).** Early research suggested that rice bran arabinoxylan compound might improve symptoms and immune function in people with CFS. But more recent evidence shows that rice bran arabinoxylan compound does not improve symptoms of CFS including fatigue. All of the studies to date have been small and/or low quality, so more high quality research is needed **Swelling (inflammation) of the liver caused by the hepatitis C virus (hepatitis C).** Early research suggests that taking rice bran arabinoxylan compound helps to clear hepatitis C virus from the bloodstream in people with a certain type of hepatitis C. It seems to work as well as pegylated interferon plus ribavirin **Liver cancer.** Early research shows that taking rice bran arabinoxylan compound in combination with standard therapy might help people with liver cancer live longer	**Contra-indication: None** **Side-effect:**	New	Reference নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					compared to standard therapy alone. It might also help prevent liver cancer from returning after treatment. • **Boosting immune function.** • **Diabetes.** • **HIV/AIDS.** • **Preventing and treating cancer.** **Other conditions.**					
77.	Ziska Pharmaceuticals Ltd, Karonsurichala, Gazipur. The Acme Laboratories Ltd.	Posaconazole 300 mg/ 16.7 mL (18 mg/ml) injection	Posaconazole INN 300 mg/ 16.7 mL	Antifungal	Posaconazole is an azole antifungal agent indicated for: injection, delayed-release tablets, and oral suspension • prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy. **Oral suspension** • treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole.	**CONTRAINDICATIONS:** Do not administer to persons with known hypersensitivity to posaconazole or other azole antifungal agents. Do not coadminister Posaconazole with the following drugs; Posaconazole increases concentrations of: Sirolimus: can result in sirolimus toxicity CYP3A4 substrates (pimozide, quinidine): can result in QTc interval prolongation and cases of TdP HMG-CoA Reductase Inhibitors Primarily Metabolized Through CYP3A4: can lead to rhabdomyolysis Ergot alkaloids: can result in ergotis. **SIDE-EFFECTS:** Common treatment-emergent adverse reactions in studies with posaconazole are diarrhea, nausea, fever, vomiting, headache, coughing, and hypokalemia. **WARNINGS AND PRECAUTIONS:** Calcineurin-Inhibitor Toxicity: Posaconazole increases concentrations of cyclosporine or tacrolimus; reduce dose of cyclosporine and tacrolimus and monitor concentrations	**New**	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						frequently. Arrhythmias and QTc Prolongation: Posaconazole has been shown to prolong the QTc interval and cause cases of TdP. Administer with caution to patients with potentially proarrhythmic conditions. Do not administer with drugs known to prolong QTc interval and metabolized through CYP3A4. Electrolyte Disturbances: Monitor and correct, especially those involving potassium (K+), magnesium (Mg++), and calcium (Ca++), before and during Posaconazole therapy. Hepatic Toxicity: Elevations in LFTs may occur. Discontinuation should be considered in patients who develop abnormal LFTs or monitor LFTs during treatment. Posaconazole injection should be avoided in patients with moderate or severe renal impairment (creatinine clearance <50 mL/min), unless an assessment of the benefit/risk to the patient justifies the use of Posaconazole injection. Midazolam: Posaconazole can prolong hypnotic/sedative effects. Monitor patients and benzodiazepine receptor antagonists should be available. Vincristine Toxicity: Concomitant administration of azole antifungals, including Posaconazole, with vincristine has been associated with neurotoxicity and other serious adverse reactions; reserve azole antifungals, including Posaconazole, for patients receiving a vinca alkaloid, including vincristine, who have no alternative antifungal treatment options.				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
78.	NIPRO JMI Pharma Ltd, Rajandrapur, Chaddagram, Cumilla.	Magnesium 470 mg + Vitamin B6 5 mg Tablet	Magnesium Oxide BP 779.465 mg equivalent to Magenesium 470.0 mg + Pyridoxine Hydrochloride BP 6.078 mg equivalent to Vitamin B6 5 mg	Vitamins and Combinations	It is indicated in identified magnesium deficiency, functional deficiency symptoms (including latent tetany), and prophylaxis. Adjunct to atherosclerosis, hypertension, ischemic heart disease, epilepsy.	**Contraindications:** It is contraindicated in severe renal impairment (creatinine clearance below 30 ml / min). Do not use concomitantly with levodopa, calcium salts, phosphates. During treatment with tetracyclines should be a 3-hour interval between administrations of the antibiotic. Side effects: abdominal pain, diarrhea	Pyridxoine Hydrochloride 20 mg and 25 mg Tablet	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
79.	NIPRO JMI Pharma Ltd, Rajandrapur, Chaddagram, Cumilla.	Doxophylli ne 650 mg SR Tablet	Doxophylline INN 650 mg	Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease (COPD)	Doxophylline is used to treat asthma, COPD and bronchospasm.	Contraindications: Doxophylline is contraindicated in individuals with known hypersensitivity to the drug or other xanthine derivatives. It is also contraindicated in patients with acute myocardial infarction, hypotension and during lactation. **Side effects:** Doxophylline rarely causes serious side effects, however possible side effects are similar for taking excess amount of caffeine. These include: nausea, vomiting, headache, upset stomach and heartburn.	200 mg, 400 mg Tablet 400 mg SR Tablet 100 mg/5ml Syrup	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
80.	NIPRO JMI Pharma Ltd, Rajandrapur, Chaddagram, Cumilla.	Cholecalcif erol 2200 IU Tablet	Cholecalciferol BP 2200 IU	Vitamins and Combinations	It is indicated in the treatment & prevention of Vitamin D3 deficiency	**Contraindications:** It is contraindicated in patients with known hypersensitivity to Vitamin D3 **Side effects:** The general side effects are hypercalcaemia, hypercalciuria, skin rash,	800 IU, 20000 IU and 40000 IU Capsule 2000 IU, 1000 IU and 400 IU Tab	BNF-71	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						pruritus, urticaria, nausea, abdominal pain				
81.	NIPRO JMI Pharma Ltd, Rajandrapur, Chaddagram, Cumilla.	Domperidone 30 mg Sustained Release capsule	Domperidone BP 30 mg	Antiemetic	Domperidone is indicated for the relief of the symptoms of nausea and vomiting, abdominal fullness and discomfort.	Contraindications: It is contraindicated in patients with known hypersensitivity to Domperidone or any components of the preparation. Domperidone should not be used whenever gastro-intestinal stimulation might be dangerous (i.e., gastro-intestinal hemorrhage, mechanical obstruction or perforation). It is also contraindicated in prolactinoma. Side Effects: Major & minor side effects for Domperidone 30 mg sustained release capsule is swelling of face, lips, eyelids, tongue, hands and feet; difficulty in breathing; skin rash; convulsions; heart rhythm disorders; disrupted menstrual cycle; breast pain and tenderness; dry mouth; loss of libido; breast like growth in men	10 mg Tablet, 20 mg Dispersible Tablet 5 mg/ml Drop 10 mg Orodispersible Tablet 15 mg, 30 mg Suppository 5 mg/ 5 ml Oral Suspension	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
82.	NIPRO JMI Pharma Ltd, Rajandrapur, Chaddagram, Cumilla.	Erdosteine 175mg/ 5ml Powder for Suspension	Erdosteine INN 175mg/ 5ml	Antitussives, Expectorants and Mucolytic	It is a mucolytic drug used in the treatment of acute and chronic bronchopulmonary diseases, rhinosinusitis, laryngopharyngitis or exacerbations of these chronic diseases in association with mucus production and mucus transport.	Contraindications: It is contraindicated to patients who have hypersensitivity to Erdosteine. It should not be used in patients with creatinine clearance >25ml/min, or with severe liver failure. Side effects: Administration of Erdosteine	300 mg Capsule	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						could occasionally cause gastro-intestinal side effect, like gastric burning, nausea and rarely diahhrea. In few cases, at the beginning of treatment, ageusia or dysgeusia have been observed. Hypersensitivity reactions (skin rash, urticaria, unexpected hyperpyrexia) are rare.				
83.	**Delta Pharma Ltd, Pakundia, Kishorganj.**	Esomeprazole BP 20 mg and Domperidone BP 30 mg Capsule.	Esomeprazole enteric coated & Domperidone sustained release blended pellets 275.00 mg equivalent to Esomeprazole BP 20 mg and Domperidone BP 30 mg.	Proton Pump inhibitor	Esomeprazole/ Domperidone SR is used for the treatment of acid reflux, Gastro esophageal reflux disease and stomach ulcers. Esomeprazole/ Domperidone SR works by decreasing the amount of acid the stomach produces which leads to the relieve of heartburn or cough.	**Contra-indications:** Esomeprazole is contraindicated in patients with known hypersensitivity to proton pump inhibitors. Hypersensitivity reactions, e.g., angioedema and anaphylactic shock have been reported with Esomeprazole use. Domperidone is contraindicated in patients having known hypersensitivity to this drug and in case of neonates. **Side-effects**: **Esomeprazole** Most common adverse reactions are: Adults (>_ 18 years) (incidence >_ 1%) are headache, diarrhea, nausea, flatulence, abdominal pain, constipation and dry mouth. Pediatric (1 to 17 years) (incidence >_ 2%) are headache, diarrhea, abdominal pain, nausea and somnolence. Pediatric (1 month to less	New Esomeprazole BP 20 mg and 40 mg Domperidone BP 10 mg.	Reference নাই DCC এর 230 তম সভায় BNF-এ অন্তর্ভূক্ত নাই এবং Combination অপ্রয়োজনীয় বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						than 1 year) (incidence 1%) are abdominal pain, regurgitation, tachypnea and increased ALT. **<u>Domperidone</u>** Domperidone may produce hyperprolactinemia (1-3%). This may result in galactorrhoea, gynaecomastia (breast enlargement), soreness and reduced libido. Dry mouth (1-9%), thirst, headache (1-2%), nervousness, drowsiness (0.4%), diarrhoea (0.2%), skin rash and itching (0.1%) may occur during treatment with Degut (Domperidone). Extra-pyramidal reactions are seen in 0.25% of patients in clinical studies. **Warning and Precautions:** **<u>Esomeprazole</u>** Exclude the possibility of malignancy when gastric ulcer is suspected and before treatment for dyspepsia. When using in combination with antibiotic, refer to the prescribing information of respective antibiotics. Impaired renal function: Dose adjustment is not required. Impaired hepatic function: Dose adjustment is not required in patients with mild to moderate liver impairment. For patients with severe liver impairment, a dose of 20 mg Esomeprazole once				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						daily should not be exceeded. **Domperidone** Domperidone should be used with absolute caution in case of children because there may be an increased risk of extra-pyramidal reactions in young children because of incompletely developed blood brain barrier. Since Degut (Domperidone) is highly metabolized in liver, it should be used with caution in patient with hepatic impairment.				
84.	**Delta Pharma Ltd, Pakundia, Kishorganj.**	Esomeprazole BP 40 mg + Domperidone BP 30 mg Capsule.	Esomeprazole enteric coated & Domperidone sustained release blended pellets 275.00 mg equivalent to Esomeprazole BP 40 mg and Domperidone BP 30 mg.	Proton Pump inhibitor	Esomeprazole/ Domperidone SR is used for the treatment of acid reflux, Gastro esophageal reflux disease and stomach ulcers. Esomeprazole/ Domperidone SR works by decreasing the amount of acid the stomach produces which leads to the relieve of heartburn or cough.	**Contra-indications:** Esomeprazole is contraindicated in patients with known hypersensitivity to proton pump inhibitors. Hypersensitivity reactions, e.g., angioedema and anaphylactic shock have been reported with Esomeprazole use. Domperidone is contraindicated in patients having known hypersensitivity to this drug and in case of neonates. **Side-effects**: **Esomeprazole** Most common adverse reactions are: Adults (>_ 18 years) (incidence >_ 1%) are headache, diarrhea, nausea, flatulence, abdominal pain, constipation and dry mouth.	New Esomeprazole BP 20 mg and 40 mg Domperidone BP 10 mg.	Reference নাই DCC এর 230 তম সভায় BNF-এ অন্তর্ভূক্ত নাই এবং Combination অপ্রয়োজনীয় বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Pediatric (1 to 17 years) (incidence >_ 2%) are headache, diarrhea, abdominal pain, nausea and somnolence. Pediatric (1 month to less than 1 year) (incidence 1%) are abdominal pain, regurgitation, tachypnea and increased ALT. **Domperidone** Domperidone may produce hyperprolactinemia (1-3%). This may result in galactorrhoea, gynaecomastia (breast enlargement), soreness and reduced libido. Dry mouth (1-9%), thirst, headache (1-2%), nervousness, drowsiness (0.4%), diarrhoea (0.2%), skin rash and itching (0.1%) may occur during treatment with Degut (Domperidone). Extra-pyramidal reactions are seen in 0.25% of patients in clinical studies. **Warning and Precautions:** **Esomeprazole** Exclude the possibility of malignancy when gastric ulcer is suspected and before treatment for dyspepsia. When using in combination with antibiotic, refer to the prescribing information of respective antibiotics. Impaired renal function: Dose adjustment is not required. Impaired hepatic function: Dose adjustment is not				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						required in patients with mild to moderate liver impairment. For patients with severe liver impairment, a dose of 20 mg Esomeprazole once daily should not be exceeded. **Domperidone** Domperidone should be used with absolute caution in case of children because there may be an increased risk of extra-pyramidal reactions in young children because of incompletely developed blood brain barrier. Since Degut (Domperidone) is highly metabolized in liver, it should be used with caution in patient with hepatic impairment.				
85.	**Delta Pharma Ltd, Pakundia, Kishorganj.**	Rabeprazole INN 20 mg and Domperidone BP 30 mg Capsule.	Rabeprazole enteric coated & Domperidone sustained release blended pellets 275.00 mg equivalent to Rabeprazole INN 20 mg and Domperidone BP 30 mg.	Proton Pump inhibitor	Rabeprazole/ Domperidone SR is used for the treatment of acid reflux, Gastro esophageal reflux disease and stomach ulcers. Esomeprazole/ Domperidone SR works by decreasing the amount of acid the stomach produces which leads to the relieve of heartburn or cough.	**Contra-indications:** Rabeprazole Sodium is contraindicated in patients with known hypersensitivity to Rabeprazole Sodium, substituted Benzimidazoles or to any component of the formulation. Domperidone is contraindicated in patients having known hypersensitivity to this drug and in case of neonates. **Side-effects**: **Rabeprazole** Studies on adults for 4 to 8 weeks shown, adverse event that occurred at a rate greater than 2% and	New Rabeprazole INN 20 mg Domperidone BP 10 mg.	USFDA DCC এর 241 তম সভায় এই কম্বিনেশন প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						greater than placebo. These adverse events include pain, pharyngitis, flatulence, infection and constipation. In studies of pediatric and adolescent patients (ages 1 to 16 years and up to 36 weeks exposure) adverse events that occurred at a rate of ≥5% of patients included abdominal pain, diarrhea and headache. **Domperidone** Domperidone may produce hyperprolactinemia (1-3%). This may result in galactorrhoea, gynaecomastia (breast enlargement), soreness and reduced libido. Dry mouth (1-9%), thirst, headache (1-2%), nervousness, drowsiness (0.4%), diarrhoea (0.2%), skin rash and itching (0.1%) may occur during treatment with Degut (Domperidone). Extra-pyramidal reactions are seen in 0.25% of patients in clinical studies. **Warning and Precautions:** Rabeprazole ● Symptomatic response to therapy with Rmax 20 (Rabeprazole Sodium) does not preclude the presence of gastric malignancy. ● Acute interstitial nephritis has been observed in patients taking PPIs. ● Use with Warfarin: monitor for increases in				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						INR and prothombin time. ● PPI therapy may be associated with increased risk of Clostridium difficile associated diarrhea. ● Bone fracture: Long-term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine. ● Hypomagnesemia has been reported rarely with prolonged treatment with PPIs. **Domperidone** Domperidone should be used with absolute caution in case of children because there may be an increased risk of extra-pyramidal reactions in young children because of incompletely developed blood brain barrier. Since Degut (Domperidone) is highly metabolized in liver, it should be used with caution in patient with hepatic impairment.				
86.	**Delta Pharma Ltd, Pakundia, Kishorganj.** Acme Laboratories Ltd., Dhamrai, Dhaka Opsonin Pharma Limited, Rupatoli, Barishal. Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka	Semaglutide INN 3 mg immediate release Tablet.	**Semaglutide INN 3 mg tablet.**	Antidiabetes	Semaglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contra-indications:** Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2. Known hypersensitivity to semaglutide or any of the components in semaglutide. **Side-effects**:	New Semaglutide 1.34 mg/ ml	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						The most common adverse reactions, reported in ≥5% of patients treated with semaglutide are: nausea, abdominal pain, diarrhea, decreased appetite, vomiting and constipation. **Warning and Precautions:** Pancreatitis: Has been reported in clinical trials. Discontinue promptly if pancreatitis is suspected. Do not restart if pancreatitis is confirmed. Diabetic Retinopathy Complications: Has been reported in a cardiovascular outcomes trial with semaglutide injection. Patients with a history of diabetic retinopathy should be monitored. Hypoglycemia: When semaglutide is used with an insulin secretagogue or insulin, consider lowering the dose of the secretagogue or insulin to reduce the risk of hypoglycemia. Acute Kidney Injury: Monitor renal function in patients with renal impairment reporting severe adverse gastrointestinal reactions. Hypersensitivity Reactions: Discontinue semaglutide if suspected and promptly seek medical advice .				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
87.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Paracetamol 325mg + Butalbital 50mg + Caffeine 40mg Tablet	Paracetamol BP 325mg + Butalbital USP 50mg + Caffeine BP 40mg	Analgesics and Antipyretics	Tension headaches and Vascular headaches e.g. migraines	**Contra-indication:** Hypersensitivity or intolerance to any component of Butalbital, Paracetamol and Caffeine Tablets. Patients with Porphyria (Porphyria is a rare condition that involves a group of diseases in which substances called porphyrins build up, negatively affecting the skin or nervous system). **Side-effect**: Drowsiness, Light-headedness, dizziness, Feeling short of breath, Nausea, vomiting, stomach pain, Feeling of intoxication, Skin rash, Itching, Breathing problems	Paracetamol 500mg + Caffeine 65mg	USFDA DCC এর 241 তম সভায় এই কম্বিনেশন প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
88.	Square Pharmaceuticals Ltd., (Dhaka Unit) Kaliakoir, Gazipur	Carbamide Peroxide 65mg/ml Ear drops	Carbamide Peroxide USP 65mg/ml	Ear and Nose Preparations	It is indicated for softening, loosening & removing of excessive ear wax.	**Contra-indication:** Hypersensitivity: Perforated tympanic membrane, discharge or pain, irritation or rash in the ear, use in eye. **Side-effect**: Hypersensitivity, minor irritation, rash, redness, dizziness, mild itching inside the ear.	New	USFDA কর্তৃক OTC হিসেবে অনুমোদিত	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
89.	Square Pharmaceuticals Ltd., (Dhaka Unit) Kaliakoir, Gazipur	Glycopyrronium bromide 9mcg + Formoterol fumarate	Glycopyrronium bromide BP 9mcg + Formoterol fumarate dehydrate BP 4.8mcg/Puff	Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease	It is a combination of glycopyrrolate, an anticholinergic, and formoterol fumarate, a long-acting beta2-adrenergic agonist (LABA) indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).	**Contra-indication:** All LABAs are contraindicated in patients with asthma without use of a long-term asthma controller medication. It is	New Glycopyrronium 50 mcg + Indacaterol 110 mcg inhalation capsules	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		dehydrate 4.8mcg/Puff HFA Inhaler		(COPD)		not indicated for the treatment of asthma. • Hypersensitivity to glycopyrrolate, formoterol fumarate, or to any component of this product. **Side-effect:** Most common adverse reactions (incidence ≥2% and more common than with placebo) include: urinary tract infection and cough. **Warnings and Precautions:** Do not initiate in acutely deteriorating COPD or to treat acute symptoms. • Do not use in combination with an additional medicine containing a LABA because of risk of overdose. • If paradoxical bronchospasm occurs, discontinue Glycopyrronium bromide + Formoterol fumarate dehydrate and institute alternative therapy. • Use with caution in patients with cardiovascular disorders. • Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, and ketoacidosis. • Be alert to hypokalemia and hyperglycemia. • Worsening of narrow-angle glaucoma may occur. Use with caution in patients with narrow-angle				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						glaucoma and instruct patients to contact a physician immediately if symptoms occur. • Worsening urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to contact a physician immediately if symptoms occur.				
90.	Square Pharmaceuticals Ltd., (Dhaka Unit) Kaliakoir, Gazipur	Glycopyrronium bromide 25mcg/ml nebulizer solution for inhalation	Glycopyrronium bromide BP 25mcg/ml	Drug used in Bronchial Asthma,Chronic obstructive pulmonary disease (COPD)	It is an anticholinergic indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).	**Contra-indication:** It is contraindicated in patients with a hypersensitivity to glycopyrrolate or any of the ingredients. **Side-effect:** Most common adverse reactions (incidence greater than or equal to 2.0% and higher than placebo) are dyspnea and urinary tract infection. **Warnings and Precautions:** Do not initiate in acutely deteriorating COPD or to treat acute symptoms. • If paradoxical bronchospasm occurs, discontinue Glycopyrronium bromide immediately and institute alternative therapy. • Worsening of narrow-angle glaucoma may occur. Use with caution in patients with narrow-angle glaucoma and instruct patients to contact a physician immediately if	New Glycopyrronium 50 mcg inhalation capsules +	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						symptoms occur. • Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder neck obstruction and instruct patients to consult a physician immediately if symptoms occur.				
91.	Square Pharmaceuticals Ltd., (Dhaka Unit) Kaliakoir, Gazipur	L-Isoleucine 8.80 gm + L-Leucine 13.60 gm + L- Lysin 7.51gm + L-Methionine 1.20 gm + L-Phenylalanine USP 1.60 gm + L-Theronine 4.60 gm + L-Tryptophan 1.50 gm + L-Valine 10.60 gm + L-Arginine 8.80 gm + L- Histidine 4.70 gm + Glycine 6.30 gm + L-Alanine 8.30 gm + L-Proline 7.10 gm + L-Aspartic Acid 2.50 gm + Asparagine	L-Isoleucine USP 8.80 gm + L-Leucine USP 13.60 gm + L-Lysine Acetate USP 10.60 gm (eqv. to Lysin 7.51gm) + L-Methionine USP 1.20 gm + L-Phenylalanine USP 1.60 gm + L-Theronine USP 4.60 gm + L-Tryptophan USP 1.50 gm + L-Valine USP 10.60 gm + L-Arginine USP 8.80 gm + L-Histidine USP 4.70 gm + Glycine USP 6.30 gm + L-Alanine USP 8.30 gm + L-Proline USP 7.10 gm + L-Aspartic Acid USP 2.50 gm + L-Asparagine Monohydrate USP 0.55 gm eqv. to Asparagine 0.48gm + N-Acetyl-L-cysteine USP 0.80 gm eqv. to Cysteine 0.59gm + L-Glutamic Acid EP 5.70 gm + Ornithine Hydrochloride INN 1.66 gm eqv. to Ornithine 1.3gm + L-Serine USP 3.70 gm	Amino Acids	Amino acid solution for parenteral nutrition in patients with severe liver diseases and for treatment of hepatic encephalopathy.	**Contra-indication:** This preparation is contraindicated for individual having- Disorder of Amino Acid metabolism of other than hepatic origin, Life endangering unstable circulation, Acidosis, Hypertension, Hypokalaemia **Side-effect:** Provided contraindications, dosage recommendation and precautions are observed, side effects are not be expected	5 % Amino Acids (Essential)	EMA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		0.48gm + Cysteine 0.59gm + L-Glutamic Acid 5.70 gm + Ornithine 1.3gm + L-Serine 3.70 gm + Tyrosine 0.7gm/1000 ml IV Infusion.	+ N-Acetyl-L-Tyrosine USP 0.86 gm eqv.to Tyrosine 0.7gm/1000ml.							
92.	Square Pharmaceuticals Ltd., (Dhaka Unit) Kaliakoir, Gazipur	Fondaparinux sodium 2.5mg/0.5ml pre-filled syringe	Fondaparinux sodium USP 2.5mg/0.5ml	DRUG used in Anemia and other Blood disorder	It is a Factor Xa inhibitor (anticoagulant) indicated for: • Prophylaxis of deep vein thrombosis (DVT) in patients undergoing hip fracture surgery (including extended prophylaxis), hip replacement surgery, knee replacement surgery, or abdominal surgery. • Treatment of DVT or acute pulmonary embolism (PE) when administered in conjunction with warfarin.	**Contra-indication:** It is contraindicated in the following conditions: • Severe renal impairment (creatinine clearance <30 mL/min) in prophylaxis or treatment of venous thromboembolism. Active major bleeding. • Bacterial endocarditis. •Thrombocytopenia associated with a positive in vitro test for anti-platelet antibody in the presence of fondaparinux sodium. • Body weight <50 kg (venous thromboembolism prophylaxis only). • History of serious hypersensitivity reaction (e.g., angioedema, anaphylactoid/anaphylactic reactions) to Fondaparinux. **Side effect:** Severe bleeding. Certain conditions can increase your risk for severe bleeding, including: some bleeding problems, some gastrointestinal	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						problems including ulcers, some types of strokes, uncontrolled high blood pressure, diabetic eye disease, soon after brain, spine, or eye surgery.				
93.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Clobetasol Propionate 0.05gm + Salicylic Acid 3gm + Urea 10gm + Lactic Acid 3gm + Lactic Acid 2gm/100gm Ointment	Clobetasol Propionate BP 0.05gm + Salicylic Acid BP 3gm + Urea BP 10gm + Lactic Acid BP 3gm + Sodium Lactate solution BP 4.98gm eqv. to Lactic Acid 2gm/100gm	Skin and Mucous Membrane Preparations	It is used in the treatment of dry resistant hyperkeratotic skin conditions, in which the outer layer of the skin becomes thickened, dry and scaly. These conditions include recalcitrant eczema, dermatitis, lichen planus and Ichthyosis vulgaris and moderate to severe plaque psoriasis.	Contra-indication: Hypersensitivity, occlusive wrappings/dressings Side effect: Burning, itching, irritation, cracking, fissuring at the site of application	New Clobetasol Propionate 0.05% + Salicylic Acid 3% ointment	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*
94.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Ciclopirox Olamine 1gm + Fluocinolone Acetonide 0.01gm/100gm Cream	Ciclopirox Olamine USP 1gm + Fluocinolone Acetonide USP 0.01gm/100gm	Skin and Mucous Membrane Preparations	It is used in the treatment of Athlete's foot, jock itch, ringworm, yeast/fungal infections, seborrheic dermatitis and allergic contact dermatitis	**Contra-indication:** Hypersensitivity, occlusive wrappings/dressings **Side effect:** Itching skin, rash, redness, burning sensation	New Ciclopirox Olamine 1% cream Fluocinolone Acetonide 0.025% cream	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*
95.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Cysteamine Hydrochloride 5gm/100gm Cream	Cysteamine Hydrochloride In-house 5gm/100gm	Skin and Mucous Membrane Preparations	Cysteamine is used in the treatment of hyperpigmentation disorders such as melasma, Postinflammatory hyperpigmentation.	**Contra-indication:** Hypersensitivity, occlusive wrappings/dressings **Side effect:** Temporary heating sensation, dryness	New	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*
96.	Square Pharmaceuticals Ltd., (Dhaka Unit) Kaliakoir, Gazipur	Iron 150 mg Capsule	Polysaccharide-Iron Complex 46% fine powder Ph. Grade 326.087 mg (eqv. to 150 mg Iron)	DRUG used in Anemia and other Blood disorder	Iron Deficiency Anemia (IDA)	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients, Known iron overload, Haemosiderosis and haemochromatosis, Active peptic ulcer, Repeated blood transfusion, Regional enteritis and ulcerative colitis, Haemolytic anaemias.	New Iron (III) hydroxide polymaltose complex INN 200mg equivalent to 50mg of elemental iron/5ml	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Side effects: Anorexia, nausea, vomiting, gastro-intestinal discomfort, constipation, diarrhea, dark stools and allergic reactions.				
97.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna Opsonin Pharma Limited, Rupatoli, Barishal.	N, N-Diethylbenzamide 12 gm/100 gm Cream	N, N-Diethylbenzamide INN 12 gm/100 gm	Other Classification	Repellents are commonly used personal protection measures to avoid mosquito bites.	**Contraindication** No data available. **Side-effects:** There are no side effects since the primary repellent in N-Diethylbenzamide, Vitamin –E,Almond oil., N, N diethyl benzamide is used in a very less amount.	New	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***Mosquito repellent*** *জাতীয় প্রডাক্ট ঔষধ হিসেবে অনুমোদনের প্রয়োজন নেই।*
98.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Paracetamol 250 mg/5 ml Syrup	Paracetamol 250 mg/5 ml	Analgesics and Antipyretics	For the treatment of mild to moderate pain, including headache, migraine, neuralgia, toothache, sore throat etc. For the reduction of fever and to be used as an adjunctive treatment to relieve symptoms of cold and flu.	**Contra-indication:** Malnutrition, Acute liver failure**,** Liver problems**,** Severe renal impairment**,** Paracetamol overdose**,** Acute inflammation of the liver due to hepatitis C virus**,** Allergies to Paracetamol **Side-effect:** Side effects of Paracetamol are usually mild, though hematological reactions including leukopenia, thrombocytopenia, pancytopenia, neutropenia, and agranulocytosis have been reported. Pancreatitis, skin rashes, and other allergic reactions occur occasionally. Difficulty in breathing or wheezing and liver problems have been seen in some occasions.	New Paracetamol 250 mg Tablet , suppository Paracetamol 120 mg/ 5 ml syrup.	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
99.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Paracetamol 250 mg/5 ml Suspension	Paracetamol 250 mg/5 ml	Analgesics and Antipyretics	For the treatment of mild to moderate pain, including headache, migraine, neuralgia, toothache, sore throat etc. For the reduction of fever and to be used as an adjunctive treatment to relieve symptoms of cold and flu.	**Contra-indication:** Malnutrition, Acute liver failure**,** Liver problems**,** Severe renal impairment**,** Paracetamol overdose**,** Acute inflammation of the liver due to hepatitis C virus**,** Allergies to Paracetamol **Side-effect:** Side effects of Paracetamol are usually mild, though hematological reactions including leukopenia, thrombocytopenia, pancytopenia, neutropenia, and agranulocytosis have been reported. Pancreatitis, skin rashes, and other allergic reactions occur occasionally. Difficulty in breathing or wheezing and liver problems have been seen in some occasions.	New Paracetamol 250 mg Tablet , suppository Paracetamol 120 mg/ 5 ml suspension.	UKMHRA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
100.	Square Pharmaceuticals Ltd., (Pabna Unit), Salgaria, Pabna	Elemental Calcium 250 mg as Calcium Carbonate BP, Elemental Magnesium 75 mg as Magnesium Hydroxide USP, Elemental Zinc 2 mg as Zinc Gluconate USP and Cholecalciferol	Elemental Calcium 250 mg as Calcium Carbonate BP, Elemental Magnesium 75 mg as Magnesium Hydroxide USP, Elemental Zinc 2 mg as Zinc Gluconate USP and Cholecalciferol Concentrate (Oily form) EP 200 I.U/ 5 ml suspension.	Metals, Salts, Minerals and Calcium Preparations	It is s indicated in children, adults and in pregnancy and lactation for the treatment of Calcium deficiency. It also helps to maintain strong bones in growing children and indicated in Nutritional rickets and brittle bone disease.	**Contraindication:** Hypercalcemia and hyperparathyroidism Hypercalciuria and nephrolithiasis Hypersensitivity to any component of this product Severe renal insufficiency Concomitant digoxin therapy (requires careful monitoring of serum calcium level) **Side-effects:** Orally administered Calcium Carbonate may be irritating to the GI tract. It may also cause constipation. Hypercalcemia is rarely produced by administration of calcium alone, but may	Many combination of Calcium, Magnesium, Zinc, Calcium carbonate, sodium alginate suspension are existed.	রেফারেন্স নাই।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		Concentrate (Oily form) EP 200 I.U./5 ml Suspension				occur when large doses are given to patients with chronic renal failure.				
101.	The IBN SINA Pharmaceutical Industries Ltd.	(Dapagliflozin + Saxagliptin + Metformin) Extended Release Tablet	Dapagliflozin Propanediol INN 2.5mg + Saxagliptin HCL INN 2.5mg + Metformin HCL BP 1000mg.	Antidiabetes	It is a sodium-glucose cotransporter 2 (SGLT2) inhibitor, a dipeptidyl peptidase-4 (DPP-4) inhibitor and a biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contra-indication:** • History of a serious hypersensitivity reaction to dapagliflozin, saxagliptin, or metformin, including anaphylaxis, angioedema, or exfoliative skin conditions. • Moderate to severe renal impairment end-stage renal disease (ESRD), or patients on dialysis. • Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin. **<u>Warnings and precautions:</u>** Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. Symptoms included malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Laboratory abnormalities included elevated blood lactate levels, anion gap acidosis, increased lactate/pyruvate ratio; and metformin plasma levels generally >5 mcg/mL. • Risk factors include renal impairment, concomitant use	New Dapagliflogin 10mg and 5mg Tablet, Saxagliptin 2.5mg and 5mg Tablet, Metformin 500mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						of certain drugs, age >65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment. Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high-risk groups are provided in the Full Prescribing Information. • If lactic acidosis is suspected, discontinue Dapagliflozin + Saxagliptin + Metformin and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.				
102.	The IBN SINA Pharmaceutical Industries Ltd.	(Dapagliflozin + Saxagliptin + Metformin) Extended Release Tablet	Dapagliflozin Propanediol INN 5.0 mg + Saxagliptin HCL INN 2.5mg + Metformin HCL BP 1000mg.	Antidiabetes	It is a sodium-glucose cotransporter 2 (SGLT2) inhibitor, a dipeptidyl peptidase-4 (DPP-4) inhibitor and a biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contra-indication:** • History of a serious hypersensitivity reaction to dapagliflozin, saxagliptin, or metformin, including anaphylaxis, angioedema, or exfoliative skin conditions. • Moderate to severe renal impairment end-stage renal disease (ESRD), or patients on dialysis. • Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin. **Warnings and precautions:** Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. Symptoms	New Dapagliflogin 10mg and 5mg Tablet, Saxagliptin 2.5mg and 5mg Tablet, Metformin 500mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						included malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Laboratory abnormalities included elevated blood lactate levels, anion gap acidosis, increased lactate/pyruvate ratio; and metformin plasma levels generally >5 mcg/mL. • Risk factors include renal impairment, concomitant use of certain drugs, age >65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment. Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high-risk groups are provided in the Full Prescribing Information. • If lactic acidosis is suspected, discontinue Dapagliflozin + Saxagliptin + Metformin and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.				
103.	The IBN SINA Pharmaceutical Industries Ltd.	(Dapagliflozin + Saxagliptin + Metformin) Extended Release Tablet	Dapagliflozin Propanediol INN 5.0 mg + Saxagliptin HCL INN 5.0 mg + Metformin HCL BP 1000mg.	Antidiabetes	It is a sodium-glucose cotransporter 2 (SGLT2) inhibitor, a dipeptidyl peptidase-4 (DPP-4) inhibitor and a biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contra-indication:** • History of a serious hypersensitivity reaction to dapagliflozin, saxagliptin, or metformin, including anaphylaxis, angioedema, or exfoliative skin conditions. • Moderate to severe renal impairment end-stage renal disease (ESRD), or patients on dialysis.	New Dapagliflogin 10mg and 5mg Tablet, Saxagliptin 2.5mg and 5mg Tablet, Metformin 500mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						• Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin. **Warnings and precautions:** Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. Symptoms included malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Laboratory abnormalities included elevated blood lactate levels, anion gap acidosis, increased lactate/pyruvate ratio; and metformin plasma levels generally >5 mcg/mL. • Risk factors include renal impairment, concomitant use of certain drugs, age >65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment. Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high-risk groups are provided in the Full Prescribing Information. • If lactic acidosis is suspected, discontinue Dapagliflozin + Saxagliptin + Metformin and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
104.	The IBN SINA Pharmaceutical Industries Ltd.	(Dapagliflozin + Saxagliptin + Metformin) Extended Release Tablet	Dapagliflozin Propanediol INN 10 mg + Saxagliptin HCL INN 5.0 mg + Metformin HCL BP 1000mg.	Antidiabetes	It is a sodium-glucose cotransporter 2 (SGLT2) inhibitor, a dipeptidyl peptidase-4 (DPP-4) inhibitor and a biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contra-indication:** • History of a serious hypersensitivity reaction to dapagliflozin, saxagliptin, or metformin, including anaphylaxis, angioedema, or exfoliative skin conditions. • Moderate to severe renal impairment end-stage renal disease (ESRD), or patients on dialysis. • Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin. **<u>Warnings and precautions:</u>** Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. Symptoms included malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Laboratory abnormalities included elevated blood lactate levels, anion gap acidosis, increased lactate/pyruvate ratio; and metformin plasma levels generally >5 mcg/mL. • Risk factors include renal impairment, concomitant use of certain drugs, age >65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment. Steps to reduce	New Dapagliflogin 10mg and 5mg Tablet, Saxagliptin 2.5mg and 5mg Tablet, Metformin 500mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						the risk of and manage metformin-associated lactic acidosis in these high-risk groups are provided in the Full Prescribing Information. • If lactic acidosis is suspected, discontinue Dapagliflozin + Saxagliptin + Metformin and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.				
105.	The IBN SINA Pharmaceutical Industries Ltd. **Opsonin Pharma Limited,** Rupatali, Barishal. **Opso Saline Limited,** Bagura Road, Barishal. Aristopharma Ltd, Shampur, Dhaka.	Netarsudil + Latanoprost Ophthalmic	Netarsudil Dimesylate INN 0.2 mg/ml + Latanoprost INN 0.05 mg/ml	Eye Preparations	Indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.	**Contra-indication:** It is a fixed dose combination of a Rho kinase inhibitor and a prostaglandin F2α analogue indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. **Side-effect:** It is a fixed dose combination of a Rho kinase inhibitor and a prostaglandin F2α analogue indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. **Warnings and precautions:** **Pigmentation:** Pigmentation of the iris, periorbital tissue (eyelid) and eyelashes can occur. Iris pigmentation likely to be permanent. **Eyelash Changes:** Gradual change to eyelashes including increased length, thickness and number of lashes. Usually reversible.	New Netarsudil 0.02% Opthalmic Solution, Latanoprost 0.005% Eye Drop	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
106.	Beximco Pharmaceuticals Ltd.	Nebivolol 5mg + Hydrochlorothiazide 25mg	Nebivolol Hydrochloride INN 5.445mg (eq. to 5 mg Nevibolol) + Hydrochlorothiazide BP 25mg	Antihypertensive	Nebivolol / Hydrochlorothiazide is a one-tablet combination is used for the treatment of raised blood pressure (hypertension). It is used instead of the two separate products for those patients who are already taking them together.	Hypersensitivity, liver impairment, anuria, sulphonamide allergy. Pregnancy, lactation. Side effects: Nebivolol - Headache, fatigue, parasthesias, dizziness. Hydrochlorothiazide - Hypotension including orthostatic hypotension, pancreatitis, intrahepatic cholestatic jaundice, diarrhoea, vomiting, sialadenitis, cramping, constipation, gastric irritation, nausea, anorexia, thrombocytopenia, photosensitivity, fever, urticaria, rash, purpura, hyperglycemia, glycosuria, hyperuricemia, restlessness, impotence.	Nebivolol 2.5mg & 5mg tablet, Hydrochlorthiazide 12.5mg & 25mg tablet	UKMHRA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
107.	Beximco Pharmaceuticals Ltd.	Beclometason 100mcg + Formoterol 6mcg + Glycopyrronium 10mcg meter dose inhaler	Beclometason 100mcg BP + Formoterol 6mcg BP + Glycopyrronium USP 10mcg/Actuation	Drug used in Bronchial Asthma, Chronic obstructive pulmonary disease (COPD)	Maintenance treatment of moderate to severe COPD where an inhaled corticosteroid plus a long-acting β_2-agonist, or a long-acting anticholinergic plus a long-acting β_2-agonist, is inadequate (for effects on symptom control and prevention of exacerbations	**Contra-indication :** The product is not indicated for the treatment of acute episodes of bronchospasm, or to treat an acute COPD exacerbation (i.e. as a rescue therapy). It is contraindicated to patitients hypersensitivity to the active substances, or to any of the excipients of the formulation. **Side-effect:** The most frequently reported adverse reactions with are oral candidiasis (which occurred in 0.8% of the exposed subjects), which is normally associated with inhaled corticosteroids; muscle spasms (0.4%), which can be attributed to the long-acting beta2-agonist component; dry mouth (0.4%), which is a typical anticholinergic effect.	New Beclomethasone 200mcg+ Formoterol Fumarate 6mcg Inhaler	EMA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
108.	Beximco Pharmaceuticals Ltd.	Telmisartan 40mg + Amlodipine 10mg Tablet	Telmisartan USP 40mg + Amlodipine Besilate BP equivalent to Amlodipine 10mg	Antihypertensive	Telmisartan/Amlodipine is an angiotensin II receptor blocker (ARB) and a dihydropyridine calcium channel blocker (DHP-CCB) combination product indicated for the treatment of hypertension alone or with other antihypertensive agents. Telmisartan/Amlodipine tablets are indicated as initial therapy in patients likely to need multiple antihypertensive agents to achieve their blood pressure goals.	**Contra-indication :** Biliary obstructive disorders, cardiogenic shock. Severe hepatic impairment. Pregnancy and lactation. Concomitant use w/ ACE inhibitors or aliskiren-containing products in patients w/ DM or renal impairment (GFR <60 mL/min). **Side-effect:** *Significant:* Hypotension, angina, acute renal failure, hyperkalaemia, peripheral oedema. Rarely, angioedema. *Nervous:* Dizziness, somnolence, migraine, fatigue, flu-like symptoms, headache, malaise, insomnia, vertigo, paraesthesia, hypoaesthesia, anxiety, depression, tremor, peripheral neuropathy. *CV:* Orthostatic hypotension, oedema, syncope, chest pain, flushing, bradycardia, palpitation.	Telmisartan 40mg+Amlodipine 5mg Tablet, Telmisartan 80mg+Amlodipine 5mg Tablet,	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
109.	Beximco Pharmaceuticals Ltd. Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka	Telmisartan 80mg + Amlodipine 10mg Tablet	Telmisartan USP 80mg + Amlodipine Besilate BP equivalent to Amlodipine 10mg	Antihypertensive	Telmisartan/Amlodipine is an angiotensin II receptor blocker (ARB) and a dihydropyridine calcium channel blocker (DHP-CCB) combination product indicated for the treatment of hypertension alone or with other antihypertensive agents. Telmisartan/Amlodipine tablets are indicated as initial therapy in patients likely to need multiple antihypertensive agents to achieve their blood pressure goals.	**Contra-indication :** Biliary obstructive disorders, cardiogenic shock. Severe hepatic impairment. Pregnancy and lactation. Concomitant use w/ ACE inhibitors or aliskiren-containing products in patients w/ DM or renal impairment (GFR <60 mL/min). **Side-effect:** *Significant:* Hypotension, angina, acute renal failure, hyperkalaemia, peripheral oedema. Rarely, angioedema. *Nervous:* Dizziness, somnolence, migraine, fatigue, flu-like symptoms, headache, malaise, insomnia, vertigo, paraesthesia, hypoaesthesia,	Telmisartan 40mg+Amlodipine 5mg Tablet, Telmisartan 80mg+Amlodipine 5mg Tablet,	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						anxiety, depression, tremor, peripheral neuropathy. *CV:* Orthostatic hypotension, oedema, syncope, chest pain, flushing, bradycardia, palpitation.				
110.	Beximco Pharmaceuticals Ltd. Square Pharmaceuticals Ltd., (Dhaka Unit) Kaliakoir, Gazipur Orion Pharma Ltd, Siddhirganj, Narayangang.	Famotidine 40mg/5ml Powder for Suspension.	Famotidine USP 40mg/5ml	H2 Receptor Blocking	Famotidine is useful in promoting the healing of stomach and duodenal ulcers and in reducing ulcer pain. Famotidine has been effective in preventing recurrence of ulcers when given in low doses for prolonged periods of time. Famotidine also is used for treating heartburn and in healing ulceration and inflammation of the esophagus (esophagitis) resulting from acid (gastroesophageal reflux disease or GERD).	**Contra-indication :** Famotidine for oral suspension is contraindicated in patients with a history of serious hypersensitivity reactions (e.g., anaphylaxis) to famotidine or other histamine-2 (H2) receptor antagonists. **Side-effect:**Side effects of famotidine are rare. The most commonly reported minor side effects are: constipation, diarrhea, fatigue, headache, insomnia, muscle pain	Famotidine 20mg & 40mg Tablet	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
111.	**ACI HealthCare Limited, Treepordi, Sonargaon, Narayanganj.**	Gabapentin 400 mg capsule	Gabapentin USP 400 mg	Anticonvulsant	It is indicated for • Postherpetic neuralgia in adults Adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy	**Contraindications:** It is contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients. **Side Effects:** Most common adverse reactions (incidence =8% and at least twice that for placebo) were: Postherpetic neuralgia: dizziness, somnolence, and peripheral edema Epilepsy in patients >12 years of age: somnolence, dizziness, ataxia, fatigue, and nystagmus Epilepsy in patients 3 to 12 years of age: viral infection, fever, nausea and/or vomiting, somnolence, and	Gabapentin 100mg, 300mg, 600mg Tablet	**USFDA** **BNF 77 (Page: 314,315)**	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						hostility. **Warnings & Precautions: Drug Reaction with Eosinophilia and Systemic Symptoms (Multiorgan hypersensitivity)**: Discontinue if alternative etiology is not established. **Anaphylaxis and Angioedema**: Discontinue and evaluate patient immediately **Driving Impairment**; **Somnolence/Sedation and Dizziness**: Warn patients not to drive until they have gained sufficient experience to assess whether their ability to drive or operate heavy machinery will be impaired. Increased seizure frequency may occur in patients with seizure disorders if Gabapentin is abruptly discontinued. **Suicidal Behavior and Ideation**: Monitor for suicidal thoughts/behavior. Neuropsychiatric Adverse Reactions in Children 3 to 12 Years of Age: Monitor for such events.				
112.	**ACI HealthCare Limited, Treepordi, Sonargaon, Narayanganj.**	Pregabalin Capsule, 200mg	Pregabalin USP 200 mg	Neuromuscular Blocking	It is indicated for • Management of neuropathic pain associated with diabetic peripheral neuropathy • Management of postherpetic neuralgia • Adjunctive therapy for the treatment of partial-onset seizures in patients 1 month of age and older • Management of fibromyalgia • Management of neuropathic pain associated with spinal cord injury	**Contraindications:** Pregabalin is contraindicated in patients with known hypersensitivity to Pregabalin or any of its components. Angioedema and hypersensitivity reactions have occurred in patients receiving Pregabalin therapy. Ingredients. **Side Effects:** Angioedema Hypersensitivity	Pregabalin 25mg,50mg, 75mg, 100mg, 150mg, 300mg Capsule	**USFDA** **BNF 77 (Page: 323)**	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Increased Risk of Adverse Reactions with Abrupt or Rapid Discontinuation Suicidal Behavior and Ideation Peripheral Edema Dizziness and Somnolence Weight Gain Tumorigenic Potential Ophthalmological Effects Creatine Kinase Elevations Decreased Platelet Count PR Interval Prolongation **Warnings & Precautions:** Angioedema (e.g. swelling of the throat, head and neck) can occur, and may be associated with life-threatening respiratory compromise requiring emergency treatment. Discontinue Pregabalin immediately in these cases. • Hypersensitivity reactions (e.g. hives, dyspnea, and wheezing) can occur. Discontinue Pregabalin immediately in these patients. • Increased seizure frequency may occur in patients with seizure disorders if Pregabalin is rapidly discontinued. Withdraw Pregabalin gradually over a minimum of 1 week. • Antiepileptic drugs, including Pregabalin, increase the risk of suicidal thoughts or behavior. • Pregabalin may cause peripheral edema. Exercise caution when co-administering Pregabalin and thiazolidinedione antidiabetic agents. • Pregabalin may cause dizziness and somnolence and impair				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						patients' ability to drive or operate machinery.				
113.	**ACI HealthCare Limited, Treepordi, Sonargaon, Narayanganj.**	Pregabalin Capsule, 225mg	Pregabalin USP 225 mg	**Neuromuscular Blocking**	It is indicated for • Management of neuropathic pain associated with diabetic peripheral neuropathy • Management of postherpetic neuralgia • Adjunctive therapy for the treatment of partial-onset seizures in patients 1 month of age and older • Management of fibromyalgia Management of neuropathic pain associated with spinal cord injury	**Contraindications:** Pregabalin is contraindicated in patients with known hypersensitivity to Pregabalin or any of its components. Angioedema and hypersensitivity reactions have occurred in patients receiving Pregabalin therapy. Ingredients. **Side Effects:** Angioedema Hypersensitivity Increased Risk of Adverse Reactions with Abrupt or Rapid Discontinuation Suicidal Behavior and Ideation Peripheral Edema Dizziness and Somnolence Weight Gain Tumorigenic Potential Ophthalmological Effects Creatine Kinase Elevations Decreased Platelet Count PR Interval Prolongation **Warnings & Precautions:** Angioedema (e.g. swelling of the throat, head and neck) can occur, and may be associated with life-threatening respiratory compromise requiring emergency treatment. Discontinue Pregabalin immediately in these cases. • Hypersensitivity reactions (e.g. hives, dyspnea, and wheezing) can occur. Discontinue Pregabalin immediately in these patients. • Increased seizure frequency may occur in patients with	Pregabalin 25mg,50mg, 75mg, 100mg, 150mg, 300mg Capsule	**USFDA** **BNF 77 (Page: 323)**	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						seizure disorders if Pregabalin is rapidly discontinued. Withdraw Pregabalin gradually over a minimum of 1 week. • Antiepileptic drugs, including Pregabalin, increase the risk of suicidal thoughts or behavior. • Pregabalin may cause peripheral edema. Exercise caution when co-administering Pregabalin and thiazolidinedione antidiabetic agents. • Pregabalin may cause dizziness and somnolence and impair patients' ability to drive or operate machinery.				
114.	**ACI HealthCare Limited, Treepordi, Sonargaon, Narayanganj.**	Doxycycline Hyclate Tablet USP, 75mg	Doxycycline Hyclate USP 75 mg	Anti-infective	Doxycycline hyclate is tetracycline class drugs indicated for: • Rickettsial infections • Sexually transmitted infections • Respiratory tract infections • Specific bacterial infections • Ophthalmic infections • Anthrax, including inhalational anthrax (post-exposure) • Alternative treatment for selected infections when penicillin is contraindicated • Adjunctive therapy for acute intestinal amebiasis and severe acne • Prophylaxis of malaria • To reduce the development of drug-resistant bacteria and maintain the effectiveness of doxycycline hyclate tablets and other antibacterial drugs, doxycycline hyclate tablets should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria	**Contraindications:** This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines. **Side Effects:** Due to oral doxycycline's virtually complete absorption, side effects of the lower bowel, The following adverse reactions have been identified during clinical trials or post-approval use of tetracycline-class drugs, including doxycycline. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. **Gastrointestinal:** Anorexia, nausea, vomiting, diarrhea, glossitis, dysphagia, enterocoli tis, and inflammatory lesions	Doxycycline Hyclate 50mg,100mg Capsule	**USFDA**	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						(with monilial overgrowth) in the anogenital region. Hepatotoxicity has been reported. These reactions have been caused by both the oral and parenteral administration of tetracyclines. Instances of esophagitis and esophageal ulcerations have been reported in patients receiving capsule and tablet forms of drugs in the tetracycline-class. Most of these patients took medications immediately before going to bed. **Skin:** Maculopapular and erythematous rashes, Stevens-Johnson syndrome, toxic epidermal necrolysis, exfoliative dermatitis, and erythema multiforme have been reported. Photosensitivity has been reported. **Renal:** Rise in BUN has been reported and is apparently dose-related. **Hypersensitivity reactions:** Urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, serum sickness, pericarditis, and exacerbation of systemic lupus erythematosus. **Blood:** Hemolytic anemia, thrombocytopenia, neutropenia, and eosinophilia have been reported. **Intracranial Hypertension:** Intracranial hypertension (IH, pseudotumor cerebri) has been associated with the use of tetracyclines. **Thyroid Gland Changes:**				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						When given over prolonged periods, tetracyclines have been reported to produce brown-black microscopic discoloration of thyroid glands. No abnormalities of thyroid function are known to occur. **Warnings & Precautions:** The use of drugs of the tetracycline-class during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). • **Clostridium difficile-associated diarrhea:** Evaluate patients if diarrhea occurs. • Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Limit sun exposure. • Overgrowth of non-susceptible organisms, including fungi, may occur. Reevaluate therapy if superinfection occurs.				
115.	**ACI HealthCare Limited, Treepordi, Sonargaon, Narayanganj.**	Doxycycline Hyclate USP, 150 mg Tablet	Doxycycline Hyclate USP 150 mg	Anti-infective	Doxycycline hyclate is tetracycline class drugs indicated for: • Rickettsial infections • Sexually transmitted infections • Respiratory tract infections • Specific bacterial infections • Ophthalmic infections • Anthrax, including inhalational anthrax (post-exposure) • Alternative treatment for selected infections when penicillin is contraindicated • Adjunctive therapy for acute intestinal amebiasis and severe acne • Prophylaxis of malaria To reduce the development of drug-resistant	**Contraindications:** This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines. **Side Effects:** Due to oral doxycycline's virtually complete absorption, side effects of the lower bowel, The following adverse reactions have been identified during clinical trials or post-approval use of tetracycline-class drugs, including doxycycline. Because these	Doxycycline Hyclate 50mg,100mg Capsule	**USFDA**	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					bacteria and maintain the effectiveness of doxycycline hyclate tablets and other antibacterial drugs, doxycycline hyclate tablets should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria	reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. **Gastrointestinal:** Anorexia, nausea, vomiting, diarrhea, glossitis, dysphagia, enterocolitis, and inflammatory lesions (with monilial overgrowth) in the anogenital region. Hepatotoxicity has been reported. These reactions have been caused by both the oral and parenteral administration of tetracyclines. Instances of esophagitis and esophageal ulcerations have been reported in patients receiving capsule and tablet forms of drugs in the tetracycline-class. Most of these patients took medications immediately before going to bed. **Skin:** Maculopapular and erythematous rashes, Stevens-Johnson syndrome, toxic epidermal necrolysis, exfoliative dermatitis, and erythema multiforme have been reported. Photosensitivity has been reported. **Renal:** Rise in BUN has been reported and is apparently dose-related. **Hypersensitivity reactions:** Urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, serum sickness, pericarditis, and exacerbation of systemic				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						lupus erythematosus. **Blood:** Hemolytic anemia, thrombocytopenia, neutropenia, and eosinophilia have been reported. **Intracranial Hypertension:** Intracranial hypertension (IH, pseudotumor cerebri) has been associated with the use of tetracyclines. **Thyroid Gland Changes:** When given over prolonged periods, tetracyclines have been reported to produce brown-black microscopic discoloration of thyroid glands. No abnormalities of thyroid function are known to occur. **Warnings & Precautions:** The use of drugs of the tetracycline-class during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). • **Clostridium difficile-associated diarrhea:** Evaluate patients if diarrhea occurs. • Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Limit sun exposure. • Overgrowth of non-susceptible organisms, including fungi, may occur. Reevaluate therapy if superinfection occurs.				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
116.	**ACI HealthCare Limited, Treepordi, Sonargaon, Narayanganj.**	Sumatriptan Succinate USP 25 mg Tablet	Sumatriptan Succinate USP 25 mg	Drug Used In Migraine	It is indicated for • Acute treatment of migraine with or without aura in adults.	**Contraindications:** • Ischemic coronary artery disease or coronary artery vasospasm, including Prinzmetal's angina • Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders • History of stroke or transient ischemic attack (TIA) or history of hemiplegic or basilar migraine because these patients are at a higher risk of stroke • Peripheral vascular disease • Ischemic bowel disease • Uncontrolled hypertension • Recent use of ergotamine-containing medication, ergot-type medication (such as dihydroergotamine or methysergide), or another 5-hydroxytryptamine (5-HT) agonist • Concurrent administration of a monoamine oxidase (MAO)-A inhibitor or recent use of an MAO-A inhibitor • Hypersensitivity to Sumatriptan Succinate tablets • Severe hepatic impairment **Side Effects:** • Myocardial ischemia, myocardial infarction, and Prinzmetal's angina • Arrhythmias • Chest, throat, neck, and/or jaw pain/tightness/pressure • Cerebrovascular events • Other vasospasm reactions • Medication overuse headache • Serotonin syndrome • Increase in blood pressure	Sumatriptan 50mg, 100mg Tablet	**USFDA**	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						• Hypersensitivity reactions • Seizures **Warnings & Precautions:** • Myocardial ischemia/infarction and Prinzmetal's angina: Perform cardiac evaluation in patients with multiple cardiovascular risk factors. • Arrhythmias: Discontinue Sumatriptan Succinate if occurs. • Chest/throat/neck/jaw pain, tightness, pressure, or heaviness: Generally not associated with myocardial ischemia; evaluate for coronary artery disease in patients at high risk. • Cerebral hemorrhage, subarachnoid hemorrhage, and stroke: Discontinue Sumatriptan Succinate if occurs. • Gastrointestinal ischemic reactions and peripheral vasospastic reactions: Discontinue Sumatriptan Succinate if occurs. • Medication overuse headache: Detoxification may be necessary. • Serotonin syndrome: Discontinue Sumatriptan Succinate if occurs. • Seizures: Use with caution in patients with epilepsy or a lowered seizure threshold.				
117.	**ACI HealthCare Limited, Treepordi, Sonargaon, Narayanganj.**	Divalproex Sodium USP 500 mg Extended Release Tablet	Divalproex Sodium USP 500 mg	**Anticonvulsant**	Indication: • Monotherapy and adjunctive therapy of complex partial seizures and simple and complex absence seizures	**Contraindications:** Hepatic disease or significant hepatic dysfunction Known mitochondrial disorders caused by mutations in mitochondrial DNA polymerase γ (POLG) Suspected POLG-related	New	**USFDA**	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						disorder in children under two years of age Known hypersensitivity to the drug Urea cycle disorders Prophylaxis of migraine headaches: Pregnant women, women of childbearing potential not using effective contraception **Side Effects:** Most common adverse reactions (reported >5%) are abdominal pain, alopecia, amblyopia/blurred vision, amnesia, anorexia, asthenia, ataxia, back pain, bronchitis, constipation, depression, diarrhea, diplopia, dizziness, dyspnea, dyspepsia, ecchymosis, emotional lability, fever, flu syndrome, headache, increased appetite, infection, insomnia, nausea, nervousness, nystagmus, peripheral edema, pharyngitis, rash, rhinitis, somnolence, thinking abnormal, thrombocytopenia, tinnitus, tremor, vomiting, weight gain, weight loss. **Warnings & Precautions:** • Hepatotoxicity; evaluate high risk populations and monitor serum liver tests • Birth defects, decreased IQ, and neurodevelopmental disorders following in utero exposure; should not be used to treat women with epilepsy or bipolar disorder who are pregnant or who plan to become pregnant or to treat a woman of childbearing				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						potential unless other medications have failed to provide adequate symptom control or are otherwise unacceptable • Pancreatitis; Divalproax ER should ordinarily be discontinued • Suicidal behavior or ideation; Antiepileptic drugs, including Divalproax ER, increase the risk of suicidal thoughts or behavior • Bleeding and other hematopoietic disorders; monitor platelet counts and coagulation tests • Hyperammonemia and hyperammonemic encephalopathy; measure ammonia level if unexplained lethargy and vomiting or changes in mental status, and also with concomitant topiramate use; consider discontinuation of valproate therapy • Hypothermia; Hypothermia has been reported during valproate therapy with or without associated hyperammonemia. This adverse reaction can also occur in patients using concomitant topiramate • Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan hypersensitivity reaction; discontinue Divalproax ER • Somnolence in the elderly can occur. Divalproax ER dosage should be increased slowly and with regular monitoring for fluid and nutritional intake				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
118.	**ACI HealthCare Limited, Treepordi, Sonargaon, Narayanganj.**	Divalproex Sodium USP 250 mg Extended Release Tablet	Divalproex Sodium USP 250 mg	**Anticonvulsant**	Indication: Monotherapy and adjunctive therapy of complex partial seizures and simple and complex absence seizures	**Contraindications:** Hepatic disease or significant hepatic dysfunction Known mitochondrial disorders caused by mutations in mitochondrial DNA polymerase γ (POLG) Suspected POLG-related disorder in children under two years of age Known hypersensitivity to the drug Urea cycle disorders Prophylaxis of migraine headaches: Pregnant women, women of childbearing potential not using effective contraception **Side Effects:** Most common adverse reactions (reported >5%) are abdominal pain, alopecia, amblyopia/blurred vision, amnesia, anorexia, asthenia, ataxia, back pain, bronchitis, constipation, depression, diarrhea, diplopia, dizziness, dyspnea, dyspepsia, ecchymosis, emotional lability, fever, flu syndrome, headache, increased appetite, infection, insomnia, nausea, nervousness, nystagmus, peripheral edema, pharyngitis, rash, rhinitis, somnolence, thinking abnormal, thrombocytopenia, tinnitus, tremor, vomiting, weight gain, weight loss. **Warnings & Precautions:** • Hepatotoxicity; evaluate high risk populations and monitor serum liver tests	New	**USFDA**	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						• Birth defects, decreased IQ, and neurodevelopmental disorders following in utero exposure; should not be used to treat women with epilepsy or bipolar disorder who are pregnant or who plan to become pregnant or to treat a woman of childbearing potential unless other medications have failed to provide adequate symptom control or are otherwise unacceptable • Pancreatitis; Divalproax ER should ordinarily be discontinued • Suicidal behavior or ideation; Antiepileptic drugs, including Divalproax ER, increase the risk of suicidal thoughts or behavior • Bleeding and other hematopoietic disorders; monitor platelet counts and coagulation tests • Hyperammonemia and hyperammonemic encephalopathy; measure ammonia level if unexplained lethargy and vomiting or changes in mental status, and also with concomitant topiramate use; consider discontinuation of valproate therapy • Hypothermia; Hypothermia has been reported during valproate therapy with or without associated hyperammonemia. This adverse reaction can also occur in patients using concomitant topiramate • Drug Reaction with Eosinophilia and Systemic Symptoms				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						(DRESS)/Multiorgan hypersensitivity reaction; discontinue Divalproax ER • Somnolence in the elderly can occur. Divalproax ER dosage should be increased slowly and with regular monitoring for fluid and nutritional intake				
119.	**ACI HealthCare Limited, Treepordi, Sonargaon, Narayanganj.**	Fenofibrate USP 48 mg Tablet	Fenofibrate USP 48 mg	**Lipid Lowering Agent**	Fenofibrate tablets are a peroxisome proliferator-activated receptor (PPAR) alpha agonist indicated as an adjunct to diet: To reduce elevated LDL-C, Total-C, TG and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidemia. For treatment of adult patients with severe hypertriglyceridemia.	**Contraindications:** Fenofibrate tablets are contraindicated Severe renal dysfunction, including dialysis patients Active liver disease Gallbladder disease Known hypersensitivity to Fenofibrate Nursing mothers **Side Effects:** Adverse reactions > 2% and at least 1% greater than placebo: Abnormal liver tests, increased AST, increased ALT, increased CPK, and rhinitis. **Warnings & Precautions:** • Myopathy and rhabdomyolysis have been reported in patients taking fenofibrate. Risks are increased during co-administration with a statin (with a significantly higher rate observed for gemfibrozil), particularly in elderly patients and patients with diabetes, renal failure, or hypothyroidism. • Fenofibrate can increase serum transaminases. Monitor liver tests, including ALT, periodically during	Fenofibrate 67mg,160mg,200mg Capsule	**USFDA**	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						therapy. • Fenofibrate can reversibly increase serum creatinine levels. Monitor renal function periodically in patients with renal impairment. • Fenofibrate increases cholesterol excretion into the bile, leading to risk of cholelithiasis. If cholelithiasis is suspected, gallbladder studies are indicated. • Use caution in concomitant treatment with oral coumarin anticoagulants. Adjust the dosage of coumarin anticoagulant to maintain the prothrombin time/INR at the desired level to prevent bleeding complications. • Acute hypersensitivity reactions, including anaphylaxis and angioedema, and delayed hypersensitivity reactions, including severe cutaneous adverse drug reactions have been reported postmarketing. Some cases were lifethreatening and required emergency treatment. Discontinue fenofibrate and treat patients appropriately if reactions occur.				
120.	**ACI HealthCare Limited, Treepordi, Sonargaon, Narayanganj.**	Bupropion Hydrochloride USP 75 mg Tablet	Bupropion Hydrochloride USP 75 mg	Antidepressants	It is indicated for Bupropion hydrochloride tablets are an amino-ketone antidepressant, indicated for the treatment of major depressive disorder (MDD).	**Contraindications**: It is contraindicated in patients with a seizure disorder, patient's diagnosis of bulimia or anorexia nervosa, Abrupt discontinuation of alcohol, benzodiazepines, barbiturates, anti-epileptic drugs, patient's diagnosis	Bupropion HCL 150mg SR Tablet	**USFDA**	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						with Monoamine Oxidase Inhibitors (MAOIs). **Side Effects:** Most common adverse reactions (incidence ≥5% and ≥1% more than placebo rate) are: agitation, dry mouth, constipation, headache/migraine, nausea/vomiting, dizziness, excessive sweating, tremor, insomnia, blurred vision, tachycardia, confusion, rash, hostility, cardiac arrhythmias, and auditory disturbance. **Warnings & Precautions:** **Neuropsychiatric adverse events during smoking cessation**: Postmarketing reports of serious or clinically significant neuropsychiatric adverse events have included changes in mood (including depression and mania), psychosis, hallucinations, paranoia, delusions, homicidal ideation, aggression, hostility, agitation, anxiety, and panic, as well as suicidal ideation, suicide attempt, and completed suicide. Observe patients attempting to quit smoking with bupropion for the occurrence of such symptoms and instruct them to discontinue bupropion and contact a healthcare provider if They experience such adverse events. **Seizure risk**: The risk is dose-related. Can minimize risk by gradually increasing the dose and limiting daily dose to 450 mg. Discontinue				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						if seizure occurs. **Hypertension**: bupropion hydrochloride tablets can increase blood pressure. Monitor blood pressure before initiating treatment and periodically during treatment. Activation of mania/hypomania: Screen patients for bipolar disorder and monitor for these symptoms. **Psychosis and other neuropsychiatric reactions**: Instruct patients to contact a healthcare professional if such reactions occur. **Angle-closure glaucoma**: Angle-closure glaucoma has occurred in patients with untreated anatomically narrow angles treated with antidepressants.				
121.	**ACI HealthCare Limited, Treepordi, Sonargaon, Narayanganj.**	Bupropion Hydrochloride USP 100 mg Tablet	Bupropion Hydrochloride USP 100 mg	**Anti-psychotic**	It is indicated for Bupropion hydrochloride tablets are an amino-ketone antidepressant, indicated for the treatment of major depressive disorder (MDD).	**Contraindications**: It is contraindicated in patients with a seizure disorder, patient's diagnosis of bulimia or anorexia nervosa, Abrupt discontinuation of alcohol, benzodiazepines, barbiturates, anti-epileptic drugs, patient's diagnosis with Monoamine Oxidase Inhibitors (MAOIs). **Side Effects:** Most common adverse reactions (incidence ≥5% and ≥1% more than placebo rate) are: agitation, dry mouth, constipation, headache/migraine, nausea/vomiting, dizziness, excessive sweating, tremor, insomnia, blurred vision,	Bupropion HCL 150mg SR Tablet	**USFDA**	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						tachycardia, confusion, rash, hostility, cardiac arrhythmias, and auditory disturbance. **Warnings & Precautions: Neuropsychiatric adverse events during smoking cessation**: Postmarketing reports of serious or clinically significant neuropsychiatric adverse events have included changes in mood (including depression and mania), psychosis, hallucinations, paranoia, delusions, homicidal ideation, aggression, hostility, agitation, anxiety, and panic, as well as suicidal ideation, suicide attempt, and completed suicide. Observe patients attempting to quit smoking with bupropion for the occurrence of such symptoms and instruct them to discontinue bupropion and contact a healthcare provider if They experience such adverse events. **Seizure risk**: The risk is dose-related. Can minimize risk by gradually increasing the dose and limiting daily dose to 450 mg. Discontinue if seizure occurs. **Hypertension**: bupropion hydrochloride tablets can increase blood pressure. Monitor blood pressure before initiating treatment and periodically during treatment. Activation of mania/hypomania: Screen patients for bipolar disorder and monitor for these symptoms. **Psychosis and other**				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						neuropsychiatric reactions: Instruct patients to contact a healthcare professional if such reactions occur. **Angle-closure glaucoma**: Angle-closure glaucoma has occurred in patients with untreated anatomically narrow angles treated with antidepressants.				
122.	**ACI HealthCare Limited, Treepordi, Sonargaon, Narayanganj.**	Bupropion Hydrochloride USP 100 mg Sustained Release Tablet	Bupropion Hydrochloride USP	**Anti-psychotic**	It is indicated for Bupropion hydrochloride tablets are an amino-ketone antidepressant, indicated for the treatment of major depressive disorder (MDD).	**Contraindications**: It is contraindicated in patients with a seizure disorder, patient's diagnosis of bulimia or anorexia nervosa, Abrupt discontinuation of alcohol, benzodiazepines, barbiturates, anti-epileptic drugs, patient's diagnosis with Monoamine Oxidase Inhibitors (MAOIs). **Side Effects:** Most common adverse reactions (incidence ≥5% and ≥1% more than placebo rate) are: agitation, dry mouth, constipation, headache/migraine, nausea/vomiting, dizziness, excessive sweating, tremor, insomnia, blurred vision, tachycardia, confusion, rash, hostility, cardiac arrhythmias, and auditory disturbance. **Warnings & Precautions: Neuropsychiatric adverse events during smoking cessation**: Postmarketing reports of serious or clinically significant neuropsychiatric adverse events have included changes in mood (including depression and mania), psychosis, hallucinations,	Bupropion HCL 150mg SR Tablet.	**USFDA**	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						paranoia, delusions, homicidal ideation, aggression, hostility, agitation, anxiety, and panic, as well as suicidal ideation, suicide attempt, and completed suicide. Observe patients attempting to quit smoking with bupropion for the occurrence of such symptoms and instruct them to discontinue bupropion and contact a healthcare provider if They experience such adverse events. **Seizure risk**: The risk is dose-related. Can minimize risk by gradually increasing the dose and limiting daily dose to 450 mg. Discontinue if seizure occurs. **Hypertension**: bupropion hydrochloride tablets can increase blood pressure. Monitor blood pressure before initiating treatment and periodically during treatment. Activation of mania/hypomania: Screen patients for bipolar disorder and monitor for these symptoms. **Psychosis and other neuropsychiatric reactions**: Instruct patients to contact a healthcare professional if such reactions occur. **Angle-closure glaucoma**: Angle-closure glaucoma has occurred in patients with untreated anatomically narrow angles treated with antidepressants.				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
123.	**ACI HealthCare Limited, Treepordi, Sonargaon, Narayanganj.**	Bupropion Hydrochloride USP 200 mg Sustained Release Tablet	Bupropion Hydrochloride USP	**Anti-psychotic**	It is indicated for Bupropion hydrochloride tablets are an amino-ketone antidepressant, indicated for the treatment of major depressive disorder (MDD).	**Contraindications**: It is contraindicated in patients with a seizure disorder, patient's diagnosis of bulimia or anorexia nervosa, Abrupt discontinuation of alcohol, benzodiazepines, barbiturates, anti-epileptic drugs, patient's diagnosis with Monoamine Oxidase Inhibitors (MAOIs). **Side Effects:** Most common adverse reactions (incidence ≥5% and ≥1% more than placebo rate) are: agitation, dry mouth, constipation, headache/migraine, nausea/vomiting, dizziness, excessive sweating, tremor, insomnia, blurred vision, tachycardia, confusion, rash, hostility, cardiac arrhythmias, and auditory disturbance. **Warnings & Precautions: Neuropsychiatric adverse events during smoking cessation**: Postmarketing reports of serious or clinically significant neuropsychiatric adverse events have included changes in mood (including depression and mania), psychosis, hallucinations, paranoia, delusions, homicidal ideation, aggression, hostility, agitation, anxiety, and panic, as well as suicidal ideation, suicide attempt, and completed suicide. Observe patients attempting to quit smoking with bupropion for the occurrence of such symptoms and instruct them	Bupropion HCL 150mg SR Tablet	**USFDA**	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						to discontinue bupropion and contact a healthcare provider if They experience such adverse events. **Seizure risk**: The risk is dose-related. Can minimize risk by gradually increasing the dose and limiting daily dose to 450 mg. Discontinue if seizure occurs. **Hypertension**: bupropion hydrochloride tablets can increase blood pressure. Monitor blood pressure before initiating treatment and periodically during treatment. Activation of mania/hypomania: Screen patients for bipolar disorder and monitor for these symptoms. **Psychosis and other neuropsychiatric reactions**: Instruct patients to contact a healthcare professional if such reactions occur. **Angle-closure glaucoma**: Angle-closure glaucoma has occurred in patients with untreated anatomically narrow angles treated with antidepressants.				
124.	**ACI HealthCare Limited, Treepordi, Sonargaon, Narayanganj.**	Bupropion Hydrochloride USP 300 mg Extended Release Tablet	Bupropion Hydrochloride USP	**Anti-psychotic**	It is indicated for Bupropion hydrochloride tablets are an amino-ketone antidepressant, indicated for the treatment of major depressive disorder (MDD).	**Contraindications**: It is contraindicated in patients with a seizure disorder, patient's diagnosis of bulimia or anorexia nervosa, Abrupt discontinuation of alcohol, benzodiazepines, barbiturates, anti-epileptic drugs, patient's diagnosis with Monoamine Oxidase Inhibitors (MAOIs).	Bupropion HCL 150mg SR Tablet	**USFDA**	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Side Effects: Most common adverse reactions (incidence ≥5% and ≥1% more than placebo rate) are: agitation, dry mouth, constipation, headache/migraine, nausea/vomiting, dizziness, excessive sweating, tremor, insomnia, blurred vision, tachycardia, confusion, rash, hostility, cardiac arrhythmias, and auditory disturbance. **Warnings & Precautions:** **Neuropsychiatric adverse events during smoking cessation**: Postmarketing reports of serious or clinically significant neuropsychiatric adverse events have included changes in mood (including depression and mania), psychosis, hallucinations, paranoia, delusions, homicidal ideation, aggression, hostility, agitation, anxiety, and panic, as well as suicidal ideation, suicide attempt, and completed suicide. Observe patients attempting to quit smoking with bupropion for the occurrence of such symptoms and instruct them to discontinue bupropion and contact a healthcare provider if They experience such adverse events. **Seizure risk**: The risk is dose-related. Can minimize risk by gradually increasing the dose and limiting daily dose to 450 mg. Discontinue if seizure occurs. **Hypertension**: bupropion hydrochloride tablets can				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						increase blood pressure. Monitor blood pressure before initiating treatment and periodically during treatment. Activation of mania/hypomania: Screen patients for bipolar disorder and monitor for these symptoms. **Psychosis and other neuropsychiatric reactions**: Instruct patients to contact a healthcare professional if such reactions occur. **Angle-closure glaucoma**: Angle-closure glaucoma has occurred in patients with untreated anatomically narrow angles treated with antidepressants.				
125.	**ACI HealthCare Limited, Treepordi, Sonargaon, Narayanganj.**	Venlafaxine Hydrochloride USP 225 mg Extended Release Tablet	Venlafaxine Hydrochloride USP 225 mg	**Antidepressant**	Venlafaxine Hydrochloride Extended Release Tablet is a serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for the treatment of : i) Major Depressive Disorder (MDD). ii) Generalized Anxiety Disorder (GAD). iii) Social Anxiety Disorder (SAD). iv) Panic Disorder (PD).	**Contraindications:** i) Serotonin Syndrome and MAOIs: Do not use MAOI's intended to treat psychiatric disorders with Venlafaxine Extended Release Tablets or within 7 days of stopping treatment with Venlafaxine Extended Release Tablets. ii) Do not use Venlafaxine Extended Release Tablets within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start Venlafaxine Extended Release Tablets in a patient who is being treated with linezolid or intravenous methylene blue. **Side Effects:**	Venlafaxine HCL 25mg, 37.5mg Tablet and 37.5mg, 75mg Capsule	**USFDA** **BNF 77 (Page: 365, 366)**	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						The following adverse reactions are discussed in greater detail in other sections of the label: i) Hypersensitivity ii) Suicidal Thoughts and Behaviors in Children, Adolescents, and Adults. iii) Serotonin Syndrome. iv) Elevations in Blood Pressure. v) Abnormal Bleeding. vi) Angle Closure Glaucoma. vii) Activation of Mania/Hypomania. viii) Discontinuation Syndrome ix) Seizure. x) Hyponatremia xi) Weight and Height changes in Pediatric Patients. xi) Appetite Changes in Pediatric Patients. xii) Interstitial Lung Disease and Eosinophilic Pneumonia. **WARNINGS AND PRECAUTIONS** • Serotonin Syndrome: Sertotonin syndrome has been reported with SSRIs and SNRIs, including Venlafaxine Extended Release Tablets, both when taken alone, but especially when co-administered with other serotonergic agents (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, amphetamines, and St. John's Wort). If such symptoms occur, discontinue Venlafaxine Extended-Release tablets and initiate				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						supportive treatment. If concomitant use of Venlafaxine Extended Release Tablets with other serotonergic drugs is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increases. • Suicidality: Monitor for clinical worsening and suicide risk. • Sustained hypertension may occur. Blood pressure monitoring recommended. • Angle Closure Glaucoma: Angle closure glaucoma has occurred in patients with untreated anatomically narrow angles treated with antidepressants. • Abrupt discontinuation or dose reduction: Discontinuation symptoms may occur (generally self-limiting; serious symptoms possible). Dose reduction recommended to be gradual. • Activation of Mania/Hypomania has occurred. • Symptomatic hyponatremia may occur. • Seizures have been reported. Use with caution in patients with seizure history. • Abnormal bleeding (most commonly ecchymosis) has been reported. • Serum cholesterol: Clinically relevant cholesterol increases may occur. Cholesterol measurements should be considered during				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						long-term therapy. • Interstitial lung disease and eosinophilic pneumonia have been reported.				
126.	**ACI HealthCare Limited, Treepordi, Sonargaon, Narayanganj.**	Venlafaxine Hydrochloride USP 150 mg Extended Release Tablets,	Venlafaxine Hydrochloride USP 150 mg	**Antidepressant**	Venlafaxine Hydrochloride Extended Release Tablet is a serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for the treatment of : i) Major Depressive Disorder (MDD). ii) Generalized Anxiety Disorder (GAD). iii) Social Anxiety Disorder (SAD). iv) Panic Disorder (PD).	**Contraindications:** i) Serotonin Syndrome and MAOIs: Do not use MAOI's intended to treat psychiatric disorders with Venlafaxine Extended Release Tablets or within 7 days of stopping treatment with Venlafaxine Extended Release Tablets. ii) Do not use Venlafaxine Extended Release Tablets within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start Venlafaxine Extended Release Tablets in a patient who is being treated with linezolid or intravenous methylene blue. **Side Effects:** The following adverse reactions are discussed in greater detail in other sections of the label: i) Hypersensitivity ii) Suicidal Thoughts and Behaviors in Children, Adolescents, and Adults. iii) Serotonin Syndrome. iv) Elevations in Blood Pressure. v) Abnormal Bleeding. vi) Angle Closure Glaucoma. vii) Activation of Mania/Hypomania. viii) Discontinuation Syndrome	Venlafaxine HCL 25mg,37.5mgTablet and 37.5mg,75mgCapsule	**USFDA** **BNF 77 (Page: 365, 366)**	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						ix) Seizure. x) Hyponatremia xi) Weight and Height changes in Pediatric Patients. xi) Appetite Changes in Pediatric Patients. xii) Interstitial Lung Disease and Eosinophilic Pneumonia. **WARNINGS AND PRECAUTIONS** • Serotonin Syndrome: Sertotonin syndrome has been reported with SSRIs and SNRIs, including Venlafaxine Extended Release Tablets, both when taken alone, but especially when co-administered with other serotonergic agents (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, amphetamines, and St. John's Wort). If such symptoms occur, discontinue Venlafaxine Extended-Release tablets and initiate supportive treatment. If concomitant use of Venlafaxine Extended Release Tablets with other serotonergic drugs is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increases. • Suicidality: Monitor for clinical worsening and suicide risk. • Sustained hypertension may occur. Blood pressure monitoring recommended. • Angle Closure Glaucoma:				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Angle closure glaucoma has occurred in patients with untreated anatomically narrow angles treated with antidepressants. • Abrupt discontinuation or dose reduction: Discontinuation symptoms may occur (generally self-limiting; serious symptoms possible). Dose reduction recommended to be gradual. • Activation of Mania/Hypomania has occurred. • Symptomatic hyponatremia may occur. • Seizures have been reported. Use with caution in patients with seizure history. • Abnormal bleeding (most commonly ecchymosis) has been reported. • Serum cholesterol: Clinically relevant cholesterol increases may occur. Cholesterol measurements should be considered during long-term therapy. • Interstitial lung disease and eosinophilic pneumonia have been reported.				
127.	Popular Pharmaceuticals Limited. Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Bilastine 10 mg ODT Tablet	Bilastine INN 10mg ODT	Antihistamine	Seasonal Allergic Rhinitis: Bilastine is indicated for the symptomatic relief of nasal and non-nasal symptoms of seasonal allergic rhinitis (SAR) in patients 12 years of age and older. Chronic Spontaneous Urticaria: Bilastineis indicated for the relief of the symptoms associated with chronic spontaneous urticaria (CSU) (e.g. pruritus and hives), in patients 18 years of age and older. Geriatrics (> 65 years of age): No dosage adjustments are necessary in patients over 65 years.	**Contraindication:** Bilastine is contraindicated in patients with: Hypersensitivity to bilastine or to any ingredient in the formulation or component of the container. **Side-effects:** The most common side effects of Bilastine include: headache, somnolence, dizziness, and fatigue and abdominal pain.	Bilastine 20mg Tablet	UKMHRA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					Pediatrics (< 12 years of age): The safety and efficacy of Bilastine in children under 12 years of age have not been established.	**WARNINGS AND PRECAUTIONS** Bilastine should be taken cautiously in case of moderate to severe renal impairment.				
128.	Popular Pharmaceuticals Limited	Itopride Hydrochloride 50mg Film Coated Tablet	Itopride Hydrochloride INN 50mg Film Coated		Itopride hydrochloride is used in the treatment of gastrointestinal symptoms of functional, nonulcer dyspepsia (chronic gastritis) i.e., sensation of bloating, early satiety, upper abdominal pain or discomfort, anorexia, heartburn, nausea and vomiting.	**Contraindication:** Itopride hydrochloride is contraindicated in patients with known hypersensitivity to itopride hydrochloride or any of the excipients. Itopride hydrochloride should not be used in patients in whom an increase in gastrointestinal motility could be harmful, e.g. gastrointestinal hemorrhage, mechanical obstruction or perforation. **Side-effects:** The most common side-effects of itopride include mild to moderate abdominal pain and diarrhea. Some other side effects that may occur include: rash, giddiness, exhaustion, back or chest pain, increased salivation, constipation headache, sleeping disorder, dizziness, galactorrhea, andgynecomastia disorders, dizziness, galactorrhea, andgynecomastia. **WARNING AND PRECAUTIONS** Itopride hydrochloride enhances the action of acetylcholine and may produce cholinergic side effects.	New	রেফারেন্স নাই DCC এর 244 তম সভায় প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
129.	Popular Pharmaceuticals Limited	Naphazoline 0.030gm + Hypromellose (Methocel E4M Premium) 0.500gm/100 ml Ophthalmic Solution	Naphazoline USP 0.030gm + Hypromellose (Methocel E4M Premium) USP 0.500gm/100ml	Decongestant and Ophthalmic Lubricant	Naphazoline Hydrochloride is indicated for use as a topical ocular vasoconstrictor and is a redness reliever. Hypromellose is used as an ocular lubricant and relieves discomfort due to minor eye irritations exposure to wind or sun dryness of the eye prevents further irritation DOSAGE AND ADMINISTRATION Instill 1 to 2 drops in the affected eye(s) up to four times daily.	**Contraindication:** Naphazoline Hydrochloride is contraindicated in the presence of an anatomically narrow angle or in narrow angle glaucoma or in persons who have shown hypersensitivity to this component. Hypromellose is contraindicated in persons who have shown hypersensitivity to this component **Side-effects:** Naphazoline Ocular: Mydriasis, increased redness, irritation, discomfort, blurring, punctate keratitis, lacrimation, increased intraocular pressure. Systemic: Dizziness, headache, nausea, sweating, nervousness, drowsiness, weakness, hypertension, cardiac irregularities, and hyperglycemia. Hypromellose Ocular: Transient mild stinging or vision blurred, eye pain, foreign body sensation in eyes, eye irritation and ocular hyperaemia. **WARNINGS AND PRECAUTIONS** Patients under therapy with MAO inhibitors may	New Naphazoline HCL +Pheniramine Maleate 0.3% Eye Drops	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						experience a severe hypertensive crisis if given a sympathomimetic drug. Use in children, especially infants, may result in CNS depression leading to coma and marked reduction in body temperature. This is for topical ophthalmic use only. Use with caution in presence of hypertension, cardiovascular abnormalities, hyperglycemia (diabetes), hyperthyroidism, infection or injury.				
130.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagnj, BANGLADESH. Somatec pharmaceuticals ltd., Sarulia, demra, dhaka Bangladesh	Triclabendazole 250 mg Tablet	Triclabendazole INN 250 mg Tablet	Anti-helminthic	Fascioliasis (against Fasciola hepatica & Fasciola gigantica)	**Contraindication:** Triclabendazole is contraindicated in patients with known hypersensitivity to triclabendazole and/or to other benzimidazole derivatives or to any of the excipients in Triclabendazole. **Side effects:** Most common adverse reactions (greater than 2%) with triclabendazole 20 mg/kg dose are abdominal pain, hyperhidrosis, nausea, decreased appetite, headache, urticaria, diarrhea, vomiting, musculoskeletal chest pain and pruritus. **Warning & Precautions:** **QT Prolongation:**Transient prolongation of the mean QTc interval was noted on the electrocardiographic recordings in dogs . Monitor ECG in patients with a history of prolongation of the QTc interval or a history of symptoms compatible with a long QT interval or when	New Triclabendazole 900 mg Bolus(Vet)	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Triclabendazole is used in patients who receive drugs that prolong the QT interval.				
131.	EVEREST Pharmaceuticals Ltd. BSCIC I/A, Kanchpur, Narayanagnj BANGLADESH	Trientine HCl 250 mg Capsule	Trientine HCl USP 250 mg Capsule	Anti-histamine	Wilson's disease who are intolerant of penicillamine or have life endangering side effects.	**Contraindications:** Hypersensitivity to this product. **Side effects:** Clinical experience with trientine hydrochloride has been limited. The following adverse reactions have been reported in a clinical study in patients with Wilson's disease who were on therapy with trientine hydrochloride: iron deficiency, systemic lupus erythematosus. In addition, the following adverse reactions have been reported in marketed use: dystonia, muscular spasm, myasthenia gravis. Trientine hydrochloride is not indicated for treatment of biliary cirrhosis, but in one study of 4 patients treated with trientine hydrochloride for primary biliary cirrhosis, the following adverse reactions were reported: heartburn; epigastric pain and tenderness; thickening, fissuring and flaking of the skin; hypochromic microcytic anemia; acute gastritis; aphthoid ulcers; abdominal pain; melena; anorexia; malaise; cramps; muscle pain; weakness; rhabdomyolysis. A causal relationship of these reactions to drug therapy could not be rejected or established.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Warning & Precautions: Patients receiving trientine hydrochloride should remain under regular medical supervision throughout the period of drug administration. Patients (especially women) should be closely monitored for evidence of iron deficiency anemia.There are no reports of hypersensitivity in patients who have been administered trientine hydrochloride for Wilson's disease. However, there have been reports of asthma, bronchitis and dermatitis occurring after prolonged environmental exposure in workers who use trientine hydrochloride as a hardener of epoxy resins. Therapy may be monitored with a 24-hour urinary copper analysis periodically (i.e., every 6-12 months).Patients should be observed closely for signs of possible hypersensitivity. There are no adequate and well-controlled studies in pregnant women.Trientine hydrochloride should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.				
132.	Renata Limited Mirpur, Dhaka Orion Pharma Ltd, Siddhirganj, Narayangang.	Clonazepam USP 0.25mg Tablet	Clonazepam USP 0.25mg	Antidepressant	• To prevent and treat seizures, panic disorder, and movement disorder • Can be used for psychosis	Should not be used in patients with a history of sensitivity to benzodiazepines, nor in patients with clinical or biochemical evidence of significant liver disease & acute narrow angle glaucoma.	Clonazepam 2mg & 0.5mg tablet 2.5 mg/ml Paediatric Drops	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
133.	Renata Limited Mirpur, Dhaka	Cetilistat INN 120mg Tablet	Cetilistat INN 120mg	Anti-obesity	Obesity (limited to patients with type 2 diabetes mellitus and dyslipidemia, and with a BMI>25 kg/m2 in spite of dietary treatment and or exercise therapy)	Diarrhoea, Flatulence, Incontinence, Pain in the stomach, Oily spotting.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*
134.	Renata Limited Mirpur, Dhaka Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka	Amlodipine Besilate BP 6.93mg eq to 5mg of Amlodipine + Bisoprolol Fumarate USP 5mg	Amlodipine Besilate BP 6.93mg eq to 5mg of Amlodipine + Bisoprolol Fumarate USP 5mg	Antihypertensive	It is indicated for the treatment of hypertension, alone or with other antihypertensive agents. (Amlodipine+Bisoprolol) may also be used as initial therapy in patients who are likely to need multiple antihypertensive agents to achieve their blood pressure goals. It is also used to treat angina pectoris, stable chronic heart failure.	• Contraindicated in patients with a known sensitivity to beta-blockers or amlodipine • Contraindicated in patients with bradycardia • Contraindicated in pregnant patients	Bisoprolol Fumarate 2.50mg + Amlodipine 5mg Film Coated Tablet Bisoprolol 2.5mg, 5mg & 10mg Tablet, Amlodipine 5mg & 10mg Tablet	**রেফারেন্স নাই।**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*
135.	Renata Limited Mirpur, Dhaka	Esomeprazole Magnesium Trihydrate USP 11.11mg equivalent to Esomeprazole 10mg/Sachet	Esomeprazole Magnesium Trihydrate USP 11.11mg equivalent to Esomeprazole 10mg/Sachet	Antiulcerant-PPI	Esomeprazole is a proton pump inhibitor indicated for the following: □ Treatment of gastroesophageal reflux disease (GERD). □ Risk reduction of NSAIDassociated gastric ulcer. □ H. pylorieradication to reduce the risk of duodenal ulcer recurrence. □ Pathological hypersecretory conditions, including Zollinger-Ellison syndrome.	Contra-indication: Patients with known hypersensitivity to proton pump inhibitors (PPIs) (angioedema and anaphylaxis have occurred) Side-effects: Most common adverse reactions □ Adults (≥18 years) (incidence>1%) are headache, diarrhea, nausea, flatulence, abdominal pain, constipation, and dry mouth. □ Pediatric (1 to 17 years) (incidence>2%) are headache, diarrhea, abdominal pain, nausea, and somnolence Pediatric (1 month to less than 1 year) (incidence 1%) areabdominal pain, regurgitation, tachypnea, and increased ALT	Esomeprazole 20/ Sachet	UKMHRA, BNF-73 page-75	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
136.	Renata Limited Mirpur, Dhaka	Paracetamol BP 500mg + Pamabrom USP 25mg Tablet	Paracetamol BP 500mg + Pamabrom USP 25mg	Analgesics	**Indication:** • Cramps • Headaches • Backaches Premenstrual and menstrual cramps	• Caloric undernutrition • Acute liver failure • Liver problems • Severe renal impairment	New	**রেফারেন্স নাই।** DCC এর 244 তম সভায় এই কম্বিনেশন প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
137.	Renata Limited Mirpur, Dhaka	Tenatoprazole Sodium INN 21.20mg Equivalent to Tenatoprazole 20mg Tablet	Tenatoprazole Sodium INN 21.20mg Equivalent to Tenatoprazole 20mg	Antiulcerant-PPI	**Indication** • Night time heartburn • Esophagitis Gastroesophageal Reflux Disease (GERD)	Tenatoprazole is contraindicated in patients with known hypersensitivity to any component of the formulation.	New	**রেফারেন্স নাই।** DCC এর 243 সভায় প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
138.	Renata Limited Mirpur, Dhaka	Tenatoprazole Sodium INN 42.40mg Equivalent to Tenatoprazole 40mg Tablet	Tenatoprazole Sodium INN 42.40mg Equivalent to Tenatoprazole 40mg	Antiulcerant-PPI	**Indication** • Night time heartburn • Esophagitis Gastroesophageal Reflux Disease (GERD)	Tenatoprazole is contraindicated in patients with known hypersensitivity to any component of the formulation.	New	**রেফারেন্স নাই।** DCC এর 243 তম সভায় প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
139.	**Acme Laboratories Ltd., Dhamrai, Dhaka. Opsonin Pharma Ltd, Rupatali, Barishal.** Drug International Ltd 252, Tongi I/A Tongi, Gazipur.	Ibuprofen USP 200 mg Soft Gelatin Capsule	Ibuprofen USP 200 mg Soft Gelatin Capsule	NSAID	Pain and inflammation in rheumatic disease and other musculoskeletal disorders, Mild to moderate pain including dysmenorrhea, Postoperative analgesia, Migraine, Dental pain	**Contraindications:** With systemic use Active gastro-intestinal bleeding, active gastro-intestinal ulceration, history of gastro-intestinal bleeding related to previous NSAID therapy, history of gastro-intestinal perforation related to previous NSAID therapy, history of recurrent gastro-intestinal haemorrhage (two or more distinct episodes), history of recurrent gastro-intestinal ulceration (two or more distinct episodes), severe heart failure. **Side effects:** Uncommon: ▸ With oral use Gastrointestinal discomfort, headache, hypersensitivity , nausea , rash (discontinue), skin	Ibuprofen **200 mg, 400 mg, 600 mg Tab & 100 mg/ 5ml Suspension, 300 mg capsule**	BNF 76, Page-1106 DCC এর 248 সভায় প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						reactions Rare or very rare: ▸ With oral use- Acute kidney injury, agranulocytosis, anaemia, angioedema, constipation, diarrhea, dyspnea, fatigue, fever, gastrointestinal disorders, haemorrhage, ypotension, influenza like illness, leucopenia, liver Disorder, meningitis aseptic (patients with connective tissue disorders such as systemic lupus erythematosus may be especially susceptible), oedema, oral disorders, pancytopenia, renal papillary necrosis, respiratory Disorders, severe cutaneous adverse reactions (SCARs), shock, tachycardia, throat pain, thrombocytopenia, vomiting				
140.	Acme Laboratories Ltd., Dhamrai, Dhaka	Oxycodone Hydrochloride 10 mg + Naltrexone Hydrochloride 1.20 mg Extended Release Capsule	Oxycodone Hydrochloride with Naltrexone Hydrochloride Extended Release Pellets at a Ratio of 100:12 Pharma Grade 70 mg eqv. to Oxycodone Hydrochloride 10 mg and Naltrexone Hydrochloride 1.20 mg	Opioid Analgesic + Opioid Antagonist	It is a combination opioid agonist/opioid antagonist product indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.	**Contraindications:** • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected gastrointestinal obstruction, including paralytic ileus • Hypersensitivity to oxycodone or naltrexone **Side effects:** Most common adverse reactions: nausea, constipation, vomiting, headache, and somnolence. **Warnings and Precautions:** • Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely, particularly during initiation and	**New** Naltrexone Hydrochloride 25 mg, 50 mg	USFDA DCC এর 248 তম সভায় প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						titration. • Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid. • Severe Hypotension: Monitor during dosage initiation and titration. Avoid use of this product in patients with circulatory shock. • Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness: Monitor for sedation and respiratory depression. Avoid use of it in patients with impaired consciousness or coma.				
141.	Acme Laboratories Ltd., Dhamrai, Dhaka	Oxycodone Hydrochloride 20 mg + Naltrexone Hydrochloride 2.40 mg Extended Release Capsule	Oxycodone Hydrochloride with Naltrexone Hydrochloride Extended Release Pellets at a Ratio of 100:12 Pharma Grade 140 mg eqv. to Oxycodone Hydrochloride 20 mg and Naltrexone Hydrochloride 2.40 mg	Opioid Analgesic + Opioid Antagonist	It is a combination opioid agonist/opioid antagonist product indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.	**Contraindications:** • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected gastrointestinal obstruction, including paralytic ileus • Hypersensitivity to oxycodone or naltrexone **Side effects:** Most common adverse reactions: nausea, constipation, vomiting, headache, and somnolence. **Warnings and Precautions:** • Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely, particularly during initiation and titration. • Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids,	**New** Naltrexone Hydrochloride 25 mg, 50 mg	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						and wean patient off of the opioid. • Severe Hypotension: Monitor during dosage initiation and titration. Avoid use of this product in patients with circulatory shock. • Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness: Monitor for sedation and respiratory depression. Avoid use of it in patients with impaired consciousness or coma.				
142.	Acme Laboratories Ltd., Dhamrai, Dhaka	Oxycodone Hydrochloride 30 mg + Naltrexone Hydrochloride 3.60 mg Extended Release Capsule	Oxycodone Hydrochloride with Naltrexone Hydrochloride Extended Release Pellets at a Ratio of 100:12 Pharma Grade 210 mg eqv. to Oxycodone Hydrochloride 30 mg and Naltrexone Hydrochloride 3.60 mg	Opioid Analgesic + Opioid Antagonist	It is a combination opioid agonist/opioid antagonist product indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.	**Contraindications:** • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected gastrointestinal obstruction, including paralytic ileus • Hypersensitivity to oxycodone or naltrexone **Side effects:** Most common adverse reactions: nausea, constipation, vomiting, headache, and somnolence. **Warnings and Precautions:** • Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely, particularly during initiation and titration. • Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid. • Severe Hypotension: Monitor during dosage initiation and	**New** Naltrexone Hydrochloride 25 mg, 50 mg	USFDA DCC এর 248 তম সভায় প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						titration. Avoid use of this product in patients with circulatory shock. • Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness: Monitor for sedation and respiratory depression. Avoid use of it in patients with impaired consciousness or coma.				
143.	Acme Laboratories Ltd., Dhamrai, Dhaka	Oxycodone Hydrochloride 40 mg + Naltrexone Hydrochloride 4.80 mg Extended Release Capsule	Oxycodone Hydrochloride with Naltrexone Hydrochloride Extended Release Pellets at a Ratio of 100:12 Pharma Grade 280 mg eqv. to Oxycodone Hydrochloride 40 mg and Naltrexone Hydrochloride 4.80 mg	Opioid Analgesic + Opioid Antagonist	It is a combination opioid agonist/opioid antagonist product indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.	**Contraindications:** • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected gastrointestinal obstruction, including paralytic ileus • Hypersensitivity to oxycodone or naltrexone **Side effects:** Most common adverse reactions: nausea, constipation, vomiting, headache, and somnolence. **Warnings and Precautions:** • Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely, particularly during initiation and titration. • Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid. • Severe Hypotension: Monitor during dosage initiation and titration. Avoid use of this product in patients with circulatory shock. • Risks of Use in Patients with	**New** Naltrexone Hydrochloride 25 mg, 50 mg	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness: Monitor for sedation and respiratory depression. Avoid use of it in patients with impaired consciousness or coma.				
144.	Acme Laboratories Ltd., Dhamrai, Dhaka	Oxycodone Hydrochloride 60 mg + Naltrexone Hydrochloride 7.20 mg Extended Release Capsule	Oxycodone Hydrochloride with Naltrexone Hydrochloride Extended Release Pellets at a Ratio of 100:12 Pharma Grade 420 mg eqv. to Oxycodone Hydrochloride 60 mg and Naltrexone Hydrochloride 7.20 mg	Opioid Analgesic + Opioid Antagonist	It is a combination opioid agonist/opioid antagonist product indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.	**Contraindications:** • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected gastrointestinal obstruction, including paralytic ileus • Hypersensitivity to oxycodone or naltrexone **Side effects:** Most common adverse reactions: nausea, constipation, vomiting, headache, and somnolence. **Warnings and Precautions:** • Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely, particularly during initiation and titration. • Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid. • Severe Hypotension: Monitor during dosage initiation and titration. Avoid use of this product in patients with circulatory shock. • Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness: Monitor for sedation and	**New** Naltrexone Hydrochloride 25 mg, 50 mg	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						respiratory depression. Avoid use of it in patients with impaired consciousness or coma.				
145.	Acme Laboratories Ltd., Dhamrai, Dhaka	Oxycodone Hydrochloride 80 mg + Naltrexone Hydrochloride 9.60 mg Extended Release Capsule	Oxycodone Hydrochloride with Naltrexone Hydrochloride Extended Release Pellets at a Ratio of 100:12 Pharma Grade 560 mg eqv. to Oxycodone Hydrochloride 80 mg and Naltrexone Hydrochloride 9.60 mg	Opioid Analgesic + Opioid Antagonist	It is a combination opioid agonist/opioid antagonist product indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.	**Contraindications:** • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected gastrointestinal obstruction, including paralytic ileus • Hypersensitivity to oxycodone or naltrexone **Side effects:** Most common adverse reactions: nausea, constipation, vomiting, headache, and somnolence. **Warnings and Precautions:** • Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely, particularly during initiation and titration. • Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid. • Severe Hypotension: Monitor during dosage initiation and titration. Avoid use of this product in patients with circulatory shock. • Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness: Monitor for sedation and respiratory depression. Avoid use of it in patients with impaired consciousness or coma.	**New** Naltrexone Hydrochloride 25 mg, 50 mg	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
146.	Acme Laboratories Ltd., Dhamrai, Dhaka	Oxycodone 4.8355 mg + Aspirin 325 mg Tablet	Oxycodone Hydrochloride USP 4.8355 mg eqv. to Oxycodone 4.3346 mg + Aspirin USP 325 mg	Opioid + Analgesic	It is indicated for the management of moderate to moderately severe pain.	**Contraindications:** These tablets are contraindicated in patients with known hypersensitivity to oxycodone or aspirin, and in any situation where opioids or aspirin are contraindicated. Aspirin is contraindicated for patients with hemophilia. **Side effects:** Nausea, vomiting, upset stomach, heartburn, upset stomach, bloating, gas, constipation. **Warnings and Precautions:** Following warnings should be considered such as Misuse and Abuse of Opioids, Respiratory Depression, Head Injury and Increased Intracranial Pressure, Hypotensive Effect, Alcohol Warning, Coagulation Abnormalities, GI Side Effects, Peptic Ulcer Disease	New Aspirin 75 mg, 100 mg, 150mg, 300 mg Tablet Aspirin 75 mg + Clopidogrel 75 mg.	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*
147.	Acme Laboratories Ltd., Dhamrai, Dhaka	Pimecrolimus 10 mg/g Cream	Pimecrolimus INN 10 mg/g	Skin Preparation	Pimecrolimus Cream, 1% is indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.	**Contraindications:** It is contraindicated in individuals with a history of hypersensitivity to pimecrolimus or any of the components of the cream. **Side effects:** The most commonly reported adverse reactions (≥1%) were application site burning, headache, nasopharyngitis, cough, influenza, pyrexia and viral infection. **Warnings and Precautions:** • Should not be used in immunocompromised adults and children, including patients on systemic immunosuppressive medications. • Avoid treatment on malignant or pre-malignant skin conditions, as these can present as dermatitis. • Should not be used in patients	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						with Netherton's Syndrome or skin diseases with a potential for increased systemic absorption.				
148.	Acme Laboratories Ltd., Dhamrai, Dhaka	Pravastatin Sodium 10 mg Tablet	Pravastatin Sodium USP 10 mg	Lipid Lowering	It is an HMG-CoA reductase inhibitor (statin) indicated as an adjunctive therapy to diet to: • Reduce the risk of MI, revascularization, and cardiovascular mortality in hypercholesterolemic patients without clinically evident CHD. • Reduce the risk of total mortality by reducing coronary death, MI, revascularization, stroke/TIA, and the progression of coronary atherosclerosis in patients with clinically evident CHD. • Reduce elevated Total-C, LDL-C, ApoB, and TG levels and to increase HDLC in patients with primary hypercholesterolemia and mixed dyslipidemia. • Reduce elevated serum TG levels in patients with hypertriglyceridemia. • Treat patients with primary dysbetalipoproteinemia who are not responding to diet. • Treat children and adolescent patients ages 8 years and older with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy.	**Contraindications:** • Hypersensitivity to any component of this medication. • Active liver disease or unexplained, persistent elevations of serum transaminases. • Pregnancy • Lactation **Side effects:** In short-term clinical trials, the most commonly reported adverse reactions (≥2% and > placebo) regardless of causality were: musculoskeletal pain, nausea/vomiting, upper respiratory infection, diarrhea, and headache. **Warnings and Precautions:** • Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): predisposing factors include advanced age (≥65), uncontrolled hypothyroidism, and renal impairment. Patients should be advised to promptly report to their physician any unexplained and/or persistent muscle pain, tenderness, or weakness. Pravastatin therapy should be discontinued if myopathy is diagnosed or suspected. • Liver enzyme abnormalities: persistent elevations in hepatic transaminases can occur. Check liver enzyme tests before initiating therapy and as clinically indicated thereafter.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
149.	Acme Laboratories Ltd., Dhamrai, Dhaka	Pravastatin Sodium 20 mg Tablet	Pravastatin Sodium USP 20 mg	Lipid Lowering	It is an HMG-CoA reductase inhibitor (statin) indicated as an adjunctive therapy to diet to: • Reduce the risk of MI, revascularization, and cardiovascular mortality in hypercholesterolemic patients without clinically evident CHD. • Reduce the risk of total mortality by reducing coronary	**Contraindications:** • Hypersensitivity to any component of this medication. • Active liver disease or unexplained, persistent elevations of serum	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					death, MI, revascularization, stroke/TIA, and the progression of coronary atherosclerosis in patients with clinically evident CHD. • Reduce elevated Total-C, LDL-C, ApoB, and TG levels and to increase HDLC in patients with primary hypercholesterolemia and mixed dyslipidemia. • Reduce elevated serum TG levels in patients with hypertriglyceridemia. • Treat patients with primary dysbetalipoproteinemia who are not responding to diet. • Treat children and adolescent patients ages 8 years and older with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy.	transaminases. • Pregnancy • Lactation **Side effects:** In short-term clinical trials, the most commonly reported adverse reactions (≥2% and > placebo) regardless of causality were: musculoskeletal pain, nausea/vomiting, upper respiratory infection, diarrhea, and headache. **Warnings and Precautions:** • Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): predisposing factors include advanced age (≥65), uncontrolled hypothyroidism, and renal impairment. Patients should be advised to promptly report to their physician any unexplained and/or persistent muscle pain, tenderness, or weakness. Pravastatin therapy should be discontinued if myopathy is diagnosed or suspected. • Liver enzyme abnormalities: persistent elevations in hepatic transaminases can occur. Check liver enzyme tests before initiating therapy and as clinically indicated thereafter.				
150.	Acme Laboratories Ltd., Dhamrai, Dhaka	Pravastatin Sodium 40 mg Tablet	Pravastatin Sodium USP 40 mg	Lipid Lowering	It is an HMG-CoA reductase inhibitor (statin) indicated as an adjunctive therapy to diet to: • Reduce the risk of MI, revascularization, and cardiovascular mortality in hypercholesterolemic patients without clinically evident CHD. • Reduce the risk of total mortality by reducing coronary death, MI, revascularization, stroke/TIA, and the progression of coronary atherosclerosis in patients with clinically evident CHD. • Reduce elevated Total-C, LDL-C, ApoB, and TG levels and to increase HDLC in patients with primary hypercholesterolemia and mixed dyslipidemia. • Reduce elevated serum TG levels in patients with hypertriglyceridemia. • Treat patients with primary dysbetalipoproteinemia who are not responding to diet.	**Contraindications:** • Hypersensitivity to any component of this medication. • Active liver disease or unexplained, persistent elevations of serum transaminases. • Pregnancy • Lactation **Side effects:** In short-term clinical trials, the most commonly reported adverse reactions (≥2% and > placebo) regardless of causality were: musculoskeletal pain, nausea/vomiting, upper respiratory infection, diarrhea, and headache.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					• Treat children and adolescent patients ages 8 years and older with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy.	**Warnings and Precautions:** • Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): predisposing factors include advanced age (≥65), uncontrolled hypothyroidism, and renal impairment. Patients should be advised to promptly report to their physician any unexplained and/or persistent muscle pain, tenderness, or weakness. Pravastatin therapy should be discontinued if myopathy is diagnosed or suspected. • Liver enzyme abnormalities: persistent elevations in hepatic transaminases can occur. Check liver enzyme tests before initiating therapy and as clinically indicated thereafter.				
151.	Acme Laboratories Ltd., Dhamrai, Dhaka	Pravastatin Sodium 80 mg Tablet	Pravastatin Sodium USP 80 mg	Lipid Lowering	It is an HMG-CoA reductase inhibitor (statin) indicated as an adjunctive therapy to diet to: • Reduce the risk of MI, revascularization, and cardiovascular mortality in hypercholesterolemic patients without clinically evident CHD. • Reduce the risk of total mortality by reducing coronary death, MI, revascularization, stroke/TIA, and the progression of coronary atherosclerosis in patients with clinically evident CHD. • Reduce elevated Total-C, LDL-C, ApoB, and TG levels and to increase HDLC in patients with primary hypercholesterolemia and mixed dyslipidemia. • Reduce elevated serum TG levels in patients with hypertriglyceridemia. • Treat patients with primary dysbetalipoproteinemia who are not responding to diet. • Treat children and adolescent patients ages 8 years and older with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy.	**Contraindications:** • Hypersensitivity to any component of this medication. • Active liver disease or unexplained, persistent elevations of serum transaminases. • Pregnancy • Lactation **Side effects:** In short-term clinical trials, the most commonly reported adverse reactions (≥2% and > placebo) regardless of causality were: musculoskeletal pain, nausea/vomiting, upper respiratory infection, diarrhea, and headache. **Warnings and Precautions:** • Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): predisposing factors include advanced age (≥65), uncontrolled hypothyroidism, and renal impairment. Patients should be advised to promptly report to their physician any unexplained and/or persistent	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						muscle pain, tenderness, or weakness. Pravastatin therapy should be discontinued if myopathy is diagnosed or suspected. • Liver enzyme abnormalities: persistent elevations in hepatic transaminases can occur. Check liver enzyme tests before initiating therapy and as clinically indicated thereafter.				
152.	Acme Laboratories Ltd., Dhamrai, Dhaka	Fosnetupitant 300 mg + Palonosetron 0.5 mg Capsule	Fosnetupitant INN 300 mg + Palonosetron Hydrochloride INN 0.560 mg eqv. to Palonosetron 0.5 mg	Antiemetic	It is a fixed combination of netupitant, a substance P/neurokinin 1 (NK1) receptor antagonist, and palonosetron, a serotonin-3 (5-HT3) receptor antagonist indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Oral palonosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.	**Contraindications:** None **Side effects:** Most common adverse reactions (incidence ≥3% and greater than palonosetron) are headache, asthenia, dyspepsia, fatigue, constipation and erythema. **Warnings and Precautions:** • Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving palonosetron with or without known hypersensitivity to other 5-HT3 receptor antagonists. • Serotonin syndrome has been reported with 5-HT3 receptor antagonists alone but particularly with concomitant use of serotonergic drugs.	**New** Palonosetron 0.5 mg Capsule Palonosetron 0.5 mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
153.	Acme Laboratories Ltd., Dhamrai, Dhaka	Ceftolozane 1 g + Tazobactam 0.5 g/Vial Injection	Sterile Lyophilized Combination of Ceftolozane and Tazobactam (2:1 Ratio) Pharma Grade 2.762 g (Contains Ceftolozane Sulfate 1.147 g eqv. to Ceftolozane 1 g and Tazobactam Sodium 0.537 g eqv. to Tazobactam 0.5 g)/Vial	Anti-infective	Ceftolozane and tazobactam is a combination of ceftolozane, a cephalosporin antibacterial, and tazobactam, a beta-lactamase inhibitor, indicated in patients 18 years or older for the treatment of the following infections caused by designated susceptible microorganisms: • Complicated Intra-abdominal Infections (cIAI), used in combination with metronidazole • Complicated Urinary Tract Infections (cUTI), Including Pyelonephritis • Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP) To reduce the development of drug-resistant bacteria and maintain the effectiveness of Ceftolozane and tazobactam and other antibacterial drugs, it should be used only to treat	**Contraindications:** This is contraindicated in patients with known serious hypersensitivity to the components of ceftolozane and tazobactam, piperacillin/tazobactam, or other members of the beta-lactam class. **Side effects:** The most common adverse reactions (≥5% in either cIAI or cUTI indication) are nausea, diarrhea, headache and pyrexia. The most common adverse reactions (≥5% in the	**New** Piperacillin 2 gm+Tazobactam 250 mg/vial	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					or prevent infections that are proven or strongly suspected to be caused by bacteria.	HABP/VABP indication) are increase in hepatic transaminases, renal impairment/renal failure, and diarrhea. **Warnings and Precautions:** • Decreased efficacy was observed in a Phase 3 cIAI trial in a subgroup of patients with baseline CrCl of 30 to ≤50 mL/min. Monitor CrCl at least daily in patients with changing renal function and adjust the dose of Ceftolozane and tazobactam accordingly. • Serious hypersensitivity (anaphylactic) reactions have been reported with beta-lactam antibacterial drugs. Exercise caution in patients with known hypersensitivity to beta-lactam antibacterial drugs. If an anaphylactic reaction to this drug occurs, discontinue the drug and institute appropriate therapy. • Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including this drug. Evaluate if diarrhea occurs.				
154.	Acme Laboratories Ltd., Dhamrai, Dhaka	Quinupristin 180 mg + Dalfopristin 420 mg/10 ml Vial Powder for Injection	Quinupristin 180 mg + Dalfopristin 420 mg /10 ml Vial	Anti-infective	It is indicated in adults for the treatment of the following infections when caused by susceptible strains of the designated microorganisms. Complicated skin and skin structure infections caused by Staphylococcus aureus (methicillin susceptible) or Streptococcus pyogenes.	**Contraindications:** It is contraindicated in patients with known hypersensitivity to this product, or with prior hypersensitivity to other streptogramins (e.g., pristinamycin or virginiamycin). **Side effects:** Nausea, vomiting, diarrhea, constipation, headache, joint or muscle pain, skin rash or itching, dizziness, sleep problems (insomnia), vaginal itching or discharge, or local reactions where the IV needle is placed (pain, swelling, or irritation).	**New**	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
155.	Acme Laboratories Ltd., Dhamrai, Dhaka	Empagliflozin 5 mg + Metformin Hydrochloride 850 mg Tablet	Empagliflozin INN 5 mg + Metformin Hydrochloride USP 850 mg	Antidiabetes	It is a diabetes medicine used with diet and exercise to treat adults with type 2 diabetes. It contains the active substances empagliflozin and metformin. It is used: • in patients whose diabetes is not sufficiently controlled by metformin alone • in combination with other diabetes medicines in patients whose diabetes is not sufficiently controlled on these medicines plus metformin • in patients who are already taking metformin and empagliflozin as separate tablets	**Contraindications:** It must not be used in patients with: • metabolic acidosis (when the body produces more acid than it gets rid of) or diabetic pre-coma (dangerous complications of diabetes); • severely reduced kidney function or conditions that could affect the kidneys such as dehydration, severe infection or a steep fall in blood pressure; • a condition that could reduce the supply of oxygen to body tissues (such as in patients with worsening heart failure, recent heart attack, breathing difficulty or a steep fall in blood pressure); •liver impairment, or problems with alcoholism or alcohol intoxication. **Side effects:** The most common side effects with this drug are hypoglycaemia (low blood sugar levels) when the medicine is taken with a sulphonylurea or insulin, infections of the urinary tract and genitals, and increased urination.	**Empagliflozin 10, 25 mg Tab., Metformin 500, 850, 1000 mg Tab.**	EMA DCC এর 246 তম সভায় প্রয়োজনীয় রেফারেন্স এবং দেশে প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হয়েছিল ।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
156.	Acme Laboratories Ltd., Dhamrai, Dhaka	Empagliflozin 12.5 mg + Metformin Hydrochloride 850 mg Tablet	Empagliflozin INN 12.5 mg + Metformin Hydrochloride USP 850 mg	Antidiabetes	It is a diabetes medicine used with diet and exercise to treat adults with type 2 diabetes. It contains the active substances empagliflozin and metformin. It is used: • in patients whose diabetes is not sufficiently controlled by metformin alone • in combination with other diabetes medicines in patients whose diabetes is not sufficiently controlled on these medicines plus metformin • in patients who are already taking metformin and empagliflozin as separate tablets	**Contraindications:** It must not be used in patients with: • metabolic acidosis (when the body produces more acid than it gets rid of) or diabetic pre-coma (dangerous complications of diabetes); • severely reduced kidney function or conditions that could affect the kidneys such as dehydration, severe infection or a steep fall in blood pressure; • a condition that could reduce the supply of oxygen to body tissues (such as in patients with worsening heart failure, recent heart attack, breathing difficulty	**Empagliflozin 10, 25 mg Tab., Metformin 500, 850, 1000 mg Tab.**	EMA DCC এর 246 তম সভায় প্রয়োজনীয় রেফারেন্স এবং দেশে প্রয়োজন নেই বিধায় আবেদন না মঞ্জুর করা হয়েছিল ।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						or a steep fall in blood pressure); •liver impairment, or problems with alcoholism or alcohol intoxication. **Side effects:** The most common side effects with this drug are hypoglycaemia (low blood sugar levels) when the medicine is taken with a sulphonylurea or insulin, infections of the urinary tract and genitals, and increased urination.				
157.	Acme Laboratories Ltd., Dhamrai, Dhaka	Sumatriptan 10 mg/Actuation Nasal Spray	Sumatriptan BP 10 mg/Actuation	**Antimigraine agent**	It is a serotonin (5-HT1B/1D) receptor agonist (triptan) indicated for the acute treatment of migraine with or without aura in adults.	**Contraindications:** •History of coronary artery disease or coronary vasospasm •Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders •History of stroke, transient ischemic attack, or hemiplegic or basilar migraine •Peripheral vascular disease •Ischemic bowel disease •Uncontrolled hypertension •Recent (within 24hours) use of another 5-HT1 agonist (e.g., another triptan) or of an ergotamine-containing medication •Concurrent or recent (past 2 weeks) use of monoamine oxidase-A inhibitor •Hypersensitivity to sumatriptan (angioedema and anaphylaxis seen) •Severe hepatic impairment **Side effects:** Most common adverse reactions (≥5% and > placebo) with sumatriptan injection were tingling, dizziness/vertigo, warm/hot sensation, burning sensation, feeling of heaviness, pressure sensation, flushing, feeling of tightness, and numbness Additional common adverse	**New** Sumatriptan 100 mg, 50 mg	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						reactions with sumatriptan include application site reactions, dysgeusia, and throat irritation. **Warnings and Precautions:** •Myocardial ischemia/infarction and Prinzmetal's angina: Perform cardiac evaluation in patients with multiple cardiovascular risk factors •Arrhythmias: Discontinue the drug if occurs •Chest/throat/neck/jaw pain, tightness, pressure, or heaviness: Generally not associated with myocardial ischemia; evaluate for coronary artery disease in patients at high risk •Cerebral hemorrhage, subarachnoid hemorrhage, and stroke: Discontinue it if occurs •Gastrointestinal ischemia and reactions, peripheral vasospastic reactions: Discontinue the drug if occurs •Medication overuse headache: Detoxification may be necessary •Serotonin syndrome: Discontinue it if occurs •Increase in blood pressure: Hypertensive crisis can occur •Hypersensitivity reactions : Angioedema and anaphylaxis can occur •Seizures: Use with caution in patients with epilepsy or a lowered seizure threshold •Local irritation: Burning and abnormal taste can occur				
158.	Acme Laboratories Ltd., Dhamrai, Dhaka	Phentermine Base 6.4 mg Tablet	Phentermine Hydrochloride USP 8 mg eqv. to Phentermine Base 6.4 mg	Lipid Lowering	Indicated as a short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity in patients with an initial body mass index greater than or equal to 30 kg/m , or greater than or equal to 27 kg/m in the presence of other risk factors.	**Contraindications:** History of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled hypertension), During or within 14 days following the administration of monoamine oxidase inhibitors, Hyperthyroidism, Glaucoma,	**New**	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Agitated states, History of drug abuse, Pregnancy & Nursing , Known hypersensitivity, or idiosyncrasy to the sympathomimetic amines. **Side effects:** Heart palpitations, fast heart rate, raised blood pressure, overstimulation, restlessness, dizziness, insomnia, euphoria.				
159.	Acme Laboratories Ltd., Dhamrai, Dhaka	Chlorhexidine Hydrochloride 10 mg/gm + Nystatin 1,00,000 IU/g Cream	Chlorhexidine Hydrochloride 10 mg/gm + Nystatin 1,00,000 IU/g	Skin Preparation	Skin infections due to *Candida* spp.	**Contraindications:** Known hypersensitivity to the active substance, especially in those with a history of possible chlorhexidine-related allergic reactions. **Side effects:** Hypersensitivity, skin reactions	Chlorhexidine 4gm/100 ml tropical solution. Chlorhexidine Hydrochloride 0.1% + Cetrimide 0.5% Cream; Nystatin 1 Lac Unit Tab, 1 Lac Unit/g Oint., 1 Lac Unit/ml Susp., 5 Lac Unit Tab	BNF 76, Page-1201	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
160.	Acme Laboratories Ltd., Dhamrai, Dhaka	Gabapentin 300 mg + Methylcobalamin 0.50 mg Film Coated Tablet	Gabapentin USP 300 mg + Methylcobalamin USP 0.50 mg	CNS	Treating nerve pain caused by neuropathic disorder or seizure disorder	**Contraindications:** Allergy, Lactation. Hypersensitivity to its ingredients. **Side effects:** Drowsiness, dizziness, loss of coordination, tiredness, blurred/double vision, unusual eye movements, or shaking (tremor) may occur.	**Gabapentin 100, 300, 600 mg Tab; 5 g/100 ml Syrup**	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
161.	Acme Laboratories Ltd., Dhamrai, Dhaka	Biotin 5000 mcg Soft Gelatin Capsule	Biotin BP 5000 mcg	Vitamin	Indicated for stronger hair & nails	**Contraindications:** There are no contraindications associated with the use of biotin. **Side effects:** Skin rashes, digestive upset, problems with insulin release, and kidney problems.	Ascorbic Acid 100 mg + Biotin 0.06 mg + Cyanocobalamin 0.005 mg+ Folic Acid 0.4 mg + Nicotinamide 40 mg + Pantothenic acid 15 mg+ Pyridoxine Hydrochloride 4 mg + Riboflavin 3.6 mg + Vitamin B1 2.5 mg	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
162.	Acme Laboratories Ltd., Dhamrai, Dhaka	Biotin 10000 mcg Soft Gelatin Capsule	Biotin BP 10000 mcg	Vitamin	Indicated for stronger hair & nails	**Contraindications:** There are no contraindications associated with the use of biotin. **Side effects:** Skin rashes, digestive upset, problems with insulin release, and kidney	Ascorbic Acid 100 mg + Biotin 0.06 mg + Cyanocobalamin 0.005 mg+ Folic Acid 0.4 mg + Nicotinamide 40 mg + Pantothenic acid 15 mg+	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						problems.	Pyridoxine Hydrochloride 4 mg + Riboflavin 3.6 mg + Vitamin B1 2.5 mg			
163.	Acme Laboratories Ltd., Dhamrai, Dhaka	Vitamin A 300 mcg + Beta Carotene 1.2 mg + Thiamine Mononitrate 5.60 mg + Riboflavin (Vitamin B_2) 5.10 mg + Nicotinamide (Vitamin B_3) 15 mg + Pantothenic Acid 10.90 mg + Pyridoxine Hydrochloride (Vitamin B_6) 7.30 mg + Biotin 40 mcg + Vitamin B_{12} 20 mcg + Ascorbic Acid (Vitamin C) 120 mg + Vitamin D_3 10 mcg + Vitamin E 60 mg + Folic Acid 400 mcg + Calcium 162 mg & Phosphorus 125 mg + Chromium 35 mcg + Copper 0.5 mg + Iron 8 mg + Iodine 150 mcg + Magnesium 50 mg + Manganese 5 mg +	Dry Vitamin A Acetate (0.5 MIU/g) Ph. Gr. 2 mg (Eqv. to Vitamin A 300 mcg) + Beta Carotene, 20% Ph. Gr. 6 mg (Eqv. to Beta Carotene 1.2 mg) + Thiamine Mononitrate (DC Grade 96%) (Vitamin B_1) Ph. Gr. 5.833 mg (Eqv. to Thiamine Mononitrate 5.60 mg) + Riboflavin (Vitamin B_2) BP 5.10 mg + Nicotinamide (Vitamin B_3) BP 15 mg + Calcium Pantothenate USP 11.848 mg (Eqv. to Pantothenic Acid 10.90 mg) + Pyridoxine Hydrochloride (Vitamin B_6) BP 7.30 mg + D-Biotin, 2% Ph. Gr. 2 mg (Eqv. to Biotin 40 mcg) + Cyanocobalamin 0.1% Ph. Gr. 20 mg (Eqv. to Vitamin B_{12} 20 mcg) + Ascorbic Acid (Vitamin C) BP 120 mg + Colecalciferol Concentrate (Powder Form) (0.1 MIU/g) (Vitamin D_3) BP 4 mg (Eqv. to Vitamin D 10 mcg)+ Dl-alpha-Tocopheryl Acetate (Powder Form, DC Grade 50%) Ph. Gr. 120 mg (Eqv. to Vitamin E 60 mg)+ Folic Acid BP 400 mcg + Dibasic Calcium Phosphate Anhydrous	Vitamins & Minerals	A complete multivitamin specially enhanced to help support our energy needs.	**Contraindications:** Iron metabolism disorder causing increased iron storage. An overload of iron in the blood. A type of blood disorder where the red blood cells burst. An ulcer from too much stomach acid. A type of stomach irritation called gastritis. Ulcerative colitis. An inflammatory condition of the intestines. Several blood transfusions. **Side effects:** Upset stomach, headache, unusual or unpleasant taste in your mouth.	**New**	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		Selenium 55 mcg + Zinc 7.5 mg + Molybdenum 0.045 mg + Panax Ginseng 200 mg Film Coated Tablet	[Ca=29.45%, P=22.87%] USP 546.568 mg (Eqv. to Calcium 162 mg & Phosphorus 125 mg) + Chromic Chloride (Hexahydrate) [Cr=19.52%] USP 0.179 mg (Eqv. to Chromium 35 mcg) + Cupric Sulphate Pentahydrate [Cu=25.45%] Ph. Gr. 0.782 mg (Eqv. to Copper 0.5 mg + Ferrous Fumarate [Fe=93.6%] BP 8.547 mg (Eqv. to Iron 8 mg) + Potassium Iodide [I=76.45%] BP 0.196 mg (Eqv. to Iodine 150 mcg) + Heavy Magnesium Oxide [Mg=60.31%] BP 82.905 mg (Eqv. to Magnesium 50 mg) + Manganese Sulfate Monohydrate [Mn=32.50%] USP 15.385 mg (Eqv. to Manganese 5 mg) + Sodium Selenate Anhydrous [Se=38.88%] BP 0.142 mg (Eqv. to Selenium 55 mcg) + Zinc Oxide [Zn=80.34%] BP 9.335 mg (Eqv. to Zinc 7.5 mg) + Sodium Molybdate Dihydrate [Mo=39.65%] BP 0.113 mg (Eqv. to Molybdenum 0.045 mg) + Panax Ginseng BP 200 mg						

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
164.	Acme Laboratories Ltd., Dhamrai, Dhaka	Vitamin A 600 mcg + Beta Carotene 1.2 mg + Thiamine Mononitrate 1.40 mg + Riboflavin (Vitamin B_2) 1.750 mg + Nicotinamide (Vitamin B_3) 20 mg + Pantothenic Acid 7.50 mg + Pyridoxine Hydrochloride (Vitamin B_6) 4 mg + Biotin 62.5 mcg + Vitamin B_{12} 3 mcg) + Ascorbic Acid (Vitamin C) 120 mg + Vitamin D_3 5 mcg+ Vitamin E 10.6 mg+ Vitamin K 30 mcg + Folic Acid 400 mcg + Calcium 162 mg & Phosphorus 125 mg + Chromium 40 mcg + Copper 1 mg + Iron 5 mg + Iodine 100 mcg + Potassium 40 mg + Magnesium 100 mg+ Manganese 2 mg+ Selenium 30 mcg + Zinc	Dry Vitamin A Acetate (0.5 MIU/g) Ph. Gr. 4 mg (Eqv. to Vitamin A 600 mcg) + Beta Carotene, 20% Ph. Gr. 6 mg (Eqv. to Beta Carotene 1.2 mg) + Thiamine Mononitrate (DC Grade 96%) (Vitamin B_1) Ph. Gr. 1.458 mg (Eqv. to Thiamine Mononitrate 1.40 mg) + Riboflavin (Vitamin B_2) BP 1.750 mg + Nicotinamide (Vitamin B_3) BP 20 mg + Calcium Pantothenate USP 8.152 mg (Eqv. to Pantothenic Acid 7.50 mg) + Pyridoxine Hydrochloride (Vitamin B_6) BP 4 mg + D-Biotin, 2% Ph. Gr. 3.125 mg (Eqv. to Biotin 62.5 mcg) + Cyanocobalamin 0.1% Ph. Gr. 3 mg (Eqv. to Vitamin B_{12} 3 mcg) + Ascorbic Acid (Vitamin C) BP 120 mg + Colecalciferol Concentrate (Powder Form) (0.1 MIU/g) (Vitamin D_3) BP 2 mg (Eqv. to Vitamin D 5 mcg)+ Dl-alpha-Tocopheryl Acetate (Powder Form, DC Grade 50%) Ph. Gr. 21.20 mg (Eqv. to Vitamin E 10.6 mg)+ Dry Vitamin K_1, 5% Ph. Gr. 0.60 mg (Eqv. to Vitamin K 30 mcg) + Folic Acid BP 400 mcg + Dibasic Calcium Phosphate Anhydrous [Ca=29.45%,	Vitamins & Minerals	A complete multivitamin that feeds our cells and helps support for our heart health.	**Contraindications:** Iron metabolism disorder causing increased iron storage. An overload of iron in the blood. A type of blood disorder where the red blood cells burst. An ulcer from too much stomach acid. A type of stomach irritation called gastritis. Ulcerative colitis. An inflammatory condition of the intestines. Several blood transfusions. **Side effects:** Confused, depression, easily angered or annoyed, feel like throwing up, gas, itching, loss of appetite, not feeling well.	**New**	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজনে নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		5 mg+ Phytosterols 1000 mg Film Coated Tablet	P=22.87%] USP 546.568 mg (Eqv. to Calcium 162 mg & Phosphorus 125 mg) + Chromic Chloride (Hexahydrate) [Cr=19.52%] USP 0.205 mg (Eqv. to Chromium 40 mcg) + Cupric Sulphate Pentahydrate [Cu=25.45%] Ph. Gr. 3.929 mg (Eqv. to Copper 1 mg) + Ferrous Fumarate [Fe=93.6%] BP 5.342 mg (Eqv. to Iron 5 mg) + Potassium Iodide [I=76.45%] BP 0.131 mg (Eqv. to Iodine 100 mcg) + Potassium Sulphate [K=22.45%] BP 178.174 mg (Eqv. to Potassium 40 mg) + Heavy Magnesium Oxide [Mg=60.31%] BP 165.810 mg (Eqv. to Magnesium 100 mg) + Manganese Sulfate Monohydrate [Mn=32.50%] USP 6.154 mg (Eqv. to Manganese 2 mg) + Sodium Selenate Anhydrous [Se=38.88%] BP 0.077 mg (Eqv. to Selenium 30 mcg) + Zinc Oxide [Zn=80.34%] BP 6.224 mg (Eqv. to Zinc 5 mg) + Phytosterols BP 1000 mg						

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
165.	Acme Laboratories Ltd., Dhamrai, Dhaka	Vitamin A 330 mcg + Thiamine Mononitrate 0.50 mg + Riboflavin (Vitamin B_2) 0.50 mg + Nicotinamide (Vitamin B_3) 5 mg + Pantothenic Acid 2.50 mg + Pyridoxine Hydrochloride (Vitamin B_6) 0.50 mg + Biotin 50 mcg + Vitamin B_{12} 1 mcg + Ascorbic Acid (Vitamin C) 50 mg + Vitamin D_3 3 mcg+ Vitamin E 5 mg+ Folic Acid 200 mcg + Iron 4.5 mg + Manganese 0.50 mg + Selenium 12.5 mcg + Zinc 2.8 mg Film Coated Tablet	Dry Vitamin A Acetate (0.5 MIU/g) Ph. Gr. 2.20 mg (Eqv. to Vitamin A 330 mcg) + Thiamine Mononitrate (DC Grade 96%) (Vitamin B_1) Ph. Gr. 0.521 mg (Eqv. to Thiamine Mononitrate 0.50 mg) + Riboflavin (Vitamin B_2) BP 0.50 mg + Nicotinamide (Vitamin B_3) BP 5 mg + Calcium Pantothenate USP 2.720 mg (Eqv. to Pantothenic Acid 2.50 mg) + Pyridoxine Hydrochloride (Vitamin B_6) BP 0.50 mg + D-Biotin, 2% Ph. Gr. 2.50 mg (Eqv. to Biotin 50 mcg) + Cyanocobalamin 0.1% Ph. Gr. 1 mg (Eqv. to Vitamin B_{12} 1 mcg) + Ascorbic Acid (Vitamin C) BP 50 mg + Colecalciferol Concentrate (Powder Form) (0.1 MIU/g) (Vitamin D_3) BP 2 mg (Eqv. to Vitamin D_3 3 mcg)+ Dl-alpha-Tocopheryl Acetate (Powder Form, DC Grade 50%) Ph. Gr. 10 mg (Eqv. to Vitamin E 5 mg)+ Folic Acid BP 200 mcg + Ferrous Fumarate [Fe=93.6%] BP 4.808 mg (Eqv. to Iron 4.5 mg) + Manganese Sulfate Monohydrate [Mn=32.50%] USP 1.538 mg (Eqv. to Manganese 0.50 mg) + Sodium Selenate Anhydrous [Se=38.88%]	Vitamins & Minerals	Complete multivitamin for kids with Micronutrients designed to nourish and revitalize at the cellular level and support growth and development.	**Contraindications:** Iron metabolism disorder causing increased iron storage. An overload of iron in the blood. A type of blood disorder where the red blood cells burst. An ulcer from too much stomach acid. A type of stomach irritation called gastritis. Ulcerative colitis. An inflammatory condition of the intestines. Several blood transfusions. **Side effects:** Upset stomach or throwing up, constipation, change in color of stool to green, diarrhea, belly pain.	**New**	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			BP 0.032 mg (Eqv. to Selenium 12.5 mcg) + Zinc Oxide [Zn=80.34%] BP 3.485 mg (Eqv. to Zinc 2.8 mg)							
166.	Acme Laboratories Ltd., Dhamrai, Dhaka	Baloxavir Marboxil 80 mg Film Coated Tablet	Baloxavir Marboxil INN 80 mg	Antiviral	For the treatment of acute uncomplicated influenza in patient 12 years of age and older who have been symptomatic for no more than 48 hours	**Contraindications:** Contraindicated in patients with a history of hypersensitivity to baloxavir marboxil or any of its ingredients. **Side effects:** Diarrhea, bronchitis, common cold symptoms (nasopharyngitis), headache, nausea.	**New**	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*
167.	Acme Laboratories Ltd., Dhamrai, Dhaka	Dehydroepiandrosterone 25 mg Film Coated Tablet	Dehydroepiandrosterone INN 25 mg	Hormone	Prasterone, also known as dehydroepiandrosterone (DHEA) is a medicine used to treat postmenopausal women with moderate to severe symptoms of vulvar and vaginal atrophy. In women with vulvar and vaginal atrophy, the wall of the vagina and surrounding tissues become thinner and can cause symptoms such as dryness, irritation and soreness around the genital area, and painful sexual intercourse.	**Contraindications:** Prasterone must not be used in patients with the following conditions: genital bleeding where the cause has not been diagnosed, known or suspected breast cancer or oestrogen-dependent cancer, previous breast cancer, untreated endometrial hyperplasia (thickening of the lining of the womb), acute (short-term) liver disease, previous liver disease where liver function tests are still abnormal, previous or current venous thromboembolism (formation of blood clots in the veins), thrombophilic disorders (abnormal blood clotting), active or recent arterial thromboembolic disease (disease caused by blood clots in the arteries), porphyria (inability to break down chemicals called porphyrins). **Side effects:** The most common side effect with DHEA (which may affect up to 1 in 10 people) is vaginal discharge.	**New**	EMA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
168.	Acme Laboratories Ltd., Dhamrai, Dhaka	Lornoxicam 8 mg Film Coated Tablet	Lornoxicam INN 8 mg	Nonsteroidal anti-inflammatory and drugs used in arthritis	- Short-term relief of acute mild to moderate pain - Symptomatic relief of pain and inflammation in osteoarthritis. - Symptomatic relief of pain and inflammation in rheumatoid arthritis	**Contraindications:** - Hypersensitivity to lornoxicam or any of the excipients - Thrombocytopenia - Hypersensitivity (symptoms like asthma, rhinitis, angioedema or urticaria) to other NSAIDs including acetylsalicylic acid - Severe heart failure - Gastro-intestinal bleeding, cerebrovascular bleeding or other bleeding disorders - History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy - Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding) - Severe hepatic impairment - Severe renal impairment (Serum creatinine > 700 µmol/l) -The third trimester of pregnancy **Side effects: T**he most frequent adverse effects of lornoxicam include nausea, dyspepsia, indigestion, abdominal pain, vomiting, and diarrhoea. These symptoms have generally occurred in less than 10% of patients in available studies. **Warnings and Precautions:** For the following disorders, lornoxicam should only be administered after careful risk-benefit assessment: - Renal impairment: Lornoxicam should be administered with precaution in patients with mild (serum creatinine 150-300 µmol/l) to moderate (serum creatinine 300 – 700 µmol/l) renal impairment due to dependency on renal prostaglandins for maintenance of renal blood flow. Treatment with lornoxicam should be	**New**	EMA DCC এর 241 তম সভায় প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						discontinued if renal function deteriorates during treatment. - Renal functions should be monitored in patients who undergo major surgery, with cardiac failure, receiving treatment with diuretics, receiving concomitant treatment with drugs that are suspected to or known to be able to cause kidney damage. - Patients with blood coagulation disorders: Careful clinical monitoring and laboratory assessment is recommended (e.g. APTT). - Hepatic impairment (e.g. liver cirrhosis): Clinical monitoring and laboratory assessments at regular intervals should be considered in patients with hepatic impairment as accumulation of lornoxicam (increase in AUC) may occur after treatment with daily doses of 12-16 mg. Apart from that, hepatic impairment does not seem to affect pharmacokinetic parameters of lornoxicam as compared to healthy subjects. - Long term treatment (longer than 3 months): Regular laboratory assessments of haematology (haemoglobin), renal functions (creatinine) and liver enzymes are recommended. - Elderly patients above 65 years: Monitoring of renal and hepatic function is recommended. Precaution is advised in elderly postoperative patients.				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
169.	Acme Laboratories Ltd., Dhamrai, Dhaka	Risedronate Sodium 35 mg Enteric Coated Tablet + Calcium 1000 mg + Colecalciferol 880 IU/ Sachet	Risedronate Sodium USP 35 mg Enteric Coated Tablet, Calcium Carbonate BP 2500 mg (Eqv. to Calcium 1000 mg) + Vitamin D_3 (Colecalciferol) BP 22 mcg (Eqv. to Colecalciferol 880 IU)/Sachet	Antiosteoporotic	Treatment of postmenopausal osteoporosis to reduce risk of vertebral or hip fractures	**Contraindications:** Contraindicated in pregnancy & lactation, while driving or using machine. **Side effects:** Upset stomach, stomach pain, headache, flu symptoms, muscle pain, diarrhea, constipation, joint or back pain.	**New** Risedronate Sodium 35 mg, 5 mg, 150 mg Tablet Ascorbic Acid 100 mg + Biotin 0.06 mg + Cyanocobalamin 0.005 mg+ Folic Acid 0.4 mg + Nicotinamide 40 mg + Pantothenic acid 15 mg+ Pyridoxine Hydrochloride 4 mg + Riboflavin 3.6 mg + Vitamin B1 2.5 mg	BNF 77 Page 716	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
170.	Acme Laboratories Ltd., Dhamrai, Dhaka	Halobetasol Propionate 0.010 g + Tazarotene 0.045 g/100 g Topical Lotion	Halobetasol Propionate USP 0.010 g + Tazarotene INN 0.045 g/100 g	Skin and Mucous Membrane Preparations	It is indicated for the topical treatment of plaque psoriasis in adults.	**Contraindications:** It is contraindicated in pregnancy **Side effects:** The most common adverse reactions are contact dermatitis (7%), application site pain (3%), folliculitis (2%), skin atrophy (2%), and excoriation (2%).	**Halobetasol Propionate 0.05% cream/ ointment** Tazarotene 1mg/ g Cream	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
171.	**Opsonin Pharma Limited,** Rupatoli, Barishal.	**Naproxen 200 mg capsule**	Naproxen BP 200 mg	**Nonsteroidal antiinflamatory and drugs used in arthritis**	Rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, juvenile arthritis, tendinitis, bursitis and acute gout. Management of mild to moderate pain associated with postoperation, orthopedic, postpartum episiotomy, uterine contraction and dysmenorrhoea.	**Contraindication:** Hypersensitivity to naproxen, gastrointestinal ulceration, asthma, nasal polyps, urticaria and hypotension. **Side-effects:** Gastrointestinal experiences: Heartburn, abdominal pain, nausea, constipation, diarrhoea, dyspepsia, stomatitis. Central nervous system: Headache, dizziness, drowsiness, lightheadedness, vertigo. Dermatological: Pruritus, skin eruptions, ecchymoses, sweating, purpura. Special senses: Tinnitus, visual disturbances, hearing disturbances. Cardiovascular: Oedema, palpitations. General: Dyspnea, thirst.	Naproxen 250 mg & 500 mg tablet, Naproxen 500 mg sustained release tablet	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
172.	**Opsonin Pharma Limited,** Rupatoli, Barishal.	**Magnesium Oxide 365 mg tablet**	Magnesium Oxide BP 365 mg	Electrolyte	• Relieving the symptoms of magnesium deficiency • Muscle, nervous system & calf cramps treatment • Constipation & Indigestion • High blood pressure during pregnancy (Pre-eclampsia. Eclampsia) • Diabetes • Regulation of calcium balance through its effects on the parathyroid gland	Do not use Magnesium in the following conditions: If anyone are allergic (hypersensitivity) to any of the other ingredients of DIMAG, if anyone have severe kidney failure or insufficiency. Like all medicines, side effects can occur in people sensitive to the contents of Magnesium. Ex: Severe allergic reaction (e.g. swelling in mouth and throat, itching, rash, redness) ,Respiratory depression, Coma.	Magnesium Hydroxide 400 mg/ 5 ml Suspension.	রেফারেন্স নাই	ঔষধটি অত্যন্ত প্রয়োজন বিধায় আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
173.	**Opsonin Pharma Limited,** Rupatali, Barishal.	**Gelatin Tannate 500 mg Capsule**	Gelatin tannate Pharma grade 500 mg	Antidiarrheal	Diarrhea, viral gastroenteritis, infectious diarrhea, non-infectious diarrhea.	Gelatin tannate must not be used in patients with known hypersensitivity to Gelatin Tannate or any other ingredient of the product	New Amonium Bicarbonate 25 gm + Gelatin 1.5 gm + Ginger 1.5 gm + Nux vomica 7 mg + Sodium Bicarbonate 65 gm	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
174.	**Opsonin Pharma Limited,** Rupatali, Barishal.	**Gelatin Tannate 250 mg powder sachet**	Gelatin tannate Pharma grade 250 mg	Antidiarrheal	Diarrhea, viral gastroenteritis, infectious diarrhea, non-infectious diarrhea.	Gelatin tannate must not be used in patients with known hypersensitivity to Gelatin Tannate or any other ingredient of the product.	New Amonium Bicarbonate 25 gm + Gelatin 1.5 gm + Ginger 1.5 gm + Nux vomica 7 mg + Sodium Bicarbonate 65 gm	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
175.	**Opsonin Pharma Limited,** Rupatali, Barishal.	**Polymyxin B Sulfate 0.5 Million Units injection**	Polymyxin B Sulfate USP 0.5 Million Units	Anti-infective	For treatment of infections of the urinary tract, meninges and blood stream caused by susceptible strains of Pseudomonas aeruginosa.	The drug is contraindicated in persons with a prior history of hypersensitivity reactions to polymixins.	Gramacidin 25 IU + Neomycin 1700 IU + polymixin 5000IU B ear drops	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
176.	**Opsonin Pharma Limited,** Rupatali, Barishal.	**Bisoprolol 1.25 mg Tablet**	Bisoprolol Fumarate USP 1.25 mg	Cardiovascular	Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides, Treatment of hypertension,	Bisoprolol is contra-indicated in patients with acute heart failure or during episodes of heart failure decompensation	Bisoprolol 2.5 mg, 5 mg & 10 mg Tablet	UK MHRA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					Treatment of chronic stable angina pectoris	requiring i.v. inotropic therapy, cardiogenic shock, second or third degree AV block, sick sinus syndrome , sinoatrial block, symptomatic bradycardia, symptomatic hypotension, severe bronchial asthma or severe chronic obstructive pulmonary disease , bradycardia, dizziness, headache, nausea, vomiting, diarrhea etc.				
177.	**Opsonin Pharma Limited,** Rupatali, Barishal.	**Calcium Carbonate 5 gm + Magnesium 1.5 gm+ Vitamin D_3 4000 IU Zinc 40 mg/100 ml suspension**	Calcium Carbonate USP 5 gm + Magnesium BP 1.5 gm+ Vitamin D_3 BP 4000 IU+Zinc USP 40 mg	Vitamin & minerals	Strong bones & Dietary supplement	**Contraindications:** Hypersensitivity of this drug is contraindicated. In addition, Suspension should not be used if you have the following conditions: Allergic reactions, Extreme loss of body water, High amount of calcium in the blood, High calcium levels, Incomplete or infrequent bowel movements, Increased activity of the parathyroid gland, Kidney disease, Kidney stone, Sarcoidosis, Tumor that dissolves bone **Side effects:** Some of the side-effects may be rare but serious. Consult your doctor if you observe any of the following side-effects, especially if they do not go away. Abdominal pain, Constipation, Headache, Loss of appetite, Nausea, Vomiting, Stomach ache, Feeling of sickness, Excessive thirst, Muscle weakness	Calcium Carbonate 500 mg +Vitamin D3 200 IU Tablet, Boron 250 mg + Calcium 600 mg + Copper 1 mg + Magnesium 40 mg + Manganese 1.8 mg + Vitamin D3 200 IU + Zinc 7 mg.	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
178.	**Opsonin Pharma Limited,** Rupatali, Barishal.	**Lidocaine (1.73% w/v) + Beclometasone dipropionate (0.025% w/v) + Clotrimazole (1%w/v) + Chloramphenicol (5%w/v) per 100 ml ear drops**	Lidocaine BP (1.73%w/v) + Beclometasone dipropionate BP (0.025%w/v) + Clotrimazole USP (1%w/v) + Chloramphenicol BP (5%w/v)	Anti-infective	Inner & outer ear infection along with acute & chronic otitis media.	No specific data found. No common side effects seen.	Clotrimazole 1 gm cream, 1% topical solution, chloramphenicol 0.5% ear drop, suspension, injection. Beclomethasone 100 mcg Inhalation solution, Lidocaine 1% injection, 10% Spray	রেফারেন্স নাই	ঔষধটি প্রয়োজন বিধায় আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
179.	**Opsonin Pharma Limited,** Rupatali, Barishal.	**Boron 0.75 mg + Calcium (Algae Source) 180 mg + Magnesium 87.5 mg + Vitamin C 12.5 mg + Vitamin D3 400 IU + Vitamin K2 25 mcg Capsule**	Boron Ph Gr. 0.75 mg + Calcium (Algae Source) USP 180 mg + Magnesium BP 87.5 mg + Vitamin C BP 12.5 mg + Vitamin D3 BP 400 IU + Vitamin K2 Ph Gr. 25 mcg Capsule	Vitamin & minerals	Osteoporosis, Osteomalacia, tetany, Hypoparathyroidism & Osteogenesis	Increased activity of Parathyroid gland, Hypercalcemia, Constipation, kidney stone, Extreme loss of body water are such condition in which Calcium intake is contraindicated. The common side effects are Flatulence, Diarrhoea, Constipation, and Allergic reactions etc. Hypercalcemia due to prolong use has rarely been reported.	**Boron:**150 µg, 250 µg, **Calcium**: 52.49 mg, 162 mg, 327 mg, 500 mg, 550 mg 600 mg, 625 mg **Magnesium:** 400 mg, 40 mg, 50 mg, 150 mg **Vitamin C:** 200 mg, 60 mg, 17.5 mg, 500 mg, 175 mg, 50 mg, 120 mg, 25 mg, 30 mg **Vitamin D3:** 2000 IU, 100 IU, 200 IU, 400 IU **Vitamin K:** 75 µg,	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
180.	Opsonin Pharma Limited, Rupatali, Barishal.	Epinephrine 18 mcg + Lidocaine Hydrochloride 36 mg per Dental Cartridge	Epinephrine USP 18 mcg + Lidocaine Hydrochloride USP 36 mg per Dental Cartridge	Anaesthetic	Local anesthetic by infiltration and/or nerve blockage for use in dentistry and stomatology, For use in pediatric patients, adults and elderly people, For all kind of dental interventions which require a long anesthetic effect, Ideal choice for procedures that require the haemostatic property of Epinephrine.	Contraindications: - Hypersensitivity to the active substance, to any of the excipients listed in this combination or to local anaesthetics of the amide type. -Hypersensitivity to methyl and/or propyl parahydroxybenzoate (methyl-/propyl paraben), or to their metabolite para amino benzoic acid (PABA).	Epinephrine 10 mcg + Lidocaine Hydrochloride 20 mg/ml	রেফারেন্স নাই	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						-Formulations of lidocaine containing parabens should be avoided in patients allergic to ester local anaesthetics or their metabolite PABA. Side effects: In common with other local anaesthetics, adverse reactions to Lidocaine Hydrochloride & Epinephrine with Adrenaline are rare and are usually the result of excessively high blood concentrations due to inadvertent intravascular injection, excessive dosage, rapid absorption or occasionally to hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. In such circumstances systemic effects occur involving the central nervous system and/or the cardiovascular system.				
181.	**Opsonin Pharma Limited,** Rupatali, Barishal.	**Epinephrine 14.4 mcg + Lidocaine Hydrochloride 36 mg per Dental Cartridge**	Epinephrine USP 14.4 mcg + Lidocaine Hydrochloride USP 36 mg per Dental Cartridge	Anaesthetic	Local anesthetic by infiltration and/or nerve blockage for use in dentistry and stomatology, For use in pediatric patients, adults and elderly people, For all kind of dental interventions which require a long anesthetic effect, Ideal choice for procedures that require the haemostatic property of Epinephrine.	Contraindications: - Hypersensitivity to the active substance, to any of the excipients listed in this combination or to local anaesthetics of the amide type. -Hypersensitivity to methyl and/or propyl parahydroxybenzoate (methyl-/propyl paraben), or to their metabolite para amino benzoic acid (PABA). -Formulations of lidocaine containing parabens should be avoided in patients allergic to ester local anaesthetics or their metabolite PABA. Side effects: In common with other local anaesthetics,	Epinephrine 10 mcg + Lidocaine Hydrochloride 20 mg/ml	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						adverse reactions to Lidocaine Hydrochloride & Epinephrine with Adrenaline are rare and are usually the result of excessively high blood concentrations due to inadvertent intravascular injection, excessive dosage, rapid absorption or occasionally to hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. In such circumstances systemic effects occur involving the central nervous system and/or the cardiovascular system.				
182.	**Opsonin Pharma Limited,** Rupatali, Barishal.	**Vitamin (A+D3) Water Miscible Type 100/20 BP 10 mg (equivalent to Vitamin A 1000 IU & Vitamin D3 200 IU) + Ascorbic Acid BP 15 mg + dl-Alpha Tocopheryl Acetate USP 5 mg (equivalent to Vitamin E 5 IU) + Pyridoxine Hydrochloride BP 500 mcg + Thiamine Hydrochloride BP**	Vitamin (A+D3) Water Miscible Type 100/20 BP 10 mg (equivalent to Vitamin A 1000 IU & Vitamin D3 200 IU) + Ascorbic Acid BP 15 mg + dl-Alpha Tocopheryl Acetate USP 5 mg (equivalent to Vitamin E 5 IU) + Pyridoxine Hydrochloride BP 500 mcg + Thiamine Hydrochloride BP 500 mcg + Riboflavin Sodium Phosphate BP 500 mcg + Nicotinamide BP 6 mg + Cyanocobalamin BP 0.9 mcg + Calcium Pantothenate BP 2.174 mg + L-Lysine USP 100mg/ 5ml.	Multi vitamis	Promotes muscle growth, weight gain and calcium retention; Helps to enhance body weight and weight gain: Ensures good eye sight: Necessary for the normal process in protein, fat carbohydrate metabolism: for RBC formation and correct functioning of nervous system & proper food assimilation and for proper cell functioning and protect body cell from free radical	Contraindications: The products are contraindicated in patients with a known hypersensitivity to any of the ingredients of the products. Side effects: Generally well tolerated.	Existing Tablet: Firmvit, Lyovit, Hulk Generic: Folic Acid 250 mcg + L-Lysine 50 mg + Nicotinamide 2.5 mg + Vitamin A 1500 IU + Vitamin B1 250 mcg + Vitamin B12 2 mcg + Vitamin B2 250 mcg + Vitamin B6 250 mcg + Vitamin C 50 mg + Vitamin D3 100 IU + Vitamin E 10 IU Tablet	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		500 mcg + Riboflavin Sodium Phosphate BP 500 mcg + Nicotinamide BP 6 mg + Cyanocobalamin BP 0.9 mcg + Calcium Pantothenate BP 2.174 mg + L-Lysine USP 100mg/ 5ml Syrup								
183.	**Opsonin Pharma Limited,** Rupatali, Barishal.	**Dalfampridine 10 mg Tablet**	Dalfampridine 10 mg	Potassium channel blockers	Dalfampridine is a potassium channel blocker indicated to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.	**Contraindications:** History of seizure. • Moderate or severe renal impairment **Side effects:** Most common side effects (incidence ≥2% and at a rate greater than the placebo rate) for Dalfampridine were urinary tract infection, insomnia, dizziness, headache, nausea, asthenia, back pain, balance disorder, multiple sclerosis relapse, paresthesia, nasopharyngitis, constipation, dyspepsia, and pharyngolaryngeal pain. **WARNINGS AND PRECAUTIONS:** Seizures: Dalfampridine can cause seizures; the risk of seizures increases with increasing Dalfampridine doses; Dalfampridine is contraindicated in patients with a prior history of	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						seizure; discontinue Dalfampridine use if seizure occurs • Renally impaired patients: Dalfampridine is contraindicated in patients with moderate to severe renal impairment (CrCl≤50 mL/min); the risk of seizures in patients with mild renal impairment (CrCl 51–80 mL/min) is unknown, but Dalfampridine plasma levels in these				
184.	**Opsonin Pharma Limited,** Rupatali, Barishal.	**Bismuth Subsalicylate 175 mg/5 ml suspension**	Bismuth Subsalicylate BP 175 mg/5 ml	Antacid	Upset stomach, indigestion, heartburn nausea and diarrhea.	**Contraindications:** Bismuth Subsalicylate should not be used by patients hypersensitive to Aspirin or other salicylates. It also should not be used by patients hypersensitive to any ingredient in the formulation. Bismuth Subsalicylate tablet should not be used by children under 16 years of age. **Side effects:** Gastrointestinal disorders: Black tongue is common (>1/100, <1/10) Black stool is very common (>1/10)	**Bismuth Subsalicylate 1.75 mg/100 ml suspension**	UKMHRA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
185.	**Opsonin Pharma Limited,** Rupatali, Barishal.	**Cefixime 500mg/ 5 ml Paediatric Drops**	Cefixime USP 500 mg/ 5 ml	Anti-infective	Cefixime is a 3rd generation oral cephalosporin antibacterial agent that indicated for the treatment of the following infections caused by designated susceptible bacteria: • Uncomplicated Urinary Tract Infections • Otitis Media • Pharyngitis and Tonsillitis • Acute Exacerbations of Chronic Bronchitis • Uncomplicated Gonorrhea (cervical/urethral)	Contraindications: Cefixime is contraindicated in patients with known allergy to cefixime or other cephalosporins. Most common adverse reactions are gastro intestinal such as diarrhea (16%), nausea (7%), loose stools (6%), abdominal pain (3%), dyspepsia (3%), and vomiting.	**Cefixime 2.5 gm/ 100 ml Paediatric Drops**	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
186.	SOMATEC PHARMACEUTICALS LTD., SARULIA, DEMRA, DHAKA BANGLADESH	Sufentanil Citrate INN 15 micrograms sublingual tablet	Sufentanil Citrate INN 15 micrograms sublingual tablet	Opioid Analgesics, Anesthetics	Sufentanil is indicated for the management of acute moderate to severe post-operative pain in adult patients.	**Contraindication:** - Hypersensitivity to the active substance or to any of the excipients listed in section - Significant respiratory depression **Side effect:** The most serious adverse reaction of sufentanil is respiratory depression, potentially leading to apnoea and respiratory arrest. Other side effects are- Dizziness, Headache, Sedation, Heart rate increased, increase or decrease Blood pressure. Constipation, Dyspepsia, Urinary retention, muscle spasms.	New	BNF 77 pg-464.	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
187.	**General Pharmaceutical Ltd (Unit-2)., Gazipur**	Cardioplegia Solution 20ml (Magnesium Chloride Hexaahydrate 3.250gm+ Potassium Chloride 1.190gm + Procain HCL 0.2728gm)20 ml Injection	Cardioplegia Solution 20ml (Magnesium Chloride Hexaahydrate BP 3.250gm+ Potassium Chloride BP 1.190gm + Procain HCL BP 0.2728gm)20ml Injection	Coronary Vasodilators	Cardioplegia (Magnesium Chloride Hexaahydrate, Potassium Chloride &,Procain HCL) indicated for use in combination with ischaemia and hypothermia to induce cardiac arrest during open-heart surgery and to preserve the myocardium during asystole.	**<u>Contraindications:</u>** Cardioplegia (Magnesium Chloride Hexaahydrate, Potassium Chloride &,Procain HCL) must not be used unless it has been diluted with Ringers Injection prior to use. Use of Cardioplegia (Magnesium Chloride Hexaahydrate, Potassium Chloride &,Procain HCL) is contraindicated in patients who are hypersensitive to procaine. As procaine is metabolised to produce para-aminobenzoic acid, it should be used with caution in patients who are allergic to para-aminobenzoic acid or its derivatives such as preservatives and sunscreens. Cross sensitivity can occur between procaine and other local anaesthetics of the paraaminobenzoic acid ester-type, para-aminobenzoic acid and hydroxybenzoate preservatives.	New	রেফারেন্স নাই পদটির রেজিঃ আছে কিন্তু DCC কর্তৃক অনুমোদনের রেফারেন্স খুঁজে পাওয়া না যাওয়ায় Post Apporval এর জন্য উপস্থাপন করা হয়।	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Procaine hydrochloride is contraindicated in patients: • with low plasma cholinesterase levels or who are receiving anticholinesterases, • with myasthenia gravis, severe shock or impaired cardiac conduction, • receiving sulfonamides. Warnings & Precaurion Cardioplegia (Magnesium Chloride Hexaahydrate, Potassium Chloride &,Procain HCL)must be diluted with Ringer's Injection before use. Do not use the solution unless it is clear and free from particulate matter. Discard any unused portion. Cardioplegia solution must not be administered by intravenous injection. Cardioplegia solution should only be used for instillation into the coronary arteries during cardiopulmonary bypass, while the coronary circulation is isolated from the systemic circulation. Cardioplegia (Magnesium Chloride Hexaahydrate, Potassium Chloride &,Procain HCL) should only be used by those who are trained in cardiac perfusion techniques and open heart surgery. Inotropic support drugs and appropriate defibrillation equipment should be readily available following use of the cardioplegia solution. The cardioplegia solution should be cooled to 4oC prior to administration, thereby assisting in the reduction of cellular metabolism. It is important to use sufficient cardioplegia solution to ensure				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						that the myocardium is evenly cooled. This especially applies to areas distal to arterial obstruction in patients with coronary artery disease. Inadequate dosage may result in uneven cooling, incomplete arrest and ischaemic injury. Maintenance of hypothermia is critical. Myocardial temperature and activity should be monitored continuously throughout the procedure. Plasma magnesium and potassium levels may rise if large volumes of diluted cardioplegia solution are instilled and allowed to return to the heart lung machine without any venting from the right heart. Therefore, right heart venting is recommended. Cardioplegia (Magnesium Chloride Hexaahydrate, Potassium Chloride &,Procain HCL) should be used with caution in very young, elderly, acutely ill or debilitated patients, or patients with hyperthyroidism or other endocrine diseases, who may be more susceptible to the systemic toxicity of procaine. Cardioplegia (Magnesium Chloride Hexaahydrate, Potassium Chloride &,Procain HCL) should also be used with caution in patients with reduced hepatic blood flow (such as in liver disease) or renal disease, since the risk of systemic toxicity is increased due to decreased clearance of procaine. Procaine should be used with caution in patients with a genetic predisposition to malignant				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						hyperthermia as the safety of local anaesthetic agents in these patients has not been fully established. A standard protocol for the management of malignant hyperthermia should be available. Adverse Reaction: When used as recommended, systemic absorption of cardioplegia solution should not occur, and hence interactions between the cardioplegia solution and other medicines are unlikely. However, the following interactions could potentially occur if Cardioplegia (Magnesium Chloride Hexaahydrate, Potassium Chloride &,Procain HCL) is absorbed systemically: Acetazolamide Acetazolamide may inhibit hydrolysis of procaine; concurrent administration may therefore theoretically extend the plasma half-life of procaine. Anticholinesterase agents Anticholinesterase agents may inhibit procaine metabolism, leading to an increased risk of toxicity if procaine is used concurrently with anticholinesterase agents. Antimyasthenic agents Procaine may antagonise the effects of antimyasthenic agents on skeletal muscle; concurrent use may, therefore, result in worsening of myasthenia gravis symptoms. Temporary dosage adjustment of antimyasthenic agents may be required. CNS depressant medicines Concurrent use of procaine with CNS depressant medicines may result in				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						enhanced CNS depressant effects. Hyaluronidase Hyaluronidase may increase the diffusion rate of procaine hydrochloride, resulting in a decreased time of onset, but an increase in systemic toxicity. Neuromuscular blocking agents Concurrent administration of procaine and neuromuscular blocking agents may prolong or enhance neuromuscular blockade. Magnesium salts may also interact with neuromuscular blocking agents. Potassium-containing or potassium-sparing medicines Potassium salts should be used sparingly, if at all, in patients receiving medicines which increase serum potassium concentrations. Examples include potassium-sparing diuretics, angiotensin converting enzyme (ACE) inhibitors, cyclosporin, and potassium-containing medicines. Hyperkalaemia is more likely to occur in patients with renal impairment. Sulfonamides Concurrent administration of procaine with sulfonamides may reduce the antibacterial action of the sulfonamide.				
188.	**General Pharmaceutical Ltd (Unit-2)., Gazipur**	Sodium Valproate 500 mg/5 ml Injection	Sodium Valproate BP 500 mg/5 ml Injection	Drug used in Epilepsy	Sodium Valproate is indicated as an intravenous alternative in patients in whom oral administration of valproate products is temporarily not feasible in the following conditions: • Monotherapy and adjunctive therapy of complex partial seizures and simple and complex absence seizures; adjunctive therapy in patients with multiple seizure types that include absence seizures.	**Contraindications:** • Hepatic disease or significant hepatic dysfunction • Known mitochondrial disorders caused by mutations in mitochondrial DNA polymerase γ (POLG) • Suspected POLG-related disorder in children under two years of age • Known hypersensitivity to the	Sodium Valproate 400mg/4ml Injection	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						drug • Urea cycle disorders • Prophylaxis of migraine headaches: Pregnant women, women of childbearing potential not using effective contraception **Warnings & Precaurion** • Hepatotoxicity; evaluate high risk populations and monitor serum liver tests • Birth defects and decreased IQ following in utero exposure; only use to treat pregnant women with epilepsy if other medications are unacceptable; should not be administered to a woman of childbearing potential unless essential • Pancreatitis; Depacon should ordinarily be discontinued • Bleeding and other hematopoietic disorders; monitor platelet counts and coagulation tests • Hyperammonemia and hyperammonemic encephalopathy; measure ammonia level if unexplained lethargy and vomiting or changes in mental status, and also with concomitant topiramate use; consider discontinuation of valproate therapy • Hypothermia; Hypothermia has been reported during valproate therapy with or without associated hyperammonemia. This adverse reaction can also occur in patients using concomitant topiramate • Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan hypersensitivity reaction; discontinue Depacon • Somnolence in the elderly can				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						occur. Depacon dosage should be increased slowly and with regular monitoring for fluid and nutritional intake **Adverse Reaction:** Adverse reactions occurring in at least 5% of patients treated with Depakote in Monotherapy or Adjunctive Complex Partial Seizures Trials: • Abdominal pain, alopecia, amblyopia/blurred vision, amnesia, anorexia, asthenia, ataxia, bronchitis, constipation, depression, diarrhea, diplopia, dizziness, dyspepsia, dyspnea, ecchymosis, emotional lability, fever, flu syndrome, headache, infection, insomnia, nausea, nervousness, nystagmus, peripheral edema, pharyngitis, rhinitis, somnolence, thinking abnormal, thrombocytopenia, tinnitus, tremor, vomiting, weight gain, weight loss Additional Adverse Reactions not included above that occurred in > 0.5% of patients treated with Depacon: • Chest pain, euphoria, hypesthesia, injection site inflammation, injection site pain, injection site reaction, pain, sweating, taste perversion, vasodilation Additional adverse reactions not included above that occurred in other clinical trials with Depakote: • Accidental injury, back pain, increased appetite, rash.				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
189.	**GLOBE PHARMACEUTICALS LTD.** **BSCIC Industrial Estate** **Begumgonj, Noakhali.** Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh.	Tofacitinib 10 mg Tablet	Tofacitinib citrate INN 16 mg equivalent to Tofacitinib 10 mg	Nonsteroidal antiinflamatory and drugs used in arthritis.	Tofacitinib is a Janus kinase (JAK) inhibitor indicated for Rheumatoid Arthritis, Psoriatic Arthritis & Ulcerative Colitis	**Contraindications:** None. **Side Effects:** Most common adverse reactions are: **Rheumatoid and Psoriatic Arthritis:** Reported during the first 3 months in rheumatoid arthritis controlled clinical trials and occurring in ≥2% of patients treated with Tofacitinib monotherapy or in combination with DMARDs: upper respiratory tract infection, nasopharyngitis, diarrhea, and headache. **Ulcerative Colitis:** Reported in ≥5% of patients treated with either 5 mg or 10 mg twice daily of Tofacitinib and ≥1% greater than reported in patients receiving placebo in either the induction or maintenance clinical trials: nasopharyngitis, elevated cholesterol levels, headache, upper respiratory tract infection, increased blood creatine phosphokinase, rash, diarrhea, and herpes zoster. **WARNINGS AND PRECAUTIONS:** Serious Infections – Do not administer Tofacitinib during an active infection, including localized infections. If a serious infection develops, interrupt Tofacitinib until the infection is controlled.	Toafacitinib 5 mg & Tofacitinib 11 mg	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						• Lymphomas and other malignancies have been reported in patients treated with Tofacitinib . • Gastrointestinal Perforations – Use with caution in patients that may be at increased risk. • Laboratory monitoring – Recommended due to potential changes in lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids. • Immunizations –Live vaccines should not be given concurrently with Tofacitinib . • Severe hepatic impairment–Not recommended .				
190.	**Advanced Chemical Industries Limited, 07 Hajeeganj, Godnayl, Narayanganj.**	Ademetionine 400 mg tablet	Ademetionine USP 400 mg as S-Adenosyl-L MethiononeDisulfate p-Toluensulfonate	**Other Classification**	It is indicated for- • Depression • Osteoarthritis • Chronic liver disease • Intrahepatic cholestasis • Fibromyalgia	**Contraindications:** Ademetionine is contraindicated in patients with known hypersensitivity to ademetionine or any components of this product. It is also contraindicated for patients with bipolar depression **Side Effects:** The most common side effects are vomiting, diarrhea, loss of appetite, dry mouth, headache, insomnia, dizziness and nervousness. It also causes confusion, anxiety, tremors, diarrhea, high blood pressure, sweating, skin rashes, allergic reaction and seizures.	New	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
191.	**Advanced Chemical Industries Limited, 07 Hajeeganj, Godnayl, Narayanganj.**	Ademetionine 400 mg/ vial for IV/IM Injection	Ademetionine USP 400 mg as S-Adenosylmethionine Butanedisulfonate lyophilized powder forIV/IM injection	**Other Classification**	It is indicated for- • Depression • Osteoarthritis • Chronic liver disease • Intrahepatic cholestasis • Fibromyalgia	**Contraindications:** Ademetionine is contraindicated in patients with known hypersensitivity to ademetionine or any components of this product. It is also contraindicated for patients with bipolar depression **Side Effects:** The most common side effects are vomiting, diarrhea, loss of appetite, dry mouth, headache, insomnia, dizziness and nervousness. It also causes confusion, anxiety, tremors, diarrhea, high blood pressure, sweating, skin rashes, allergic reaction and seizures.	New	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
192.	**Advanced Chemical Industries Limited, 07 Hajeeganj, Godnayl, Narayanganj.**	Sodium alginate BP 1000 mg + Potassium Bicarbonate BP 200 mg + Calcium Carbonate USP 200 mg./10ml suspension	Sodium alginate BP 1000 mg + Potassium Bicarbonate BP 200 mg + Calcium Carbonate USP 200 mg./10ml suspension	**Antacid, Adsorbent**	It is indicated for- • Reflux of acid, bile and pepsin into the oesophagus • Heartburn indigestion • Accompanying reflux oesophagitis, including symptoms of laryngopharyngeal reflux like hoarseness and other voice disorders, sore throats and cough • GERD with or following withdrawal of acid suppressing therapy	**Contraindications:** This medicinal product is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients, or any of the excipients, including methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216). **Side Effects:** In addition to the desired effect of the drug, some side effects may appear such as: nausea, constipation, diarrhea or headache. In these cases consult a physician. In case too big dosage has been taken, there might appear a sensation of swelling. In this case it is advisable to consult a physician.	Sodium alginate 5 gm/100 ml suspension, Sodium alginate BP 500 mg + Potassium Bicarbonate BP 100 mg Tablet Sodium alginate BP 500 mg + Potassium Bicarbonate BP 100 mg/5 ml suspension.	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
193.	**Advanced Chemical Industries Limited, 07 Hajeeganj, Godnayl, Narayanganj.**	Sodium Alginate BP 250 mg +Sodium Bicarbonate BP 106.50 mg + Calcium Carbonate USP 187.50 mg Chewable tablet.	Sodium Alginate BP 250 mg + Sodium Bicarbonate BP 106.50 mg + Calcium Carbonate USP 187.50 mg	**Antacid, Adsorbent**	It is indicated for- • Reflux of acid, bile and pepsin into the oesophagus • Heartburn indigestion • Accompanying reflux oesophagitis, including symptoms of laryngopharyngeal reflux like hoarseness and other voice disorders, sore throats and cough • GERD with or following withdrawal of acid suppressing therapy	**Contraindications:** This medicinal product is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients, or any of the excipients, including methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216). **Side Effects:** In addition to the desired effect of the drug, some side effects may appear such as: nausea, constipation, diarrhea or headache. In these cases consult a physician. In case too big dosage has been taken, there might appear a sensation of swelling. In this case it is advisable to consult a physician.	New Sodium alginate 5 gm/100 ml suspension, Sodium alginate BP 500 mg + Potassium Bicarbonate BP 100 mg Tablet Sodium alginate BP 500 mg + Potassium Bicarbonate BP 100 mg/5 ml suspension	**UKMHRA**	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
194.	**UniMed UniHealth Pharmaceuticals Ltd., B.K.Bari, Gazipur.**	Ofloxacin 0.300gm + Clotrimazole 1.00gm + Baclomethasone Dipropionate 0.025gm + Lidocaine Hydrochloride 2.00gm/100 ml Ear Drops	Ofloxacin BP 0.300gm + Clotrimazole BP 1.00gm + Baclomethasone Dipropionate BP 0.025gm + Lidocaine Hydrochloride BP 2.00gm/100ml	Antifungl Agent	Ear Drops are recommended for the treatment of superficial bacterial and fungal infections of the external auditory canal and middle ear, caused by organisms susceptible to the action of Ofloxacin and Clotrimazole.	Contra-indications Patients sensitive to Ofloxacin or other quinolones, or to any of the components of this medication. - Viral infections of the ear Side Effects The following adverse reactions may be observed when using this product: itching, burning, irritation, dryness, earache, headache, vertigo, dizziness, redness, folliculitis, hypertrichosis, acneform eruptions and hypopigmentation. - This preparation is not for ophthalmic use	Ofloxacin 100 mg, 200 mg, 400 mg Tablet Ofloxacin 3mg/ml Eye and Ear Drops. (বিএস এম এম ইউ এর ডাক্তারের রেফারেন্স আছে)	**রেফারেন্স নাই**	বর্ণিত ইন্ডিকেশনে ঔষধটি কার্যকর বিধায় অনুমোদন করা যেতে পারে।	বর্ণিত ইন্ডিকেশনে ঔষধটি কার্যকর বিধায় আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
195.	Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Isavuconazonium Sulfate 186 mg Eqv.to Isavuconazole 100 mg Capsule	Isavuconazonium Sulfate INN 186-mg Eqv.to Isavuconazole 100 mg	Antifungal	Isavuconazole is indicated for the treatment of • Invasive aspergillosis. • Mucormycosis in patients for whom amphotericin B is inappropriate. Consideration should be given to official guidance on the appropriate use of antifungal agents.	**Contra-indication:** Hypersensitivity to the active substance or to any of the excipients. Co-administration with ketoconazole. Co-administration with high-dose ritonavir (>200 mg every 12 hours). C-administration with strong CYP3A4/5 inducers such as rifampicin, rifabutin, carbamazepine, long-acting barbiturates (e.g. phenobarbital), phenytoin and St. john's wort or with moderate CYP3A4/5 inducers such as efavirenz, nafcillin and etravirine. Patients with familial short QT syndrome. **Side-effects:** Most frequent adverse reactions: nausea, vomiting, diarrhea, headache, elevated liver chemistry tests, hypokalemia, constipation, dyspnea, cough, peripheral edema, and back pain **WARNINGS AND PRECAUTIONS:** **Hepatic Adverse Drug Reactions:** Serious hepatic reactions have been reported. Evaluate liver-related laboratory tests at the start and during the course of Isavuconazole therapy. Infusion-related reactions were reported during intravenous administration of Isavuconazole. Discontinue the infusion if these reactions occur **Hypersensitivity Reactions:** Serious hypersensitivity and severe skin reactions, such as	New	US FDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						anaphylaxis or Stevens Johnson syndrome, have been reported during treatment with other azole antifungal agents. Discontinue Isavuconazole for exfoliative cutaneous reactions. **Embryo-Fetal Toxicity:** Do not administer to pregnant women unless the benefit to the mother outweighs the risk to the fetus. Inform pregnant patients of the hazard . **Drug Interactions:** Review patient's concomitant medications. Several drugs may significantly alter isavuconazole concentrations. Isavuconazole may alter concentrations of several drugs. **Drug Particulates:** Intravenous formulation may form insoluble particulates following reconstitution. Administer Isavuconazole through an in-line filter.				
196.	Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Isavuconazonium Sulfate Contains Isavuconazole 200mg/Vial Lyophilized Powder for Injection	Isavuconazonium Sulfate Ph.Gr. Contains Isavuconazole 200mg/Vial	Antifungal	Isavuconazole is indicated for the treatment of • Invasive aspergillosis. • Mucormycosis in patients for whom amphotericin B is inappropriate. Consideration should be given to official guidance on the appropriate use of antifungal agents.	Contra-indication: Hypersensitivity to the active substance or to any of the excipients. Co-administration with ketoconazole. Co-administration with high-dose ritonavir (>200 mg every 12 hours). C-administration with strong CYP3A4/5 inducers such as rifampicin, rifabutin, carbamazepine, long-acting barbiturates (e.g. phenobarbital), phenytoin and St. john's wort or with moderate CYP3A4/5 inducers such as efavirenz, nafcillin and etravirine. Patients with familial short QT syndrome.	New	US FDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Side-effects: Most frequent adverse reactions: nausea, vomiting, diarrhea, headache, elevated liver chemistry tests, hypokalemia, constipation, dyspnea, cough, peripheral edema, and back pain **WARNINGS AND PRECAUTIONS:** **Hepatic Adverse Drug Reactions:** Serious hepatic reactions have been reported. Evaluate liver-related laboratory tests at the start and during the course of Isavuconazole therapy. Infusion-related reactions were reported during intravenous administration of Isavuconazole. Discontinue the infusion if these reactions occur **Hypersensitivity Reactions:** Serious hypersensitivity and severe skin reactions, such as anaphylaxis or Stevens Johnson syndrome, have been reported during treatment with other azole antifungal agents. Discontinue Isavuconazole for exfoliative cutaneous reactions. **Embryo-Fetal Toxicity:** Do not administer to pregnant women unless the benefit to the mother outweighs the risk to the fetus. Inform pregnant patients of the hazard . **Drug Interactions:** Review patient's concomitant medications. Several drugs may significantly alter isavuconazole concentrations. Isavuconazole may alter concentrations of several drugs. **Drug Particulates:** Intravenous formulation may form insoluble				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						particulates following reconstitution. Administer Isavuconazole through an in-line filter.				
197.	Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka	Telmisartan 40 mg + Amlodipine Besilate 13.88 mg Eqv.to Amlodipine 10 mg Tablet	Telmisartan USP 40 mg + Amlodipine Besilate BP 13.88 mg Eqv.to Amlodipine 10 mg	Antihypertensive	Telmisartan and Amlodipine is an angiotensin II receptor blocker (ARB) and a dihydropyridine calcium channel blocker (DHP-CCB) combination product indicated for the treatment of hypertension alone or with other antihypertensive agents to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. • Telmisartan and Amlodipine combination tablets are indicated as initial therapy in patients likely to need multiple antihypertensive agents to achieve their blood pressure goals.	**Contra-indication:** • Known hypersensitivity (e.g., anaphylaxis or angioedema) to telmisartan, amlodipine or any other component of this product. • Do not co-administer aliskiren with telmisartan and amlodipine combination in patients with diabetes. **Side-effects:** Most common side effects of Telmisartan are- Upper respiratory infection (7%), urinary tract infection (1%), back pain (3%), diarrhea (3%), Myalgia (3%), Fatigue (1%), Sinusitis (3%), Peripheral edema (1%), chest pain (1%), hypertension (1%), dyspepsia (1%), headache (1%), dizziness (1%) pharyngitis (1%).	Telmisartan 40 mg + Amlodipine 5 mg Telmisartan 80 mg + Amlodipine 5 mg Telmisartan 20 mg, 40 mg, 80 mg Tablet. Amlodipine 5 mg Tablet	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
198.	Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka	Telmisartan 80 mg + Hydrochlorothiazide 25 mg Tablet	Telmisartan USP 80 mg + Hydrochlorothiazide BP 25 mg	Antihypertensive	• Treatment of essential hypertension. Telmisartan/Hydrochlorothiazide fixed dose combination (Telmisartan 80 mg/Hydrochlorothiazide 25 mg) is indicated in adults whose blood pressure is not adequately controlled on Telmisartan/Hydrochlorothiazide 80 mg/12.5 mg (Telmisartan 80 mg /Hydrochlorothiazide 12.5 mg) or adults who have been previously stabilized on telmisartan and hydrochlorothiazide given separately.	**Contra-indication:** Hypersensivity to any of the active substances Hypersensitivity to other sulphonaside-derived substances (since hydrochlorothiazide is a sulphonaside-derived medicinal product). Second and third trimesters of pregnancy Cholestasis and biliary obstructive disorders Severe hepatic impairment. Severe renal impairment (creatinine clearance < 30 ml/min)	Telmisartan 40 mg + Amlodipine 5 mg Telmisartan 80 mg + Amlodipine 5 mg Telmisartan 20 mg, 40 mg, 80 mg Tablet. Amlodipine 5 mg Tablet	US FDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Refractory hypokalaemia, hypercalcaemia The concomitant use of Telmisartan/Hydrochlorothiazide with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 $m^{2)}$ **Side-effects:** Upper respiratory infection (7%), urinary tract infection (1%), back pain (3%), diarrhea (3%), Myalgia (3%), Fatigue (1%), Sinusitis (3%), Peripheral edema (1%), chest pain (1%), hypertension (1%), dyspepsia (1%), headache (1%), dizziness (1%) pharyngitis (1%)				
199.	Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka	Sodium Hyaluronate 16 mg + Chondrotin Sulfate Sodium 40 mg /ml Injection (Prefilled Syringe)	Sodium Hyaluronate BP 16 mg + Chondrotin Sulfate Sodium USP 40 mg /ml	Eye Preparations	Sodium Hyaluronate & Chondroitin Sulfate Sodium Prefilled syringe is indicated for use as a surgical aid in anterior segment produces including cataract extraction and intraocular lens implantation. It maintains a deep chamber during anterior segment surgery, enhances visualization during the surgical procedure and protects the corneal endothelium and other ocular tissues. The viscoelasticity of the solution maintains the normal position of the vitreous face and prevents formation of a flat chamber during surgery.	**Contra-indication:** There are no known contraindications to the use of Sodium Hyaluronate & Chondroitin Sulfate Sodium Prefilled syringe when used as recommended.	Sodium Hyaluronate 30 mg + Chondrotin Sulfate Sodium 40 mg /ml Injection	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
200.	Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka	Dry Vitamin A Palmitate 500 - 2 mg Eqv.to Vitamin A 1000 IU + Vitamin C 150 mg + Vitamin D3 4 mg Eqv. to Vitamin Cholecalciferol 400 IU + Vitamin E Acetate 50% 100 mg Eqv. to Vitami E 50	Dry Vitamin A Palmitate 500 BP 2 mg Eqv.to Vitamin A 1000 IU + Vitamin C BP 150 mg + Vitamin D3 BP 4 mg Eqv. to Vitamin Cholecalciferol 400 IU + Vitamin E Acetate 50% BP 100 mg Eqv. to Vitami E 50 IU + Vitamin K1 5% BP 0.06 mg + Thiamine Nitrate BP 1.860 mg Eqv.to Thiamine 1.5 mg + Riboflavin BP 1.70 mg + Niacin USP 20 mg + Pyridoxine HCl BP 2 mg	Vitamins and Combinations	It is indicated to provide nutritional support for the eye and help to filter blue light and support the health of eyes. As well as for the prevention and treatment of vitamin and mineral deficiencies. It is also indicated to meet the increased demands for vitamins and minerals.	**Contra-indication:** This product is contraindicated in patients with known hypersensivity to any of the ingredients of the product. **Side-effects:** Generally, this product is well tolerated.		রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		IU + Vitamin K1 5% 0.06 mg + Thiamine Nitrate 1.860 mg Eqv.to Thiamine 1.5 mg + Riboflavin 1.70 mg + Niacin 20 mg + Pyridoxine HCl 2 mg + Folic Acid 0.4 mg + Vitamin B_{12} 0.60 mg + Biotin 0.03 mg + Calcium-D Pantothenate 10.870 mg + Calcium Carbonate 454.698 mg Eqv.to Calcium 181.876 mg + Dibasic Calcium Phosphate Anhydrous 61.520 mg Eqv.to Phosphorus 14 mg & Calcium 18.124 mg+ Potassium Iodide 0.196 mg Eqv.to Iodine 150 mcg + Magnesium Oxide Heavy 165.80 mg Eqv.to Magnesium	+ Folic Acid BP 0.4 mg + Vitamin B_{12} USP 0.60 mg + Biotin BP 0.03 mg + Calcium-D Pantothenate BP 10.870 mg + Calcium Carbonate USP 454.698 mg Eqv.to Calcium 181.876 mg + Dibasic Calcium Phosphate Anhydrous USP 61.520 mg Eqv.to Phosphorus 14 mg & Calcium 18.124 mg+ Potassium Iodide BP 0.196 mg Eqv.to Iodine 150 mcg + Magnesium Oxide Heavy BP 165.80 mg Eqv.to Magnesium 100 mg + Zinc Oxide BP 28.628 mg Eqv.to Zinc 23 mg + Sodium Selenate Ph. Gr.0.168 mg Eqv.to Selenium 70 mcg + Cupric Oxide Ph. Gr. 2.505 mg Eqv. to Copper 2 mg + Manganese Sulphate Monohydrate BP 6.152 mg Eqv.to Manganese 2 mg + Chromic Chloride USP 0.615 mg Eqv.to Chromium 120 mcg + Sodium Molybdate BP 0.19 mg Eqv.to Molybdenum 75 mcg + Magigold Extract USP 200 mg Eqv.to Lutein 10 mg + Zeaxanthin USP 20 mg + Lycopene USP 3 mg					

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		100 mg + Zinc Oxide 28.628 mg Eqv.to Zinc 23 mg + Sodium Selenate 0.168 mg Eqv.to Selenium 70 mcg + Cupric Oxide 2.505 mg Eqv. to Copper 2 mg + Manganese Sulphate Monohydrate 6.152 mg Eqv.to Manganese 2 mg + Chromic Chloride 0.615 mg Eqv.to Chromium 120 mcg + Sodium Molybdate 0.19 mg Eqv.to Molybdenum 75 mcg + Magigold Extract 200 mg Eqv.to Lutein 10 mg + Zeaxanthin 20 mg + Lycopene 3 mg Film Coated Tablet								

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
201.	Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka	Biotin 5 mg + Copper 2 mg + Manganese 5 mg + Selenium 40 mcg + Zinc 25 mg Film Coated Tablet	Biotin BP 5 mg + Copper Ph. Gr. 2 mg + Manganese BP 5 mg + Selenium Ph. Gr. 40 mcg + Zinc BP 25 mg	Vitamins and Combinations	This tablet is indicated for the treatment, control, prevention, & improvement of the following diseases, conditions and symtoms: • Hair loss • Skin and hair growth • Healthy nervous system and bone marrow maintenance • Biotin deficiency in pregnancy • Long-term tube feeding • Malnutrition • Rapid weight loss • Copper deficiency • Wound healing • Osteoarthritis • Brittle bones • Manganese deficiency • Osteoporosis • Diseases of the heart and blood vessels • Stroke • Hardening of the arteries • Cancer of the prostate • Stomach cancer • Lung cancer • Zinc deficiencies • Diarrhoea in malnutrition children • Wilson's disease	**Contraindication:** These tablets are contraindicated in patients with a history of hypersensitive reaction to Biotin, Cupric Oxide, Manganese Sulphate Monohydrate, Sodium Selenate and Zinc Oxide. In addition, the mentioned tablet should not be used in the following conditions: Fertility problems in men High doses Higher doses Hypersensitivity Inhalation by children Large amounts **Side Effects:** The various reported side effects of the drug are nausea, vomiting, bloody diarrhea, fever, stomach pain etc.	Ascorbic Acid 100 mg + Biotin 0.06 mg + Cyanocobalamin 0.005 mg+ Folic Acid 0.4 mg + Nicotinamide 40 mg + Pantothenic acid 15 mg+ Pyridoxine Hydrochloride 4 mg + Riboflavin 3.6 mg + Vitamin B1 2.5 mg	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
202.	Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka	Cholecalciferol 1.32 g /100 ml Oral Solution	Cholecalciferol BP 1.32 g /100 ml	Vitamins and Combinations	Treatment and prevention of vitamin D deficien	**Contraindication:** Hypersensitivity to cholecalciferol, ergocalciferol or vitamin D metabolites (eg. Calcitriol, calcifediol, alfacalcidol, calcipotriol), Hypercalemia or hypercalciuria, Nephrolithiasis, Nephrocalcinosis and Hypervitaminosis D. **Side-effects:** High dose of cholecalciferol can cause weakness, fatigue, sleepiness, headache, loss of appetite, dry mouth, metallic taste, nausea and vomiting. Vitamin D toxicity, including nephrocalcinosis/renal failure, hypertension can occur with	Cholecalciferol 400 IU, 2000 IU, 1000 IU. Cholecalciferol 7.5 mg/vial.	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						prolonged use of cholecalciferol, relatively low doses can produce toxicity in hypersensitive infants and children. Hypervitaminosis D is reversible upon discontinuation of treatment unless renal damage is severe.				
203.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Bisoprolol Fumarate EP 10mg + Perindopril Arginine INN 5mg Film Coated Tablet	Bisoprolol Fumarate EP 10mg + Perindopril Arginine INN 5mg	Antihypertensive	It is used to treat high blood pressure (hypertension) and/or to reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who have already had a heart attack and/or an operation to improve the blood supply to the heart by widening the vessels that supply it.	**CONTRAINDICATIONS:** • are allergic to Bisoprolol or any other beta-blocker, to Perindopril or any other ACE inhibitor, or to any of the other ingredients of this medicine, • have a heart disease characterized by a slow or irregular heart rate (atrioventricular block second or third degree, sinoatrial block, sick sinus syndrome), **SIDE EFFECTS:** • vertigo • dizziness • headache	**New** **Bisoprolol Fumarate + Aspirin:** 5mg/75mg, 10mg/75mg, 5mg/100mg, 10mg/100mg **Bisoprolol Fumarate + Amlodipine:** 5mg/5mg, 5mg/10mg, 10mg/5mg, 10mg/10mg **Bisoprolol Fumarate+ Hydrochlorothiazide:** 2.5mg/6.25mg, 5mg/6.25mg, 10mg/6.25mg **Perindopril + Amlodipine:** 3.5mg/2.5mg, 7mg/5mg, 14mg/10mg, 5mg/5mg, 5mg/10mg, 10mg/5mg, 10mg/10mg	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
204.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Bisoprolol Fumarate EP 10mg + Perindopril Arginine INN 10mg Film Coated Tablet	Bisoprolol Fumarate EP 10mg + Perindopril Arginine INN 10mg	Antihypertensive	It is used to treat high blood pressure (hypertension) and/or to reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who have already had a heart attack and/or an operation to improve the blood supply to the heart by widening the vessels that supply it.	**CONTRAINDICATIONS:** • are allergic to Bisoprolol or any other beta-blocker, to Perindopril or any other ACE inhibitor, or to any of the other ingredients of this medicine, • have a heart disease characterized by a slow or irregular heart rate (atrioventricular block	**New** **Bisoprolol Fumarate + Aspirin:** 5mg/75mg, 10mg/75mg, 5mg/100mg, 10mg/100mg **Bisoprolol Fumarate + Amlodipine:** 5mg/5mg, 5mg/10mg,	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						second or third degree, sinoatrial block, sick sinus syndrome), **SIDE EFFECTS:** • vertigo • dizziness • headache	10mg/5mg, 10mg/10mg **Bisoprolol Fumarate+ Hydrochlorothiazide:** 2.5mg/6.25mg, 5mg/6.25mg, 10mg/6.25mg **Perindopril + Amlodipine:** 3.5mg/2.5mg, 7mg/5mg, 14mg/10mg, 5mg/5mg, 5mg/10mg, 10mg/5mg, 10mg/10mg			
205.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Bisoprolol Fumarate EP 5mg + Perindopril Arginine INN 5mg Film Coated Tablet	Bisoprolol Fumarate EP 5mg + Perindopril Arginine INN 5mg	Antihypertensive	It is used to treat high blood pressure (hypertension) and/or to reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who have already had a heart attack and/or an operation to improve the blood supply to the heart by widening the vessels that supply it.	**CONTRAINDICATIONS:** • are allergic to Bisoprolol or any other beta-blocker, to Perindopril or any other ACE inhibitor, or to any of the other ingredients of this medicine, • have a heart disease characterized by a slow or irregular heart rate (atrioventricular block second or third degree, sinoatrial block, sick sinus syndrome), **SIDE EFFECTS:** • vertigo • dizziness • headache	**New** **Bisoprolol Fumarate + Aspirin:** 5mg/75mg, 10mg/75mg, 5mg/100mg, 10mg/100mg **Bisoprolol Fumarate + Amlodipine:** 5mg/5mg, 5mg/10mg, 10mg/5mg, 10mg/10mg **Bisoprolol Fumarate+ Hydrochlorothiazide:** 2.5mg/6.25mg, 5mg/6.25mg, 10mg/6.25mg **Perindopril + Amlodipine:** 3.5mg/2.5mg, 7mg/5mg, 14mg/10mg, 5mg/5mg, 5mg/10mg, 10mg/5mg, 10mg/10mg	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
206.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Bisoprolol Fumarate EP 5mg + Perindopril Arginine INN 10mg Film Coated Tablet	Bisoprolol Fumarate EP 5mg + Perindopril Arginine INN 10mg	Antihypertensive	It is used to treat high blood pressure (hypertension) and/or to reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who have already had a heart attack and/or an operation to improve the blood supply to the heart by widening the vessels that supply it.	**CONTRAINDICATIONS:** • are allergic to Bisoprolol or any other beta-blocker, to Perindopril or any other ACE inhibitor, or to any of the other ingredients of this medicine, • have a heart disease characterized by a slow or irregular heart rate (atrioventricular block second or third degree, sinoatrial block, sick sinus syndrome), **SIDE EFFECTS:** • vertigo • dizziness • headache	**New** **Bisoprolol Fumarate + Aspirin:** 5mg/75mg, 10mg/75mg, 5mg/100mg, 10mg/100mg **Bisoprolol Fumarate + Amlodipine:** 5mg/5mg, 5mg/10mg, 10mg/5mg, 10mg/10mg **Bisoprolol Fumarate+ Hydrochlorothiazide:** 2.5mg/6.25mg, 5mg/6.25mg, 10mg/6.25mg **Perindopril + Amlodipine:** 3.5mg/2.5mg, 7mg/5mg, 14mg/10mg, 5mg/5mg, 5mg/10mg, 10mg/5mg, 10mg/10mg	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।*
207.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Estradiol Valerate BP 2mg + Dienogest BP 3mg Film Coated Tablet	Estradiol Valerate BP 2mg + Dienogest BP 3mg	Contraceptives	• Estradiol + Dienogest is an estrogen/progestin COC, indicated for use by women to prevent pregnancy. (1) The efficacy of Estradiol + Dienogest in women with a body mass index (BMI) of >30 kg/m2 has not been evaluated. • Treatment of heavy menstrual bleeding in women without organic pathology who choose to use an oral contraceptive as their method of contraception.	**CONTRAINDICATIONS:** • Undiagnosed abnormal uterine bleeding. • Breast cancer or other estrogen- or progestin-sensitive cancer. • Pregnancy **SIDE EFFECTS:** The most common adverse reactions (≥ 2%) in clinical trials for Estradiol Valerate + Dienogest are headache (including migraines) 13%, breast pain 7%, menstrual disorders 7%, nausea or vomiting 6%, acne 4%, mood changes 3% and increased weight 3%.	**New** **Estradiol** 60mg/100gm Vaginal Gel, **Estradiol** 2mg Tablet, **Drospirenone + Estradiol** 500mcg + 1mg Tablet, **Drospirenone + Estradiol** 250mcg + 500mcg Tablet & **Dienogest** 2mg Tablet	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						WARNINGS AND PRECAUTIONS: • Headache: Evaluate significant change in headaches and discontinue Estradiol Valerate + Dienogest if indicated. • Uterine bleeding: Evaluate irregular bleeding or amenorrhea.				
208.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Estradiol Valerate BP 2mg + Dienogest BP 2mg Film Coated Tablet	Estradiol Valerate BP 2mg + Dienogest BP 2mg	Contraceptives	• Estradiol + Dienogest is an estrogen/progestin COC, indicated for use by women to prevent pregnancy. (1) The efficacy of Estradiol + Dienogest in women with a body mass index (BMI) of >30 kg/m2 has not been evaluated. • Treatment of heavy menstrual bleeding in women without organic pathology who choose to use an oral contraceptive as their method of contraception.	**CONTRAINDICATIONS:** • Undiagnosed abnormal uterine bleeding. • Breast cancer or other estrogen- or progestin-sensitive cancer. • Pregnancy **SIDE EFFECTS:** The most common adverse reactions (≥ 2%) in clinical trials for Estradiol Valerate + Dienogest are headache (including migraines) 13%, breast pain 7%, menstrual disorders 7%, nausea or vomiting 6%, acne 4%, mood changes 3% and increased weight 3%. **WARNINGS AND PRECAUTIONS:** • Headache: Evaluate significant change in headaches and discontinue Estradiol Valerate + Dienogest if indicated. • Uterine bleeding: Evaluate irregular bleeding or amenorrhea.	**New** **Estradiol** 60mg/100gm Vaginal Gel, **Estradiol** 2mg Tablet, **Drospirenone + Estradiol** 500mcg + 1mg Tablet, **Drospirenone + Estradiol** 250mcg + 500mcg Tablet & **Dienogest** 2mg Tablet	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
209.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur. Nuvista Pharma Ltd.	Estradiol Valerate BP 1mg Film Coated Tablet	Estradiol Valerate BP 1mg	Hormone	• Treatment of moderate to severe vasomotor symptoms associated with the menopause. • Treatment of moderate to severe symptoms of vulvar and vaginal atrophy associated with the menopause. When prescribing solely for the treatment of symptoms of vulvar and vaginal atrophy, topical vaginal products should be considered. • Treatment of hypoestrogenism due to hypogonadism, castration or primary ovarian failure. • Treatment of breast cancer (for palliation only) in appropriately selected women and men with metastatic disease. • Treatment of advanced androgen-dependent carcinoma of the prostate (for palliation only). • Prevention of osteoporosis. When prescribing solely for the prevention of postmenopausal osteoporosis, therapy should only be considered for women at significant risk of osteoporosis and for whom non-estrogen medications are not considered to be appropriate.	**CONTRAINDICATIONS:** • Known or suspected estrogen-dependent neoplasia. • Known or suspected pregnancy. **SIDE EFFECTS:** Increase or decrease in weight Reduced carbohydrate tolerance Aggravation of porphyria Edema Arthralgias; leg cramps Changes in libido Urticaria, Angioedema, Anaphylactoid/anaphylactic reactions Hypocalcemia Exacerbation of asthma Increased triglycerides. **WARNINGS AND PRECAUTIONS:** Estrogen administration may lead to severe hypercalcemia in patients with breast cancer and bone metastases. If hypercalcemia occurs, use of the drug should be stopped and appropriate measures taken to reduce the serum calcium level. Physicians are advised to discuss the patient information leaflet with patients for whom they prescribe Estradiol Valerate.	**New** **Estradiol** 2mg Tablet	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
210.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Estradiol Valerate BP 3mg Film Coated Tablet	Estradiol Valerate BP 3mg	Hormone	The symptomatic relief of menopausal symptoms. It is may also contribute to the prevention of osteoporosis in naturally occurring or surgically induced estrogen-deficiency states when combined with other important therapeutics such as diet, calcium and vitamin D intake, smoking cessation and regular physical weight bearing exercises.	**CONTRAINDICATIONS:** • Known or suspected estrogen-dependent malignant neoplasia (e.g., endometrial cancer). • Known or suspected pregnancy. • Hypersensitivity **SIDE EFFECTS:** • Increased blood sugar levels; decreased glucose tolerance • Abdominal discomfort	**New** **Estradiol** 2mg Tablet	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						(cramps, pressure, pain, bloating); nausea; vomiting.				
211.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Bilastine INN 0.25gm/100 ml Oral Solution	Bilastine INN 0.25gm/100ml	Antihistamine	Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria.	**CONTRAINDICATIONS:** Hypersensitivity to the active substance Bilastine or to any of the excipients. **SIDE EFFECTS:** • Somnolence • Headache	**New** **Bilastine** 20mg Tablet	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
212.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Carbonyl Iron INN 88.5mg + Ferrous Gluconate BP 12.951mg (E.q. to Elemental Iron 1.5mg) + Folic Acid BP 1mg + Cyanocobalamin USP 1.2mg + Ascorbic Acid USP 120mg + Docusate Sodium USP 50mg Film Coated Tablet	Carbonyl Iron INN 88.5mg + Ferrous Gluconate BP 12.951mg (E.q. to Elemental Iron 1.5mg) + Folic Acid BP 1mg + Cyanocobalamin USP 1.2mg + Ascorbic Acid USP 120mg + Docusate Sodium USP 50mg	Drug used in Anemia and other Blood disorder	It is indicating for the treatment of all anemias' that are responsive to oral iron therapy.	**CONTRAINDICATIONS:** Hypersensitivity **SIDE-EFFECTS:** • Diarrhea • Nausea • Vomiting	**New** Elemental Iron + Folic Acid + Nicotinamide + Pyridoxine Hydrochloride + Riboflavin + Vitamin B1 + Zinc 47 mg + 500 mcg + 20 mg + 2 mg + 2 mg + 5 mg + 22.5 mg Capsule	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
213.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Sarecycline HCl 150mg Film Coated Tablet	Sarecycline HCl 150mg	Anti-infective	Sarecycline is a tetracycline-class drug indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.	**CONTRAINDICATIONS:** Sarecycline is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines. **SIDE-EFFECTS:** Most common adverse reaction (incidence ≥ 1%) is nausea. **WARNINGS AND PRECAUTIONS:**	**New**	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						The use of Sarecycline during tooth development (second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). If Clostridium difficile associated Diarrhea (antibiotic associated colitis) occurs, discontinue SARECYCLINE. Central nervous system side effects, including light-headedness, dizziness or vertigo, have been reported with tetracycline use. Patients who experience these symptoms should be cautioned about driving vehicles or using hazardous machinery. These symptoms may disappear during therapy and may disappear when the drug is discontinued. SARECYCLINE may cause intracranial hypertension. Discontinue SARECYCLINE if symptoms occur. Photosensitivity can occur with SARECYCLINE. Patients should minimize or avoid exposure to natural or artificial sunlight.				
214.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Armodafinil INN 50mg Tablet	Armodafinil INN 50mg	Adrenergic	Armodafinil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea (OSA), narcolepsy, or shift work disorder (SWD). **LIMITATIONS OF USE:** In OSA, It is indicated to treat excessive sleepiness and not as treatment for the underlying obstruction.	**CONTRAINDICATIONS**: Armodafinil is contraindicated in patients with known hypersensitivity to modafinil or Armodafinil. **SIDE-EFFECTS:** Most common adverse reactions (≥5%): headache, nausea, dizziness, and insomnia. **WARNINGS AND PRECAUTIONS:** • Serious Rash, including Stevens - Johnson	**Armodafinil** 150mg Tablet **Armodafinil** 250mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						syndrome: discontinue ARMODAFINIL at the first sign of rash, unless the rash is clearly not drug-related. • DRESS/Multi-organ Hypersensitivity Reactions: if suspected, discontinue ARMODAFINIL.				
215.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Calcium Carbonate (Heavy) USP 1498.382mg + Dry Vitamin D3 (Cholecalciferol) USP 5mg + Vitamin K2 INN 0.09mg Film Coated Tablet	Calcium Carbonate (Heavy) USP 1498.382mg + Dry Vitamin D3 (Cholecalciferol) USP 5mg + Vitamin K2 INN 0.09mg	Metals, Salts, Minerals and Calcium Preparations	This combination is used as supplement to prevent or treat low blood calcium levels in people who do not get enough calcium levels such as bone loss (osteoporosis), weak bones (osteomalacia/rickets), decreased activity of the parathyroid gland (hyperparathyroidism), and a certain muscle disease (latent tetany).	**CONTRAINDICATIONS:** None **SIDE-EFFECTS:** • Nausea • Constipation • Decreased appetite	**New** **Calcium + Vitamin D3** 500 mg + 200 IU Tablet	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
216.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Daptomycin 350mg/Vial Injection	Daptomycin INN 350mg/Vial	Anti-infective	It is a lipopeptide antibacterial indicated for the treatment of- • Complicated skin and skin structure infections (cSSSI) in adult patients • Staphylococcus aureus bloodstream infections (bacteremia), including those with right-sided infective endocarditis in adult patients. **LIMITATIONS OF USE:** • Daptomycin for Injection is not indicated for the treatment of pneumonia. • Daptomycin for Injection is not indicated for the treatment of left-sided infective endocarditis due to S. aureus. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Daptomycin for Injection and other antibacterial drugs, Daptomycin for Injection should be used to treat infections that are proven or strongly suspected to be caused by bacteria	**CONTRAINDICATIONS:** Known hypersensitivity to daptomycin **SIDE-EFFECTS:** **Adult cSSSI Patients:** The most common adverse reactions that occurred in ≥2% of adult cSSSI patients receiving daptomycin4 mg/kg were diarrhea, headache, dizziness, rash, abnormal liver function tests, elevated creatinine phosphokinase (CPK), urinary tract infections, hypotension, and dyspne. **Adult S. aureus bacteremia/endocarditis Patients:** The most common adverse reactions that occurred in ≥5% of S. aureus bacteremia/endocarditis patients receiving daptomycin6 mg/kg were sepsis, bacteremia, abdominal pain, chest pain, edema, pharyngolaryngeal pain,	**New**	USFDA DCC এর ২৪২ তম সভায় প্রয়োজন নাই বিধায় আবেদন নামঞ্জুর করা হয়।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						pruritus, increased sweating, insomnia, elevated CPK and hypertension. **<u>WARNINGS AND PRECAUTIONS:</u>** **Anaphylaxis/hypersensitivity reactions (including life-threatening):** Discontinue daptomycin and treat signs/symptoms. **Myopathy and rhabdomyolysis:** Monitor CPK levels and follow muscle pain or weakness; if elevated CPK or myopathy occurs, consider discontinuation of daptomycin. **Eosinophilic pneumonia:** Discontinue daptomycin and consider treatment with systemic steroids. **Peripheral neuropathy:** Monitor for neuropathy and consider discontinuation. **Potential nervous system and/or muscular system effects in pediatric patients younger than 12 months:** Avoid use of daptomycin in this age group. **Clostridium difficile–associated diarrhea:** Evaluate patients if diarrhea occurs. **Persisting or relapsing S. aureusbacteremia/endocarditis**: Perform susceptibility testing and rule out sequestered foci of infection. Decreased efficacy was observed in adult patients with moderate baseline renal impairment.				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
217.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Daptomycin 500mg/Vial Injection	Daptomycin INN 500mg/Vial	Anti-infective	It is a lipopeptide antibacterial indicated for the treatment of- • Complicated skin and skin structure infections (cSSSI) in adult patients • Staphylococcus aureus bloodstream infections (bacteremia), including those with right-sided infective endocarditis in adult patients. • Staphylococcus aureus bloodstream infections (bacteremia) in pediatric patients (1 to 17 years of age. **LIMITATIONS OF USE:** • Daptomycin for Injection is not indicated for the treatment of pneumonia. • Daptomycin for Injection is not indicated for the treatment of left-sided infective endocarditis due to S. aureus. • Daptomycin for Injection is not recommended in pediatric patients younger than one year of age due to the risk of potential effects on muscular, neuromuscular, and/or nervous systems (either peripheral and/or central) observed in neonatal dogs.	**CONTRAINDICATIONS:** Known hypersensitivity to daptomycin **SIDE-EFFECTS:** **Adult cSSSI Patients**: The most common adverse reactions that occurred in ≥2% of adult cSSSI patients receiving DAPTOMYCIN 4 mg/kg were diarrhea, headache, dizziness, rash, abnormal liver function tests, elevated creatine phosphokinase (CPK), urinary tract infections, hypotension, and dyspnea. **Pediatric cSSSI Patients**: The most common adverse reactions that occurred in ≥2% of pediatric patients receiving DAPTOMYCIN were diarrhea, vomiting, abdominal pain, pruritus, pyrexia, elevated CPK, and headache. **Adult S. aureus bacteremia/endocarditis Patients**: The most common adverse reactions that occurred in ≥5% of S. aureusbacteremia/endocarditis patients receiving DAPTOMYCIN 6 mg/kg were sepsis, bacteremia, abdominal pain, chest pain, edema, pharyngolaryngeal pain, pruritus, increased sweating, insomnia, elevated CPK, and hypertension. **Pediatric S. aureus bacteremia Patients**: The most common adverse reactions that occurred in ≥5% of pediatric patients receiving DAPTOMYCIN were vomiting and elevated CPK. **WARNINGS AND PRECAUTIONS:** Anaphylaxis/hypersensitivity reactions (including life-	**New**	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						threatening): Discontinue DAPTOMYCIN and treat signs/symptoms. Myopathy and rhabdomyolysis: Monitor CPK levels and follow muscle pain or weakness; if elevated CPK or myopathy occurs, consider discontinuation of DAPTOMYCIN. Eosinophilic pneumonia: Discontinue DAPTOMYCIN and consider treatment with systemic steroids. Peripheral neuropathy: Monitor for neuropathy and consider discontinuation. Potential nervous system and/or muscular system effects in pediatric patients younger than 12 months: Avoid use of DAPTOMYCIN in this age group. Clostridium difficile–associated diarrhea: Evaluate patients if diarrhea occurs. Persisting or relapsing S. aureus bacteremia/endocarditis: Perform susceptibility testing and rule out sequestered foci of infection. Decreased efficacy was observed in adult patients with moderate baseline renal impairment.				
218.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Elemental Potassium 20mEq + Elemental Zinc 7.8mg + Elemental Sodium 10mEq + Sodium Chloride 2.045mg + Anhydrous Glucose 25	Elemental Potassium BP 20mEq + Elemental Zinc USP 7.8mg + Elemental Sodium USP 10mE + Sodium Chloride BP 2.045mg + Anhydrous Glucose BP 25 gm/1000ml	Metals, Salts, Minerals and Calcium Preparations	This Oral Solution is an effective alkalinizing agent useful in those conditions where long-term maintenance of alkaline urine is desirable, such as in patients with uric acid and cystine calculi of the urinary tract. In addition, it is a valuable adjuvant when administered with uricosuric agents in gout therapy, since urates tend to crystallize out of acid urine. It is also effective in correcting the acidosis of certain renal tubular disorders.	**CONTRAINDICATIONS:** Severe renal impairment with oliguria or azotemia, untreated Addison's disease, or severe myocardial damage. In certain situations, when patients are on a sodium-restricted diet, the use of potassium citrate may be preferable; or, when patients are on a potassium-restricted diet, the use of sodium citrate may be preferable.	**New** **Anhydrous Glucose + Potassium Chloride + Sodium Chloride + Trisodium Citrate** 6.75 gm + 750 mg + 1.3 gm + 1.45 gm Oral Saline	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		gm/1000ml Solution				**SIDE-EFFECTS:** It is generally well tolerated without any unpleasant side effects when given in recommended doses to patients with normal renal function and urinary output. However, as with any alkalinizing agent, caution must be used in certain patients with abnormal renal mechanisms to avoid development of hypercalcemia or alkalosis, especially in the presence of hypocalcaemia. Potassium intoxication causes listlessness, weakness, mental confusion, and tingling of extremities.				
219.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Elemental Potassium 4.7mEq + Elemental Sodium 2.3mEq + Sodium Chloride 197.853mg + Anhydrous Glucose 5.7 gm/Sachet	Elemental Potassium BP 4.7mEq + Elemental Sodium USP 2.3mEq + Sodium Chloride BP 197.853mg + Anhydrous Glucose BP 5.7 gm	Metals, Salts, Minerals and Calcium Preparations	This Oral Solution is an effective alkalinizing agent useful in those conditions where long-term maintenance of alkaline urine is desirable, such as in patients with uric acid and cystine calculi of the urinary tract. In addition, it is a valuable adjuvant when administered with uricosuric agents in gout therapy, since urates tend to crystallize out of acid urine. It is also effective in correcting the acidosis of certain renal tubular disorders.	**CONTRAINDICATIONS:** Severe renal impairment with oliguria or azotemia, untreated Addison's disease, or severe myocardial damage. In certain situations, when patients are on a sodium-restricted diet, the use of potassium citrate may be preferable; or, when patients are on a potassium-restricted diet, the use of sodium citrate may be preferable. **SIDE-EFFECTS:** It is generally well tolerated without any unpleasant side effects when given in recommended doses to patients with normal renal function and urinary output. However, as with any alkalinizing agent, caution must be used in certain patients with abnormal renal mechanisms to avoid development of hypercalcemia or alkalosis, especially in the presence of hypocalcaemia. Potassium	**New** **Anhydrous Glucose + Potassium Chloride + Sodium Chloride + Trisodium Citrate** 6.75 gm + 750 mg + 1.3 gm + 1.45 gm Oral Saline	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						intoxication causes listlessness, weakness, mental confusion, and tingling of extremities.				
220.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Zinc Mono-L-Methionine Sulphate INN 142.527mg (E.q. to 30mg of Elemental Zinc)/Capsule	Zinc Mono-L-Methionine Sulphate INN 142.527mg (E.q. to 30mg of Elemental Zinc)/Capsule	Metals, Salts, Minerals and Calcium Preparations	It is indicated for - • **Nutrient Metabolism**: Zinc is a constituent of over two dozen enzymes involved in digestion and metabolism, including healthy storage and metabolism of carbohydrates. It is also related to the normal absorption and actions of the B vitamins. • **Immune Support**: Zinc plays an important role in supporting the body's defense system, promoting healthy neutrophil, natural killer cell, and T-lymphocyte function. • **Tissue Development and Repair**: Zinc plays a fundamental role in collagen formation and healthy tissue development, including enzymes vital to tissue respiration. It is also essential for normal fetal and reproductive development, as well as contributing to healthy prostatic function.	**CONTRAINDICATIONS:** It is contraindicated in those who are hypersensitive to any component of a zinc-containing supplement. **SIDE-EFFECTS:** If pregnant or lactating, consult your physician before taking this product. In rare cases, zinc can cause nausea, vomiting or a metallic taste. High intakes of zinc can cause fever, diarrhea or fatigue and may impair immune response.	**New** **Zinc** 20mg Tablet **Zinc** 10mg/5ml Syrup **Ferrous Sulphate + Folic Acid + Zinc** 150mg + 500mcg + 22.5mg Capsule	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
221.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Acebrophylline USP 100mg Film Coated Tablet	Acebrophylline USP 100mg	Drug used in Bronchial Asthma, Chronic obstructive pulmonary disease (COPD)	Acebrophylline, a xanthine derivative, is prescribed as a bronchodilator for the treatment of bronchial asthma and COPD in adults. This drug alter mucus gel secretion phase by lowering viscosity and increasing the serous gel phase. By augmenting ciliary motility, Acebrophylline increases the mucociliary clearance. **LIMITATIONS OF USE:** Caution should be exercised in patients with cardiac arrhythmias, other cardiovascular diseases, hyperthyroidism or hypertension, gastric and duodenal ulceration or convulsive disorders. Patients with hepatic and renal insufficiency should take it with caution.	**CONTRAINDICATIONS:** • Hypersensitivity to ambroxol, acebrophylline, theophylline or any other xanthine derivativel • Patients suffering from acute myocardial infarction • Patients with hypotension, hemodynamic instability, and arrhythmias • Patients with renal disease or liver disorder **SIDE-EFFECTS:** • Transient nausea and dizziness • abdominal discomfort, stomach/abdominal distension, vomiting, abdominal pain, diarrhea, constipation, heart burn, loss of appetite, esophageal bleeding, rashes, urticaria, itching, drowsiness.	**New**	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
222.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Tizanidine USP 4mg Capsule	Tizanidine USP 4mg	Skeleton Muscle Relaxant	Tizanidine is a central alpha-2-adrenergic agonist indicated for the management of spasticity. Because of the short duration of therapeutic effect, treatment with Tizanidine should be reserved for those daily activities and times when relief of spasticity is most important	**CONTRAINDICATIONS:** Concomitant use with potent inhibitors of CYP1A2, such as fluvoxamine or ciprofloxacin. **SIDE-EFFECTS:** The most common adverse reactions (greater than 2% of 264 patients taking tizanidine and greater than in placebo-treated patients in three multiple dose, placebo-controlled studies) were dry mouth, somnolence, asthenia, dizziness, urinary tract infection, constipation, liver function tests abnormal, vomiting, speech disorder, amblyopia, urinary frequency, flu syndrome, SGPT/ALT increased, dyskinesia, nervousness, pharyngitis, and rhinitis **WARNINGS AND PRECAUTIONS:** • Hypotension: monitor for signs and symptoms of hypotension, in particular in patients receiving concurrent antihypertensive; Tizanidine should not be used with other α2-adrenergic agonists. • Sedation: Tizanidine may interfere with everyday activities; sedative effects of Tizanidine, alcohol, and other CNS depressants are additive.	**Tizanidine** 2mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
223.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Phenazopyridine HCl 200mg Film Coated Tablet	Phenazopyridine HCl USP 200mg	Opioid Analgesics	It is indicated for the symptomatic relief of pain, burning, urgency frequency, and other discomforts arising from irritation of the mucosa of the lower urinary tract caused by infection, trauma, surgery, endoscopic procedures, or the passage of sounds or catheters. **LIMITATIONS OF USE:** The use of Phenazopyridine HCl for relief of symptoms should not delay definitive diagnosis and treatment of causative conditions. Because it provides only symptomatic relief, prompt appropriate treatment of the cause of pain must be instituted and Phenazopyridine HCl should be discontinued when symptoms are controlled. The analgesic action may reduce or eliminate the need for systemic analgesics or narcotics. It is, however, compatible with antibacterial therapy and can help to relieve pain and discomfort during the interval before antibacterial therapy controls the infection. Treatment of a urinary tract infection with Phenazopyridine HCl should not exceed 2 days because there is a lack of evidence that the combined administration of Phenazopyridine HCl and an antibacterial provides greater benefit than administration of the antibacterial alone after 2 days.	**CONTRAINDICATIONS:** Hypersensitivity, Renal Insufficiency **SIDE-EFFECTS:** Headache, rash, pruritus and occasional gastrointestinal disturbance. An anaphylactoid like reaction has been described. Methemoglobinemia, hemolytic anemia, renal and hepatic toxicity have been reported, usually at over dosage levels.	**New**	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
224.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Diethyltoluamide 12% Cream	Diethyltoluamide INN 12%	Other Classification	Diethyltoluamide is an active ingredient that is predominantly indicated for as an insect repellant used to repel biting pests like mosquitoes and ticks. When used appropriately, Diethyltoluamide (DEET) containing products are designed to be applied directly to people's skin as a means to elicit a repelling action to keep insects from targeting human skin. At the amounts and doses recommended for use on human children and adults, noticeable absorption or systemic exposure is not expected. Owing to the proportional difference in size between humans and insects, however, the exposure of insects to the applied DEET (whether topically or via inhalation of DEET) is expected to be enough to interfere with the insects' sensory attraction to human skin.	**CONTRAINDICATIONS:** Hypersensitivity **SIDE-EFFECTS:** Not Available	**New**	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***Mosquito repellent*** ***জাতীয় প্রডাক্ট ঔষধ হিসেবে অনুমোদনের প্রয়োজন নেই।***
225.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Diethyltoluamide 10% Cream	Diethyltoluamide INN 10%	Other Classification	Diethyltoluamide is an active ingredient that is predominantly indicated for as an insect repellant used to repel biting pests like mosquitoes and ticks. When used appropriately, Diethyltoluamide (DEET) containing products are designed to be applied directly to people's skin as a means to elicit a repelling action to keep insects from targeting human skin. At the amounts and doses recommended for use on human children and adults,	**CONTRAINDICATIONS:** Hypersensitivity **SIDE-EFFECTS:** Not Available	**New**	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***Mosquito repellent*** ***জাতীয় প্রডাক্ট ঔষধ হিসেবে অনুমোদনের প্রয়োজন নেই।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					noticeable absorption or systemic exposure is not expected. Owing to the proportional difference in size between humans and insects, however, the exposure of insects to the applied DEET (whether topically or via inhalation of DEET) is expected to be enough to interfere with the insects' sensory attraction to human skin.					
226.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Thiamine Mononitrate (Vitamin B1) USP 100mg + Pyridoxine Hydrochloride (Vitamin B6) USP 100mg + Cyanocobalamin 1% (Vitamin B12) USP 500mg Film Coated Tablet	Thiamine Mononitrate (Vitamin B1) USP 100mg + Pyridoxine Hydrochloride (Vitamin B6) USP 100mg + Cyanocobalamin 1% (Vitamin B12) USP 500mg	Vitamins and Combinations	Multivitamin is a once-daily multivitamin/mineral formula, coupling fundamental support with convenience in a gentle hypoallergenic formula well tolerated by sensitive individuals. It provides a comprehensive profile of highly bio-available vitamins, fully-chelated minerals and antioxidants to support optimal health	**CONTRAINDICATIONS:** Hypersensitivity, Pregnancy **SIDE-EFFECTS:** • Upset stomach • Headache • Unusual or unpleasant taste in your mouth	**New** **Cyanocobalamin + Pyridoxine Hydrochloride + Vitamin B1** 200mcg + 200mg + 100mg Tablet **Cyanocobalamin + Elemental Iron + Folic Acid** 25mg + 100mg + 1mg/5ml Syrup	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।
227.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Halobetasol Propionate USP 0.01gm and Tazarotene INN 0.045gm/100gm Topical Lotion	Halobetasol Propionate USP 0.01gm and Tazarotene INN 0.045gm/100gm	Skin and Mucous Membrane Preparations	This Lotion is a combination of halobetasol propionate and tazarotene indicated for the topical treatment of plaque psoriasis in adults.	**CONTRAINDICATIONS:** This Lotion is contraindicated in pregnancy. **SIDE-EFFECTS:** The most common adverse reactions are contact dermatitis (7%), application site pain (3%), folliculitis (2%), skin atrophy (2%), and excoriation (2%). **WARNINGS AND PRECAUTIONS:** • Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression may occur, with the potential for glucocorticosteroid insufficiency during or after treatment. • Systemic effects of topical corticosteroids may also include Cushing's syndrome, hyperglycemia, and glucosuria.	**New** **Halobetasol Propionate** 50mg/100gm Cream **Halobetasol Propionate** 50mg/100gm Ointment	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						• Systemic absorption may require evaluation for HPA axis suppression.				
228.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Plazomicin 500 mg/10mL Injection	Plazomicin INN 500 mg/10mL	Anti-infective	Plazomicin is an aminoglycoside antibacterial indicated for the treatment of patients 18 years of age or older with Complicated Urinary Tract Infections (cUTI) including Pyelonephritis. • As only limited clinical safety and efficacy data are available, reserves PLAZOMICIN for use in patients who have limited or no alternative treatment options. • To reduce the development of drug-resistant bacteria and maintain effectiveness of PLAZOMICIN and other antibacterial drugs, PLAZOMICIN should be used only to treat infections that are proven or strongly suspected to be caused by susceptible microorganisms.	**CONTRAINDICATIONS:** Plazomicin is contraindicated in patients with known hypersensitivity to any aminoglycoside. **SIDE-EFFECTS:** Most common adverse reactions (≥ 1% of patients treated with PLAZOMICIN) are decreased renal function, diarrhea, hypertension, headache, nausea, vomiting and hypotension. **WARNINGS AND PRECAUTIONS:** Hypersensitivity Reactions, including anaphylaxis: Reported for aminoglycoside. If an allergic reaction occurs, discontinue PLAZOMICIN. Clostridium difficile-Associated Diarrhea: Reported for nearly all systemic antibacterial drugs. Evaluate if diarrhea occurs	**New**	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
229.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Mirogabalin 2.5mg Film Coated Tablet	Mirogabalin INN 2.5mg	Neuromuscular Blocking	Inhibits calcium ions influx and suppresses release of neurotransmitters in the nervous system to reduce pain. It is usually used to treat peripheral neuropathic pain.	**CONTRAINDICATIONS:** Hypersensitivity, Pregnancy **SIDE-EFFECTS:** General malaise Loss of appetite Nausea, vomiting Jaundice [liver dysfunction]	**New**	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
230.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Mirogabalin 5mg Film Coated Tablet	Mirogabalin INN 5mg	Neuromuscular Blocking	Inhibits calcium ions influx and suppresses release of neurotransmitters in the nervous system to reduce pain. It is usually used to treat peripheral neuropathic pain.	**CONTRAINDICATIONS:** Hypersensitivity, Pregnancy **SIDE-EFFECTS:** General malaise, Loss of appetite, Nausea, vomiting, Jaundice [liver dysfunction]	**New**	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
231.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Mirogabalin 10mg Film Coated Tablet	Mirogabalin INN 10mg	Neuromuscular Blocking	Inhibits calcium ions influx and suppresses release of neurotransmitters in the nervous system to reduce pain. It is usually used to treat peripheral neuropathic pain.	**Contraindications:** Hypersensitivity, Pregnancy **Side-effects:** General malaise, Loss of appetite, Nausea, vomiting, Jaundice [liver dysfunction]	**New**	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
232.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Mirogabalin 15mg Film Coated Tablet	Mirogabalin INN 15mg	Neuromuscular Blocking	Inhibits calcium ions influx and suppresses release of neurotransmitters in the nervous system to reduce pain. It is usually used to treat peripheral neuropathic pain.	**CONTRAINDICATIONS:** Hypersensitivity, Pregnancy **SIDE-EFFECTS:** General malaise Loss of appetite Nausea, vomiting Jaundice [liver dysfunction	**New**	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
233.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Olmesartan Medoxomil BP 40mg + Amlodipine BP 10mg + Hydrochlorothiazide BP 12.5mg Film Coated Tablet	Olmesartan Medoxomil BP 40mg + Amlodipine BP 10mg + Hydrochlorothiazide BP 12.5mg	Antihypertensive	• Olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets is a combination of an angiotensin 2 receptor blocker, a dihydropyridine calcium channel blocker, and a thiazide diuretic indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. • Olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets are not indicated for initial therapy.	**CONTRAINDICATIONS:** • Anuria, Hypersensitivity to sulfonamide-derived drugs. • Does not co administer aliskiren with olmesartan medoxomil, amlodipine and hydrochlorothiazide in patients with diabetes. **SIDE-EFFECTS:** Most common adverse reactions (incidence ≥2%) are dizziness, peripheral edema, headache, fatigue, nasopharyngitis, muscle spasms, nausea, upper respiratory tract infection, diarrhea, urinary tract infection, and joint swelling. **WARNINGS AND PRECAUTIONS:** • Avoid fetal or neonatal exposure. • Hypotension in volume- or salt-depleted patients with treatment initiation may occur. Correct volume-depletion prior to administration. • Increased angina or	**New** **Olmesartan Medoxomil + Amlodipine + Hydrochlorothiazide** (20mg + 5mg + 12.5mg) Film Coated Tablet. **Olmesartan Medoxomil + Amlodipine + Hydrochlorothiazide** (40mg + 5mg + 12.5mg) Film Coated Tablet.	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						myocardial infarction with calcium channel blockers may occur upon dosage initiation or increase.				
234.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Olmesartan Medoxomil 40mg + Amlodipine 10mg + Hydrochlorothiazide 25mg Film Coated Tablet	Olmesartan Medoxomil BP 40mg + Amlodipine BP 10mg + Hydrochlorothiazide BP 25mg	Antihypertensive	• Olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets is a combination of an angiotensin 2 receptor blocker, a dihydropyridine calcium channel blocker, and a thiazide diuretic indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. • Olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets are not indicated for initial therapy.	**CONTRAINDICATIONS:** Anuria, Hypersensitivity to sulfonamide-derived drugs. Does not co administer aliskiren with olmesartan medoxomil, amlodipine and hydrochlorothiazide in patients with diabetes. **SIDE-EFFECTS:** Most common adverse reactions (incidence ≥2%) are dizziness, peripheral edema, headache, fatigue, nasopharyngitis, muscle spasms, nausea, upper respiratory tract infection, diarrhea, urinary tract infection, and joint swelling. **WARNINGS AND PRECAUTIONS:** Avoid fetal or neonatal exposure. Hypotension in volume- or salt-depleted patients with treatment initiation may occur. Correct volume-depletion prior to administration. Increased angina or myocardial infarction with calcium channel blockers may occur upon dosage initiation or increase. Avoid in patients with severely impaired renal function (creatinine clearance ≤30 mL/min). Withhold or discontinue olmesartan medoxomil, amlodipine and hydrochlorothiazide if progressive renal impairment becomes evident. Thiazides should be used with	**New** **Olmesartan Medoxomil + Amlodipine + Hydrochlorothiazide** (20mg + 5mg + 12.5mg) Film Coated Tablet. **Olmesartan Medoxomil + Amlodipine + Hydrochlorothiazide** (40mg + 5mg + 12.5mg) Film Coated Tablet.	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						caution in patients with mildly to moderately impaired hepatic function or progressive liver disease. Avoid in patients with severely impaired hepatic function. Observe for signs of fluid or electrolyte imbalance (5.6). Thiazide diuretics may cause an exacerbation or activation of systemic lupus erythematosus. Thiazides have been associated with acute angle-closure glaucoma. Sprue- like enteropathy has been reported. Consider discontinuation of olmesartan medoxomil, amlodipine and hydrochlorothiazide in cases where no other etiology is found.				
235.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Spironolactone BP 25mg + Hydrochlorothiazide BP 25mg Film Coated Tablet	Spironolactone BP 25mg + Hydrochlorothiazide BP 25mg	Antihypertensive	**EDEMATOUS CONDITIONS FOR PATIENTS WITH:** **Congestive heart failure:** • For the management of edema and sodium retention when the patient is only partially responsive to, or is intolerant of, other therapeutic measures, • The treatment of diuretic-induced hypokalemia in patients with congestive heart failure when other measures are considered inappropriate, • The treatment of patients with congestive heart failure taking digitalis when other therapies are considered inadequate or inappropriate. **Cirrhosis of the liver accompanied by edema and/or ascites:** Aldosterone levels may be exceptionally high in this condition. SPIRONOLACTONE + HYDROCHLOROTHIAZIDE is indicated for maintenance therapy together with bed rest and the restriction of fluid and sodium. **The Nephrotic Syndrome:** For nephrotic patients when treatment of the underlying disease, restriction of fluid and sodium intake, and the use of other diuretics do not provide an adequate response. **Essential hypertension:** For patients with essential hypertension in whom other measures are considered inadequate or inappropriate, In hypertensive patients for the treatment of a diuretic-induced hypokalemia when other measures are considered	**CONTRAINDICATIONS:** Spironolactone + Hydrochlorothiazide is contraindicated in patients with anuria, acute renal insufficiency, significant impairment of renal excretory function, hypercalcemia, hyperkalemia, Addison's disease or other conditions associated with hyperkalemia, and in patients who are allergic to thiazide diuretics or to other sulfonamide-derived drugs. Spironolactone + Hydrochlorothiazide may also be contraindicated in acute or severe hepatic failure. **SIDE EFFECTS:** The following adverse reactions have been reported and, within each category (body system), are listed in order of decreasing severity. • Cardiovascular: Hypotension including	**New** **Frusemide + Spironolactone** 20mg + 50mg Tablet **Hydrochlorothiazide + Losartan Potassium** 12.5mg + 25mg Tablet **Hydrochlorothiazide + Olmesartan Medoxomil** 12.5mg + 20mg Tablet **Hydrochlorothiazide + Telmisartan** 12.5mg + 40mg Tablet **Hydrochlorothiazide + Valsartan** 12.5 mg + 80 mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					inappropriate. **USAGE IN PREGNANCY** The routine use of diuretics in an otherwise healthy woman is inappropriate and exposes mother and fetus to unnecessary hazard. Diuretics do not prevent development of toxemia of pregnancy, and there is no satisfactory evidence that they are useful in the treatment of developing toxemia. Edema during pregnancy may arise from pathologic causes or from the physiologic and mechanical consequences of pregnancy. SPIRONOLACTONE + HYDROCHLOROTHIAZIDE is indicated in pregnancy when edema is due to pathologic causes just as it is in the absence of pregnancy (however, see Precautions: Pregnancy). Dependent edema in pregnancy, resulting from restriction of venous return by the expanded uterus, is properly treated through elevation of the lower extremities and use of support hose; use of diuretics to lower intravascular volume in this case is unsupported and unnecessary. There is hypervolemia during normal pregnancy which is not harmful to either the fetus or the mother (in the absence of cardiovascular disease), but which is associated with edema, including generalized edema, in the majority of pregnant women. If this edema produces discomfort, increased recumbency will often provide relief. In rare instances, this edema may cause extreme discomfort that is not relieved by rest. In these cases, a short course of diuretics may provide relief and may be appropriate.	orthostatic hypotension (may be aggravated by alcohol, barbiturates, narcotics, or antihypertensive drugs). • Digestive: Pancreatitis, jaundice (intrahepatic cholestatic jaundice), diarrhea, vomiting, sialoadenitis, cramping, constipation, gastric irritation, nausea, anorexia. • Musculoskeletal: Muscle spasm. **WARNINGS:** Administration of SPIRONOLACTONE + HYDROCHLOROTHIAZIDE with the following drugs or potassium sources may lead to severe hypercalcemia: • other potassium-sparing diuretics • ACE inhibitors • angiotensin II receptor antagonists • aldosterone blockers • Non-steroidal anti-inflammatory drugs (NSAIDs), e.g., indomethacin.				
236.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Posaconazole 4gm /100 ml Oral Suspension	Posaconazole INN 4gm /100 ml	Antifungal	Posaconazole is an azole antifungal agent indicated for: injection, delayed-release tablets, and oral suspension • prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy. **Oral suspension** • treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole.	**CONTRAINDICATIONS:** Do not administer to persons with known hypersensitivity to posaconazole or other azole antifungal agents. Do not coadminister Posaconazole with the following drugs; Posaconazole increases concentrations of: Sirolimus: can result in sirolimus toxicity CYP3A4 substrates (pimozide, quinidine): can result in QTc	**New**	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						interval prolongation and cases of TdP HMG-CoA Reductase Inhibitors Primarily Metabolized Through CYP3A4: can lead to rhabdomyolysis Ergot alkaloids: can result in ergotis. **SIDE-EFFECTS:** Common treatment-emergent adverse reactions in studies with posaconazole are diarrhea, nausea, fever, vomiting, headache, coughing, and hypokalemia. **WARNINGS AND PRECAUTIONS:** Calcineurin-Inhibitor Toxicity: Posaconazole increases concentrations of cyclosporine or tacrolimus; reduce dose of cyclosporine and tacrolimus and monitor concentrations frequently. Arrhythmias and QTc Prolongation: Posaconazole has been shown to prolong the QTc interval and cause cases of TdP. Administer with caution to patients with potentially proarrhythmic conditions. Do not administer with drugs known to prolong QTc interval and metabolized through CYP3A4. Electrolyte Disturbances: Monitor and correct, especially those involving potassium (K+), magnesium (Mg++), and calcium (Ca++), before and during Posaconazole therapy. Hepatic Toxicity: Elevations in LFTs may occur. Discontinuation should be considered in patients who develop abnormal LFTs or monitor LFTs during treatment.				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Posaconazole injection should be avoided in patients with moderate or severe renal impairment (creatinine clearance <50 mL/min), unless an assessment of the benefit/risk to the patient justifies the use of Posaconazole injection. Midazolam: Posaconazole can prolong hypnotic/sedative effects. Monitor patients and benzodiazepine receptor antagonists should be available. Vincristine Toxicity: Concomitant administration of azole antifungals, including Posaconazole, with vincristine has been associated with neurotoxicity and other serious adverse reactions; reserve azole antifungals, including Posaconazole, for patients receiving a vinca alkaloid, including vincristine, who have no alternative antifungal treatment options.				
237.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	L-Carnitine Fumarate INN 584.819mg (E.q. to L-Carnitine 340mg) + Ubidecarenone BP 50mg + Zinc Ascorbate INN 31.780mg (E.q. to Elemental Zinc 5mg) + Lycopene (As 6% Powder) USP 41.667mg	L-Carnitine Fumarate INN 584.819mg (E.q. to L-Carnitine 340mg) + Ubidecarenone BP 50mg + Zinc Ascorbate INN 31.780mg (E.q. to Elemental Zinc 5mg) + Lycopene (As 6% Powder) USP 41.667mg (E.q. To Lycopene 2.50mg) + Astaxanthin (As 10% Powder) INN 80mg (E.q. to Astaxanthin 8mg)	Other Classification	This combination is mainly used as supplement for the treatment of male infertility. L-Carnitine improves sperm motility; Ubidecarenone improves sperm count and morphology. Zinc is used to increase testosterone level and lycopene acts as an antioxidant in the process of spermatogenesis and Astaxanthin improves sperm health.	**CONTRAINDICATIONS:** Hypersensitivity **SIDE-EFFECTS:** • Diarrhea • Nausea • Vomiting	**New** **Ubidecarenone** 30mg, 60mg Capsule **Astaxanthin** 2mg, 4mg Capsule	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		(E.q. To Lycopene 2.50mg) + Astaxanthin (As 10% Powder) INN 80mg (E.q. to Astaxanthin 8mg) Film Coated Tablet								
238.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Cranberry 1.33gm + D-Mannose 2gm + Potassium Magnesium Citrate 6.52gm/100 ml syrup	Cranberry Pharma grade 1.33gm + D-Mannose BP 2gm + Potassium Magnesium Citrate Pharma Grade 6.52gm/100ml	Diuretics or Anti-infective	Cranberry contains high levels of antioxidants which have health promoting properties. It contains special phyto-chemicals which prevent the adherence of bacteria to membranes. Cranberry, D-Mannose & Potassium Magnesium Citrate syrup is used for urinary tract infection.	**CONTRAINDICATIONS:** Hypersensitivity **SIDE-EFFECTS:** Diarrhea Nausea Vomiting	**New**	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
239.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur	Cranberry 72mg + Vitamin C 100mg + Vitamin E 12mg + Vitamin D3 5mcg Capsule	Cranberry 72mg + Vitamin C 100mg + Vitamin E 12mg + Vitamin D3 5mcg	Diuretics or Anti-infective	Cranberry is used for the prevention and treatment of Urinary Tract Infections. It is also used for kidney stones, neurogenic bladder, to deodorize urine in people with difficulty controlling urination. Vitamin C and E act as antioxidant and Vitamin D3 maintains the health of bones and teeth.	**CONTRAINDICATIONS:** Hypersensitivity **SIDE-EFFECTS:** Diarrhea Mild stomach upset Taken long period of time might increase the chance of getting kidney stones	**New** **Vitamin C** 250mg. 500mg, 1gm Tablet **Vitamin E** 200mg Tablet	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
240.	Nuvista Pharma Ltd.	Dequalinium Chloride 10 mg vaginal Tablet	Dequalinium Chloride INN 10mg	Antiseptic and Disinfectants	Bacterial Vaginosis	**Contraindications:** 1. Hypersensitivity to the active substance or to any of the excipients. 2. Ulceration of the vaginal epithelium and the vaginal portion of the cervix. 3. Young girls who have not yet had their first menstruation, and thus did not reach sexual maturity must not use of it. **Side effects:** Infections and infestations, Nervous system disorder, Gastrointestinal disorders, Reproductive system and breast disorders	NEW	BNF-77 Page No. 812	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
241.	Nuvista Pharma Ltd.	Calcium L-Methyl Folate 0.4 mg Tablet	Calcium L-Methyl Folate USP 0.4 mg	Contraceptives	L-metylfolate 7.5 mg and 15 mg is formulated to meet the distinctive nutritional requirement of individuals who have suboptimal L-methylfolate levels in the cerebrospinal fluid, plasma, and/or red blood cells and have major depressive disorder (MDD).	**Contraindications:** 1. Undiagnosed megaloblastic anaemia 2. Pernicious 3. Aplastic or normocytic anaemias **Side effects:** Upset stomach or throwing up, Belly pain, Not hungry, Diarrhea, Feeling sleepy, Headache, Pimples (acne).	NEW	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
242.	Nuvista Pharma Ltd.	Progesterone 25mg/ml Injection	Progesterone USP 25mg/ml Injection	Hormone	Progesterone USP 25 mg/ml injection is for women who need extra progesterone while undergoing treatment in an Assisted Reproductive Technology (ART) who are unable to use or tolerate vaginal preparations	**Contraindications:** 1. Current or past history of thrombophlebitis, thromboembolic disorders, or cerebral apoplexy. 2. Liver dysfunction or disease 3. Known or suspected malignancy of breast or genital organs. 4. Undiagnosed vaginal bleeding 5. Missed abortion 6. Known sensitivity to progesterone injection **Side effects:** Chest pain and discomfort, Fever and chills, Difficulty in passing urine, Breast pain and tenderness, Muscle and joint pain, White or brownish discharge from the vagina, Headache, Dizziness, Depression, Viral infections, Breast lumps, Loss of vision or blurred vision.	Progesterone 100 mg, 200 mg capsule.	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
243.	Nuvista Pharma Ltd.	Levothyroxine Sodium 75 mcg Tablet	Levothyroxine Sodium USP 75 mcg Tablet	Hormone	Levothyroxine Sodium Tablets are L-thyroxine (T4) indicated for: • Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. • Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.	**Contraindications:** Levothyroxine is contraindicated in patients with untreated subclinical (suppressed serum TSH level with normal T3 and T4 levels) or overt thyrotoxicosis of any etiology and in patients with acute myocardial infarction. Levothyroxine is	Levothyroxine Sodium 25mcg, 50mcg & 100mcg	BNF-77 Page No. 758 and USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						contraindicated in patients with uncorrected adrenal insufficiency since thyroid hormones may precipitate an acute adrenal crisis by increasing the metabolic clearance of glucocorticoids. The drug is contraindicated in patients with hypersensitivity to any of the inactive ingredients. **Side effects:** Fatigue, increased appetite, weight loss, heat intolerance, fever, excessive sweating, headache, hyperactivity, nervousness, anxiety, insomnia, tremors, muscle weakness, Dyspnea, Diarrhea, vomiting, hair loss, impaired fertility.				
244.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Cemiplimab-RWLC 350mg/7ml Injection	Cemiplimab-RWLC INN 350mg/7ml	**Anticancer**	**Cemiplimab-rwlc** is indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation.	**Contraindication:** Cemiplimab-rwlc is contraindicated in patients with known hypersensitivity to Cemiplimab-rwlc or any other components of this product. **Precaution:** Symptoms and signs of immune-mediated adverse reactions should be monitored. Patients should be monitored for signs and symptoms of infusion-related reactions. It can cause fetal harm when administered to a pregnant woman. **Warning:** Included as part of the "Precaution" Section. **Side effects:** The most common side effects are rash, pruritus, diarrhea, nausea, constipation, fatigue, musculoskeletal pain, decreased appetite etc	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
245.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Erdafitinib 3 mg Tablet	Erdafitinib INN 3.00 mg	**Anticancer**	**Erdafitinib** is indicated for the treatment of adult patients with locally advanced or metastatic Urothelial Carcinoma (mUC), that has-Susceptible FGFR3 or FGFR2 genetic alterations, and Progressed during or following at least one line of prior platinum-containing chemo therapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.	**Contraindication:** It is contraindicated in patients with known hypersensitivity to Erdafitinib or any other components of this product. **Precaution:** Erdafitinib can cause ocular disorders, including central serous retinopathy/retinal pigment epithelial detachment (CSR/RPED) resulting in visual field defect. Increases in phosphate levels are a pharmacodynamic effect of Erdafitinib. Monitoring is needed for hyperphosphatemia and manage with dose modifications when required. It can cause fetal harm when administered to a pregnant woman. **Warning:** Included as part of the "Precaution" Section. **Side effects:** The most common side effects are- Ocular Disorders, Hyper phosphatemia.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
246.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Lorlatinib 100 mg Tablet	Lorlatinib INN 100.00 mg	**Anticancer**	**Lorlatinib** is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic Non-small Cell Lung Cancer (NSCLC) whose disease has progressed on Crizotinib and at least one other ALK inhibitor for metastatic disease; or Alectinib as the first ALK inhibitor therapy for metastatic disease; or Ceritinib as the first ALK inhibitor therapy for metastatic disease.	**Contraindication:** It is contraindicated in patients taking strong CYP3A inducers, due to the potential for serious hepato toxicity. **Precaution:** Concomitant use of Lorlatinib with moderate CYP3A inducers should be avoided. A broad spectrum of central nervous system (CNS) effects can occur in patients receiving Lorlatinib include seizures, hallucinations, and	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						changes in cognitive function, mood (including suicidal ideation), speech, mental status, and sleep. Withhold and resume at the same dose or at a reduced dose or permanently discontinue Lorlatinib based on severity. Serum cholesterol and triglycerides and ECG should be monitored prior to initiating Lorlatinib and periodically thereafter. Immediately withhold Lorlatinib in patients with suspected ILD/pneumonitis. Permanently discontinue Lorlatinib for treatment-related ILD/pneumonitis of any severity. It can cause fetal harm when administered to a pregnant woman. **Warning:** Included as part of the "Precaution" Section. **Side effects:** The most common side effects are Risk of Serious Hepato toxicity with concomitant use of Strong CYP3A Inducers, Central Nervous System Effects, Hyper lipidemia**,** Atrio ventricular Block, Interstitial Lung Disease/Pneumonitis.				
247.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Alpelisib 50 mg Tablet	Alpelisib INN 50.00 mg	**Anticancer**	**Alpelisib** is indicated in combination with Fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CAmutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.	**Contraindication:** It is contraindicated in patients with hypersensitivity to Alpelisib or any component of the product. **Warning and Precaution:** Patients should be advised of the signs and symptoms of	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						severe hypersensitivity reactions, severe cutaneous reactions, hyperglycemia, new or worsening respiratory symptoms, diarrhea. It can cause fetal harm when administered to a pregnant woman. **Side effects:** The most common side effects are severe hypersensitivity, severe cutaneous reactions, hyperglycemia, pneumonitis, diarrhea etc.				
248.	Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Alpelisib 200 mg Tablet	Alpelisib INN 200.00 mg	**Anticancer**	**Alpelisib** is indicated in combination with Fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CAmutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.	**Contraindication:** It is contraindicated in patients with hypersensitivity to Alpelisib or any component of the product. **Warning and Precaution:** Patients should be advised of the signs and symptoms of severe hypersensitivity reactions, severe cutaneous reactions, hyperglycemia, new or worsening respiratory symptoms, diarrhea. It can cause fetal harm when administered to a pregnant woman. **Side effects:** The most common side effects are severe hypersensitivity, severe cutaneous reactions, hyperglycemia, pneumonitis, diarrhea etc.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
249.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka. **Advanced Chemical Industries Limited, 07 Hajeeganj,**	Sarecycline 60 mg tablet	Sarecycline Hcl INN 64.500 mg eq.to Sarecycline 60 mg.	**Anti-infective**	Sarecycline is a tetracycline-class drug indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older	**Contraindication** Sarecycline is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
	Godnayl, Narayanganj. **Delta Pharma Ltd, Pakundia, Kishorganj.** **SOMATEC PHARMACEUTICALS LTD., SARULIA, DEMRA, DHAKA BANGLADESH.** Eskayef Pharmaceuticals Limited, Tongi, Gazipur.					**Warning and Precaution:** The use of Sarecycline during tooth development (second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). **Side-effects:** Most common adverse reaction (incidence ≥ 1%) is nausea.				
250.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka. **Advanced Chemical Industries Limited, 07 Hajeeganj, Godnayl, Narayanganj.** **Delta Pharma Ltd, Pakundia, Kishorganj.** **SOMATEC PHARMACEUTICALS LTD., SARULIA, DEMRA, DHAKA BANGLADESH** Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Sarecycline 100 mg tablet	Sarecycline Hcl INN 107.500 mg eq.to sarecycline 100 mg	**Anti-infective**	Sarecycline is a tetracycline-class drug indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older	**Contraindication** Sarecycline is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines. **Warning and Precaution:** The use of Sarecycline during tooth development (second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). **Side-effects:** Most common adverse reaction (incidence ≥ 1%) is nausea.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
251.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Mafenide acetate (sterile) 50 gm/vial powder for solution	Mafenide acetate USP 50 gm	Antimicrobial agent	For 5% Topical Solution is indicated for use® as an adjunctive topical antimicrobial agent to control bacterial infection when used under moist dressings over meshed autografts on excised burn wounds.	**Contraindication** Patients who are hypersensitive to mafenide acetate. It is not known whether there is cross sensitivity to other sulfonamides. **Warning and Precaution:** Fatal hemolytic anemia with disseminated intravascular coagulation, presumablyrelated to a glucose-6-phosphate dehydrogenase deficiency, has	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						been reported following therapywith mafenide acetate **Side-effects:** In the clinical setting of severe burns, it is often difficult todistinguish between an adverse reaction to mafenide acetate and burn sequelae. In a clinical studyof pediatric patients with acute burns requiring autografts who received Mafenide Acetate 5 % SOLUTION in addition to double antibiotic solution (DAB) wound therapy (neomycin sulfate 40mg and polymyxin B 200,000 units/liter), the incidence of rash (4.6%) and itching (2.8%) in thegroup which received Mafenide Acetate 5% Solution was not different from that experienced®with DAB dressings alone (5.7% and 1.3%, respectively). From other clinical settings, a single case of bone marrow depression and a single case of an acuteattack of porphyria have been reported following therapy with mafenide acetate. Fatal hemolyticanemia with disseminated intravascular coagulation, presumably related to a glucose-6-phosphatedehydrogenase deficiency, has been reported following therapy with mafenide acetate. Thefollowing adverse reactions have been reported with topical mafenide acetate therapy: Dermatologic and Allergic: Pain or burning sensation, rash and pruritis (often localized tothearea covered by the wound dressing), erythema, skin maceration from				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						prolonged wet dressings,facial edema, swelling, hives, blisters, eosinophilia Respiratory or Metabolic: Tachypnea, hyperventilation, decrease in pCO, metabolic acidosis, increase in serum chloride.				
252.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Milnacipran HCL 100 mg tablet	Millnacipran Hcl INN100 mg	Antidepressant	Millnacipran is a selective serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for the management of fibromyalgia.It is not approved for use in pediatric patients	**Contraindication** Use of monoamine oxidase inhibitors concomitantly or in close temporal proximity Use in patients with uncontrolled narrow-angle glaucoma **Warning and Precaution:** Increased risk of suicidal ideation, thinking, and behavior in children, adolescents, and young adults taking antidepressants for major depressive disorder (MDD) and other psychiatric disorders. It is not approved for use in pediatric patients. **Side-effects:** The most frequently occurring adverse reactions (≥ 5% and greater than placebo) were nausea, headache, constipation, dizziness, insomnia, hot flush, hyperhidrosis, vomiting, palpitations, heart rate increased, dry mouth, and hypertension	Milnacipran Hcl 12.5 mg & 50 mg tablet	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
253.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Dacomitinib 45 mg tablet	Dacomitinib INN 45 mg	Anticancer	Dacomitinib is a kinase inhibitor indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.	**Contraindication** None. **Warning and Precaution:** Interstitial Lung Disease (ILD): Permanently discontinue Dacomitinib if ILD is confirmed. Diarrhea: Withhold and reduce the dose of Dacomitinib based on the severity.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Side-effects: Most common adverse reactions are followings: (incidence >20%) diarrhea, rash, paronychia, stomatitis, decreased appetite,dry skin, decreased weight, alopecia, Caugh, pruritus.				
254.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Glycopyrrolate 25 mcg per ml inhalation solution	Glycopyrrolate INN 25 mcg per ml	Anticholinergic	Glycopyrrolate is an anticholinergic indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD)	**Contraindication** Glycopyrrolate is contraindicated in patients with a hypersensitivity to glycopyrrolate or any of the ingredients **Warning and Precaution:** Do not initiate in acutely deteriorating COPD or to treat acute symptoms. If paradoxical bronchospasm occurs, discontinue Glycopyrrolate immediately and institute alternative therapy. Worsening of narrow-angle glaucoma may occur. Use with caution in patients with narrow-angle glaucoma and instruct patients to contact a physician immediately if symptoms occur. Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder neck obstruction and instruct patients to consult a physician immediately if symptoms occur. **Side-effects:** Most common adverse reactions (incidence greater than or equal to 2.0% and higher than placebo) are dyspnea and urinary tract infection.	Glycopyrrolate .02% oral solution Glycopyrrolate 200 mcg/ml injection	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
255.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Glycopyrrolate 1 mg tablet	Glycopyrrolate USP 1 mg	Anticholinergic	Glycopyrrolate is an anticholinergic indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD)	**Contraindication** Glycopyrrolate is contraindicated in patients with a hypersensitivity to glycopyrrolate or any of the ingredients. **Side-effects:** The following adverse reactions are described in greater detail in other sections: Paradoxical bronchospasm Immediate hypersensitivity reactions Worsening of narrow-angle glaucoma Worsening of urinary retention	Glycopyrrolate .02% oral solution Glycopyrrolate 200 mcg/ml injection	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
256.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Levofolinic acid 10 mg injection per ml of vial	Calcium Levofolinate Pentahydrate INN 12.80000 mg eq.to Levofolinic acid 10 mg.	Antidote against folic acid antagonists	Prevention of methotrexate-induced adverse effects ► BY INTRAMUSCULAR INJECTION, OR BY INTRAVENOUS INJECTION, OR BY INTRAVENOUS INFUSION ► Adult: Usual dose 7.5 mg every 6 hours for 10 doses, usually started 12–24 hours after beginning of methotrexate infusion Suspected methotrexate overdosage ► BY INTRAVENOUS INFUSION, OR BY INTRAVENOUS INJECTION ► Adult: Initial dose at least 50% of the dose of methotrexate, intravenous infusion to be administered at a maximum rate of 160 mg/minute, consult poisons information centres for advice on continuing management Adjunct to fluorouracil in colorectal cancer ► BY SLOW INTRAVENOUS INJECTION ► Adult: (consult product literature)	**Contraindication** Intrathecal injection **Warning and Precaution:** Avoid simultaneous administration of methotrexate. not indicated for pernicious anaemia or other megaloblastic anaemias caused by vitamin B12 deficiency **Side-effects:** ► Common or very common Dehydration. Diarrhoea. Mucosal toxicity. Nausea. vomiting ► Uncommon Fever ► Rare or very rare Agitation (with high doses). Depression (with high doses). Epilepsy exacerbated. Gastrointestinal disorder. Insomnia (with high doses). urticaria	New	BNF 76 Page 917	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
257.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Chlorthalidone 15 mg tablet	Chlorthalidone USP 15 mg	Antihypertensive	Chlorthalidone USP is indicated in the management of hypertension either alone or in combination with other antihypertensive drugs. Chlorthalidone is indicated as adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis, and corticosteroid and estrogen therapy.	**Contraindication** Anuria. Known hypersensitivity to chlorthalidone or other sulfonamide-derived drugs **Side-effects:**	Chlorthalidone 25 mg tablet	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					Chlorthalidone has also been found useful in edema due to various forms of renal dysfunction such as nephrotic syndrome, acute glomerulonephritis, and chronic renal failure.	The following adverse reactions have been observed, but there is not enough systematic collection of data to support an estimate of their frequency. Gastrointestinal System Reactions: Anorexia, gastric irritation, nausea, vomiting, cramping, diarrhea, constipation, jaundice (intrahepatic cholestatic jaundice), pancreatitis. Central Nervous System Reactions: Dizziness, vertigo, paresthesias, headache, xanthopsia. Hematologic Reactions: Leukopenia, agranulocytosis, thrombocytopenia, aplastic anemia. Dermatologic: Hypersensitivity Reactions: purpura, photosensitivity, rash, urticaria, necrotizing angiitis (vasculitis) (cutaneous vasculitis), Lyell's syndrome (toxic epidermal necrolysis). Cardiovascular Reaction: Orthostatic hypotension may occur and may be aggravated by alcohol, barbiturates or narcotics. Other Adverse Reactions: Hyperglycemia, glycosuria, hyperuricemia, muscle spasm, weakness, restlessness, impotence. Whenever adverse reactions are moderate or severe, chlorthalidone dosage should be reduce or therapy withdrawn. Other Adverse Reactions from Increased Cholinergic Activity.				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
258.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Asenapine 2.5 mg Sub lingual Tablet	Asenapine Maleate INN 3.5150 mg eq to Asenapine 2.5 mg	Antipsychotic	Asenapine is indicated for: Schizophrenia in adults Bipolar I disorder Acute monotherapy of manic or mixed episodes, in adults and pediatric patients 10 to 17 years of age Adjunctive treatment to lithium or valproate in adults Maintenance monotherapy treatment in adults	**Contraindication** •Severe hepatic impairment (Child-Pugh C). •Known hypersensitivity to asenapine, or to any components in the formulation. **Warning and Precaution:** Increased mortality in elderly patients with dementia-related psychosis **Side-effects:** ▯ Schizophrenia Adults: akathisia oral hypoesthesia, somnolence. ▯ Bipolar I Disorder Adults (Monotherapy): somnolence, oral hypoesthesia, dizziness, extrapyramidal symptoms (excluding akathisia) and akathisia. ▯ Bipolar I Disorder Pediatric Patients (Monotherapy): somnolence, dizziness, dysgeusia, oral paresthesia, nausea, increased appetite, fatigue, increased weight. ▯ Bipolar I Disorder Adults (Adjunctive): somnolence, oral hypoesthesia.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*
259.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Revefenacin 175 µg/3 ml nebulizer solution	Revefenacin INN 175 µg/3 ml	Drug used in Chronic obstructive pulmonary disease (COPD)	Revefenacin is an anticholinergic indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)	**Contraindication** Contraindicated in patients with hypersensitivity to revefenacin or any component of this product. **Warning and Precaution:** Use with caution in patients with narrow-angle glaucoma, prostatic hyperplasia. **Side-effects:** Most common adverse reactions (incidence greater than or equal to 2% and more common than placebo) include cough, nasopharyngitis, upper respiratory tract infection, headache, and back pain.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
260.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Salbutamol 1 mg & Guaifenesin 50 mg per 5 ml syrup	Salbutamol sulfate BP .0241 g eq to .02 g salbutamol & Guaifenesin BP 1 gm per 100 ml	Expectorant & bronchodilator	Salbutamol is a selective beta-adrenoceptor agonist indicated for the treatment or prevention of bronchospasm. It provides short acting (four hours) bronchodilation in reversible airway obstruction due to asthma, chronic bronchitis and emphysema. Bronchodilators should not be the only or main treatment in patients with persistent asthma. In patients with persistent asthma unresponsive to salbutamol, treatment with inhaled corticosteroids is recommended to achieve and maintain control. Failing to respond to treatment with salbutamol may signal a need for urgent medical advice or treatment. The combination of salbutamol with guaifenesin is designed to relieve respiratory obstruction and improve pulmonary ventilation.	**Contraindication** Salbutamol + Guaifenesin is contraindicated in patients with a history of hypersensitivity to any ingredient of the preparation.Non-i.v. formulations of salbutamol must not be used to arrest uncomplicated premature labour or threatened abortion. **Side-effects:** As the combination product contains salbutamol and guaifenesin, the type and severity of adverse reactions associated with eachof the components may be expected. The adverse reaction profile is derived from the individual components since there are limited clinical and post marketing reports available for the combination product. Adverse reactions are listed below by system organ class and frequency.Very common and common reactions were generally determined from clinical trial data. Rare and very rare reactions were generally determined from spontaneous data. Salbutamol **Immune system disorders** **Very rare:** Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse. **Metabolism and nutrition disorders** Rare: Hypokalaemia.Potentially serious hypokalaemia may result from beta-2 agonist therapy.	New Salbutamol 2mg/5 ml	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Nervous system disorders Very common: Tremor. Common: Headache. Very rare: Hyperactivity. Cardiac disorders Common: Tachycardia, palpitations. Rare: Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles. Vascular disorders: Rare: Peripheral vasodilatation. **Musculoskeletal and connective tissue disorders** Common: Muscle cramps. Very rare: Feeling of muscle tension. Guaiphenesin **Immune system disorders** Unknown: Hypersensitivity and allergic reactions including anaphylactic reactions, angioedema, rash, urticaria and dyspnoea. **Gastrointestinal disorders** Unknown: nausea, vomiting, abdominal discomfort.				
261.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Salbutamol 2 mg & Guaifenesin 100 mg capsule	Salbutamol Sulfate BP 2.412 mg eq.to Salbutamol 2mg & Guaifenesin BP 100 mg	Expectorant & bronchodilator	Salbutamol is a selective beta-adrenoceptor agonist indicated for the treatment or prevention of bronchospasm. It provides short acting (four hours) bronchodilation in reversible airway obstruction due to asthma, chronic bronchitis and emphysema. Bronchodilators should not be the only or main treatment in patients with persistent asthma. In patients with persistent asthma unresponsive to salbutamol, treatment with inhaled corticosteroids is recommended to achieve and maintain control. Failing to respond to treatment with salbutamol may signal a need for urgent medical advice or treatment. The combination of salbutamol with guaifenesin is designed to relieve respiratory obstruction and improve pulmonary ventilation.	**Contraindication** Salbutamol + Guaifenesin is contraindicated in patients with a history of hypersensitivity to any ingredient of the preparation.Non-i.v. formulations of salbutamol must not be used to arrest uncomplicated premature labour or threatened abortion. **Side-effects:** As the combination product contains salbutamol and guaifenesin, the type and severity of adverse reactions associated with eachof the	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						components may be expected. The adverse reaction profile is derived from the individual components since there are limited clinical and post marketing reports available for the combination product. Adverse reactions are listed below by system organ class and frequency. Very common and common reactions were generally determined from clinical trial data. Rare and very rare reactions were generally determined from spontaneous data. Salbutamol **Immune system disorders** **Very rare:** Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse. **Metabolism and nutrition disorders** Rare: Hypokalaemia.Potentially serious hypokalaemia may result from beta-2 agonist therapy. **Nervous system disorders** Very common: Tremor. Common: Headache. Very rare: Hyperactivity. Cardiac disorders Common: Tachycardia, palpitations. Rare: Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles. Vascular disorders: Rare: Peripheral vasodilatation. **Musculoskeletal and connective tissue disorders** Common: Muscle cramps.				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Very rare: Feeling of muscle tension. Guaiphenesin **Immune system disorders** Unknown: Hypersensitivity and allergic reactions including anaphylactic reactions, angioedema, rash, urticaria and dyspnoea. **Gastrointestinal disorders** Unknown: nausea, vomiting, abdominal discomfort.				
262.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Larotrectinib 100 mg capsule	Larotrectinib sulfate INN 122.8000 mg eq to larotrectinib 100 mg	Anticancer	Larotrectinib is a kinase inhibitor indicated for the treatment of adult and pediatric patients with solid tumors that: Have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, Are metastatic or where surgical resection is likely to result in severe morbidity, and Have no satisfactory alternative treatments or that have progressed following treatment. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial.	**Contraindication** None **Warning and Precaution:** Neurotoxicity, Hepatotoxicity, Embryo-Fetal Toxicity. **Side-effects:** The most common adverse reactions (≥ 20%) with Larotrectinib were fatigue, nausea, dizziness, vomiting, increased AST, cough, increased ALT, constipation, and diarrhea.	Larotrectinib 100 mg capsule (only for Export)	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
263.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Larotrectinib 25 mg capsule	Larotrectinib sulfate INN 30.7000 mg eq to Larotrectinib 25 mg	Anticancer	Larotrectinib is a kinase inhibitor indicated for the treatment of adult and pediatric patients with solid tumors that: Have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, Are metastatic or where surgical resection is likely to result in severe morbidity, and Have no satisfactory alternative treatments or that have progressed following treatment. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial.	**Contraindication** None **Warning and Precaution:** Neurotoxicity, Hepatotoxicity, Embryo-Fetal Toxicity. **Side-effects:** The most common adverse reactions (≥ 20%) with Larotrectinib were fatigue, nausea, dizziness, vomiting, increased AST, cough, increased ALT, constipation, and diarrhea.	Larotrectinib 25 mg capsule (only for Export)	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
264.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Larotrectinib 20 mg per ml oral solution	Larotrectinib sulfate INN 2.46000 gm eq. to Larotrectinib 2 gm per 100 ml.	Anticancer	Larotrectinib is a kinase inhibitor indicated for the treatment of adult and pediatric patients with solid tumors that: Have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, Are metastatic or where surgical resection is likely to result in severe morbidity, and Have no satisfactory alternative treatments or that have progressed following treatment. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial.	**Contraindication** None **Warning and Precaution:** Neurotoxicity, Hepatotoxicity, Embryo-Fetal Toxicity. **Side-effects:** The most common adverse reactions (≥ 20%) with Larotrectinib were fatigue, nausea, dizziness, vomiting, increased AST, cough, increased ALT, constipation, and diarrhea.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
265.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka. Opsonin Pharma Limited, Rupatoli, Barishal.	Methenamin e Hippurarate 1 gm tablet	Methenamine Hippurate USP 1000 mg	Urinary antiinfective	Methenamine hippurate is indicated for prophylactic or suppressive treatment of frequently recurring urinary tract infections when long-term therapy is considered necessary. This drug should only be used after eradication of the infection by other appropriate antimicrobial agents.	**Contraindications:** Methenamine hippurate is contraindicated in patients with renal insufficiency, severe hepatic insufficiency, or severe dehydration. It should not be used as the sole therapeutic agent in acute parenchymal infections causing systemic symptoms. **Warning and Precaution:** Large doses of methenamine (8 grams daily for 3 to 4 weeks) have caused bladder irritation, painful and frequent micturition, albuminuria, and gross hematuria. **Side effects:** Adverse effects of Methenamine have been reported in fewer than 3.5% of patients treated. These reactions are following: nausea, vomiting, and rarely pruritus, rash, dysuria.Side effects were encountered in only 1.1% of these children.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
266.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Itraconazole 65 mg capsule	Itraconazole BP 65 mg	Antifungal	Itraconazole is indicated for the treatment of the followingfungal infections in immunocompromised and non immunocompromised adult patients: Blastomycosis, pulmonary and extrapulmonary Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis, andAspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to Amphotericin B therapy.	**Contraindication** Itraconazole is contraindicated in patients with known hypersensitivity to itraconazole. There is limited information regarding cross-hypersensitivity between itraconazole and other azole antifungal agents **Warning and Precaution:** Hepatotoxicity, Cardiac Dysrhythmias, Peripheral Neuropathy, Hearing Loss **Side-effects:** Congestive Heart Failure Hepatotoxicity Cardiac Dysrhythmias Peripheral Neuropathy Hearing Loss Hypersensitivity Reactions	Itraconazole 100 mg capsule	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*
267.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Brigatinib 30 mg tablet	Brigatinib INN 30 mg	Anticancer	Brigatinib is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib. This indication is approved under accelerated approval based on tumor response rate and duration of response [see Clinical Studies]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.	**Contraindication** None **Warning and Precaution:** Interstitial Lung Disease (ILD)/Pneumonitis Hypertension, Bradycardi, Visual Disturbance, Creatine Phosphokinase (CPK) Elevation, Pancreatic Enzyme Elevation, Hyperglycemia, Embryo-Fetal Toxicity. **Side-effects:** Interstitial Lung Disease (ILD)/Pneumonitis Hypertension Bradycardia Visual Disturbance Creatine Phosphokinase (CPK) Elevation ancreatic Enzyme Elevation	Brigatinib INN 90 mg	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
268.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Brigatinib 180 mg tablet	Brigatinib INN 180 mg	Anticancer	Brigatinib is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib. This indication is approved under accelerated approval based on tumor response rate and duration of response [see Clinical Studies]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.	**Contraindication** None **Warning and Precaution:** Interstitial Lung Disease (ILD)/Pneumonitis Hypertension, Bradycardi, Visual Disturbance, Creatine Phosphokinase (CPK) Elevation, Pancreatic Enzyme Elevation, Hyperglycemia, Embryo-Fetal Toxicity. **Side-effects:** Interstitial Lung Disease (ILD)/Pneumonitis Hypertension Bradycardia Visual Disturbance Creatine Phosphokinase (CPK) Elevation ancreatic Enzyme Elevation	Brigatinib INN 90 mg	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
269.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Alprazolam 3 mg extended release tablet	Alprazolam BP 3 mg	Hypnotics,Sedatives & Anxiolitic	ALPRAZOLAM extended release Tablets are indicated for the treatment of panic disorder, with or without agoraphobia. This claim is supported on the basis of two positive studies with ALPRAZOLAM conducted in patients whose diagnoses corresponded closely to the DSM-III-R/IV criteria for panic disorder. Panic disorder (DSM-IV) is characterized by recurrent unexpected panic attacks, ie, a discrete period of intense fear or discomfort in which four (or more) of the following symptoms develop abruptly and reach a peak within 10 minutes: (1) palpitations, pounding heart, or accelerated heart rate; (2) sweating; (3) trembling or shaking; (4) sensations of shortness of breath or smothering; (5) feeling of choking; (6) chest pain or discomfort; (7) nausea or abdominal distress; (8) feeling dizzy, unsteady, lightheaded, or faint; (9) derealization (feelings of unreality) or depersonalization (being detached from oneself); (10) fear of losing control; (11) fear of dying; (12) paresthesias (numbness or tingling sensations); (13) chills or hot flushes. The longer-term efficacy of ALPRAZOLAM has not been systematically evaluated. Thus, the physician who elects to use this drug for periods longer than 8 weeks should periodically reassess the usefulness of the drug for the	**Contraindication** ALPRAZOLAM Tablets are contraindicated in patients with known sensitivity to this drug or other benzodiazepines. ALPRAZOLAM may be used in patients with open angle glaucoma who are receiving appropriate therapy, but is contraindicated in patients with acute narrow angle glaucoma. ALPRAZOLAM is contraindicated with ketoconazole and itraconazole, since these medications significantly impair the oxidative metabolism mediated by cytochrome P450 3A(CYP3A). **Warning and Precaution:** Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death	Alprazolam 1 mg extended release tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					individual patient.	**Side-effects:** Cardiac disorders: Frequent: palpitation; Infrequent: sinus tachycardia Ear and Labyrinth disorders: Frequent: Vertigo; Infrequent: tinnitus, ear pain Eye disorders: Frequent: blurred vision; Infrequent: mydriasis, photophobia Gastrointestinal disorders: Frequent: diarrhea, vomiting, dyspepsia, abdominal pain, Infrequent: dysphagia, salivary hypersecretion General disorders and administration site conditions: Frequent: malaise, weakness, chest pains; Infrequent: fall, pyrexia, thirst, feeling hot and cold, edema, feeling jittery, sluggishness, asthenia, feeling drunk, chest tightness, increased energy, feeling of relaxation, hangover, loss of control of legs, rigors				
270.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Zolmitriptan 125 mg per 5 ml vial nasal spray	Zolmitriptan USP 2.5mg/Spray	Drug used in migraine	It is a Selective serotonin receptor agonists , Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years and older	**Contraindication:** History of ischemic heart disease or coronary artery vasospasm. Symptomatic Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders. History of stroke, transient ischemic attack, or hemiplegic or basilar migraine. Peripheral Vascular Disease. Ischemic bowel disease. Uncontrolled hypertension. **Warning and Precaution:** Myocardial Ischemia/Infarction, and Prinzmetal Angina, Arrhythmias,Chest/Throat/Neck/Jaw Pain, Tightness, and	Zolmitriptan INN 5mg/Spray	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Pressure,Cerebral Hemorrhage, Subarachnoid Hemorrhage, and Stroke, Gastrointestinal Ischemic Reactions and Peripheral Vasospastic Reactions, Medication Overuse Headache: Detoxification may be necessary, Serotonin Syndrome, Patients with Phenylketonuria. **Side-effects:** The most common adverse reactions (5% and placebo) were: • Adults: unusual taste, paresthesia, dizziness, and hyperesthesia. • Pediatrics: unusual taste.				
271.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka. Healthcare Pharmaceuticals Ltd, Rajendrapur, Gazipur.	Lacosamide 200 mg Tablet	Lacosamide INN 200 mg	Anticonvulsant	Indicated for the treatment of partial-onset seizures in patients 4 years of age and older	**Contraindication:** None **Warning and Precaution:** • Suicidal Behavior and Ideation •Patients should be advised that Lacosamide may cause dizziness and ataxia •Caution is advised for patients with known cardiac conduction problems •Patients should be advised that Lacosamide may cause syncope. • In patients with seizure disorders, Lacosamide should be gradually withdrawn to minimize the potential of increased seizure frequency •Multiorgan Hypersensitivity Reactions **Side-effects:** • Adjunctive therapy: Most common adverse reactions in adults (≥10% and greater than placebo) are diplopia, headache,	Lacosamide INN 100 mg	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						dizziness, nausea • Monotherapy: Most common adverse reactions are similar to those seen in adjunctive therapy studies • Pediatric patients: Adverse reactions are similar to those seen in adult patients .				
272.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka. Healthcare Pharmaceuticals Ltd, Rajendrapur, Gazipur.	Lacosamide 150 mg Tablet	Lacosamide INN 150 mg	Anticonvulsant	Indicated for the treatment of partial-onset seizures in patients 4 years of age and older	**Contraindication:** None **Warning and Precaution:** • Suicidal Behavior and Ideation •Patients should be advised that Lacosamide may cause dizziness and ataxia •Caution is advised for patients with known cardiac conduction problems •Patients should be advised that Lacosamide may cause syncope. • In patients with seizure disorders, Lacosamide should be gradually withdrawn to minimize the potential of increased seizure frequency •Multiorgan Hypersensitivity Reactions **Side-effects:** • Adjunctive therapy: Most common adverse reactions in adults (≥10% and greater than placebo) are diplopia, headache, dizziness, nausea • Monotherapy: Most common adverse reactions are similar to those seen in adjunctive therapy studies • Pediatric patients: Adverse reactions are similar to those seen in adult patients	Lacosamide INN 100 mg	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
273.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Lercanidipine Hydrochloride 20 mg Tablet	Lercanidipine Hydrochloride INN 20 mg.	Antihypertensive	Lercanidipine is indicated for the treatment of mild to moderate essential hypertension.	**Contraindications:** -Hypersensitivity to lercanidipine, to any dihydropyridine or to any of the excipients. -Left ventricular outflow tract obstruction. -Untreated congestive cardiac failure. -Unstable angina pectoris. **Warning and Precaution:** Sick Sinus Syndrome, Angina pectoristc **Side effects:** **Uncommon:** Headache, dizziness, faster heartbeats, awareness of the beating of the heart, flushing (transient episodic redness of the face and neck), ankle swelling. **Rare:** Sleepiness, weakness, tiredness, nausea, vomiting, diarrhoea, abdominal pain, indigestion, rash, muscle pain, passage of large amounts of urine, angina pectoris. **Very rare, not known:** Decrease in blood pressure which may lead to fainting, allergic reaction, swelling of gums, increase in liver enzyme blood test values, fall in blood pressure which can cause dizziness, light-headedness or fainting, increase in the usual number of times one urinates, chest pain and heart attack.	Lercanidipine Hydrochloride INN 10 mg	UKMHRA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
274.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Dextromethorphan Hydrobromide 0.40gm +Guaifenesin 4.0gm +Phenylephrine 0.10gm/100	Dextromethorphan Hydrobromide BP 0.40 gm + Guaifenesin BP 4.0 gm + Phenylephrine Hydrochloride BP 0.1218 gm (eq. to Phenylephrine 0.1 gm)/100ml	Expectorant	This combination medication is used to temporarily treat cough, chest congestion, and stuffy nose symptoms caused by the common cold, flu, allergies, hay fever, or other breathing illnesses (e.g., sinusitis, bronchitis). Guaifenesin is an expectorant that helps to thin and loosen mucus in the lungs, making it easier to cough up the mucus. Dextromethorphan is a cough suppressant that affects a	**Contraindications:** Some medicines can cause unwanted or dangerous effects when used together.Not all possible interactions are listed in this medication guide. Taking this medicine with other drugs that make you sleepy or slow your breathing can worsen these	Dextromethorphan Hydrobromide 0.40gm + Phenylephrine HCl 0.20gm + Triprolidine HCl 0.05gm/100ml Syrup	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		ml Pediatric Drop			certain part of the brain (Cough center), reducing the urge to cough. This product also contains a decongestant, which helps relieve stuffy nose symptoms. This medication is usually not used for ongoing coughs from smoking, asthma, other longterm breathing problems (e.g., emphysema), or coughs with a lot of mucus, unless directed by your doctor.	effects. Ask your doctor before taking this medicine with a sleeping pill, narcotic pain medicine, muscle relaxer, or medicine for anxiety, depression, or seizures. **Side Effects:** Dizziness, headache, nausea, nervousness, or trouble sleeping may occur. If any of these effects persist or worsen, contact your doctor or pharmacist promptly. If your doctor has prescribed this drug, remember that your doctor has prescribed it because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.Tell your doctor if any of these unlikely but serious side effects occur: mental/mood changes (e.g., confusion, hallucinations), shaking (tremors), weakness.				
275.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Quetiapine 400 mg extended release Tablet	Quetiapine Fumarate 461 mg eq. to Quetiapine 400 mg	Antipsychotic Drug	Schizophrenia; mania, either alone or with mood stabilisers; depression in bipolar disorder; adjunctive treatment in major depressive disorder.	**Contraindication:** Hypersensitivity to Quetiapine **Warning and Precaution:** Increased mortality in elderly patients With dementia-related psychosis; and suicidal Thoughts and behaviors **Side effects:** The most commonly reported adverse effects with quetiapine are somnolence, dizziness, dry mouth, mild asthenia, constipation, tachycardia, orthostatic hypotension, dyspepsia, syncope, neuroleptic malignant syndrome, leucopenia, neutropenia, peripheral edema, weight gain, elevations in serum transaminases, and rhinitis.	Quetiapine 25mg 100mg Tablet & 300mg ER Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
276.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Acalabrutinib 100 mg Capsule	Acalabrutinib INN 100 mg	Anticancer	Acalabrutinib is a kinase inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.	**Contraindication:** None **Warning and Precaution:** Serious and Opportunistic Infections, Hemorrhage, Cytopenias, Second Primary Malignancies, Atrial Fibrillation and Flutter. **Side-effects:** Most common adverse reactions (reported in ≥ 20% of patients) were: anemia, thrombocytopenia, headache, neutropenia, diarrhea, fatigue, myalgia, and bruising.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
277.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Erdafitinib 4 mg Tablet	Erdafitinib INN 4 mg	Anticancer	**Erdafitinib** is indicated for the treatment of adult patients with locally advanced or metastatic Urothelial Carcinoma (mUC), that has-Susceptible FGFR3 or FGFR2 genetic alterations, and Progressed during or following at least one line of prior platinum-containing chemo therapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.	**Contraindication:** It is contraindicated in patients with known hypersensitivity to Erdafitinib or any other components of this product. **Warning and Precaution:** Erdafitinib can cause ocular disorders, including central serous retinopathy/retinal pigment epithelial detachment (CSR/RPED) resulting in visual field defect. Increases in phosphate levels are a pharmacodynamic effect of Erdafitinib. Monitoring is needed for hyperphosphatemia and manages with dose modifications when required. It can cause fetal harm when administered to a pregnant woman. **Side effects:** The most common adverse reactions including laboratory abnormalities (≥20 %) were phosphate increased, stomatitis, fatigue, creatinine increased, diarrhea, dry mouth, onycholysis, alanine aminotransferase increased, alkaline phosphatase increased,	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						sodium decreased, decreased appetite, albumin decreased, dysgeusia, hemoglobin decreased, dry skin, aspartate aminotransferase increased, magnesium decreased, dry eye, alopecia, palmar-plantar erythrodysesthesia syndrome, constipation, phosphate decreased, abdominal pain, calcium increased, nausea, and musculoskeletal pain				
278.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Erdafitinib 5 mg Tablet	Erdafitinib INN 5 mg	Anticancer	Erdafitinib is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has susceptible FGFR3 or FGFR2 genetic alterations and progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.	**Contraindication:** None **Warning and Precaution:** Erdafitinib can cause ocular disorders, including central serous retinopathy/retinal pigment epithelial detachment (CSR/RPED) resulting in visual field defect. Increases in phosphate levels are a pharmacodynamic effect of Erdafitinib. Monitoring is needed for hyperphosphatemia and manages with dose modifications when required. It can cause fetal harm when administered to a pregnant woman. **Side-effects:** The most common adverse reactions including laboratory abnormalities (≥20 %) were phosphate increased, stomatitis, fatigue, creatinine increased, diarrhea, dry mouth, onycholysis, alanine aminotransferase increased, alkaline phosphatase increased, sodium decreased, decreased appetite, albumin decreased, dysgeusia, hemoglobin decreased, dry skin, aspartate aminotransferase increased, magnesium decreased, dry eye, alopecia, palmar-plantar	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						erythrodysesthesia syndrome, constipation, phosphate decreased, abdominal pain, calcium increased, nausea, and musculoskeletal pain.				
279.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Galcanezumab-gnlm 1ml solution Pre-filled Syringe (PFS)	Galcanezumab-gnlm INN 1ml solution Eq. Galcanezumab-gnlm 120 mg Pre-filled Syringe (PFS)	Drug used in migraine	Galcanezumab-gnlm is a calcitonin-gene related peptide antagonist indicated for the preventive treatment of migraine in adults.	**Contraindication**: Contraindicated in patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients. **Warning and Precaution:** Hypersensitivity Reactions: If a serious hypersensitivity reaction occurs, discontinue administration of Galcanezumab-gnlm Galcanezumab-gnlm and initiate appropriate therapy. Hypersensitivity reactions could occur days after administration, and may be prolonged. **Side-effects:** The most common adverse reactions (incidence ≥2% and at least 2% greater than placebo) in galcanezumab-gnlm clinical studies were injection site reactions.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
280.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Drug International Ltd (Unit-2) Plot # 13A & 14A, Tongi I/A, Tongi, Gazipur.	Alpelisib 150 mg Tablet	Alpelisib INN 150 mg	Anticancer	**Alpelisib** is indicated in combination with Fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CAmutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.	**Contraindication:** It is contraindicated in patients with hypersensitivity to Alpelisib or any component of the product. **Warning and Precaution:** Patients should be advised of the signs and symptoms of severe hypersensitivity reactions, severe cutaneous reactions, hyperglycemia, new or worsening respiratory symptoms, and diarrhea. It can cause fetal harm when administered to a pregnant woman. **Side effects:** The most common side effects are severe	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						hypersensitivity, severe cutaneous reactions, hyperglycemia, pneumonitis, diarrhea etc.				
281.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Teicoplanin 100 mg per vial Lyophilized Powder for Injection	Teicoplanin INN 100 mg per vial	Anti-infective	-In the treatment of serious infections due to micro organisms sensitive to this antibiotic, including staphylococci resistant to other agents. -As antimicrobial prophylaxis in orthopedic and vascular surgery at risk of gram-positive infection.	**Contraindication:** Previous hypersensitivity to teicoplanin. **Side-effects:** Common or very common Fever. Pain. skin reactions ▶ Uncommon Bronchospasm. Diarrhoea. Dizziness. Eosinophilia. Headache. Hearing impairment. Hypersensitivity. Leucopenia. Nausea. Thrombocytopenia. vomiting ▶ Rare or very rare Abscess. red man syndrome ▶ Frequency not known Agranulocytosis. Angioedema. Chills, Neutropenia. Overgrowth of nonsusceptible organisms. Renal impairment. Seizure. severe cutaneous adverse reactions	Teicoplanin 200 mg/vial Injection & Teicoplanin 400 mg/vial Injection	BNF 76 Page 524	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
282.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Anidulafungin 50 mg per vial Lyophilized Powder for Injection	Anidulafungin INN 50 mg per vial	Antifungal	Anidulafungin is an echinocandin antifungal drug indicated in adults for the treatment of: - Candidemia and other forms of Candida infections (intraabdominal abscess and peritonitis) - Esophageal candidiasis	**Contraindications:** Persons with known hypersensitivity to anidulafungin, any component of Anidulafungin, or other echinocandins. **Warning and Precaution:** Hepatic Effects: Risk of abnormal liver function tests, hepatitis, hepatic failure; monitor hepatic function during therapy Hypersensitivity: Anaphylaxis, including shock has been reported. Risk of infusion-related adverse reactions, possibly histamine-mediated, including rash, urticaria, flushing, pruritus, bronchospasm,dyspnea, and hypotension; to reduce occurrence, do not exceed a rate	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						of infusion of 1.1 mg/minute **Side effects**: Candidemia and other forms of Candida infections: Most common adverse reactions (≥15%) are hypokalemia, nausea, diarrhea, vomiting, pyrexia, insomnia • Esophageal candidiasis: Most common adverse reactions (5%) are diarrhea, pyrexia, anemia, headache, vomiting, nausea				
283.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Ilaprazole 5 mg Tablet	Ilaprazole INN 5 mg	Proton pump inhibitor (PPI)	Indicated for the treatment of- • Dyspepsia • Peptic ulcer disease (PUD) • Gastroesophageal reflux disease (GERD) • Duodenal ulcer	**Contraindication:** Ilaprazole should not be prescribed to individuals who are allergic to other PPIs. **Side-effects:** Nausea, Abdominal pain, Constipation, Diarrhoea, Flatulence.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
284.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Ilaprazole 20 mg Tablet	Ilaprazole INN 20 mg	Proton pump inhibitor (PPI)	Indicated for the treatment of- • Dyspepsia • Peptic ulcer disease (PUD) • Gastroesophageal reflux disease (GERD) • Duodenal ulcer	**Contraindication:** Ilaprazole should not be prescribed to individuals who are allergic to other PPIs. **Side-effects:** Nausea, Abdominal pain, Constipation, Diarrhoea, Flatulence.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
285.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Pimavanserin 34 mg Capsule	Pimavanserin Tartrate INN 40 mg Eq. to Pimavanserin 34 mg	Antipsychotic	It is an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson's Disease psychosis.	**Contraindication:** None **Warning and Precaution:** QT Interval Prolongation: Increases in QT interval; avoid use with drugs that also increase the QT interval and in patients with risk factors for prolonged QT interval. **Side effect:**Most common adverse reactions (≥5% and twice the rate of placebo): peripheral edema and confusional state	Pimavanserin 17 mg Tablet	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
286.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Esketamine 5 mg solution for Injection/Infusion	Esketamine Hydrochloride BP/Ph.Eur. 28.850 mg/5ml eq. to Esketamine 25 mg	general anaesthesia	- Induction and maintenance of general anaesthesia, as the only anaesthetic or in combination with another anaesthetic - Anaesthesia and pain relief (analgesia) in emergency medicine - Supplementation of regional or local anaesthesia.	**Contraindications:** Patients to whom elevation of blood pressure or intracranial pressure forms a serious risk. As sole anaesthetic agent in patients with manifest ischemic cardiac disorders. Eclampsia and pre-eclampsia. In combination with xanthine derivatives and ergometrine Hypersensitivity to the active substance or to any of the excipients **Side effect:** Adverse effects are usually dependent on the dose and speed of injection and are spontaneously reversible. Nervous system and psychiatric (CNS) adverse effects are more common if esketamine is given as the only anaesthetic.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।*
287.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Esketamine 25 mg solution for Injection/Infusion	Esketamine Hydrochloride BP/Ph.Eur. 288.300 mg/10ml eq. to Esketamine 250 mg	general anaesthesia	- Induction and maintenance of general anaesthesia, as the only anaesthetic or in combination with another anaesthetic - Anaesthesia and pain relief (analgesia) in emergency medicine - Supplementation of regional or local anaesthesia.	**Contraindications:** Patients to whom elevation of blood pressure or intracranial pressure forms a serious risk. As sole anaesthetic agent in patients with manifest ischemic cardiac disorders. Eclampsia and pre-eclampsia. In combination with xanthine derivatives and ergometrine Hypersensitivity to the active substance or to any of the excipients **Side effect:** Adverse effects are usually dependent on the dose and speed of injection and are spontaneously reversible. Nervous system and psychiatric (CNS) adverse effects are more common if esketamine is given as the only anaesthetic.	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
288.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Ferric maltol 231.500 mg (eq. to 30mg Iron) Capsule	Ferric maltol INN 231.500 mg eq. to 30mg Iron	DRUG used in Anemia and other Blood disorder	Iron replacement product indicated for the treatment of iron deficiency in adults.	**Contraindications:** •Hypersensitivity to the active substance or any excipient •Hemochromatosis and other iron overload syndromes •Patients receiving repeated blood transfusions. **Warning and Precaution:** • IBD flare: Avoid use in patients with IBD flare. • Iron overload: Accidental overdose of iron products is a leadin cause of fatal poisoning in children under 6. Keep out of reach of children. **Side effect:** Most common adverse reactions (incidence > 1%) are flatulence, diarrhea, constipation, feces discolored, abdominal pain, nausea, vomiting and abdominal discomfort/distension.	Ferric Citrate 1000mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
289.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Sodium Oxybate 500 mg/ml Oral Solution	Sodium Oxybate INN 50 gm/100ml	Antidepressants	Indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy	**Contraindications:** In combination with sedative hypnotics or alcohol Succinic semialdehyde dehydrogenase deficiency **Warning and Precaution:** CNS depression, Depression and suicidality, Confusion/Anxiety, Parasomnias, High sodium content in Xyrem. **Side effect:** Most common adverse reactions in adults (≥5% and at least twice the incidence with placebo) were nausea, dizziness, vomiting, somnolence, enuresis, and tremor. Most common adverse reactions in pediatric patients (≥5%) were enuresis, nausea, headache, vomiting, weight decreased, decreased appetite, and dizziness.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
290.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Sodium Feredetate 190 mg/5ml Oral Solution	Sodium Feredetate BP 3.80 gm/100 ml	DRUG used in Anemia and other Blood disorder	Sodium Feredetate is indicated for Iron deficiency anaemia, • Notably in paediatrics. • In pregnancy when other forms of oral iron may not be well tolerated. • Anaemias secondary to rheumatoid arthritis.	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients Iron preparations are contraindicated in patients with haemochromatosis and haemosiderosis. Iron is contraindicated in patients receiving repeated blood transfusions or in patients receiving parenteral iron therapy. **Side effect:** Itchy skin rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing, mild diarrhea.	New	BNF 76 Page 992	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
291.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Nilotinib 50 mg Capsule	Nilotinib Hydrochloride Monohydrate Ph.eur. 55.1450 mg eq. to 50 mg Nilotinib	Anticancer	It is a kinase inhibitor indicated for the treatment of chronic phase and accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia (CML) in adult patients resistant to or intolerant to prior therapy that included imatinib	**Contraindication:** Do not use in patients with hypokalemia, hypomagnesemia, or long QT syndrome. **Warning and Precaution:** Myelosuppression, QT Prolongation, Elevated serum lipase **Side-effect:** In CML-CP patients, the most commonly reported drug-related adverse reactions (>10%) were rash, pruritis, nausea, fatigue, headache, constipation, diarrhea and vomiting. The common serious drug-related adverse reactions were thrombocytopenia and neutropenia. In CML-AP patients, the mostcommonly reported drug-related adverse reactions (>10%) were rash, pruritus and constipation. The common serious drug-related adverse reactions were thrombocytopenia, neutropenia, pneumonia, febrile neutropenia, leukopenia, intracranial hemorrhage, elevated lipase and pyrexia.	Nilotinib 150mg,200mg Capsule	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
292.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Talazoparib 1 mg Capsule	Talazoparib Tosylate INN 1.4530 mg eq. to Talazoparib 1 mg	Anticancer	Indicated for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer.	**Contraindication:** None. **Warning and Precaution:** Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML), Myelosuppression, Embryo-Fetal Toxicity. **Side-effect:** • Most common (≥20%) adverse reactions of any grade were: Fatigue, anemia, nausea, neutropenia, headache, thrombocytopenia, vomiting, alopecia, diarrhea, decreased appetite. • Most common laboratory abnormalities (≥25%) were: Decreases in hemoglobin, platelets, neutrophils, lymphocytes, leukocytes, and calcium. Increases in glucose, alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
293.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Biapenem 600 mg per Vial Injection	Biapenem for Injection (Sterile) INN 600 mg per Vial	Antibiotic	It is usually used to treat serious infections, sepsis, pneumonia, pulmonary abscess, secondary infection inchronic respiratory lesions, complicated cystitis, pyelonephritis, peritonitis and parametritis. It has broadspectrum action including gram positive and gramnegative aerobic and anaerobic bacteria, includingorganisms producing β-Lactamases.	**Contraindication:** Biapenem is well tolerated. **Side-effect:** The following serious adverse reactions are discussed elsewhere in the label: Skin eruptions/rashes, Nausea, Diarrhoea, Eosinophilia ALT/AST level increased	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
294.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Biapenem 300 mg per Vial Injection	Biapenem for Injection (Sterile) INN 300 mg per Vial	Antibiotic	It is usually used to treat serious infections, sepsis, pneumonia, pulmonary abscess, secondary infection inchronic respiratory lesions, complicated cystitis, pyelonephritis, peritonitis and parametritis. It has broadspectrum action including gram positive and gramnegative aerobic and anaerobic bacteria, includingorganisms producing β-Lactamases.	**Contraindication:** Biapenem is well tolerated. **Side-effect:** The following serious adverse reactions are discussed elsewhere in the label: Skin eruptions/rashes, Nausea, Diarrhoea, Eosinophilia ALT/AST level increased	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
295.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Lorlatinib 100 mg Tablet	Lorlatinib INN 100 mg	Anticancer	Treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on Crizotinib and other ALK inhibitors.	**Contraindication:** Concomitant use with strong CYP3A inducers **Warning and Precaution:** Risk of Serious Hepatotoxicity with Concomitant Use of Strong CYP3A Inducers, Central Nervous System (CNS) Effects: CNS effects include seizures, hallucinations and changes in cognitive function, mood (including suicidal ideation), speech, mental status, and sleep. Embryo-Fetal Toxicity, Interstitial Lung Disease/Pneumonitis, Hyperlipidemia. **Side-effect:** Edema, Peripheral neuropathy, Cognitive effects, Dyspnea, Fatigue, Weight gain, Arthralgia, Mood effects, and Diarrhea.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
296.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Doxapram Hydrochloride 2 mg/ml solution for Infusion	Doxapram Hydrochloride USP 2 mg/ml	Respiratory stimulants	Acute respiratory failure ► BY INTRAVENOUS INFUSION ► Adult: 1.5–4 mg/minute, adjusted according to response, to be given concurrently with oxygen and whenever possible monitor with frequent measurement of blood gas tensions	**Contraindication:** Cerebral oedema. Cerebrovascular accident. Coronary artery disease. Epilepsy and other convulsive disorders. Hyperthyroidism. Physical obstruction of respiratory tract. Severe hypertension. status asthmaticus **Side effect:** Arrhythmias. Chest discomfort. Confusion. Cough. Dizziness. Dyspnoea. Fever. Flushing. Hallucination. Headache. Hyperhidrosis. Movement disorders. Nausea. Neuromuscular dysfunction. Oral disorders. Perineal warmth. Reflexes abnormal .respiratory disorders. Seizure. Urinary disorders. vomiting	Doxapram Hydrochloride 20 mg/ml ampoule Solution for Injection	BNF 76 Page 297	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
297.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Levofolinic Acid 10 mg solution for Injection	Calcium Levofolinate BP/Ph.Eur. 1.0804 gm /100 ml eq. to Levofolinic Acid 1 gm	folic acid analogs	▶Prevention of methotrexate-induced adverse effects Adult: Usual dose 7.5 mg every 6 hours for 10 doses, usually started 12–24 hours after beginning of methotrexate infusion ▶Suspected methotrexate overdosage Adult: Initial dose at least 50% of the dose of methotrexate, intravenous infusion to be administered at a maximum rate of 160 mg/minute, consult poisons information centres for advice on continuing management	**Contraindication:** Intrathecal injection **Warning and Precaution:** Avoid simultaneous administration of methotrexate. not indicated for pernicious anaemia or other megaloblastic anaemias caused by vitamin B12 deficiency **Side-effect:** ▶ **Common or very common** Dehydration. Diarrhoea. mucosal Toxicity. Nausea. vomiting ▶ **Uncommon** Fever ▶ **Rare or very rare Agitation (with high doses).** depression (With high doses). Epilepsy exacerbated. Gastrointestinal Disorder. Insomnia (with high doses). Urticarial	New	BNF 76 Page 917	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
298.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Magnesium 0.243 gm Powder for oral solution	Magnesium Aspartate DihydratePh. Eur. 3.2446 gm (eq. to 0.243 gm Magnesium)	Metals, Salts, Minerals	Treatment and prevention of magnesium deficiency	**Contraindication:** Disorders of cardiac conduction **Side-effect:** ▶ Uncommon Diarrhoea. faeces soft ▶ Rare or very rare Fatigue. hypermagnesaemia ▶ Frequency not known Gastrointestinal irritation	New	BNF 76 Page 1018	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
299.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Opsonin Pharma Limited, Rupatali, Barishal.	Imipenem 500mg, Cilastatin 500 mg & Relebactam 250 mg / Vial Sterile Powder for Injection	Imipenem,Cilastatin, Relebactam for Injection (Sterile Mixture) INN 1324.00mg / Vial eq. to Imipenem 500mg, Cilastatin 500 mg & Relebactam 250 mg	Anti-infective	Indicated in patients 18 years of age and older who have limited or no alternative treatment options, for the treatment of the following infections caused by susceptible gram-negative bacteria: •Complicated urinary tract infections, including pyelonephritis (cUTI) •Complicated intra-abdominal infections (cIAI)	**Contraindication:** Contraindicated in patients with a history of known severe hypersensitivity. **Warning and Precaution:** •Hypersensitivity Reactions •Seizures and Central Nervous System Adverse Reactions •Increased Seizure Potential Due to Interaction with Valproic Acid: concentration of valproic acid,	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						which may increase the risk of breakthrough seizures. •Clostridium difficile-Associated Diarrhea (CDAD) **Side-effect:** The most frequently reported adverse reactions occurring in greater than or equal to 2 % of patients treated with imipenem/cilastatin plus relebactam 250 mg were diarrhea, nausea, headache, vomiting, alanine aminotransferase increased, aspartate aminotransferase increased, phlebitis/infusion site reactions, pyrexia, and hypertension.				
300.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Niraparib 100 mg Capsule	Niraparib Tosylate Monohydrate INN 159.4 mg eq. to Niraparib 100 mg	Anticancer	Indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.	**Contraindication:** None. **Warning and Precaution:** Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML), Bone Marrow Suppression, Cardiovascular Effects: Monitor blood pressure and heart rate monthly for the first year and periodically thereafter during treatment, Embryo-Fetal Toxicity. **Side-effect:** Most common adverse reactions (incidence ≥10%) are thrombocytopenia, anemia, neutropenia, leukopenia, palpitations, nausea, constipation, vomiting, abdominal pain/distention, mucositis/stomatitis, diarrhea, dyspepsia, dry mouth, fatigue/asthenia, decreased appetite, urinary tract infection, AST/ALT elevation, myalgia, back pain, arthralgia, headache, dizziness, dysgeusia, insomnia, anxiety, nasopharyngitis, dyspnea, cough, rash, and hypertension.	Niraparib 100 mg Capsule (only for export)	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
301.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Lacosamide 200 mg/20ml solution for Infusion	Lacosamide INN 200 mg/20ml	Anti-Epileptic	Indicated as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older and in the treatment of diabetic neuropathic pain.	**Contraindication:** None **Warning and Precaution:** • Suicidal Behavior and Ideation •Patients should be advised that Lacosamide may cause dizziness and ataxia •Caution is advised for patients with known cardiac conduction problems •Patients should be advised that Lacosamide may cause syncope. • In patients with seizure disorders, Lacosamide should be gradually withdrawn to minimize the potential of increased seizure frequency •Multiorgan Hypersensitivity Reactions **Side-effect:** Most common adverse reactions (≥10% and greater than placebo) are diplopia, headache, dizziness, nausea	Lacosamide 1.00 gm/100 ml oral solution	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
302.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Gadobutrol 604.72 mg/ml Injectable Solution	Gadobutrol INN 604.72 mg/ml	Gadolinium-based contrast agent	Indicated for intravenous use in diagnostic MRI in adults and children (2 years of age and older) to detect and visualize areas with disrupted blood brain barrier (BBB) and/or abnormal vascularity of the central nervous system.	**Contraindication:** None **Warning and Precautions:** Nephrogenic Systemic Fibrosis has occurred in patients with impaired elimination of GBCAs. Higher than recommended dosing or repeated dosing appears to increase the risk. Anaphylactic and other hypersensitivity reactions with cardiovascular, respiratory or cutaneous manifestations, ranging from mild to severe, including death, have occurred. Monitor patients closely during and after administration of Gadavist. **Side effect:** The most frequent (≥ 0.5%) adverse reactions	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						associated with Gadavist in clinical studies were headache, nausea, injection site reaction, dysgeusia and feeling hot.				
303.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Neomycin 500 mg Tablet	Neomycin sulfate BP/Ph. Eur. 550mg eq. to 500 mg Neomycin	Anti Infactive	indicated for pre-operative sterilisation of the bowel and may be useful in the treatment of impending hepatic coma, including portal systemic encephalopathy	**Contraindication:** Neomycin tablets should not be given when intestinal obstruction is present. Hypersensitivity to aminoglycosides. Infants under 1 year. **Side-effect:** Nausea, vomiting, diarrhoea, increased salivation, stomatitis, nephrotoxicity, ototoxicity, rise in serum levels of hepatic enzymes and bilirubin, blood dyscrasias, haemolytic anaemia, confusion, paraesthesia, disorientation, nystagmus, hypersensitivity reactions including dermatitis, pruritus, drug fever and anaphylaxis.	Neomycin Sulphate 20gm + Gentamycin Sulfate 2.5gm/100gm Powder	BNF 76 Page 511	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*
304.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Tiopronin 100 mg delayed release tablet	Tiopronin INN 100 mg	Renal-Urologic Agent	Tiopronin is a reducing and complexing thiol indicated, in combination with high fluid intake, alkali, and diet modification, for the prevention of cystine stone formation in adults and pediatric patients 20 kg and greater with severe homozygous cystinuria, who are not responsive to these measures alone	**Contraindication:** Hypersensitivity to tiopronin or any component of tiopronin **Warning and Precautions:** •Proteinuria, including nephrotic syndrome, and membranous nephropathy, has been reported with tiopronin use. Pediatric patients receiving greater than 50 mg/kg of tiopronin per day may be at increased risk for proteinuria. •Hypersensitivity reactions have been reported during tiopronin treatment. **Side effect:** Most common adverse reactions (≥10%) are nausea, diarrhea or soft stools, oral ulcers, rash, fatigue, fever, arthralgia, proteinuria, and emesis.	New	USFDA	ইউরোলজিস্ট এর মতামতের ভিত্তিতে আবেদন মঞ্জুরের বিষয়ে সিদ্ধান্ত গ্রহণ করা যেতে পারে।	ইউরোলজিস্ট এর মতামত গ্রহন করতে হবে।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
305.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Tiopronin 300 mg delayed release tablet	Tiopronin INN 300 mg	Renal-Urologic Agent	Tiopronin is a reducing and complexing thiol indicated, in combination with high fluid intake, alkali, and diet modification, for the prevention of cystine stone formation in adults and pediatric patients 20 kg and greater with severe homozygous cystinuria, who are not responsive to these measures alone	**Contraindication:** Hypersensitivity to tiopronin or any component of tiopronin **Warning and Precautions:** •Proteinuria, including nephrotic syndrome, and membranous nephropathy, has been reported with tiopronin use. Pediatric patients receiving greater than 50 mg/kg of tiopronin per day may be at increased risk for proteinuria. •Hypersensitivity reactions have been reported during tiopronin treatment. **Side-effect:** Most common adverse reactions (≥10%) are nausea, diarrhea or soft stools, oral ulcers, rash, fatigue, fever, arthralgia, proteinuria, and emesis.	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
306.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka **Advanced Chemical Industries Limited, 07 Hajeeganj, Godnayl, Narayanganj.**	Omarigliptin 12.5 mg Tablet	Omarigliptin INN 12.5 mg	Antidiabetic	Treatment of Type 2 Diabetes Mellitus and Chronic Renal Insufficiency.	**Contraindication:** Patients with a history of hypersensitivity to components of this drug. Severe ketosis, diabetic coma or precoma in type 1 diabetes.severe infection in which glycemic control is desired by insulin injection, before & after surgery.Patients with severe coma. **Side-effects:** Hypoglycemia, Acute pancreatitis, Bowel obstruction, Intestinal obstruction	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল ।***
307.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka **Advanced Chemical Industries Limited, 07 Hajeeganj,**	Omarigliptin 25 mg Tablet	Omarigliptin INN 25 mg	Antidiabetic	Treatment of Type 2 Diabetes Mellitus and Chronic Renal Insufficiency.	**Contraindication:** Patients with a history of hypersensitivity to components of this drug. Severe ketosis, diabetic coma or precoma in type 1 diabetes.severe infection in which glycemic control is	New	রেফারেন্স নাই	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল ।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
	Godnayl, Narayanganj.					desired by insulin injection, before & after surgery.Patients with severe coma. **Side-effects:** Hypoglycemia, Acute pancreatitis, Bowel obstruction, Intestinal obstruction				
308.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Atomoxetin 40 mg Capsule	Atomoxetin Hydrochloride USP 45.7110 mg eq, to Atomoxetin 40 mg	CNS stimulants	Inhibitor indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD)	**Contraindication:** Phaeochromocytoma. Severe, cardiovascular disease. severe cerebrovascular disease **Warning and Precautions:** Suicidal ideation in children andadolescents **Side-effects:** Common or very common Anxiety. Appetite decreased. Arrhythmias (uncommon in children). Asthenia. chills (in Adults). Constipation. Depression. Dizziness. Drowsiness. Dry mouth (in adults). Feeling jittery (in adults). Flatulence (In adults). Gastrointestinal discomfort. Genital pain (rare in children). Headaches. Hyperhidrosis (uncommon in children). Menstrual cycle irregularities (in adults). mood Altered. Mydriasis (in children). Nausea. Palpitations (uncommon in children). Prostatitis (in adults). Sensation Abnormal (uncommon in children). Sexual dysfunction (Rare in children). Skin reactions. Sleep disorders. Taste Altered (in adults). Thirst (in adults). tremor (uncommon In children). Urinary disorders (rare in children). Vasodilation (in adults). Vomiting. weight decreased	Atomoxetine 10 mg Tablet	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						▶ Uncommon Behaviour abnormal. Chest pain (very common In children). Dyspnoea. Feeling cold (in adults). Hypersensitivity. Muscle spasms (in adults). Peripheral coldness (in adults) .QT interval prolongation. Suicidal behaviour. Syncope. Tic (very common in children). vision blurred ▶ Rare or very rare Hallucination (uncommon in children). Hepatic disorders. Psychosis (uncommon in children). Raynaud's phenomenon. seizure (uncommon in children)				
309.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Atomoxetin 100 mg Capsule	Atomoxetin Hydrochloride USP 114.2780 mg eq, to Atomoxetin 100 mg	CNS stimulants	Inhibitor indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD)	**Contraindication:** Phaeochromocytoma. Severe, cardiovascular disease. severe cerebrovascular disease **Warning and Precautions:** Suicidal ideation in children andadolescents **Side-effects:** Common or very common Anxiety. Appetite decreased. Arrhythmias (uncommon in children). Asthenia. chills (in Adults). Constipation. Depression. Dizziness. Drowsiness. Dry mouth (in adults). Feeling jittery (in adults). Flatulence (In adults). Gastrointestinal discomfort. Genital pain (rare in children). Headaches. Hyperhidrosis (uncommon in children). Menstrual cycle irregularities (in adults). mood Altered. Mydriasis (in children). Nausea. Palpitations (uncommon in children). Prostatitis (in adults). Sensation	Atomoxetine 10 mg Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Abnormal (uncommon in children). Sexual dysfunction (Rare in children). Skin reactions. Sleep disorders. Taste Altered (in adults). Thirst (in adults). tremor (uncommon In children). Urinary disorders (rare in children). Vasodilation (in adults). Vomiting. weight decreased ▶ Uncommon Behaviour abnormal. Chest pain (very common In children). Dyspnoea. Feeling cold (in adults). Hypersensitivity. Muscle spasms (in adults). Peripheral coldness (in adults) .QT interval prolongation. Suicidal behaviour. Syncope. Tic (very common in children). vision blurred ▶ Rare or very rare Hallucination (uncommon in children). Hepatic disorders. Psychosis (uncommon in children). Raynaud's phenomenon. seizure (uncommon in children)				
310.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Milnacipran Hydrochloride 25 mg Tablet	Milnacipran Hydrochloride INN 25 mg	Anti-Depressant	Milnacipran is a selective serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for the management of Fibromyalgia. Milnacipran is not approved for use in pediatric patients	**Contraindications:** Use of monoamine oxidase inhibitors concomitantly or in close temporal proximity. Use in patients with uncontrolled narrow-angle glaucoma. **Warning and Precaution:** Increased risk of suicidal ideation, thinking, and behavior in children, adolescents, and young adults taking antidepressants for major depressive disorder (MDD) and other psychiatric disorders. It is not approved for use in pediatric patients.	Milnacipran HCl 50 mg Tablet	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Side effects: The most frequently occurring adverse reactions are nausea, headache, constipation, dizziness, insomnia, hot flush, hyperhidrosis, vomiting, palpitations, heart rate increased, dry mouth, and hypertension.				
311.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Anidulafungin 100 mg per vial Powder for injection	Anidulafungin INN 100 mg per vial	Antifungal	Anidulafungin is an echinocandin antifungal drug indicated in adults for the treatment of: - Candidemia and other forms of Candida infections (intraabdominal abscess and peritonitis) - Esophageal candidiasis	**Contraindications:** Persons with known hypersensitivity to anidulafungin **Warning and Precaution:** • Hepatic Effects: Risk of abnormal liver function tests, hepatitis, hepatic failure; monitor hepatic function during therapy • Hypersensitivity: Anaphylaxis, including shock has been reported. Risk of infusion-related adverse reactions, possibly histamine-mediated, including rash, urticaria, flushing, pruritus, bronchospasm,dyspnea, and hypotension; to reduce occurrence, do not exceed a rate of infusion of 1.1 mg/minute **Side effects:** Candidemia and other forms of *Candida* infections: Most common adverse reactions are hypokalemia, nausea, diarrhea, vomiting, pyrexia, insomnia Esophageal candidiasis: Most common adverse reactions are diarrhea, pyrexia, anemia, headache, vomiting, nausea and dyspepsia	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
312.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka The IBN SINA Pharmaceutical Industries Ltd.	Netarsudil 0.020 gm + Latanoprost 0.0050 gm. Per 100ml Ophthalmic solution.	Netarsudil Dimesylate INN 0.0280 gm (eq. to Netarsudil 0.020 gm) + Latanoprost USP 0.0050 gm. Per 100ml	Antiglaucoma	Netarsudil & lasanoprost 0.02%/0.005% is a fixed dose combination of a Rho kinase inhibitor and a prostaglandin F2α analogue indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension	**Contraindication:** None. **Warning and Precaution:** • Pigmentation: Pigmentation of the iris, periorbital tissue (eyelid) and eyelashes can occur. Iris pigmentation likely to be permanent. • Eyelash Changes: Gradual change to eyelashes including increasedlength, thickness and number of lashes. Usually reversible. **Side effects:** The most common adverse reaction is conjunctival hyperemia (59%). Other common adverse reactions were: instillation site pain (20%), corneal verticillata (15%), and conjunctival hemorrhage (11%).	Latanoprostene Bunod 0.024% Ophthalmic Solution Netarsudil 0.2mg/ml Ophthalmic solution	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
313.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Sodium Chloride 120mg/4ml nebuliser solution	Sodium Chloride BP/Ph. Eur. 120mg/4ml	Electrolytes	► BY INHALATION OF NEBULISED SOLUTION ► Adult: 4 mL 2–4 times a day, temporary irritation, such as coughing, hoarseness, or reversible bronchoconstriction may occur; an inhaled bronchodilator can be used before treatment with hypertonic sodium chloride to reduce the risk of these adverse effects	**Contraindication:** None **Side-effects:** Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia. Too rapid infusion of hypertonic solutions may cause local pain and venous irritation. Rate of administration should be adjusted according to tolerance. Use of the largest peripheral vein and a well-placed small bore needle is recommended. The physician should also be alert to the possibility of adverse reactions to drug additives. Prescribing information for drug additives to be administered in	Sodium Chloride 3gm/100ml IV Infusion	BNF 76 Page 274	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						this manner should be consulted. Symptoms may result from an excess or deficit of one or more of the ions present in the solution; therefore, frequent monitoring of electrolyte levels is essential. Hypernatremia may be associated with edema and exacerbation of congestive heart failure due to the retention of water, resulting in an expanded extracellular fluid volume. If infused in large amounts, chloride ions may Cause a loss of bicarbonate ions, resulting in an acidifying effect. If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.				
314.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Esketamine 0.14 mg/200mcl spray solution	Esketamine Hydrochloride BP/Ph. Eur. 0.0323 gm/vial (eq. to Esketamine 0.028 gm)	general anaesthesia	- Induction and maintenance of general anaesthesia, as the only anaesthetic or in combination with another anaesthetic - Anaesthesia and pain relief (analgesia) in emergency medicine - Supplementation of regional or local anaesthesia.	**Contraindications:** Patients to whom elevation of blood pressure or intracranial pressure forms a serious risk. As sole anaesthetic agent in patients with manifest ischemic cardiac disorders. Eclampsia and pre-eclampsia. In combination with xanthine derivatives and ergometrine Hypersensitivity to the active substance or to any of the excipients **Warning and Precaution:** Increases in Blood Pressure: Patients with cardiovascular and cerebrovascular conditions and risk factors may be at an increased risk of associated adverse effects.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Cognitive Impairment: SPRAVATO may impair attention, judgment, thinking, reaction speed and motor skills. Impaired Ability to Drive and Operate Machinery: Do not drive or operate machinery until the next day after a restful sleep. Embryofetal Toxicity: May cause fetal harm. Consider pregnancy planning and prevention in females of reproductive potential. **Side effect:** Adverse effects are usually dependent on the dose and speed of injection and are spontaneously reversible. Nervous system and psychiatric (CNS) adverse effects are more common if esketamine is given as the only anaesthetic.				
315.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka **Delta Pharma Ltd, Pakundia, Kishorganj.** Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Lasmiditan 50 mg Tablet	Lasmiditan Hemisuccinate INN 57.8240 mg equivalent to lasmiditan 50 mg	Antimigraine	Lasmiditan is a serotonin (5-HT) 1F receptor agonist indicated for the acute treatment of migraine with or without aura in adults.	**Contra-indications:** None. **Side-effects**: Most common adverse reactions (≥5% and > placebo) were dizziness, fatigue, paresthesia, and sedation **Warning and Precautions:** Driving Impairment: Advise patients not to drive or operate machinery until at least 8 hours after taking each dose of Lasmiditan. Patients who cannot follow this advice should not take Lasmiditan. Patients may not be able to assess their own driving competence and the degree of impairment caused by Lasmiditan. ● Central Nervous System	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						(CNS) Depression: Lasmiditan may cause CNS depression and should be used with caution if used in combination with alcohol or other CNS depressants. ● Serotonin Syndrome: Reactions consistent with serotonin syndrome were reported in patients treated with Lasmiditan. Discontinue Lasmiditan if symptoms of serotonin syndrome occur.				
316.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka **Delta Pharma Ltd, Pakundia, Kishorganj.** Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Lasmiditan 100 mg Tablet	Lasmiditan Hemisuccinate INN 115.650 mg equivalent to lasmiditan 100 mg	Antimigraine	Lasmiditan is a serotonin (5-HT) 1F receptor agonist indicated for the acute treatment of migraine with or without aura in adults.	**Contra-indications:** None. **Side-effects**: Most common adverse reactions (≥5% and > placebo) were dizziness, fatigue, paresthesia, and sedation **Warning and Precautions:** Driving Impairment: Advise patients not to drive or operate machinery until at least 8 hours after taking each dose of Lasmiditan. Patients who cannot follow this advice should not take Lasmiditan. Patients may not be able to assess their own driving competence and the degree of impairment caused by Lasmiditan. ● Central Nervous System (CNS) Depression: Lasmiditan may cause CNS depression and should be used with caution if used in combination with alcohol or other CNS depressants. ● Serotonin Syndrome: Reactions	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						consistent with serotonin syndrome were reported in patients treated with Lasmiditan. Discontinue Lasmiditan if symptoms of serotonin syndrome occur.				
317.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Gilteritinib 40 mg Tablet	Gilteritinib Fumarate INN 44.2000 mg (equivalent to Gilteritinib 40 mg)	Anticancer	Indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation	**Contraindication:** Hypersensitivity to gilteritinib or any of the excipients. Anaphylactic reactions have been observed in clinical trials. **Warning and Precautions:** Posterior reversible encephalopathy syndrome (PRES), Prolonged QT Interval, Pancreatitis, Embryo-Fetal Toxicity. **Side effects:** The most common adverse reactions (≥20%) were transaminase increased, myalgia/arthralgia, fatigue/malaise, fever, mucositis, edema, rash, noninfectious diarrhea, dyspnea, nausea, cough, constipation, eye disorders, headache, dizziness, hypotension, vomiting, and renal impairment.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
318.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Methylphenidate Hydrochloride 0.1000 gm/100 ml oral solution	Methylphenidate Hydrochloride USP 0.1000 gm/100 ml	CNS Stimulant	Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).	**Contraindication:** **Agitation:** Methylphenidate HCL is contraindicated in marked anxiety, tension and agitation since the drug may aggravate these symptoms. **Hypersensitivity to Methylphenidate:** it is contraindicated in patients known to be hypersensitive to Methylphenidate or other components of the product. **Glaucoma:** It is contraindicated in patients with Glaucoma. **Tics:** It is contraindicated in patients with motor tics or with a	Methylphenidate Hydrochloride 10 mg Extended Release Tablet	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						family history or diagnosis of Tourette's syndrome. **Monoamine Oxidase Inhibitors:** It is contraindicated during treatment monoamine oxidase inhibitors and also within a minimum of 14 days following discontinuation of treatment with a monoamine oxidase inhibitor. **Side effects:** Insomnia, anxiety, Nasopharyngitis, decreased appetite, Nervousness, restlessness, sleep disorder, agitation, dyskinesia, tremor, headache, drowsiness, dizziness, tachycardia, palpitation, arrhythmias, changes in blood pressure and heart rate, cough, nausea, dry mouth, rash, pruritus, urticaria, fever, scalp hair loss, hyperhidrosis, feeling jittery, arthralgia & weight decreased.				
319.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Orion Pharma Ltd, Siddhirganj, Narayangang.	Tenapanor 50 mg Tablet	Tenapanor Hydrochloride INN 53.20 mg (equivalent to Tenapanor 50 mg)	sodium/hydrogen exchanger 3 (NHE3) inhibitor	Indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults.	**Contraindication:** •Pediatric patients less than 6 years of age. •Patients with known or suspected mechanical gastrointestinal obstruction. **Side effects:** Most common adverse reactions (≥2%) are diarrhea, abdominal distension, flatulence and dizziness.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
320.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Phenytoin Sodium 100 mg/2ml Injection	Fosphenytoin Sodium INN 150 mg/2ml (equivalent to Phenytoin Sodium 100 mg)	Anti-Epileptic	Indicated for the treatment of generalized tonic-clonic status epilepticus and prevention and treatment of seizures occurring during neurosurgery. Phenytoin Sodium can also be substituted, as short-term use, for oral phenytoin.	**Contraindication:** • Hypersensitivity to its ingredients, phenytoin, hydantoins • Sinus bradycardia, sinoatrial block, second and third degree A-V block, and Adams-Stokes syndrome • A history of prior acute hepatotoxicity attributable to phenytoin • Coadministration with	Phenytoin Sodium 50mg/ml injection	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						delavirdine **Warning and Precautions:** Cardiovascular risk associated with rapid infusion rates **Side effects:** Most common adverse reactions (incidence ≥10%) are: • Adults: pruritus, nystagmus, dizziness, somnolence, and ataxia • Pediatrics: vomiting, nystagmus, and ataxia				
321.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka. **Delta Pharma Ltd, Pakundia, Kishorganj.** Acme Laboratories Ltd., Dhamrai, Dhaka. Opsonin Pharma Limited, Rupatoli, Barishal Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka	Semaglutide 7mg Tablet	Semaglutide INN 7mg	Antidiabetic	Semaglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contra-indications:** Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2. Known hypersensitivity to semaglutide or any of the components in semaglutide. **Side-effects**: The most common adverse reactions, reported in ≥5% of patients treated with semaglutide are: nausea, abdominal pain, diarrhea, decreased appetite, vomiting and constipation. **Warning and Precautions:** Pancreatitis: Has been reported in clinical trials. Discontinue promptly if pancreatitis is suspected. Do not restart if pancreatitis is confirmed. Diabetic Retinopathy Complications: Has been reported in a cardiovascular outcomes trial with semaglutide	Semaglutide 1.34mg/ml Pre-filled Pen for Injection	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						injection. Patients with a history of diabetic retinopathy should be monitored. Hypoglycemia: When semaglutide is used with an insulin secretagogue or insulin, consider lowering the dose of the secretagogue or insulin to reduce the risk of hypoglycemia. Acute Kidney Injury: Monitor renal function in patients with renal impairment reporting severe adverse gastrointestinal reactions. Hypersensitivity Reactions: Discontinue semaglutide if suspected and promptly seek medical advice.				
322.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka Acme Laboratories Ltd., Dhamrai, Dhaka Opsonin Pharma Limited, Rupatoli, Barishal Aristopharma Ltd. Plot No. 14-22, Road No. 11 & 12, Shampur-Kadamtali I/A, Dhaka-1204, Dhaka	Semaglutide 14mg Tablet	Semaglutide INN 14mg	Antidiabetic	Semaglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contra-indications:** Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2. Known hypersensitivity to semaglutide or any of the components in semaglutide. **Side-effects**: The most common adverse reactions, reported in ≥5% of patients treated with semaglutide are: nausea, abdominal pain, diarrhea, decreased appetite, vomiting and constipation. **Warning and Precautions:** Pancreatitis: Has been reported in clinical trials. Discontinue promptly if pancreatitis is suspected. Do not restart if pancreatitis is	Semaglutide 1.34mg/ml Pre-filled Pen for Injection	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						confirmed. Diabetic Retinopathy Complications: Has been reported in a cardiovascular outcomes trial with semaglutide injection. Patients with a history of diabetic retinopathy should be monitored. Hypoglycemia: When semaglutide is used with an insulin secretagogue or insulin, consider lowering the dose of the secretagogue or insulin to reduce the risk of hypoglycemia. Acute Kidney Injury: Monitor renal function in patients with renal impairment reporting severe adverse gastrointestinal reactions. Hypersensitivity Reactions: Discontinue semaglutide if suspected and promptly seek medical advice.				
323.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Aprepitant 7.2 mg/ml Injectable Emulsion	Aprepitant USP 7.2 mg/ml	Antiemetic	Indicated in adults, in combination with other antiemetic agents, for the prevention of: • acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin. • nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).	**Contraindication:** Known hypersensitivity to any component of this drug. • Concurrent use with pimozide. **Warning and Precautions:** • CYP3A4 Interactions: Aprepitant is a substrate, weak-to-moderate inhibitor and inducer of CYP3A4; • Warfarin (a CYP2C9 substrate): Risk of decreased INR of prothrombin time; monitor INR in 2-week period, particularly at 7 to 10 days, following initiation of Aprepitant • Hormonal Contraceptives: Efficacy of contraceptives may be reduced during administration of and for 28 days following the last dose of Aprepitant	Aprepitant INN 40 mg	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Side effects: ▯ Most common adverse reactions with the 3-day oral aprepitant regimen in conjunction with MEC (≥1% and greater than standard therapy) were: fatigue and eructation. ▯ Most common adverse reactions with the single-dose fosaprepitant regimen in conjunction with HEC were generally similar to that seen in prior HEC studies with oral aprepitant. In addition, infusion site reactions (3%) occurred. ▯ Most common adverse reactions with single-dose (≥2%) were: headache and fatigue.				
324.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Paracetamol 500 mg & Metoclopramide HCl 5mg per Tablet	Paracetamol 500 mg & Metoclopramide HCl 5mg	Analgesic & Antipyretic + Antiemitic	It is used to treat the signs of migraine, such as headache, feeling sick (nausea) or being sick (vomiting) in adults 18 years And over.	**Contraindication:** - Hypersensitivity to the active substances or to any of the excipients - Gastrointestinal haemorrhage, obstruction or perforation, since stimulation of gastrointestinal motility constitutes a risk in these situations. - History of neuroleptic or metoclopramide-induced tardive dyskinesia. - Confirmed epilepsy, since the frequency and severity of seizures may be increased. - Confirmed or suspected phaeochromocytoma, because of the risk of hypertensive crisis. - Combination with levodopa because of a mutual antagonism. - Metoclopramide should be not be used in the immediate post-operative period (up to 3-4 days) following pyloroplasty or gut anastomosis, as vigorous gastro-intestinal contractions may adversely affect healing.	Paracetamol 120mg Dispersible Tablet, 500mg Tablet, 120mg/5ml syrup and suspension; Metoclopramide 10mg Tablet, 5mg/5ml Syrup, 1mg/1ml Drop,	BNF 76 Page 469	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						- Use in children less than 1 year of age due to increased risk of extrapyramidal disorders. **Side effects:** Like all medicines, this medicine can cause side effects, although not everybody gets them. Stop taking this tablet and see a doctor or go to a hospital straight away if: • You have an allergic reaction. Severe allergic reactions can occur very rarely and usually Happen soon after taking this tablet. These can involve diffiulty breathing, tightness in the throat, rapidly spreading rashes, dizziness, very fast heart beat or even loss of consciousness • You are short of breath, have bluish skin colouration, headache, tiredness, dizziness and loss of consciousness. These could be signs of a very rare but serious side effect called methaemoglobinaemia • You are paler than normal, are sweating, have a high temperature, fast heartbeat, stiff muscles, fast breathing and feel confused, drowsy or agitated. These could be signs of a serious side effectect called neuroleptic malignant syndrome • Shortness of breath, slow heart beat and chest pain				
325.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Durvalumab 500 mg in 10 ml vial solution for Injection.	Durvalumab 50 mg/ ml ready to fill Solution	Anticancer	indicated for the treatment of patients with: • Locally advanced or metastatic urothelial carcinoma who: Have disease progression during or following platinum-containing chemotherapy. Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.	**Contraindication:** None. **Side effects:** Most common adverse reactions (≥15% of patients with urothelial carcinoma) were fatigue, musculoskeletal pain, constipation, decreased appetite, nausea, peripheral edema, and urinary tract infection.	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Most common adverse reactions (≥20% of patients with unresectable, Stage III NSCLC) were cough, fatigue, pneumonitis/radiation pneumonitis, upper respiratory tract infections, dyspnea, and rash.				
326.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Avelumab 200 mg in 10 ml vial solution for injection.	Avelumab 20 mg/ ml ready to fill Solution	Anticancer	Indicated for: • Adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC). • Patients with locally advanced or metastatic urothelial carcinoma (UC) who: • Have disease progression during or following platinum-containing chemotherapy • Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.	**Contraindication:** None. **Side effects:** Most common adverse reactions (> 20%) were: Avelumab in patients with metastatic Merkel cell carcinoma: Fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, rash, decreased appetite, and peripheral edema. Avelumab in patients with locally advanced or metastatic urothelial carcinoma: fatigue, infusion-related reaction, musculoskeletal pain, nausea, decreased appetite, and urinary tract infection. Avelumab with axitinib in patients with RCC: diarrhea, hepatotoxicity, cough, dyspnea, abdominal pain, and headache. palmar-plantar erythrodysesthesia, dysphonia, decreased appetite, hypothyroidism, rash,	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
327.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Romosozumab 105 mg in 1.17 ml prefilled syringe (PFS) solution for injection.	Romosozumab 105 mg in 1.17 ml ready to fill Solution	Treatment of Osteoporosis	Indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.	**Contraindication:** •Hypocalcemia •Hypersensitivity **Side effects:** The Most common adverse reactions (≥ 5%) reported with Romosozumab in clinical trials	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						were arthralgia and headache.				
328.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Atomoxetine Hydrochloride 0.40gm/100 ml oral solution.	Atomoxetine Hydrochloride USP 0.40gm/100ml (eq. to Atomoxetine 0.4 g)	CNS stimulants	Inhibitor indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD)	**Contraindication:** Phaeochromocytoma. Severe, cardiovascular disease. severe cerebrovascular disease **Side-effects:** Common or very common Anxiety. Appetite decreased. Arrhythmias (uncommon in children). Asthenia. chills (in Adults). Constipation. Depression. Dizziness. Drowsiness. Dry mouth (in adults). Feeling jittery (in adults). Flatulence (In adults). Gastrointestinal discomfort. Genital pain (rare in children). Headaches. Hyperhidrosis (uncommon in children). Menstrual cycle irregularities (in adults). mood Altered. Mydriasis (in children). Nausea. Palpitations (uncommon in children). Prostatitis (in adults). Sensation Abnormal (uncommon in children). Sexual dysfunction (Rare in children). Skin reactions. Sleep disorders. Taste Altered (in adults). Thirst (in adults). tremor (uncommon In children). Urinary disorders (rare in children). Vasodilation (in adults). Vomiting. weight decreased ► Uncommon Behaviour abnormal. Chest pain (very common In children). Dyspnoea. Feeling cold (in adults).	Atomoxetine 10 mg Tablet	UKMHRA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Hypersensitivity. Muscle spasms (in adults). Peripheral coldness (in adults) .QT interval prolongation. Suicidal behaviour. Syncope. Tic (very common in children). vision blurred ► Rare or very rare Hallucination (uncommon in children). Hepatic disorders. Psychosis (uncommon in children). Raynaud's phenomenon. seizure (uncommon in children)				
329.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Polysaccharide-Iron complex 4.3480 gm/100ml oral solution.	Polysaccharide-Iron complex INN/In-house 4.3480 gm/100ml (eq. to Elemental Iron 2.0 gm.	Iron Suppliment	Use for treatment of uncomplicated iron deficiency anemias	**Contraindication:** No information provided **Side·effects:** Common side effects of polysaccharide iron complex are constipation, diarrhea, nausea, dark stools, and abdominal pain.	Iron Sucrose 2.5ml Injection (50mg elemental iron)	BNF 76 Page 992	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
330.	Incepta Pharmaceuticals Ltd.; Zirabo, Savar, Dhaka	Valproate Sodium BP 576.283 mg /5 ml Injection	Valproate Sodium BP 576.283 mg /5 ml eq. Valproic Acid 500 mg/5ml	Antiepileptic	The treatment of epileptic patients who would normally be maintained on oral sodium valproate, and for whom oral therapy is temporarily not possible.	**Contraindications:** - Active liver disease - Personal or family history of severe hepatic dysfunction, especially drug related - Hypersensitivity to sodium valproate - Porphyria **Side Effects:** -Hepato-biliary disorders: rare cases of liver injury. -Gastrointestinal disorders: (nausea, gastralgia, diarrhoea) frequently occur at the start of treatment, but they usually disappear after a few days without discontinuing treatment. -Nervous system disorders: Sedation has been reported occasionally, usually when in combination with other anticonvulsants -Psychiatric disorder: Confusion has been	Sodium Valproate EP 100 mg / ml (400 mg/ 4 ml ampoule)	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						reported -Metabolic disorders: Cases of isolated and moderate hyperammonaemia without change in liver function tests may occur frequently are usually transient and should not cause treatment discontinuation.				
331.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Salicylic acid 2 % facial cleanser solution	Salicylic acid BP 2 gm per 100 gm	Skin and Mucous Membrane Preparations	Salicylic acid topical (for the skin) is used in the treatment of acne, dandruff, seborrhea, or psoriasis, and to remove corns, calluses, and warts.	**Contraindication** It should not be used in any patient known to be sensitive to Salicylic Acid or any other listed ingredients. Stop using this medicine and get emergency medical help if you have: hives, itching; difficult breathing, feeling light-headed; or swelling of your face, lips, tongue, or throat. Do not use this medicine on a child or teenager who has a fever, flu symptoms, or chickenpox **Side-effects:** An allergic reaction (shortness of breath, closing of the throat, swelling of the lips, face or tongue or hives) or severe skin irritation. Salicylates applied to the skin and absorbed into the bloodstream can cause Reye's syndrome, a serious and sometimes fatal condition in children. Common side effects may include: minor skin irritation, rash, or peeling; or changes in the color of treated skin (usually whitening)	Salicylic acid .5 % gel Salicylic acid 25 % cream	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
332.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Palmitoleic acid 210 mg soft gelatin capsule	Palmitoleic acid (Omega-7) INN 210 mg	Nonclassified	Omega 7 is a naturally-occurring monounsaturated fatty acid that has been shown to have beneficial effects in dealing with insulin resistance, obesity and cardiovascular complications	**Contraindication** Generally well tolerated **Side-effects:** Consuming too much may deplete potassium, cause muscle weakness and irregular heartbeat. Urine colour change Laxative effect	New	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।*
333.	Incepta Pharmaceuticals Ltd, Savar, Dhaka.	Magnesium sulfate heptahydrate 500 mg per ml injectable solution.	Magnesium sulfate Heptahydrate USP 10 gm per 20 ml	Anticonvulsant	(a) Treatment of magnesium deficiency in hypomagnesaemia. (b) Prevention and control of generalised seizures in patients with severe pre- eclampsia or eclampsia	**Contraindication** Use of Magnesium Sulfate 50% w/v Solution for Injection or Infusion is contraindicated in patients with known hypersensitivity to magnesium and its salts, hepatic encephalopathy, hepatic failure, renal failure, myasthenia gravis or cardiac disease. **Side-effects:** Excessive administration of magnesium leads to the development of hypermagnesaemia. Symptoms of hypermagnesaemia may include nausea, vomiting, flushing, thirst, and hypotension due to peripheral vasodilation, drowsiness, confusion, loss of tendon reflexes due to neuromuscular blockade, muscle weakness, respiratory depression, cardiac arrhythmias, coma and cardiac arrest. Acute ingestion of magnesium sulfate and similar magnesium containing compounds may also cause gastrointestinal irritation and watery diarrhoea.	Magnesium sulfate 2.5 gm/5 ml, injection, 4 gm/100 ml IV infusion	**রেফারেন্স নাই**	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
334.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Clobetasol Propionate .5 mg & salicylic acid 60 mg lotion	Clobetasol Propionate BP .05 gm & salicylic acid BP 6 gm per 100 gm	Topical steroid	Clobetasol propionate+salicylic acid Ointment is prescribed for dry, scaly and resistant Psoriasis, Hyperkeratotic Dermatoses, Recalcitrant Eczema, and Ichthyosis. Clobetasol, an analog of Prednisolone, has a high degree of Glucocorticoid activity and a slight degree of mineralocorticoid activity. Topical Salicylic Acid is used to clear and prevent pimples and skin blemishes in people who have acne. Topical Salicylic Acid is also effective for treating skin conditions that involve scaling or overgrowth of skin cells which may lead to diseases such as: Psoriasis: A skin disease in which red, scaly patches form on some areas of the body. Ichthyoses: An inborn condition that causes skin dryness, scaling, dandruff, corns, calluses, and warts on the hands or feet. Salicylic Acid is in the class of medications called Keratolytic agents. It treats acne by reducing swelling and redness. Also, Salicylic Acid clean out blocked skin pores to allow pimples to shrink. It is also effective for other skin conditions by softening and loosening dry, scaly, or thickened skin so that it falls off or can be removed easily.	**Contraindication** The ointment is not meant for children less than 12 years if age. This drug is contraindicated in patients who are under treatment for Ulcerative conditions, Rosacea, Pruritus, and acute infections. Also, the usage of the drug should be discontinued if hypersensitivity to any of its ingredients is noted. **Side-effects:** Perioral Dermatitis Striae especially in flexures Dermal and epidermal atrophy especially on the face Steroid Purpura Prolonged usage of the ointment in excessive amount can lead to sufficient systemic levels to Adrenal Suppression, Cushing's Syndrome, Diabetes and Hypertension.	Clobetasol Propionate 0.05% + Salicylic Acid 3% Ointment	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
335.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Chlorhexidine Dihychloride 1 mg & Neomycin Sulphate 5 mg per gm Nasal cream	Chlorhexidine Dihychloride BP .1 g & Neomycin Sulphate USP.5 g per gm	Antimicrobial	Eradication of nasal infection with, and carriage of, Staphylococci.	**Contraindication** Patients who have previously shown a hypersensitivity reaction to neomycin or chlorhexidine, although such reactions are extremely rare. **Side-effects:** Swelling of the face,throat,tongue Difficulty in breathing Blistering	New	BNF 76 Page 1168	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
336.	Incepta Pharmaceuticals Ltd (Dhamrai Unit). Nuvista Pharma Ltd.	Drospirenone 4 mg Tablets	Drospirenone BP 4 mg	Oral contraceptives	Drosperinone is a progestin indicated for use by females of reproductive potential medication adjustments or monitoring. (5.7)to prevent pregnancy	**Contraindication** Drosperinone is contraindicated in females with the following conditions: Renal impairment Adrenal insufficiency Presence or history of cervical cancer or progestin sensitive cancers	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Liver tumors, benign or malignant, or hepatic impairment Undiagnosed abnormal uterine bleeding **Side-effects:** common adverse reactions (>1%) are: acne, metrorrhagia, headache, breast pain, weight increased, dysmenorrhea, nausea, vaginal hemorrhage, libido decreased, breast tenderness, menstruation irregular				
337.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Menthol 4.4 mg & zinc oxide 206 mg per gm ointment	Menthol USP .44 g & zinc oxide BP 20.60 g per gm	Skin care agent	A moisture barrier that prevents & helps heal skin irritation from urine, diarrhea, perspiration, fistula, drainage, feeding tube side leakage, wound drainage (peri-wound skin). The product is excellent first aid for minor burns, cuts, and scrapes. At some point, however, someone found that this product was an effective solution for treating dry and itchy vaginal skin—much like Vagisil Cream or other products designed to help with vaginal discomfort.	**Contraindication** Hypersensitivity is a major contraindication. In addition, the Ointment should not be used if you have the following conditions: Allergic Allergic reactions **Side-effects:** Hives, itching, skin rash, peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat., Pruritus.	New	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
338.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	N,N-diethyl-meta toluamiden .4 gm multidose spray	N,N-diethyl-meta toluamide INN 40 gm per 100 ml	Other Classification	DEET (chemical name, N,N-diethyl-meta-toluamide) is the active ingredient in many repellent products. It is widely used to repel biting pests such as mosquitoes and ticks. Every year, an estimated one-third of the U.S. population use DEET to protect them from mosquito-borne illnesses like West Nile Virus, the Zika virus or malaria and tick-borne illnesses like Lyme disease and Rocky Mountain spotted fever.	**Contraindication** No data available. **Side-effects:** Using insect repellents containing DEET should not be harmful if label directions are followed and the product is used safely. In rare cases, using DEET products may cause skin rashes. Some persons who used products containing a high concentration of DEET or who were exposed to excessive amounts of DEET have experienced skin rashes, blisters, and skin and mucous membrane irritation.	New	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***Mosquito repellent*** ***জাতীয় প্রডাক্ট ঔষধ হিসেবে অনুমোদনের প্রয়োজন নেই।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
339.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	N,N-diethyl-meta toluamiden .5 gm lotion	N,N-diethyl-meta toluamide INN 50 gm per 100 gm	Other Classification	DEET (chemical name, N,N-diethyl-meta-toluamide) is the active ingredient in many repellent products. It is widely used to repel biting pests such as mosquitoes and ticks. Every year, an estimated one-third of the U.S. population use DEET to protect them from mosquito-borne illnesses like West Nile Virus, the Zika virus or malaria and tick-borne illnesses like Lyme disease and Rocky Mountain spotted fever.	**Contraindication** No data available. **Side-effects:** Using insect repellents containing DEET should not be harmful if label directions are followed and the product is used safely. In rare cases, using DEET products may cause skin rashes. Some persons who used products containing a high concentration of DEET or who were exposed to excessive amounts of DEET have experienced skin rashes, blisters, and skin and mucous membrane irritation.	New	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***Mosquito repellent*** *জাতীয় প্রডাক্ট ঔষধ হিসেবে অনুমোদনের প্রয়োজন নেই।*
340.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Citronella Oil 25 ml/100 ml +Eucalyptus Oil 25 ml/100 ml Solution	Citronella Oil INN 22.375 gm/100 ml eq.to Citronella Oil 25 ml/100 ml + Eucalyptus Oil USP 23.1750 gm/100 ml eq.to. Eucalyptus Oil 25 ml/100 ml	Other Classification	As an insect repellent	**Contraindication** No data available. **Side-effects:** Citronella oil+eucalyptus oil can cause skin irritation or allergy. When this happens, the area may become red, blotchy, itchy, or swollen.	New	**রেফারেন্স নাই**	আবেদন অনুমোদন করা যেতে পারে।	***Mosquito repellent*** *জাতীয় প্রডাক্ট ঔষধ হিসেবে অনুমোদনের প্রয়োজন নেই।*
341.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	N Diethylbenzamide 120 mg ,Vitamin –E,Almond oil cream; 100 gm cream	N-Diethylbenzamide INN 12 gm ,Vitamin –E BP .5 gm ,Almond oil cream BP 1.5 gm per 100 gm	Other Classification	Repellents are commonly used personal protection measures to avoid mosquito bites.	**Contraindication** No data available. **Side-effects:** There are no side effects since the primary repellent in N-Diethylbenzamide, Vitamin –E, Almond oil. N, N diethyl benzamide is used in a very less amount.	New	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***Mosquito repellent*** *জাতীয় প্রডাক্ট ঔষধ হিসেবে অনুমোদনের প্রয়োজন নেই।*
342.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Pimecrolimus 1% Cream	Pimecrolimus INN 1gm/100gm	Immunosuppressant	Indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable	**Contraindication:** Pimecrolimus Cream 1% is contraindicated in individuals with a history of hypersensitivity to pimecrolimus or any of the components of the cream. **Side-effects:** The most	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						commonly reported adverse reactions (≥1%) were application site burning, headache, nasopharyngitis, cough, influenza, pyrexia and viral infection.				
343.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Blue Tablet: Estradiol 2 mg. White Tablet: Estradiol 2 mg. + Norethisterone Acetate 1 mg. Red Tablet: Estradiol 1 mg.	Blue Tablet: Estradiol Hemihydrate BP. Pur. 2.0660 mg eq. Estradiol 2 mg White Tablet: Estradiol Hemihydrate BP. Pur. 2.0660 mg eq. Estradiol 2 mg + Norethisterone Acetate BP. Pur. 1 mg Red Tablet: Estradiol Hemihydrate BP. Pur. 1.0330 mg eq. Estradiol 1 mg	Hormone Replacement Therapy (HRT)	Hormone Replacement Therapy (HRT) for oestrogen deficiency symptoms in postmenopausal women with at least 6 months since last menses. Prevention of osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of osteoporosis	**Contraindication :** - Known, past or suspected breast cancer - Known, past or suspected oestrogen-dependent malignant tumours (e.g. endometrial cancer) - Undiagnosed genital bleeding - Untreated endometrial hyperplasia - Previous or current venous thromboembolism (deep venous thrombosis, pulmonary embolism) - Active or previous arterial thromboembolic disease (e.g. angina, myocardial infarction) - Known thrombophilic disorders (e.g. protein C, protein S or antithrombin deficiency - Acute liver disease or a history of liver disease as long as liver function tests have failed to return to normal - Known hypersensitivity to the active substances or to any of the excipients - Porphyria. **Side-effects:** Breast cancer, abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or cancer), ovarian cancer, blood clots in the veins of the legs or lungs (venous thromboembolism), heart disease, stroke, probable memory loss if Hormone Replacement Therapy (HRT) is started over the age of 65.	New	**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
344.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Glycerol (Glycerin) 10 gm, Light Liquid Paraffin 10 gm & White Soft Paraffin 5 gm per 100 ml paraffin gentle wash.	Glycerol (Glycerin) BP 10 gm, Light Liquid Paraffin BP 10 gm & White Soft Paraffin BP 5 gm per 100 ml	Topical emollients	Paraffin Gentle Wash Soap-free cleanser for dry and sensitive skin. Suitable for conditions eg, eczema, dermatitis&psoriasis. Shower Balm: An effective moisturising treatment for dry, sensitive skin including dry skin associated with atopic eczema (dermatitis), contact dermatitis, senile pruritus, ichthyosis and psoriasis	**Contraindication:** Hypersensitivity to any of the ingredients of Gentle Wash. **Side-effects:** Very rarely, mild skin reactions have been seen	New	**রেফারেন্স নাই**	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
345.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Liquid Paraffin 85.0900 gm per 100 gm paraffin Bath Oil	Liquid Paraffin BP 85.0900 gm per 100 gm	Topical emollients	Liquid paraffin Emollient Bath Additive is an emollient, moisturising and protective oil for the symptomatic relief of red, inflamed, damaged, dry or chapped skin, especially when associated with endogenous or exogenous eczema. Metically, paraffin wax is often applied to the hands and feet. The wax is a natural emollient, helping make skin supple and soft. When applied to the skin, it adds moisture and continues to boost the moisture levels of the skin after the treatment is complete. It can also help open pores and remove dead skin cells. That may help make the skin look fresher and feel smoother.	**Contraindication:** Hypersensitivity to any of the ingredients. **Side-effects:** Very rarely, mild skin reactions have been seen	New	**রেফারেন্স নাই**	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
346.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Glycerol (Glycerin) 10gm + Light Liquid Paraffin 10gm + White Soft Paraffin 5gm per 100gm Cream	Glycerol (Glycerin) BP 10gm + Light Liquid Paraffin BP 10gm + White Soft Paraffin BP 5gm per 100gm	Topical emollients	This medication is used as a moisturizer to treat or prevent dry, rough, scaly, itchy skin and minor skin irritations (e.g., diaper rash, skin burns from radiation therapy). Emollients are substances that soften and moisturize the skin and decrease itching and flaking. Some products (e.g., zinc oxide, white petrolatum) are used mostly to protect the skin against irritation (e.g., from wetness). Dry skin is caused by a loss of water in the upper layer of the skin.	**Contraindication:** Paraffin Cream (Glycerol) is contraindicated in patients Less than 2 months of age. Pediatric patients less than 2 months of age may have immature pancreatic exocrine function, which could impair hydrolysis of PARAFFIN Cream (Glycerol), leading to impaired absorption of phenylbutyrate and hyperammonemia. With known hypersensitivity to phenylbutyrate. Signs of hypersensitivity include wheezing, dyspnea, coughing, hypotension, flushing, nausea,	New	**রেফারেন্স নাই**	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						and rash. Patients less than 2 months of age. Known hypersensitivity to phenylbutyrate. **Side-effects:** The most common adverse reactions (occurring in at least 10% of patients) reported during short-term treatment with PARAFFIN Cream (Glycerol) were diarrhea, flatulence, and headache.				
347.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Trifarotene 0.0050gm/100gm Cream	Trifarotene INN 0.0050gm/100gm	Antiacnes	Indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.	**Contraindication:** None **Side-effects:** Most common adverse reactions (incidence ≥ 1%) in patients treated with Trifarotene Cream were application site irritation, application site pruritus, and sunburn	New	USFDA	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
348.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Malathion 0.5gm/100ml Lotion	Malathion BP/Ph.Eur. 0.5gm/100ml	Anti-Parasitic Agent	Indicated for patients infected with Pediculus humanus capitis (head lice and their ova) of the scalp hair.	**Contraindication:** contraindicated for neonates and infants because their scalps are more permeable and may have increased absorption of malathion.This Lotion should also not be used on individuals known to be sensitive to malathion **Side-effects:** Angioedema. Eye swelling. Hypersensitivity. skin reactions	New	BNF 76 Page 1202 USFDA	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
349.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Halobetasol Propionate 0.10mg/gram Lotion	Halobetasol Propionate USP 0.10mg/gram	Corticosteroid	Indicated for the topical treatment of plaque psoriasis in adults.	**Contraindication:** None **Side-effects:** The most common adverse reactions (≥1%) were upper respiratory tract infection, application site dermatitis and hyperglycemia.	Halobetasol Propionate 0.05% Cream	USFDA	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।
350.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Icosapent Ethyl 1 gm soft gelatin capsule	Icosapent Ethyl INN/ In-house 1 gm	Lipid Lowering agent	Indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia.	**Contraindications:** Icosapent ethyl 1 gm capsule iscontraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Icosapent ethyl 1 gm capsule or any of its components. **Side-effects:** The most common	New	USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						reported adverse reaction (incidence >2% and greater than placebo) was arthralgia.				
351.	Drug International Ltd (Unit-3) 31/1, Satrong Road, Gopalpur, Tongi Industrial Area Gazipur, Bangladesh.	Canagliflozin INN 50mg & Metformin Hydrochloride USP 500 mg Film Coated Tablet.	Canagliflozin Hemihydrate INN 51.0 mg (Eqv. to 50 mg Canagliflozin) & Metformin Hydrochloride USP 500 mg .	**Anti-diabetic**	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contraindication: It is contraindicated in patients** moderate to severe renal impairment (eGFR below 45 mL/min/1.73 m2), end stage renal disease or dialysis . It is also contraindicated in patients with known hypersensitivity to canagliflozin & metformin HCl or any other components of this product. **Precautions:** It is not recommended in hepatic impairment or hypoxic states , hypotension, Hypoglycemia, Genital mycotic infections & Acute kidney injury Patients. Patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue it. **Warning:** Lactic acidosis and lower limb amputation **Lactic Acidosis**: Postmarketing cases of metformin-associated lacticacidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. **Risk of Lower Limb Amputation :** In patients with type2 diabetes who have established cardiovascular disease (CVD) or at risk for CVD, canagliflozin has been	**New** Canagliflozin 100mg Tablet. Metformin Hydrochloride 750 mg, 850 mg, 1 gm Tablet	US-FDA Canagliflozin 50mg & Metformin Hydrochloride 500 mg Film Coated Tablet DCC-২৪৯ এ প্রয়োজন নাই বিধায় নামঞ্জুর করা হয় (পৃষ্ঠা-৭৪)।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						associated with lower limb amputations, most frequently of the toe and midfoot; some also involved the leg. Before initiating, consider factors that may increase the risk of amputation. **Side effects:** The most common side effects are female genital mycotic infections, urinary tract infection, nausea, vomiting, stomach upset, diarrhea, bloating/gas, frequent urination,. etc.				
352.	Drug International Ltd (Unit-3) 31/1, Satrong Road, Gopalpur, Tongi Industrial Area Gazipur, Bangladesh.	Canagliflozin 50mg & Metformin Hydrochloride 1000 mg Extended Release Tablet	Canagliflozin Hemihydrate INN 51.0 mg (Eqv. to 50 mg Canagliflozin) & Metformin Hydrochloride USP 1000 mg.	**Anti-diabetic**	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contraindication:It is contraindicated in patients** moderate to severe renal impairment (eGFR below 45 mL/min/1.73 m2), end stage renal disease or dialysis . It is also contraindicated in patients with known hypersensitivity to canagliflozin& metforminHCl or any other components of this product. **Precautions:** It is not recommended in hepatic impairment or hypoxic states , hypotension, Hypoglycemia, Genital mycotic infections & Acute kidney injury Patients. Patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue it. **Warning:**	New Canagliflozin 100mg Tablet. Metformin Hydrochloride 750 mg, 850 mg, 1 gm Tablet	US-FDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Lactic acidosis and lower limb amputation **Lactic Acidosis**: Postmarketing cases of metformin-associated lacticacidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. **Risk of Lower Limb Amputation :**In patients with type2 diabetes who have established cardiovascular disease (CVD) or at risk for CVD, canagliflozin has been associated with lower limb amputations, most frequently of the toe and midfoot; some also involved the leg. Before initiating, consider factors that may increase the risk of amputation. **Side effects:** The most common side effects are female genital mycotic infections, urinary tract infection, nausea, vomiting, stomach upset, diarrhea, bloating/gas, frequent urination,. etc.				
353.	Drug International Ltd (Unit-3) 31/1, Satrong Road, Gopalpur, Tongi Industrial Area Gazipur, Bangladesh.	Canagliflozin 150mg & Metformin Hydrochloride 500 mg Extended Release Tablet	Canagliflozin Hemihydrate INN 153.00 mg (Eqv. to 150 mg Canagliflozin) & Metformin Hydrochloride USP 500 mg.	**Anti-diabetic**	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contraindication:It is contraindicated in patients** moderate to severe renal impairment (eGFR below 45 mL/min/1.73 m2), end stage renal disease or dialysis . It is also contraindicated in patients with known hypersensitivity to canagliflozin& metforminHCl or any other components of this product.	**New** Canagliflozin 100mg Tablet. Metformin Hydrochloride 750 mg, 850 mg, 1 gm Tablet	US-FDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Precautions: It is not recommended in hepatic impairment or hypoxic states , hypotension, Hypoglycemia, Genital mycotic infections & Acute kidney injury Patients. Patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue it. **Warning:** Lactic acidosis and lower limb amputation **Lactic Acidosis**: Postmarketing cases of metformin-associated lacticacidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. **Risk of Lower Limb Amputation :**In patients with type2 diabetes who have established cardiovascular disease (CVD) or at risk for CVD, canagliflozin has been associated with lower limb amputations, most frequently of the toe and midfoot; some also involved the leg. Before initiating, consider factors that may increase the risk of amputation. **Side effects:** The most common side effects are female genital mycotic infections, urinary tract infection, nausea, vomiting, stomach upset, diarrhea, bloating/gas, frequent urination,. etc				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
354.	Drug International Ltd (Unit-3) 31/1, Satrong Road, Gopalpur, Tongi Industrial Area Gazipur, Bangladesh.	Canagliflozin 150mg & Metformin Hydrochloride 1000 mg Extended Release Tablet	Canagliflozin Hemihydrate INN 153.00 mg (Eqv. to 150 mg Canagliflozin) & Metformin Hydrochloride USP 1000 mg .	**Anti-diabetic**	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contraindication:It is contraindicated in patients** moderate to severe renal impairment (eGFR below 45 mL/min/1.73 m2), end stage renal disease or dialysis . It is also contraindicated in patients with known hypersensitivity to canagliflozin& metforminHCl or any other components of this product. **Precautions:** It is not recommended in hepatic impairment or hypoxic states , hypotension, Hypoglycemia, Genital mycotic infections & Acute kidney injury Patients. Patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue it. **Warning:** Lactic acidosis and lower limb amputation **Lactic Acidosis**: Postmarketing cases of metformin-associated lacticacidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. **Risk of Lower Limb Amputation :**In patients with type2 diabetes who have established cardiovascular disease (CVD) or at risk for CVD, canagliflozin has been associated with lower limb amputations, most frequently of the toe and midfoot; some also involved the leg. Before	**New** Canagliflozin 100mg Tablet. Metformin Hydrochloride 750 mg, 850 mg, 1 gm Tablet	US-FDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						initiating, consider factors that may increase the risk of amputation. **Side effects:** The most common side effects are female genital mycotic infections, urinary tract infection, nausea, vomiting, stomach upset, diarrhea, bloating/gas, frequent urination,. etc.				
355.	Drug International Ltd (Unit-3) 31/1, Satrong Road, Gopalpur, Tongi Industrial Area Gazipur, Bangladesh.	Dapagliflozin 5 mg & Metformin HCl 1000 mg Extended Release Tablet	Dapagliflozin Propanediol INN 6.15 mg (Eqv. to 5 mg Dapagliflozin) & Metformin HCl USP 1000 mg.	**Anti-diabetic**	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contraindication:It is contraindicated in patients Moderate to severe renal impairment (eGFR below 60 mL/min/1.73 m2), end stage renal disease or patients on**dialysis. It is also contraindicated in patients with known hypersensitivity to dapagliflozin& metforminHCl or any other components of this product. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin. **Precautions:** Patients who present with signs and symptoms of metabolic acidosis for ketoacidosis regardless of blood glucose level. If suspected, discontinue it, evaluate and treat promptly. Before initiating this medicine, consider risk factors for ketoacidosis. It is not recommended in hepatic impairment, hypotension, bladder cancer,	**New** Dapagliflozin 5 mg, 10 mg Metformin Hydrochloride 750 mg, 850 mg, 1 gm Tablet	DCC এর ২৪৪ তম সভায় প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						hypoglycemia, Genital mycotic infections & Acute kidney injury Patients. **Warning:** Risk factors include renal impairment, concomitant use of certain drugs, age >65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment. If lactic acidosis is suspected, discontinue this medication and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended. **Side effects:**The most common side effects are nasopharyngitis, urinary tract infection, diarrhea, and headache. etc.				
356.	Drug International Ltd (Unit-3) 31/1, Satrong Road, Gopalpur, Tongi Industrial Area Gazipur, Bangladesh.	Dapagliflozin 2.5 mg & Metformin HCl 1000 mg Extended Release Tablet	DapagliflozinPropanediol INN 3.075 mg (Eqv. to 2.5 mg Dapagliflozin) & Metformin HCl USP 1000 mg.	**Anti-diabetic**	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contraindication:It is contraindicated in patients Moderate to severe renal impairment (eGFR below 60 mL/min/1.73 m2), end stage renal disease or patients on**dialysis. It is also contraindicated in patients with known hypersensitivity to dapagliflozin& metforminHCl or any other components of this product. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin.	**New** Dapagliflozin 5 mg, 10 mg Metformin Hydrochloride 750 mg, 850 mg, 1 gm Tablet	US-FDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Precautions: Patients who present with signs and symptoms of metabolic acidosis for ketoacidosis regardless of blood glucose level. If suspected, discontinue it, evaluate and treat promptly. Before initiating this medicine, consider risk factors for ketoacidosis. It is not recommended in hepatic impairment, hypotension, bladder cancer, hypoglycemia, Genital mycotic infections & Acute kidney injury Patients. **Warning:** Risk factors include renal impairment, concomitant use of certain drugs, age >65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment. If lactic acidosis is suspected, discontinue this medication and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended. **Side effects:** The most common side effects are nasopharyngitis, urinary tract infection, diarrhea, and headache. etc.				

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
357.	Drug International Ltd (Unit-3) 31/1, Satrong Road, Gopalpur, Tongi Industrial Area Gazipur, Bangladesh	Dapagliflozin 5 mg & Metformin HCl 500 mg Extended Release Tablet	DapagliflozinPropanediol INN 6.15 mg (Eqv. to 5.0 mg Dapagliflozin)& Metformin HCl USP 500 mg .	**Antibiotic**	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contraindication:It is contraindicated in patients Moderate to severe renal impairment (eGFR below 60 mL/min/1.73 m2), end stage renal disease or patients on**dialysis. It is also contraindicated in patients with known hypersensitivity to dapagliflozin& metforminHCl or any other components of this product. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin. **Precautions:** Patients who present with signs and symptoms of metabolic acidosis for ketoacidosis regardless of blood glucose level. If suspected, discontinue it, evaluate and treat promptly. Before initiating this medicine, consider risk factors for ketoacidosis. It is not recommended in hepatic impairment, hypotension, bladder cancer, hypoglycemia, Genital mycotic infections & Acute kidney injury Patients. **Warning:** Risk factors include renal impairment, concomitant use of certain drugs, age >65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment. If lactic acidosis	**New** Dapagliflozin 5 mg, 10 mg Metformin Hydrochloride 750 mg, 850 mg, 1 gm Tablet	US-FDA DCC এর ২৪৪ তম সভায় প্রয়োজন নাই বিধায় নামঞ্জুর করা হয়।।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						is suspected, discontinue this medication and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended **Side effects:** The most common side effects are nasopharyngitis, urinary tract infection, diarrhea, and headache. etc.				
358.	Drug International Ltd (Unit-3) 31/1, Satrong Road, Gopalpur, Tongi Industrial Area Gazipur, Bangladesh	Dapagliflozin10 mg & Metformin HCl 1000 mg Extended Release Tablet.	DapagliflozinPropanediol INN 12.3 mg (Eqv. to 10 mg Dapagliflozin) & Metformin HCl USP 1000 mg .	Anti-diabetic	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with <u>type 2 diabetes</u> mellitus.	**Contraindication:It is contraindicated in patients Moderate to severe renal impairment (eGFR below 60 mL/min/1.73 m2), end stage renal disease or patients on**dialysis. It is also contraindicated in patients with known hypersensitivity to dapagliflozin& metforminHCl or any other components of this product. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin. **Precautions:** Patients who present with signs and symptoms of metabolic acidosis for ketoacidosis regardless of blood glucose level. If suspected, discontinue it, evaluate and treat promptly. Before initiating this medicine, consider risk factors for ketoacidosis. It is not recommended in hepatic impairment, hypotension, bladder cancer,	**New** Dapagliflozin 5 mg, 10 mg Metformin Hydrochloride 750 mg, 850 mg, 1 gm Tablet	US-FDA DCC এর ২৪৪ তম সভায় প্রয়োজন নাই বিধায় নামঞ্জুর করা হয় ।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						hypoglycemia, Genital mycotic infections & Acute kidney injury Patients. **Warning:** Risk factors include renal impairment, concomitant use of certain drugs, age >65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment. If lactic acidosis is suspected, discontinue this medication and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended **Side effects:** The most common side effects are nasopharyngitis, urinary tract infection, diarrhea, and headache. etc.				
359.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Multivitamin & Multiminarel For Men	Vitamin A (20% as beta-Carotene) BP 5.2500mg + Sodium Ascorbate BP 101.244mg + Cholecalciferol (Vitamin D3 1000IU) BP 10.000mg + Dry Vitamin E Acetate (50%) USP 40.6000mg + Vitamin k (5%) USP 1.200mg +Thiamine Mononitrate BP 1.480mg + Riboflavin (Vit-B2) BP 1.300mg + Niacin (As Nicotinamide) USP 16.000mg + Pyridoxine	Multivitamin & Multiminerals	This Medication is a Multi vitamin and iron product which is used to treat or prevent vitamin deficiency due to poor diet, certain illnesses. Vitamin and iron are important building blocks of the body and help keep men in good health.	**Contraindication :** **H**ypersensitivity to any component or any of the ingredients of the product. This product is not indicated for child. Keep Out of reach of children. **Side-effect:** Constipation, Diarrhea or upset of stomach may occur. These effects are actually temporary and may disappear as your body adjustd to the medication.		**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			Hydrocloride BP 2.430mg + Folic Acid BP 0.200mg + Vitamin B12 (Cyanocobalamin 0.1%) BP 6.000mg + Biotin USP 0.040mg + Calcium D Panthonate BP 16.301mg +Calcium Carbonate BP 457.000mg + Dried Ferrous Sulphate BP 21.758mg + Anhydrous Calcium Hydrogen Phosphate BP 87.892mg + Potassium Iodide BP 0.200 mg +Manganese Oxide BP 165.775 mg + Zinc OxideBP 13.700mg+ Sodium Selenate (micronized) Ph. Grade 0.240+Cupric Oxide (micronized) Ph. Grade 1.127mg +Manganese Sulphate BP6.326mg + Chromic Chloride 100% USP 0.107mg + Sodium Molybdte 100% BP 0.126mg + Potassium Chloride BP 153.026mg + Lycopene US-NF 0.600mg Tablet						
360.	Beacon Pharmaceuticals Ltd, Kathali, Bhaluka, Mymensingh	Multivitamin & Multiminarel For Men	Vitamin A (20% as beta-Carotene) BP 5.2500mg + Sodium Ascorbate BP 84.370mg + Cholecalciferol (Vitamin D3 1000IU) BP 10.000mg + Dry Vitamin E Acetate (50%) USP 3.1600mg + Vitamin k1 (5%) USP	Multivitamin & Multiminerals	This Medication is a Multi vitamin and iron product which is used to treat or prevent vitamin deficiency due to poor diet, certain illnesses. Vitamin and iron are important building blocks of the body and help keep men in good health.	**Contraindication :** **H**ypersensitivity to any component or any of the ingredients of the product. This product is not indicated for child. Keep Out of reach of children. **Side-effect:** Constipation, Diarrhea or upset of stomach may occur. These		**রেফারেন্স নাই**	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			1.00mg +Thiamine Mononitrate BP 1.357mg + Riboflavin (Vit-B2) BP 1.100mg + Niacin (As Nicotinamide) USP 14.000mg + Pyridoxine Hydrocloride BP 2.430mg + Folic Acid BP 0.400mg + Vitamin B12 (Cyanocobalamin 0.1%) BP 6.000mg + Biotin USP 0.040mg + Calcium D Panthonate BP 16.301mg + Calcium Carbonate BP 431.610mg + Dried Ferrous Sulphate BP 48.956mg + Anhydrous Calcium Hydrogen Phosphate BP 87.892mg + Potassium Iodide BP 0.200 mg +Manganese Oxide BP 165.775 mg + Zinc Oxide BP 9.957mg + Sodium Selenate (micronized) Ph. Grade 0.043+Cupric Oxide (micronized) Ph. Grade 0.626mg +Manganese Sulphate BP 4.950mg + Chromic Chloride 100% USP 0.097mg + Sodium Molybdate 100% BP 0.126mg + Potassium Chloride BP 153.026 mg Tablet.			effects are actually temporary and may disappear as your body adjustd to the medication.				
361.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Carisoprodol 350 mg Tablet	Carisoprodol USP 350 mg	Skeletal Muscle Relaxant	It is a muscle relaxant indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions in adults.	**Contraindication :** • Acute intermittent porphyria. • Hypersensitivity reactions to a carbamate such as meprobamate. **Side-effects:** Most common adverse reactions (incidence > 2%) are drowsiness, dizziness, and headache.	New	USFDA DCC এর 244 তম সভায় প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

SI. NO.	Name of the Manufacturer	Name of the Medicine with dosage form	Generic Name with Strength	Therapeutic Class	Indication	Contra-indication, Side-effects, warnings and precautions	Status (New Molecule/ Existing)	আবেদনকারী কর্তৃক USFDA/ UKMHRA/ EMA / BNF এর দাখিলকৃত Ref.	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Warnings and precautions: Due to sedative properties, may impair ability to perform hazardous tasks such as driving or operating machinery • Additive sedative effects when used with other CNS depressants including alcohol • Cases of abuse, dependence and withdrawal • Seizures				

Annex-C: Proposed Product for Import (Human)

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
1.	AstraZeneca Pharmaceuticals LP, 4601 Highway 62 East, Mount Vernon, IN 47620 United States of America **Importer:** (MGH Healthcare Ltd.)	**Kombiglyze XR 2.5mg/1000 mg**	Saxagliptin 2.5mg + Metformin hydrochloride 1000mg Tablet.	Antidiabetes	Kombiglyze XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate.	**Contraindications:** Kombiglyze XR is contraindicated in patients with: • Severe renal impairment (eGFR below 30mL/min/1.73m^2). • Hypersensitivity to metformin hydrochloride. • Acute or chronic metabolic acidosis, including diabetic ketoacidosis. Diabetic ketoacidosis should be treated with insulin. • History of serious hypersensitivity reaction to Kombiglyze XR or saxagliptin, such as anaphylaxis, angioedema, or exfoliative skin conditions. **Side-effects:** Kombiglyze XR can cause serious side effects, including: • Allergic (hypersensitivity) reactions, such as: ▪ Swelling of your face, lips, throat, and other areas on your skin. ▪ Raised, red areas on your skin (hives). ▪ Difficulty with swallowing or breathing. ▪ Skin rash, itching, flaking, or peeling. • Low blood sugar (hypoglycemia). May become worse in people who also take another medication to treat diabetes, such as sulfonulureas or insulin. Symptoms of low blood sugar		CPP-USFDA DCC এর ২৪০ তম সভায় প্রয়োজন নাই বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						include: ▪ Shaking ▪ Sweating ▪ Rapid heartbeat ▪ Change in vision ▪ Hunger ▪ Headache ▪ Change in mood. • Joint pain. Some people who take medicines called DDP-4 inhibitors, may develop joint pain that can be severe. • Skin reaction. Some people who take medicines called DDP-4 inhibitors, may develop skin reaction called bullous pemphigoid that can require treatment in a hospital. Common side effects of Kombiglyze XR include: • Upper respiratory tract infection. • Stuffy or runny nose or sore throat. • Urinary tract infection. • Headache • Diarrhea • Nausea and vomiting. **WARNINGS AND PRECAUTIONS:** Lactic acidosis: Warn patients against excessive alcohol intake. KOMBIGLYZE XR not recommended in hepatic impairment and contraindicated in renal impairment. Ensure normal renal function before initiating and at least annually thereafter. Temporarily discontinue KOMBIGLYZE XR for surgical procedures necessitating restricted intake of food and fluids.				

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						• Vitamin B12 deficiency: Metformin may lower vitamin B12 levels. Measure hematological parameters annually. • Hypoglycemia: When used with an insulin secretagogue (e.g., sulfonylurea), a lower dose of the insulin secretagogue may be required to reduce the risk of hypoglycemia. • Macrovascular outcomes: No conclusive evidence of macrovascular risk reduction with KOMBIGLYZE XR or any other antidiabetic drug.				
2.	AstraZeneca Pharmaceuticals LP, 4601 Highway 62 East, Mount Vernon, IN 47620 United States of America **Importer:** (MGH Healthcare Ltd.)	**Kombiglyze XR 5mg/1000mg**	Saxagliptin 5mg + metformin hydrochloride 1000mg Tablet.	Antidiabetes	Kombiglyze XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate	**Contraindications:** Kombiglyze XR is contraindicated in patients with: • Severe renal impairment (eGFR below 30mL/min/1.73m^2). • Hypersensitivity to metformin hydrochloride. • Acute or chronic metabolic acidosis, including diabetic ketoacidosis. Diabetic ketoacidosis should be treated with insulin. • History of serious hypersensitivity reaction to Kombiglyze XR or saxagliptin, such as anaphylaxis, angioedema, or exfoliative skin conditions. **Side-effects:** Kombiglyze XR can cause serious side effects, including: • Allergic (hypersensitivity) reactions, such as: ▪ Swelling of your face, lips, throat, and other areas on your		CPP-USFDA DCC এর ২৪০ তম সভায় প্রয়োজন নাই বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						skin. ▪ Raised, red areas on your skin (hives). ▪ Difficulty with swallowing or breathing. ▪ Skin rash, itching, flaking, or peeling. • Low blood sugar (hypoglycemia). May become worse in people who also take another medication to treat diabetes, such as sulfonulureas or insulin. Symptoms of low blood sugar include: ▪ Shaking ▪ Sweating ▪ Rapid heartbeat ▪ Change in vision ▪ Hunger ▪ Headache ▪ Change in mood. • Joint pain. Some people who take medicines called DDP-4 inhibitors, may develop joint pain that can be severe. • Skin reaction. Some people who take medicines called DDP-4 inhibitors, may develop skin reaction called bullous pemphigoid that can require treatment in a hospital. Common side effects of Kombiglyze XR include: • Upper respiratory tract infection. • Stuffy or runny nose or sore throat. • Urinary tract infection. • Headache • Diarrhea				

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						• Nausea and vomiting. **WARNINGS AND PRECAUTIONS:** Lactic acidosis: Warn patients against excessive alcohol intake. KOMBIGLYZE XR not recommended in hepatic impairment and contraindicated in renal impairment. Ensure normal renal function before initiating and at least annually thereafter. Temporarily discontinue KOMBIGLYZE XR for surgical procedures necessitating restricted intake of food and fluids. • Vitamin B12 deficiency: Metformin may lower vitamin B12 levels. Measure hematological parameters annually. • Hypoglycemia: When used with an insulin secretagogue (e.g., sulfonylurea), a lower dose of the insulin secretagogue may be required to reduce the risk of hypoglycemia. • Macrovascular outcomes: No conclusive evidence of macrovascular risk reduction with KOMBIGLYZE XR or any other antidiabetic drug.				
3.	AstraZeneca Pharmaceuticals LP, 4601 Highway 62 East, Mount Vernon, IN 47620 United States of America **Importer:** (MGH Healthcare Ltd.)	**XIGDUO XR 5mg/1000mg**	Dapagliflozin 5mg + metformin hydrochloride 1000mg Tablet.	Antidiabetes	Xigduo is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate	**Contraindications:** Xigduo XR is contraindicated in patients with: • Moderate to severe renal impairment (eGFR below 60mL/min/1.73m^2), end stage renal disease or patients on dialysis • History of serious hypersensitivity reaction to dapagliflozin or hypersensitivity to metformin		CPP-USFDA DCC এর ২৪৪ তম সভায় প্রয়োজন নাই বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						hydrochloride. • Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin. **Side-effects:** The most common adverse reactions associated with XIGDUO XR (5% or greater incidence) were female genital mycotic infection, nasopharyngitis, urinary tract infection, diarrhea, and headache. • Adverse reactions reported in >5% of patients treated with metformin extended-release and more commonly than in patients treated with placebo are: diarrhea and nausea/vomiting. **WARNINGS AND PRECAUTIONS:** Lactic acidosis: Warn patients against excessive alcohol intake. XIGDUO XR should generally be avoided in hepatic impairment and contraindicated in moderate to severe renal impairment. Ensure normal or mildly impaired renal function before initiating and at least annually thereafter. Temporarily discontinue XIGDUO XR in patients undergoing radiologic studies with intravascular administration of iodinated contrast materials or any surgical procedures necessitating restricted intake of food and fluids. • Hypotension: Before initiating XIGDUO XR, assess volume status and correct hypovolemia in the elderly, in patients with renal				

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						impairment or low systolic blood pressure, and in patients on diuretics. Monitor for signs and symptoms during therapy. • Hypoglycemia: In patients taking insulin or an insulin secretagogue with XIGDUO XR, consider a lower dose of insulin or the insulin secretagogue to reduce the risk of hypoglycemia. • Vitamin B12 deficiency: Metformin may lower vitamin B12 levels. Measure hematological parameters annually. • Genital mycotic infections: Monitor and treat if indicated. • Increased LDL-C: Monitor and treat per standard of care. • Bladder Cancer: An imbalance in bladder cancers was observed in clinical trials. Dapagliflozin should not be used in patients with active bladder cancer and should be used with caution in patients with a prior history of bladder cancer. • Macrovascular outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with XIGDUO XR or any other antidiabetic drug.				
4.	AstraZeneca Pharmaceuticals LP, 4601 Highway 62 East, Mount Vernon, IN 47620 United States of America **Importer:** (MGH Healthcare	**XIGDUO XR 10mg/1000mg**	Dapagliflozin 10mg; metformin hydrochloride 1000mg.	Antidiabetes	Xigduo is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both Dapagliflozin and metformin is	**Contraindications:** Xigduo XR is contraindicated in patients with: • Moderate to severe renal impairment (eGFR below 60mL/min/1.73m^2), end stage renal disease or patients on dialysis • History of serious hypersensitivity reaction to dapagliflozin or		CPP-USFDA DCC এর ২৪৪ তম সভায় প্রয়োজন নাই বিধায় আবেদন	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
	Ltd.)				appropriate	hypersensitivity to metformin hydrochloride. • Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin. **Side-effects:** The most common adverse reactions associated with XIGDUO XR (5% or greater incidence) were female genital mycotic infection, nasopharyngitis, urinary tract infection, diarrhea, and headache. • Adverse reactions reported in >5% of patients treated with metformin extended-release and more commonly than in patients treated with placebo are: diarrhea and nausea/vomiting. **<u>WARNINGS AND PRECAUTIONS:</u>** Lactic acidosis: Warn patients against excessive alcohol intake. XIGDUO XR should generally be avoided in hepatic impairment and contraindicated in moderate to severe renal impairment. Ensure normal or mildly impaired renal function before initiating and at least annually thereafter. Temporarily discontinue XIGDUO XR in patients undergoing radiologic studies with intravascular administration of iodinated contrast materials or any surgical procedures necessitating restricted intake of food and fluids. • Hypotension: Before initiating		নামঞ্জুর করা হয়েছিল।		

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						XIGDUO XR, assess volume status and correct hypovolemia in the elderly, in patients with renal impairment or low systolic blood pressure, and in patients on diuretics. Monitor for signs and symptoms during therapy. • Hypoglycemia: In patients taking insulin or an insulin secretagogue with XIGDUO XR, consider a lower dose of insulin or the insulin secretagogue to reduce the risk of hypoglycemia. • Vitamin B12 deficiency: Metformin may lower vitamin B12 levels. Measure hematological parameters annually. • Genital mycotic infections: Monitor and treat if indicated. • Increased LDL-C: Monitor and treat per standard of care. • Bladder Cancer: An imbalance in bladder cancers was observed in clinical trials. Dapagliflozin should not be used in patients with active bladder cancer and should be used with caution in patients with a prior history of bladder cancer. • Macrovascular outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with XIGDUO XR or any other antidiabetic drug.				
5.	**Manufacturer:** Amgen Manufacturing Limited, USA **Local Representative:**	**Aerinex**	Erenumab INN 140 mg/ml Solution for Injection in a Pre-filled		Aerinex is indicated for the treatment of prophylaxis of migraine in adults who have at least 4 migraine days per month	**Contraindication** None **Side Effects:** General disorders and administration site condition, gastrointestinal disorders, musculoskeletal and connective		CPP-EMA	আবেদন অনুমোদন করা যেতে পারে।	অনুমোদন করা হল।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
	Novartis Bangladesh Ltd. AHN Tower 7th Floor 13 C R Dutta Road (Old Sonargaon Road) Biponan C/A, Dhaka 1000 Bangladesh		Syringe			tissue disorders & skin and subcutaneous tissue disorders.				
6.	**Manufacturer:** Novartis Pharma S.A.E, Cairo - Egypt **Local Representative:** Novartis Bangladesh Ltd. AHN Tower 7th Floor 13 C R Dutta Road (Old Sonargaon Road) Biponan C/A, Dhaka 1000 Bangladesh	Flotac	Diclofenac Resinate INN 75 mg Hard Gelatin Capsules		Flotac is indicated for the treatment of: • Acute arthritis (including acute attacks of gout). • Chronic arthritis, especially rheumatoid arthritis (chronic polyarthritis). • Ankylosing spondylitis (Morbus Bechterew) and other inflammatory, rheumatoid syndroms of the vertrebral column. • Irritation in cases of osteoarthritis and spondylarthritis • Inflammatory soft-tissue rheumatic diseases • Painful swelling	**Contraindication:** own hypersensitivity to the active stance or to any of the excipients. • Known reactions in the form of bronchospasm, asthma, rhinitis or urticaria following intake of acetylsalicylic acid or other NSAIDs in the past • Unexplained haematopoietic disorders • Cerebrovascular or other active bleeding • Last trimester of pregnancy • Severe hepatic dysfunction • Severe renal dysfunction • Severe cardiac failure • Paediatric population • Known heart failure (NYHA II-IV), ischemic heart disease, peripheral arterial occlusive disease and/or Cerebrovascular disease **Side Effects:** Headache, dizziness, Vertigo, Nausea, vomiting, diarrhea, dyspepsia, abdominal pain, flatulence, decreased appetite,		CPP-Egypt & Germany DCC এর ২৩৫ তম সভায় এই মাত্রা FDA অননুমোদিত এবং BNF-এ অন্তর্ভুক্ত নাই বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					and inflammation following injuries or operations. • Tumour pain especially when the skeleton is affected or in cases of inflammatory peritumoural oedema	Transaminases increased & Rash.				
7.	**Manufacturer:** Delpharm Huningue S.A.S, France **Local Representative:** Novartis Bangladesh Ltd. AHN Tower 7th Floor 13 C R Dutta Road (Old Sonargaon Road) Biponan C/A, Dhaka 1000 Bangladesh	Voltaren	Diclofenac Resinate INN 1.5 % Oral Drops Solution		Voltaren is indicated for the treatment of: • Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, Juvenile rheumatoid arthritis, ankylosing spondylitis, Osteoarthritis including spondylarthritis. • Painful syndromes of the vertebral column • Non-articular rheumatism • Painful post-traumatic and post-operative pain, inflammation, and swelling, e.g. following dental or	**Contraindication:** • Known hypersensitivity to the active substance or to any of the excipients. • Active gastric or intestinal ulcer, bleeding or perforation. • Last trimester of pregnancy. • Hepatic failure. • Renal failure (GFR <15 mL/min/1.73m2). • Severe cardiac failure. • Like other non-steroidal anti-inflammatory drugs (NSAIDs), Voltaren is also contraindicated in patients in whom the use of acetylsalicylic acid or other NSAIDs can precipitateasthma, angioedema, urticaria, or acute rhinitis (i.e. NSAID-induced cross-reactivity reactions) **Side Effects:** Headache, dizziness, Vertigo, Nausea, vomiting, diarrhea, dyspepsia, abdominal pain, flatulence, decreased appetite, Transaminases increased & Rash.		CPP-Swizerland DCC এর ২৩৯ তম সভায় প্রয়োজন নাই বিধায় আবেদন নামঞ্জুর করা হয়েছিল।	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					orthopedic surgery. • Painful and/or inflammatory gynaecological conditions e.g. primary dysmenorrhea or adnexitis • As an adjuvant in severe painful inflammatory infections of the ear, nose or throat, e.g. pharyngotonsillitis, otitis. In keeping with general therapeutic principles, the underlying disease should be treated with basic therapy, as appropriate. Fever alone is not an indication.					
8.	Sanofi S.p.A Via Valcanello, 4 03012 Anagni Italy. **Local Agent**: Sanofi Bangladesh Ltd.	Priftin (Rifapentine) 150mg Tab	Rifapentine 150mg Tab	Anti-infective	**Indication:** Indicated for the treatment of Latent Tuberculosis infection (LTB) caused by M Tuberculosis in combination with isoniazid at high risk progress of TB disease.	**Contraindications:** **Hypersensitivity** PRIFTIN is contraindicated in patients with a history of hypersensitivity to rapamycin's. **Adverse Reactions:** The following serious and otherwise important adverse drug reactions are discussed in greater detail in other sections of labeling: • Hepatotoxicity • Hypersensitivity	New	CPP-USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						• Discoloration of Body Fluids • Clostridium Difficile-Associated Diarrhea • Porphyria				
9.	Baxter Healthcare Corporation **Local Agent**: Swadesh, 30 Bijoynagar road, 3rd floor, Dhaka.	Suprane, Inhalant	Desflurane USP 240 ml	Aneasthetic	Desflurane, USP is indicated as an inhalation agent for induction and/or maintenance of anesthesia for inpatient and outpatient surgery in adults	Desflurane, USP should not be used in patients with a known or suspected genetic susceptibility to malignant hyperthermia.	New	CPP-USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
10.	Bieffe Medital S.A **Local Agent**: Swadesh, 30 Bijoynagar road, 3rd floor, Dhaka.	Plasmalyte- A Solution for infusion	Sodium Gluconate 0.502% W/V + Magnesium Chloride Hexahydrate0.03% W/V + Sodium Acetate Trihydrate 0.368% W/V + Potassium Chloride 0.037% W/V + Sodium Chloride 0.526 W/V	Metals, Salts, Minerals	To provide a source of Electrolyte Fluids for Electorlyte Deficient Patient.	Plasma Lyte A Infusion must not be used in hyperchloraemia, hypernatraemia, heperkalaemia, kidney failure, slow heartbeat, metabolice respiratory alkalosis, hypoccalcaemia	New	CPP-USFDA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
11.	Pierrel Pharma srl Starda Statale Appia 7 Bis, 46-48, Capua (CE), 1-81043, Italy.	Orabloc 1:100,000 (Solution for Injection)	Articaine HCL 40 mg + Adrenaline Tartrate 0.0182mg	Anesthetic	ORABLOC is an amide local anesthetic containing a vasoconstrictor indicated for local, infiltrative, or	**Contraindication:** Known hypersensitivity to sulfite **Side Effect:** The most common adverse reactions (incidence >2%) are headache and pain.		CPP- UK	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
	Local Agent: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.				conductive anesthesia in both simple and complex dental procedures	**WARNINGS AND PRECAUTIONS:** Accidental Intravascular Injection: May be associated with convulsions followed by coma and respiratory arrest. Resuscitative equipment, oxygen and other resuscitative drugs should be available. • Systemic Toxicity • Vasoconstrictor Toxicity: Local anesthetic solutions like [Tradename] that contain a vasoconstrictor should be used cautiously, especially in patients with impaired cardiovascular function or vascular disease. • Methemoglobinemia • Anaphylaxis and Allergic-Type Reactions.				
12.	Pierrel Pharma srl Strada Statale Appia 7 Bis, 46-48, Capua (CE), 1-81043, Italy. **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Orabloc 1:200,000 (Solution for Injection)	Articaine HCL 40 mg + Adrenaline Tartrate 0.0091mg	Anesthetic	ORABLOC is indicated for local, infiltrative, or conductive anesthesia in both simple and complex dental procedures in adults and pediatric patients 4 years of age and older.	**Contraindication:** Known hypersensitivity to sulfite **Side Effect:** The most common adverse reactions (incidence >2%) are headache and pain. **WARNINGS AND PRECAUTIONS:** Accidental Intravascular Injection: May be associated with convulsions followed by coma and respiratory arrest. Resuscitative equipment, oxygen and other resuscitative drugs should be available. • Systemic Toxicity • Vasoconstrictor Toxicity: Local anesthetic solutions like [Tradename] that contain a vasoconstrictor should be used cautiously, especially in patients with impaired cardiovascular function or vascular disease. • Methemoglobinemia • Anaphylaxis and Allergic-Type Reactions.		CPP-UK	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
13.	Laboratoire AGUETTANT SAS Olivier CESBRON Address: 1 rue Alexander Fleming, 69007-LYON-FRANCE **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	NUTRYELT (solution for Infusion)	Zine 10000 ug Copper 300 ug + Manganese 55ug+sodium fluoride 950 ug+ potassium iodid 130 ug + sodium selenite 70ug sodium molybdate 20ug + chromium chloride 10ug + ferrous gluconate 1000ug	Metals, Salts, Minerals	NUTRYELT is a concentrate for solution for infusion. It contains 9 essential trace elements (iron, copper, manganese, zinc, fluorine, iodine, selenium, chromium, molybdenum). These trace elements are considered as essential because the body cannot produce them but needs them in very small quantities in order to function properly. NUTRYELT is used to provide trace elements in adults needingintravenous (into a vein) feeding..	**Contraindication** Hypersensitivity to Nutryelt Tartrate or to any of the excipients Special warnings and precautions for use If you are allergic (hypersensitive) to any of the ingredients of NUTRYELT If you have abnormally highlevel of any of the ingredients of the product in your blood. (If you have any doubt, ask your doctor). If you have pronounced cholestasis (yellowing of the skin or whites of the eyes caused by liver or blood problem). If you have an excess of copper (wilson's disease) or iron in the body (hemochromatosis). **Side effects** Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor you notice any of the following: Frequency not known (cannot be estimated from the available data): pain at the application site. Case of hypersensitivity reactions including fatal anaphylactic reactions have been reported in patients receiving IV iron-containing products. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national.		CPP-France	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
14.	Protina Pharmaceutical GmbH Adalperostr. 37, 85737 Ismaning, Germany **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Magnesium Diasporal 400mg (Granules for oral solution)	Magnesium 400 mg	Metals, Salts, Minerals	Magnesium-Diasporal® 300 mg is used to treat and prevent magnesium deficiency. Nervous system and muscle complaints (tremors, muscle cramps, tetany) and changes in personality can all be symptoms of magnesium deficiency	**Undesirable effects** Like all medicines, this medicine can cause side effects, although not everybody gets them. Uncommon(may affect 1 to 10 users in 1,000): Soft stools to diarrhea at thebeginning of treatment (harmless and will usually decrease in frequency as the treatment advances). Very rare (may affect less than 1 user in 10,000): Fatigue if Magnesium Diasporal 300 mg is used for a longer period of time If you get any side effects, you should temporarily interrupt the treatment. After the symptoms improve and / or eliminated you can restart treatment, with a reduced dosage.		CPP-Germany	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
15.	Laboratoire AGUETTANT SAS Olivier CESBRON Address: 1 rue Alexander Fleming, 69007-LYON-FRANCE **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Phenylephrine Aguettant 500mcg/10ml (Solution for Injection)	Phenylephrine 50 mcg/ml	Adrenergic	Phenylephrine Injection is indicated in adults and children for the treatment of hypotensive states e.g. circulatory failure, during spinal anaesthesia or drug induced hypotension	**Contraindication** Hypersensitivity to phenylephrine or to any of the excipients listed in section 6.1. Patients taking monoamine oxidase inhibitors, or within 14 days of ceasing such treatment. Severe hypertension and hyperthyroidism. Avoid in patients with prostatic enlargement. **Side effects** Summary of the safety profile The most common adverse events of phenylephrine are bradycardia, hypertensive episodes, nausea and vomiting. Hypertension is more frequent with high doses. The most commonly reported		CPP-France	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						cardiovascular adverse event appears to be bradycardia, likely due to baroreceptor-mediated vagal stimulation and consistent with the pharmacological effect of phenylephrine.				
16.	Laboratoire AGUETTANT SAS Olivier CESBRON Address: 1 rue Alexander Fleming, 69007-LYON – FRANCE **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Noradrenaline Aguettant 8 mg /50 ml (Solution for Infusion)	Noradrenaline Tartrate 0.16mg/ml	Adrenergic	Noradrenaline (Norepinephrine) Concentrate is used in an emergency to increase blood pressure to normal levels.	**<u>Contraindication</u>** Hypersensitivity to noradrenaline tartrate or to any of the excipients Special warnings and precautions for use Noradrenaline should only be administered by healthcare professionals who are familiar with its use. Elderly patients may be especially sensitive to the effects of noradrenaline. Particular caution should be observed in patients with coronary, mesenteric or peripheral vascular thrombosis because noradrenaline may increase the ischemia and extend the area of infarction. Similar caution should be observed in patients with hypotension following myocardial infarction, in patients with Prinzmetal's variant angina and in patients with diabetes, hypertension or hyperthyroidism. Noradrenaline should be used with caution in patients who exhibit profound hypoxia or hypercarbia. Noradrenaline should be used only in conjunction with appropriate blood volume replacement. When infusing noradrenaline, the blood pressure and rate of flow should be checked frequently to avoid hypertension. Extravasation of the solution may		CPP-France	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						cause local tissue necrosis. The infusion site should be checked frequently. If extravasation occurs, the infusion should be stopped and the area should be infiltrated with phentolamine without delay. Prolonged administration of any potent vasopressor may result in plasma volume depletion which should be continuously corrected by appropriate fluid and electrolyte replacement therapy. If plasma volumes are not corrected, hypotension may recur when the infusion is discontinued, or blood pressure may be maintained at the risk of severe peripheral and visceral vasoconstriction (e.g., decreased renal perfusion) with diminution in blood flow and tissue perfusion with subsequent tissue hypoxia and lactic acidosis and possible ischaemic injury. *Interaction with other medicinal products and other forms of interaction* The use of noradrenaline with volatile halogenated anaesthetic agents, monoamine oxidase inhibitors, linezolid, tricyclic antidepressants, adrenergic-serotoninergic drugs or any other cardiac sensitising agents is not recommended because severe, prolonged hypertension and possible arrhythmias may result. *Fertility, pregnancy and lactation* **Pregnancy** Noradrenaline may impair placental perfusion and induce fetal bradycardia. It may also exert a				

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						contractile effect on the pregnant uterus and lead to fetal asphyxia in late pregnancy. These possible risks to the fetus should therefore be weighed against the potential benefit to the mother. **Breastfeeding** No information is available on the use of noradrenaline in lactation. **Side effects** Anxiety, Headache, Arrhythmias (when used in conjunction with cardiac sensitising agents), bradycardia, stress cardiomyopathy, Hypertension, peripheral ischaemia including gangrene of the extremities, plasma volume depletion with prolonged use, Dyspnoea, Extravasation necrosis at injection site				
17.	Laboratoire AGUETTANT SAS Olivier CESBRON Address: 1 rue Alexander Fleming, 69007-LYON – FRANCE **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.	Noradrenaline Aguettant 8mg/4ml (Concentrate for Solution for Infusion)	Noradrenaline Tartrate 2mg/ml	Adrenergic	Noradrenaline (Norepinephrine) Concentrate is used in an emergency to increase blood pressure to normal levels.	**Contraindication** Hypersensitivity to noradrenaline tartrate or to any of the excipients Special warnings and precautions for use Noradrenaline should only be administered by healthcare professionals who are familiar with its use. Elderly patients may be especially sensitive to the effects of noradrenaline. Particular caution should be observed in patients with coronary, mesenteric or peripheral vascular thrombosis because noradrenaline may increase the ischemia and extend the area of infarction. Similar caution should be observed in patients with hypotension following myocardial infarction, in		CPP-France	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						patients with Prinzmetal's variant angina and in patients with diabetes, hypertension or hyperthyroidism. Noradrenaline should be used with caution in patients who exhibit profound hypoxia or hypercarbia. Noradrenaline should be used only in conjunction with appropriate blood volume replacement. When infusing noradrenaline, the blood pressure and rate of flow should be checked frequently to avoid hypertension. Extravasation of the solution may cause local tissue necrosis. The infusion site should be checked frequently. If extravasation occurs, the infusion should be stopped and the area should be infiltrated with phentolamine without delay. Prolonged administration of any potent vasopressor may result in plasma volume depletion which should be continuously corrected by appropriate fluid and electrolyte replacement therapy. If plasma volumes are not corrected, hypotension may recur when the infusion is discontinued, or blood pressure may be maintained at the risk of severe peripheral and visceral vasoconstriction (e.g., decreased renal perfusion) with diminution in blood flow and tissue perfusion with subsequent tissue hypoxia and lactic acidosis and possible ischaemic injury. *Interaction with other medicinal products and other forms of interaction* The use of noradrenaline with				

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						volatile halogenated anaesthetic agents, monoamine oxidase inhibitors, linezolid, tricyclic antidepressants, adrenergic-serotoninergic drugs or any other cardiac sensitising agents is not recommended because severe, prolonged hypertension and possible arrhythmias may result. *Fertility, pregnancy and lactation* Pregnancy Noradrenaline may impair placental perfusion and induce fetal bradycardia. It may also exert a contractile effect on the pregnant uterus and lead to fetal asphyxia in late pregnancy. These possible risks to the fetus should therefore be weighed against the potential benefit to the mother. *Breastfeeding* No information is available on the use of noradrenaline in lactation. **Side effects** Anxiety, Headache, Arrhythmias (when used in conjunction with cardiac sensitising agents), bradycardia, stress cardiomyopathy, Hypertension, peripheral ischaemia including gangrene of the extremities, plasma volume depletion with prolonged use, Dyspnoea, Extravasation necrosis at injection site				
18.	Laboratoire AGUETTANT SAS Olivier CESBRON Address: 1 rue Alexander Fleming, 69007-	Phenylephrine Aguettant 500mcg/10ml Pre-filled syringe. (Solution for Injection)	Phenylephrine 50mcg/ml	Adrenergic	Phenylephrine Injection is indicated in adults and children for the treatment of hypotensive states e.g. circulatory failure, during spinal	**Contraindication** Hypersensitivity to phenylephrine or to any of the excipients listed in section 6.1. Patients taking monoamine oxidase inhibitors, or within 14 days of ceasing such treatment.		CPP-France	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
	LYON – FRANCE **Local Agent**: Zas Corporation Ltd., 80/22 Mymenshing Road, Nurjahan Tower (3rd Floor) Dhaka-1000, Bangladesh.				anaesthesia or drug induced hypotension	Severe hypertension and hyperthyroidism. Avoid in patients with prostatic enlargement. **Side effects** The most common adverse events of phenylephrine are bradycardia, hypertensive episodes, nausea and vomiting. Hypertension is more frequent with high doses. The most commonly reported cardiovascular adverse event appears to be bradycardia, likely due to baroreceptor-mediated vagal stimulation and consistent with the pharmacological effect of phenylephrine.				
19.	Made for F. Hoffmann-La Roche Ltd Basel, Switzerland by Shionogi & Co., Ltd., Osaka, Japan Local agent: Roche Bangladesh Limited	Xofluza 20 mg Tablets	Baloxavir Marboxil	Antiviral	Xofluza is indicated for the treatment of influenza in patients aged 12 and above who have been symptomatic for no more than 48 hours	**Contraindication:** Xofluza is contraindicated in patients with a known hypersensitivity to baloxavir marboxil or any of the excipients **Side effects:** Adverse events reported in at least 1% of adult and adolescent subjects treated with XOFLUZA included diarrhea (3%), bronchitis (2%), nasopharyngitis (1%), headache (1%) and nausea (1%). **WARNINGS AND PRECAUTIONS:** Risk of Bacterial Infection: Serious bacterial infections may begin with influenza-like symptoms, may coexist with, or occur as a complication of influenza. XOFLUZA has not been shown to prevent such complications. Prescribers should be alert to potential secondary bacterial infections and treat them as appropriate.	New	CPP-Japan	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
20.	Boehringer Ingelheim Pharma GmbH and Co. KG, Birkendorfer Strasse 65 88397 Biberach/Riss, Germany. Local agent: Radiant Export Import Enterprise Lubdhok, 4th Floor, 474P, Road No-3, Sector-12, Uttara, Dhaka 1230, Bangladesh.	Praxbind 2.5g/50ml solution for injection/infusion (50mg/ml)	Idarucizumab Internal standard	Anticoagulant	Praxbind is a specific reversal agent for dabigatran and is indicated in patients treated with dabigatran etexilate when rapid reversal of the anticoagulant effects of dabigatran is required: •For emergency surgery/urgent procedures •In life-threatening or uncontrolled bleeding	**Contraindication:** Idarucizumab is contraindicated in hypersensitivity to drug, Caution is necessary if hereditary fructose intolerance **Side effects:** In a phase III trial the safety of Praxbind has been evaluated in 503 patients, who had uncontrolled bleeding or required emergency surgery or procedures and were under treatment with Pradaxa, as well as in 224 volunteers in phase I trials. No adverse reactions have been identified.	New	CPP-Germany	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
21.	Fresenius Kabi Austria GmbH, Hafnerstraße 36, 8055 Graz, Austria **Local agent:** Radiant Export Import Enterprise Lubdhok, 4th Floor, 474P, Road No-3, Sector-12, Uttara, Dhaka 1230, Bangladesh	Omegaven "Fresenius" emulsion for infusion, 50ml	(Highly refined fish oil 100mg + purified egg phospholipids (egg lecithin) 12mg + glycerol Ph. Eur. 25mg)/ml	Caloric Agents	Parenteral nutrition supplementation with long chain omega-3-fatty acids, especially eicosapentaenoic and docosahexaenoic acid, when oral or enteral nutrition is impossible, insufficient or contraindicated.	**Contraindication:** Hypokalaemia, hyperhydration, hypotonic dehydration, unstable metabolism, acidosis **Side effects:** Abdominal pain, nausea, vomiting, shivering, tiredness, headache, thrombocytopenia, haemolysis, anaphylactic reaction, rash, urticaria, priapism	New	CPP-Austria, Germany	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
22.	Fresenius Kabi Austria GmbH, Hafnerstraße 36, 8055 Graz, Austria **Local agent:** Radiant Export Import Enterprise Lubdhok, 4th Floor, 474P, Road No-3, Sector-12, Uttara, Dhaka	Omegaven "Fresenius" emulsion for infusion, 100ml	(Highly refined fish oil100mg + purified egg phospholipids (egg lecithin) 12mg + glycerol Ph. Eur. 25mg)/ml	Caloric Agents	Parenteral nutrition supplementation with long chain omega-3-fatty acids, especially eicosapentaenoic and docosahexaenoic acid, when oral or enteral nutrition is impossible, insufficient or contraindicated.	**Contraindication:** Hypokalaemia, hyperhydration, hypotonic dehydration, unstable metabolism, acidosis **Side effects:** Abdominal pain, nausea, vomiting, shivering, tiredness, headache, thrombocytopenia, haemolysis, anaphylactic reaction, rash, urticaria, priapism	New	CPP – Austria, Germany	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	সংশ্লিষ্ট বিশেষজ্ঞদের সমন্বয়ে একটি কমিটি গঠণের সিদ্ধান্ত গৃহীত হয় এবং কমিটির মতামত প্রাপ্তির পর টেকনিক্যাল সাবকমিটিতে উপস্থাপনের সিদ্ধান্ত গৃহীত হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
	1230, Bangladesh									
23.	Fresenius Kabi Austria GmbH, Hafnerstraße 36, 8055 Graz, Austria **Local agent:** Radiant Export Import Enterprise Lubdhok, 4th Floor, 474P, Road No-3, Sector-12, Uttara, Dhaka 1230, Bangladesh	Dipeptiven 200mg/ml Concentrate for solution for infusion, 50ml	N(2)-L-alanyl-L-glutamine 200mg/ml	Caloric Agents	Dipeptiven is indicated as part of an intravenous parenteral nutrition regimen as a supplement to amino acid solutions or an amino acid containing infusion regimen, e.g. in patients in hypercatabolic and/or hypermetabolic states.	**Contraindication:** Dipeptiven should not be administered to patients with severe renal insufficiency (creatinine clearance < 25 ml/minute), severe hepatic insufficiency, severe metabolic acidosis or known hypersensitivity to the active substances or to any of the excipients. **Side effects:** Abdominal pain, cough, Diarrhoea, headache, nasal congestion, pharyngolaryngeal pain,vomiting, Hypersensitivity reactions	New	CPP-Austria, Germany	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
24.	Fresenius Kabi Austria GmbH, Hafnerstraße 36, 8055 Graz, Austria **Local agent:** Radiant Export Import Enterprise Lubdhok, 4th Floor, 474P, Road No-3, Sector-12, Uttara, Dhaka 1230, Bangladesh	Dipeptiven 200mg/ml Concentrate for solution for infusion, 100ml	N(2)-L-alanyl-L-glutamine 200mg/ml	Caloric Agents	Dipeptiven is indicated as part of an intravenous parenteral nutrition regimen as a supplement to amino acid solutions or an amino acid containing infusion regimen, e.g. in patients in hypercatabolic and/or hypermetabolic states.	**Contraindication:** Dipeptiven should not be administered to patients with severe renal insufficiency (creatinine clearance < 25 ml/minute), severe hepatic insufficiency, severe metabolic acidosis or known hypersensitivity to the active substances or to any of the excipients. **Side effects:** Abdominal pain, cough, Diarrhoea, headache, nasal congestion, pharyngolaryngeal pain,vomiting, Hypersensitivity reactions	New	CPP-Austria, Germany	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
25.	Fresenius Kabi AB, 751 74 Uppsala, Sweden **Local agent:** Radiant Export Import Enterprise	SmofKabiven emulsion for infusion, 986ml (Three Chamber Bag)	1st chamber contains: Amino acid solution with electrolytes corresponding to Aminoven 10% to 500ml	Caloric Agents	Parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or	**Contraindication:** -Hypersensitivity to fish, egg, soya or peanut protein or to any of the active substances or excipients -Severe liver insufficiency -Severe blood coagulation disorders -Severe renal insufficiency without	New	CPP-Sweden, Germany	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	সংশ্লিষ্ট বিশেষজ্ঞদের সমন্বয়ে একটি কমিটি গঠণের সিদ্ধান্ত গৃহীত হয় এবং কমিটির মতামত প্রাপ্তির

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
	Lubdhok, 4th Floor, 474P, Road No-3, Sector-12, Uttara, Dhaka 1230, Bangladesh		2nd chamber contains: Glucose 42% to 298ml 3rd chamber contains: SMOFlipid 20% to 188ml		contraindicated.	access to hemofiltration or dialysis -Uncontrolled hyperglycaemia **Side effects:** Lack of appetite, nausea, vomiting, dizziness, headache, tachycardia, dyspnoea, hypotension, hypertension, hypersensitivity reactions				পর টেকনিক্যাল সাবকমিটিতে উপস্থাপনের সিদ্ধান্ত গৃহীত হয়।
26.	Fresenius Kabi AB, 751 74 Uppsala, Sweden **Local agent:** Radiant Export Import Enterprise Lubdhok, 4th Floor, 474P, Road No-3, Sector-12, Uttara, Dhaka 1230, Bangladesh	SmofKabiven emulsion for infusion, 1477ml (Three Chamber Bag)	1st chamber contains: Amino acid solution with electrolytes corresponding to Aminoven 10% to 750ml 2nd chamber contains: Glucose 42% to 446ml 3rd chamber contains: SMOFlipid 20% to 281ml	Caloric Agents	Parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated.	**Contraindication:** -Hypersensitivity to fish, egg, soya or peanut protein or to any of the active substances or excipients -Severe liver insufficiency -Severe blood coagulation disorders -Severe renal insufficiency without access to hemofiltration or dialysis -Uncontrolled hyperglycaemia **Side effects:** Lack of appetite, nausea, vomiting, dizziness, headache, tachycardia, dyspnoea, hypotension, hypertension, hypersensitivity reactions	New	CPP- Sweden, Germany	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	সংশ্লিষ্ট বিশেষজ্ঞদের সমন্বয়ে একটি কমিটি গঠণের সিদ্ধান্ত গৃহীত হয় এবং কমিটির মতামত প্রাপ্তির পর টেকনিক্যাল সাবকমিটিতে উপস্থাপনের সিদ্ধান্ত গৃহীত হয়।
27.	Fresenius Kabi AB, 751 74 Uppsala, Sweden **Local agent:** Radiant Export Import Enterprise Lubdhok, 4th Floor, 474P, Road No-3, Sector-12, Uttara, Dhaka 1230, Bangladesh	SmofKabiven Perifer emulsion for infusion, 1206ml (Three Chamber Bag)	1st chamber contains: Glucose 13% to 656ml 2nd chamber contains: Amino acid solution with electrolytes corresponding to Aminoven 10% to 380ml 3rd chamber contains: SMOFlipid 20% to 170ml	Caloric Agents	Parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated.	**Contraindication:** -Hypersensitivity to fish, egg, soya or peanut protein or to any of the active substances or excipients -Severe liver insufficiency -Severe blood coagulation disorders -Severe renal insufficiency without access to hemofiltration or dialysis -Uncontrolled hyperglycaemia **Side effects:** Lack of appetite, nausea, vomiting, dizziness, headache, tachycardia, dyspnoea, hypotension, hypertension, hypersensitivity reactions	New	CPP - Sweden, Germany	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	সংশ্লিষ্ট বিশেষজ্ঞদের সমন্বয়ে একটি কমিটি গঠণের সিদ্ধান্ত গৃহীত হয় এবং কমিটির মতামত প্রাপ্তির পর টেকনিক্যাল সাবকমিটিতে উপস্থাপনের সিদ্ধান্ত গৃহীত হয়।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
28.	Fresenius Kabi AB, 751 74 Uppsala, Sweden **Local agent:** Radiant Export Import Enterprise Lubdhok, 4th Floor, 474P, Road No-3, Sector-12, Uttara, Dhaka 1230, Bangladesh	SmofKabiven Perifer emulsion for infusion, 1448ml (Three Chamber Bag)	1st chamber contains: Glucose 13% to 788ml 2nd chamber contains: Amino acid solution with electrolytes corresponding to Aminoven 10% to 456ml 3rd chamber contains: SMOFlipid 20% to 204ml	Caloric Agents	Parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated.	**Contraindication:** -Hypersensitivity to fish, egg, soya or peanut protein or to any of the active substances or excipients -Severe liver insufficiency -Severe blood coagulation disorders -Severe renal insufficiency without access to hemofiltration or dialysis -Uncontrolled hyperglycaemia **Side effects:** Lack of appetite, nausea, vomiting, dizziness, headache, tachycardia, dyspnoea, hypotension, hypertension, hypersensitivity reactions	New	CPP - Sweden, Germany	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
29.	**Manufacturer:** Septodont 94107 Saint-Maur-Des-Fosses Cedex, France **Local Agent:** UniHealth Ltd., House-46, Sheikh Kamal Saroni, Road No.16, Rangs Nasim Square, Dhaka.	Lignospan Special solution for injection (Lidocaine hydrochloride anhydrous 21.34mg eqivalent to 20mg Lidocaine hydrochloride + Adrenaline acid tartrate 0.0228mg equivalent to 0.0125mg adrenaline/1ml)	Lignospan Special solution for injection (Lidocaine hydrochloride anhydrous 21.34mg eqivalent to 20mg Lidocaine hydrochloride + Adrenaline acid tartrate 0.0228mg equivalent to 0.0125mg adrenaline/1ml)	Anaesthetics (Local)	LIGNOSPAN SPECIAL is a local anaesthetic indicated for the local and loco-regional anaesthesia in dental surgery in adults and in children and adolescents aged 4 to 18 years of age. LIGNOSPAN SPECIAL is appropriate for procedures of long duration and when there is a risk of significant bleeding into the operative field.	**Contraindications** : • Hypersensitivity to lidocaine (or to any local anaesthetics agent of the amide type) or to adrenaline or to any of the excipients. • Children (age below 4 years old). Due to lidocaine • Severe conduction disturbances; • Poorly controlled epileptic patient. Due to adrenaline: • Uncontrolled/severe hypertension; Company Core Product Information Page 3 / 12 Lidocaine 20 mg/ml with Adrenaline 0.0125 mg/ml • Severe ischemic heart disease; • Persistent/refractory tachyarrhythmia; • Thyrotoxicosis; • Pheochromocytoma **Description of selected adverse reactions** : 1 Laryngo-pharyngeal oedema may characteristically occur with hoarseness and / or dysphagia; 2 Bronchospasm (bronchoconstriction) may characteristically occur with dyspnoea; 3 These neural pathologies may occur with the various		CPP-France	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						symptoms of abnormal sensations (i.e., paresthesia, hypoesthesia, dysesthesia, hyperesthesia, etc) of the lips, tongue and oral tissues. 4 Hypoxia and hypercapnia are secondary to respiratory depression and/or to seizures and sustained muscular exertion; 5 These neurally mediated effects are due to the presence of local anaesthetic/vasoconstrictor at excessive concentrations regionally or in the systemic circulation; 6 This mostly occurs in patients with underlying cardiac disease or those receiving certain drugs (section 4.5); 7 This is due to excessive local effect of the vasoconstrictor; 8 This occurs by accidental biting or chewing of the lips or tongue while the anaesthesia persists.				
30.	**Manufacturer:** Septodont 94107 Saint-Maur-Des-Fosses Cedex, France **Local Agent:** UniHealth Ltd., House-46, Sheikh Kamal Saroni, Road No.16, Rangs Nasim Square, Dhaka.	Septanest 1/100000, solution for injection (Articaine hydrochloride 40.00mg + Adrenalin (as Adrenaline acid tartrate) 0.010mg/1ml)	Septanest 1/100000, solution for injection (Articaine hydrochloride 40.00mg + Adrenalin (as Adrenaline acid tartrate) 0.010mg/1ml)	Anaesthetics (Local)	**Septanest** is a local anaesthetic (a medicine for preventing pain and discomfort in a part of the body during medical procedures)	CONTRA-INDICATIONS Application to damaged skin . application to the middle ear (may cause ototoxicity) . complete heart block . injection into infected tissues . injection into inflamed tissues . preparations containing preservatives should not be used for caudal, epidural, or spinal block, or for intravenous regional anaesthesia (Bier's block) SIDE-EFFECTS: Face oedema . gingivitis . headache . nausea . sensation abnormal		FSC-France	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
31.	Sino-Swed Pharmaceutical Corp. Ltd. 16 Beizha Road, Mashan, Wuxi, 214092, China Local Agent: Orion Infusion Ltd.	Intralipid 20%	20% Purified Soybean Oil BP (20% Fat Emulsion) IV Infusion	Caloric Agents	INTRALIPID is indicated in patients needing intravenous nutrition to supply energy and essential fatty acids. INTRALIPID is also indicated in patients with essential fatty acid deficiency (EFAD) who cannot maintain or restore a normal essential fatty acid pattern by oral intake.	Contra-indications INTRALIPID is contraindicated in patients with acute shock and in patients with severe hyperlipemia. Severe liver Insufficiency. Hemophagocytotic syndrome. Hypersensitivity to egg-, soya-or peanut protein or to any of the active substances or excipients. Undesirable effects INTRALIPID infusion may cause a rise in body temperature and, less frequently, shivering, chills and nausea/vomiting (incidence<1%). Reports of other adverse events in conjunction with INTRALIPID infusion are extremely rare, less than one adverse event per one million infusions. Trombocytopenia has been reported in association with prolonged treatment with INTRALIPID in infants. Transient increase in liver function tests after prolonged intravenous nutrition with or without INTRALIPID has also been noted. Increased cholesterol has been observed with infants after long term treatment with Intralipid 10%. The reasons are not clear at present. Fat overload syndrome. An impaired capacity to eliminate INTRALIPID may lead to the fat overload syndrome as a result of over dosage. However, this syndrome may appear also at recommended rates of infusion in association with a sudden change in the patient's clinical condition, such as renal function impairment or	Refined Soyabeen Oil 10 gm/100 ml IV Injection	CPP-Uk	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						infection. The fat overload syndrome is characterised by hyperlipemia, fever, fat Infiltration and disorders in various organs and coma. All symptoms are usually reversible if the infusion of INTRALIPID is discontinued.				
32.	Manufacturer: Sun Pharmaceutical Industries Ltd. Halol-Baroda Highway, Halol-389350, Gujarat State, India Importer: Sun Pharmaceutical (Bangladesh) Ltd, Police Plaza Concord , 14 Floor, Tower B, Gulshan-1, Dhaka	Decitabine for injection 50mg/vial	Decitabine for injection 50mg/vial	Antineoplastic agent	Decitabine injection is indicated for treatment of adult patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British subtypes (refractory anaemia, refractory anaemia with ringed sideroblasts, refractory anaemia with excess blasts, refractory anaemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups	Contra-indication: None Side effects: Most commonly occurring adverse reactions in patients treated with decitabine for injection were neutropenia, thrombocytopenia, anemia, fatigue, pyrexia, nausea, cough, petechiae, constipation, diarrhea, and hyperglycemia. Most frequently reported adverse reactions occuring in 1 % of patients leading to discontinuation were thrombocytopenia, neutropenia, pneumonia, Mycobacterium avium complex infection, cardio respiratory arrest, increased blood bilirubin, intracranial hemorrhage and abnormal liver function tests. Most frequently reported adverse reactions occuring in ³ 1 % of patients leading to delayed dose neutropenia, pulmonary edema, atrial fibrillation, central line infection and febrileneutropenia. Most frequently reported adverse reactions occuring in ³ 1 % of patients leading to reduced dose were neutropenia, thrombocytopenia, anemia, lethargy, edema, tachycardia, depression, pharyngitis. The following adverse events were reported in 5% of patients 2	New	CPP- USA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						receiving 15 mg/m intravenously every 8 hours for 3 days every6 weeks : Blood and lymphatic system disorders: neutropenia, thrombocytopenia, anemia NOS, febrile neutropenia, (details in dossier)				
33.	Manufacturer : Abbott Healthcare Private Limited, India for Piramal Enterprise Limited, India **Local Agent:** Renata Limited Mirpur, Dhaka	Haemaccel, Solution for Infusion	Polygeline 3.5gm/100 ml	Plasma Substitute	1. As an immediate short term measure in plasma volume restoration in hypovolaemia due to blood or plasma loss, dehydration or peri-operative loss of circulating fluid. 2. Extra Corporeal circulation. 3. Isolated organ perfusion.	**Contra-indications:** Known hypersensitivity to constituents of the preparation. Existing anaphylactoid reactions. Haemaccel should not be used to correct drug-induced hypotensive effects **Side-effects:** During or after the infusion of volume-expanding solutions, transient urticarial skin reactions (wheals), hypotension, tachycardia, bradycardia, nausea/vomiting, dyspnoea, increases in temperature and/or shivering may occasionally occur.	পদটির রেজিস্ট্রেশন রয়েছে, কিন্তু DCC রেফারেন্স নাই। (রেজি নং: ১০৮-৮২৬-৭৭)	CPP-UK	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
34.	Fresenius Kabi Austria GmbH, Hafnerstraβe 36, A-8055 Graz, Austria **Local agent:** Radiant Export Import Enterprise Lubdhok, 4th Floor, 474P, Road No-3, Sector-12, Uttara, Dhaka 1230, Bangladesh.	Aminosteril N-Hepa 8% solution for infusion, 500ml	Each 100ml solution contains: L-Isoleucine Ph. Eur. 1.040g, L-leucine Ph. Eur. 1.309g , L-Lysine monoacetate Ph. Eur. 0.971g (=L-lysine 0.688g), L-methionine	Parenteral Nutrition	Parenteral amino acid supply in severe form of hepatic failure (liver insufficiency) with and without encephalopathy	**Contraindication**: As for all amino acid solutions the administration of Aminosteril N-Hepa 8% is contra-indicated in the following conditions: Disturbance of amino acid metabolism, metabolic acidosis, fluid overload, hyponatremia, hypokalemia, renal insufficiency, decompensated cardiac insufficiency, shock, hypoxia **Side effects**: IV injection of Aminosteril N-Hepa 8%, as well as other special solutions, can lead to an increase in the release of acid and gastric juice and to exacerbation of the ulcer. Therefore, it is necessary to first check the need for prophylactic	New	CPP-Austria, Germany	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			Ph. Eur. 0.110g , N-acetyl-L-cysteine Ph. Eur. 0.070g (=L-cystein Ph. Eur. 0.052g), L-phenylalanine Ph. Eur. 0.088g, L-threonine Ph. Eur. 0.440g, L-tryptophan Ph. Eur. 0.070g, L-valine Ph. Eur. 1.008g, L-arginine Ph. Eur. 1.072g, L-histidine Ph. Eur. 0.280g, Glycine Ph. Eur. 0.5829, L-alanine Ph. Eur. 0.464g, L-proline Ph. Eur. 0.573g, L-serine Ph. Eur. 0.224g &			administration of H_2 antagonists.				

No	Name of the manufacturer	Name of the product	Generic Name with dosage form	Therapeutic Class	Indication	Contraindication & side effect	Status (New Molecule / Existing)	CPP/ FSC	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			Glacial acetic acid Ph. Eur. 0.4421g							
35.	Sanochemia Pharmazeutika AG Boltzmanngasse 11 1090 Wien Austria **Local agent:** Cytochem Health Care, Baitul Lazz (3rd Floor), 183, Green Road, Dhanmondi, Dhaka, Bangladesh.	Cyclolux 10ml, 0.5mmol/ml Solution for Injection	Gadoteric Acid 279.32 mg (as meglumine Salt) equivalent to 0.5 mmol.	Diagnostic Use Only	Gadoteric acid is indicated for intravenous use with magnetic resonance imaging (MRI) in brain (intracranial), spine and associated tissues in adult and pediatric patients (2 years of age and older) to detect and visualize areas with disruption of the blood brain barrier (BBB) and/or abnormal vascularity	**Contraindication:** Gadoteric acid administration is hypersensitivity to GDCAs, before administration all patients should be assessed for any history of prior reactions to contrast media or other allergens that required the administration of steroids or intubation, bronchial asthma, and/or allergic **Side effects:** The most common adverse effects (>0.2%) in clinical studies were nausea, headache, injection site pain, injection site coldness, and burning sensation. Drugs with gadolinium-based contrasting agents can increase the risk of nephrogenic systemic fibrosis (NSF) for those with impaired elimination of the drug.	New	CPP-Austria	নির্ধারিত ০৭ (সাত) দেশের মধ্যে কোন দেশের FSC দাখিল করেনি বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***নির্ধারিত ০৭ (সাত) দেশের মধ্যে কোন দেশের FSC দাখিল করেনি বিধায় আবেদন নামঞ্জুর করা হল।***

Annex-D: Products for Locally Manufacture (Veterinary)

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
1.	Renata Limited Mirpur, Dhaka	Prednisolone Sodium Phosphate USP 2000mg + Dexamethasone Sodium Phosphate USP 400mg)/100 ml (Vet) Injection	Prednisolone Sodium Phosphate USP 2000mg + Dexamethasone Sodium Phosphate USP 400mg)/100ml	Anti-inflammatory	• Glucocorticoids have been used in an attempt to treat practically every malady that afflicts man or animal. • Three broad uses are 1) Replacement of glucocorticoid activity in patients with adrenal insufficiency, 2) as an anti-inflammatory agent, and 3) as an immunosuppressive. • Ketosis, allergic states, neoplasias • Chronic granulomatous enteritis in horses. • Collagen diseases (e.g., systemic lupus) • Dermatologic diseases (e.g., pemphigus, allergic dermatoses) • GI diseases (e.g., ulcerative colitis exacerbations) • Inflammatory diseases, pulmonary disorders • Induction of parturition, blood calcium reduction Paralysis before and after parturition, mastitis, allergic skin disease.	• Except in emergency: renal impairment; diabetes mellitus; chronic nephritis, congestive heart failure, osteoporosis, laminitis. • Use cautiously in patients which wound healing is necessary. Avoid use in pregnant animals. Withdrawal Period: Not Known	New	-	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
2.	Renata Limited Mirpur, Dhaka	Flavomycin INN 80mg/gm Powder (Vet)	Flavomycin INN 80mg/gm Powder (Vet)	Antibiotic	Flavomycin is a performance enhancer for use in poultry, cattle, rabbits, and aquatic species. Flavomycin allows for the early establishment of normal gut microflora by sparing beneficial bacteria. Through its sparing effect on	Contraindications: Not Established. Side effects: Not established. Withdrawal period: Zero days	New	-	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					the beneficial intestinal microflora, Flavomycin has been proven to be effective in reducing the shedding and infection rates of several harmful intestinal bacteria, such as Salmonella spp., Clostridium and E. coli. Due to its effect on pathogenic bacteria, Flavomycin contributes to a thinning of the intestinal wall, which leads to a better absorption of nutrients and specifically pigments, an improvement of litter quality, provides support of animals during stress situations, e.g., heat stress, etc					
3.	Renata Limited Mirpur, Dhaka	Bacitracin Zinc USP 156.90 mg Equivalent to Bacitracin 150mg Powder (Vet)	Bacitracin Zinc USP 156.90 mg Equivalent to Bacitracin 150mg	Antibiotic	Bacitracin powder is recommended for use in sheep, calves, beef cattle, broiler and turkeys to improve feed efficiency and mass gain. It is also recommended for use in layers for increased egg production.	Does not mix or use simultaneously with any feeding stuff containing any other antibiotic or growth promoter. Withdrawal period: Zero days	New	-	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
4.	Renata Limited Mirpur, Dhaka	Tylosin Phosphate USP 276.74mg/g equivalent to Tylosin 250,000 IU/g Powder (Vet)	Tylosin Phosphate USP 276.74mg/g equivalent to Tylosin 250,000 IU/g	Antibiotic	For prevention and treatment of infections caused by tylosin-sensitive pathogenic microorganisms - mycoplasmosis, chronic respiratory disease, and infectious synovitis in chickens and turkeys; Infectious sinusitis in turkeys; spirochetosis (borreliosis) in chickens;	Tylosin is contraindicated in patients hypersensitive to it or other macrolide antibiotics. It must not be given to laying hens in poultry farms, which produce eggs for consumption (its use in stock layers is not contraindicated). It must not be included in compositions containing more than 2% of	Tylosin 20% Powder (DCC-238)		আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						bentonite. Most clinicians feel that tylosin is contraindicated in horses, as severe and sometimes fatal diarrheas may result from its use in that species. Withdrawal Period: Cattle: Nil				
5.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Oxytetracycline Hydrochloride 60 mg + Neomycin Sulphate 40 mg + Vitamin A 7500 IU+Vitamin D3 1500 IU + Vitamin B1 1 mg + Vitamin B2 2 mg + Vitamin B6 2 mg + Vitamin B12 7.5 mcg + Ascorbic Acid 25 mg + Pantothenic Acid 7.50 mg +	Vitamin B1 (Thiamine Hydrochloride) USP + Vitamin B2 (Riboflavin) USP + Vitamin B6 (Pyridoxine Hydrochloride) USP + Vitamin A Acetate 0.5 MIU/gm (water dispersible) Feed Grade + Vitamin D3 0.5 MIU/gm Feed Grade + Vitamin E 50 (water dispersible) Feed Grade + Vitamin K3	Antibiotic with Vitamin, Mineral & Amino Acid combination	Highly effective combination of broad-spectrum antibiotics and vitamins. The product stimulates egg production, increases growth, improves feed conversion and is used as a vitamin supplement during periods of diseases and stress. Gastrointestinal, respiratory and urinary infections caused by oxytetracycline and neomycin sensitive micro-organisms, like Bordetella, Campylobacter, Chlamydia,E. coli, Haemophilus, Klebsiella, Mycoplasma, Pasteurella, Rickettsia, Salmonella, Staphylococcus and Streptococcus spp. in calves, goats, sheep, poultry.	Contraindications: Hypersensitivity to tetracyclines or aminoglycocides. Side-effect: Hypersensitivity reaction may occur. Withdrawal period: Meat: 7 days Egg: 1 day	New	-	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		Vitamin K3 5 mg + Nicotinamide 15 mg + Folic Acid 0.30 mg + DL Methionine 30 mg + L-Lysine 50 mg per g powder (Vet).	MSB Feed Grade + Nicotinamide USP + Calcium Pantothenate BP + Vitamin B12 (Cyanocobalamin 1%) USP + Folic Acid USP + Ascorbic Acid USP + Oxytetracycline Hydrochloride BP + Neomycin Sulphate USP + DL-Methionine Feed Grade + L-Lysine HCL Feed Grade.							
6.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Benzalkonium Chloride 80% Solution (Vet)	Benzalkonium Chloride BP 80gm/100ml	Disinfectant	Benzalkonium Chloride is a powerful disinfectant specialized for prevention and treatment of bacterial infections on shrimp/fish. It can also promote good water quality, inhabit algae growth and kill fungus. Benzalkonium Chloride **is** free of activated chloride, phenol, mercury and other heavy metals. Best solution for bacterial & fungal fish	Contraindications: None Side-effect: Unknown	New	-	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					diseases. Benzalkonium Chloride can be used under a wide range of pH conditions. Effective in reducing substrate odor, sludge and algae.					
7.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Diclazuril 2.5gm/100ml Oral Solution (Vet)	Diclazuril USP 2.5gm/100ml	Anti-Coccidial	Diclazuril Oral is effective in the prevention and treatment of coccidial infections in lambs caused by Eimeria crandallis or Eimeria ovinoidalis and in calves caused by Eimeria bovis or Eimeria zuernii. It is effective in the prevention and treatment of coccidial infections in poultry caused by Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mitis (mivati), and E. maxima. Because diclazuril is effective against E. maxima later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with E. maxima.	Contraindications: Do not use in layers producing eggs for human consumption. Side-effect: None. Withdrawal period: Boiler: 0 days		-	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
8.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Lincomycin HCL 250mg + Neomycin 140mg/ml Oral Solution (Vet)	Lincomycin Hydrochloride USP 27.242gm (eq. to Lincomycin 250mg +Neomycin Sulfate BP 20.702gm (eq. to Neomycin 250mg)/100m	Antibiotic	Poultry: Treatment of chronic respiratory diseases (CRD) caused by Mycoplasma infections as well as any infection due to *E. coli* bacteria sensitive to Lincomycin and Neomycin.	Contraindications: Do not administer to animals hypersensitive to Amino-glycosides and/or Lincosamide. Side-effect: Unknown Withdrawal period: Meat: 2 days Egg: 2 days	Lincomycin Base + Spectinomycin 22.2 gm + 44.4 gm/100 gm Water Soluble Powder (ACME)	-	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			l							
9.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Moxidectin 1% Injection (Vet)	Moxidectin BP 1gm/100ml	Anti-parasitic	Moxidectin is a synthetic anti parasitic agent which is highly effective against ecto and endo parasites of Cattle & sheep/goat. It is well absorbed from the site of injection & distributed internally to the areas of the body affected. It interferes with neurotransmitter of parasites resulting paralysis of the worm & removal from the body.	Contraindications: Do not use in sick, debilitated or underweight animal. Side-effect: Subcutaneous injection may cause local transient reaction in animal. Withdrawal period: Meat: 21 days	Moxidectin USP 0.50gm/100ml Pour-on Solution (Renata, DCC-250)	USFDA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
10.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Danofloxacin 5.0% Injection (Vet)	Danofloxacin Mesylate INN 6.345gm (eq. to Danofloxacin 5gm)/100ml	Antibiotic	For the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica and Pasteurella multocida in beef cattle and for the control of BRD in beef cattle at high risk of developing BRD associated with Mannheimia haemolytica and Pasteurella multocida	Contraindications: Danofloxacin is not recommended for use in the case of resistant bacteria to other fluoroquinolones. Side-effect: Hypersensitivity reaction causing lameness. Withdrawal period: Meat: 5 days.	New	-	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
11.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Danofloxacin 2.5% Injection (Vet)	Danofloxacin Mesylate INN 3.173gm (eq. to Danofloxacin 2.5gm)/100ml	Antibiotic	For the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica and Pasteurella multocida in beef cattle and for the control of BRD in beef cattle at high risk of developing BRD associated with Mannheimia haemolytica and Pasteurella multocida	Contraindications: Danofloxacin is not recommended for use in the case of resistant bacteria to other fluoroquinolones. Side-effect: Hypersensitivity reaction causing lameness.	New	-	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
						Withdrawal period: Meat: 5 days Milk: 48 hours				
12.	Eskayef Pharmaceuticals Limited, Rupganj, Narayanganj.	Cloxacillin 1gm/vial IM injection (Vet)	Cloxacillin Sodium (Sterile) BP 1091.721mg (eq. to Cloxacillin 1000mg)/10ml Vial	Antibiotic	Cloxacillin is highly effective against mastitis, metritis, pyometra,bronchitis, pneumonia, hemorrhagic septicemia, Black quarter, Calf scour, Colibacillosis, Bone and joint infections ets	Contraindications: Should not be administered to the animals hypersensitive to Cloxacillin. Side-effect: Unknown Withdrawal period: Meat: 25 days Milk: 3 days and 6 hours	New	-	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
13.	Eskayef Pharmaceuticals Limited, Rupganj, Narayanganj.	Cloxacillin 2gm/vial IM Injection (Vet)	Cloxacillin Sodium (Sterile) BP 2183.442mg (eq. to Cloxacillin 2000mg)/10ml Vial	Antibiotic	Cloxacillin is highly effective against mastitis, metritis, pyometra,bronchitis, pneumonia, hemorrhagic septicemia, Black quarter, Calf scour, Colibacillosis, Bone and joint infections ets	Contraindications: Do not administer to the animals hypersensitive to Cloxacillin. Side-effect: Unknown Withdrawal period: Meat: 25 days Milk: 3 days and 6 hours.	New	-	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
14.	Eskayef Pharmaceuticals Limited,	Amoxicillin 2000mg + Clavulanic Acid 400mg IM Injection	Co-Amoxiclav for Injection (Sterile Material) BP	Antibiotic	Amoxicillin with Clavulanic acid powder for injection is a broad spectrum bactericidal antibiotic which is highly effective against mastitis, metritis, pyometra,bronchitis, pneumonia,	Contraindications: Do not administer to the animals hypersensitive to Amoxicillin with Clavulanic acid.	Clavulanic acid 35 mg + Amoxicillin 140	-	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
	Rupganj, Narayanganj.	(Vet)	2596.916mg (Amoxicillin Sodium 2120.316mg eq. to Amoxicillin 2000mg and Potassium Clavulanate 476.60mg eq. to Clavulanic Acid 400mg)/20ml Vial		hemorrhagic septicemia, Black quarter, Calf scour, Colibacillosis, Bone and joint infections etc.	Side-effect: Allergic reaction, diarrhoea. Withdrawal period: Meat: 25 days Milk: 3 days and 6 hours	mg/ ml Injection (Vet) (DCC-240)			
15.	Eskayef Pharmaceuticals Limited, Rupganj, Narayanganj.	Amoxicillin 1000mg + Clavulanic Acid 200mg IM Injection (Vet)	Co-Amoxiclav for Injection (Sterile Material) BP 1298.458mg (Amoxicillin Sodium 1060.158mg eq. to Amoxicillin 1000mg and Potassium Clavulanate 238.300mg eq. to Clavulanic Acid 200mg)/10ml Vial	Antibiotic	Amoxicillin with Clavulanic acid powder for injection is a broad spectrum bactericidal antibiotic which is highly effective against mastitis, metritis, pyometra,bronchitis, pneumonia, hemorrhagic septicemia, Black quarter, Calf scour, Colibacillosis, Bone and joint infections etc.	Contraindications: Do not administer to the animals hypersensitive to Amoxicillin with Clavulanic acid. Side-effect: Allergic reaction, diarrhoea. Withdrawal period: Meat: 25 days Milk: 3 days and 6 hours	Clavulanic acid 35 mg + Amoxicillin 140 mg/ ml Injection (Vet) (DCC-240)	-	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
16.	Eskayef Pharmaceuticals Limited, Tongi, Gazipur.	Ceftiofur 250mg Powder for Injection (Vet)	Ceftiofur Sodium (Sterile Lyophilized Powder) USP 261mg eq. to Ceftiofur 250mg)/5ml vial	Antibiotic	Ceftiofur is indicated for the treatment of bovine respiratory diseases (shipping fever, pneumonia)associated with *Mannheimia haemolytica , Pasteurella multocida* & *Histophilus somni*, acute bovine interdigital (foot rot, pododermatitis) . **Poultry**: It is indicated for the control of early chick mortality associated with *E. coli* organisms in day old chick.	Contraindications: Should not be administered to the animals hypersensitive to Ceftiofur. Side-effect: The use of Ceftiofur may result in some sign of immediate and transient local pain to the animal. Withdrawal period: Meat: 4 days Milk: 0 day	Ceftiofur 0.5 g/Vial Injection Ceftiofur 1g/Vial Injection	-	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
17.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Ceftiofur 250 mg/Vial Powder for Solution for Injection (Vet)	Ceftiofur Sodium (Sterile) USP 260.50 mg eqv. to 250 mg Ceftiofur/Vial	Cephalosporin Antibiotic	Ceftiofur is indicated for the treatment of bovine respiratory diseases (shipping fever, pneumonia)associated with *Mannheimia haemolytica , Pasteurella multocida* & *Histophilus somni*, acute bovine interdigital necrobacillosis (foot rot, pododermatitis). Poultry Ceftiofur is indicated for the control of early chick mortality associated with *E. coli* organisms in day old chick.	Contraindications: Contraindicated to the animals hypersensitive to Ceftiofur Sodium. Side effects: The use of Ceftiofur results in some signs of immediate and transient local pain at the site of injection of the animal. Withdrawal period: Meat: 4 days Milk: 0 day	Ceftiofur 0.5 g/vial Injection Ceftiofur 1g/ vial Injection	-	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
18.	The ACME Laboratories Ltd., Dhulivita, Dhamra	Amoxicillin 3 g/Vial Powder for Solution for Injection (Vet)	Amoxicillin Sodium (Sterile) BP 3.18 g eqv. to Amoxicillin 3 g/Vial	B-lactum Antibiotic	Amoxicillin is indicated for the treatment of the following infectious diseases in cattle, horse, sheep/goat, dog and cat: • <u>*Urogenital Tract diseases*</u>: Mastitis, metritis, pyometra, nephritis, postpartum infections, retained placenta, cystitis etc.	Contraindications: Contraindicated in animals hypersensitive to Amoxicillin. **Side effects**: Hypersensitivity reactions (rash, fever, eosinophilia, neutropenia, agranulocytosis,	Amoxicillin 1g/Vial Injection Amoxicillin 2g/Vial Inj	-	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
	i, Dhaka				• *Respiratory diseases:* Pneumonia, bronchitis, calf diphtheria, sinusitis, laryngitis etc. • *GI tract diseases:* Calf scour, gastritis, enteritis (Colibacillosis, Salmonellosis) • *Local bacterial infections:* Abscess, wounds, infected eczema, otitis etc. • Secondary bacterial infections in viral or parasitic diseases and post-operative antibiotic therapy.	thrombocytopenia, leukopenia, anemias and lymphadenopathy, anaphylaxis), local irritation may occur in some cases. Withdrawal period: Cow**:** Meat- 18 days, Milk- 1 day.	Amoxicillin 150 mg /ml Injection Amoxicillin 1000 mg /bolus			
19.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Ciprofloxacin 20g/100 ml Oral Solution (Vet)	Ciprofloxacin Hydrochloride USP 23.288 g eqv. to Ciprofloxacin 20 g/100 ml	Antibiotic	For the treatment of disease caused by both gram positive and gram negative bacteria like Colibacillosis, Salmonellosis, Infectious Coryza, Mycoplasmosis (CRD), Streptococcosis, Staphylococcosis, Pasteurellosis, Secondary bacterial infection in case of viral diseases such as Gumboro, Ranikhet etc.	Contraindications: Ciprofloxacin should not be used with chloramphenicol, macrolide and tetracycline. Side effects: Lack of appetite, vomiting, central nervous system disorder such as epilepsy or dizziness may be observed. Withdrawal period: Meat: 12 days. Egg: Not known.	Ciprofloxacin 100 mg/ml oral solution, Ciprofloxacin 1000 mg/bolus, Ciprofloxacin 200 mg/g WSP.	-	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
20.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Ceftriaxone 3 g/Vial Powder for Solution for Injection (Vet)	Ceftriaxone Sodium (Sterile) USP 3.572 g eqv. to Ceftriaxone 3 g/Vial	Cephalosporin Antibiotic	Ceftriaxone injection is indicated for the treatment of wide variety of infections caused by sensitive Gram-positive, Gram-negative and anaerobic organisms. This drug has high potential application in • Respiratory tract infections (Broncho-pneumonia, Pneumonia) • Mammary gland infections (Mastitis)	Contraindications: Ceftriaxone Injection is contraindicated in animals hypersensitive to cephalosporin. Side effects: Hypersensitive reactions (acute anaphylaxis or angioedema, allergic	Ceftriaxone 0.5 g/vial Inj. Ceftriaxone 1 g/vial Inj.	-	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
					• Uro-genital tract infections (Metritis, Pyometra, Nephritis, Cystitis) • Gastrointestinal infections (Calf scour, enteritis, diarrhea) • Skin and soft tissue infections (external wound, abscesses etc) • Bone and joint infections (Arthritis) • Otitis (externa, media, interna)	agranulocytosis, fever, serum sickness, urticaria, diarrhea, thrombocytosis etc.) may occur in some haemorrhagic septicaemia, black quarter, anthrax, foot patients. Withdrawal period: Meat & Milk: Not known	Ceftriaxone 2 g/Vial Inj.			
21.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Benzyl Alcohol 50 mg/5 ml Solvent for Injectable Solution (Vet) [To use as solvent for Cefquinome Injection 225 mg/Vial & 450 mg/Vial which has been approved in DCC-248]	Benzyl Alcohol BP 50 mg/5 ml	Diluents	It is used as a sterile solvent for Injectable Solution.	**Contraindications:** No contraindication is denoted for this solvent. **Side effects:** Not applicable.	New	-	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
22.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Benzyl Alcohol 100 mg/10 ml Solvent for Injectable Solution (Vet) [To use as solvent for Cefquinome Injection 225 mg/Vial & 450 mg/Vial which has been approved in DCC-248]	Benzyl Alcohol BP 100 mg/10 ml	Diluent	It is used as a sterile solvent for Injectable Solution.	**Contraindications:** No contraindication is denoted for this solvent. **Side effects:** Not applicable.	New	-	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
23.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Apramycin 500 mg/g Water Soluble Powder (WSP) (Vet)	Apramycin Sulfate BP 0.910 g eqv. to Apramycin 500 mg/g	Antibiotic	Colibacillosis, Salmonellosis & bacterial enteritis in poultry, calves & pig.	**Contraindications:** Apramycin powder is contraindicated in animals hypersensitive to Apramycin. **Side Effects:** Administered orally apramycin is well tolerated. Sometimes diarrhea may occur while using the drug doses and for a prolonged period of time. Withdrawal period: Calves: 28 days. Poultry: Meat - 7 days. Eggs - Should not be used in laying birds producing eggs for human consumption.	Apramycin Sulfate. 250g/kg water soluble powder (DCC-248)	-	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
24.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Apramycin 2000 mg/10 ml Injection (Vet)	Apramycin Sulfate BP 3.636 g eqv. to Apramycin 2000 mg/10 ml	Antibiotic	Colibacillosis, Salmonellosis & bacterial enteritis in poultry, calves & pig.	**Contraindications:** Apramycin Injection is contraindicated in animals hypersensitive to Apramycin and other aminoglycoside antibiotics; kidney dysfunction. **Side Effects:** Irritation at injection sites and diarrhea following administration of large doses. Withdrawal period: Calves: 28 days. Poultry: Meat - 7 days. Eggs - Should not be used in laying birds producing eggs	Apramycin Sulfate. 250g/kg water soluble powder (DCC-248)	–	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
25.	The ACME Laboratories Ltd., Dhulivita, Dhamrai, Dhaka	Apramycin 6000 mg/30ml Injection (Vet)	Apramycin Sulfate BP 11.156 g eqv. to Apramycin 6000 mg/30 ml	Antibiotic	Colibacillosis, Salmonellosis & bacterial enteritis in poultry, calves & pig.	**Contraindications:** Apramycin Injection is contraindicated in animals hypersensitive to Apramycin and other aminoglycoside antibiotics ;kidney dysfunction. **Side Effects:** Irritation at injection sites and diarrhea following administration of large doses. Withdrawal period: Calves: 28 days. Poultry: Meat - 7 days. Eggs - Should not be used in laying birds producing eggs	Apramycin Sulfate. 250g/kg water soluble powder (DCC-248)	-	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
26.	Incepta Vaccine Ltd. (Animal Vaccine Division)	Avian Influenza Type A Virus Strain H9N2 (Inactivated) NLT 10^{7} EID_{50} + Newcastle disease virus (Inactivated) NLT 10^{8} EID_{50} 250 ml, 500 doses Emulsion (Injection) (Vet)	Avian Influenza Type A Virus Strain H9N2 (Inactivated) NLT 10^{7} EID_{50} + Newcastle disease virus (Inactivated) NLT 10^{8} EID_{50}	Vaccine	For protection against Avian Influenza (strain H9N2) and Newcastle disease, recommended for broilers, layers and breeders to boost the immunity of flocks previously vaccinated with live vaccine (ND). Suggested for ideal protection to progeny against early infections. This vaccine has been developed for use in breeder hens to give broad protection against Avian Influenza type A virus strain H9N2 and Newcastle Disease. When injected, the vaccine produces a high level of circulating antibody (humoral immunity), which is maintained throughout the production cycle. This provides high levels of parental immunity in the progeny and confer protection to the chicks during the critical first few days of life.	**Contraindications:** Temporary lameness may occur in birds following vaccination. While birds are going through the reaction period, keep them comfortable by providing adequate heat and good ventilation. This reaction should be self-limiting. **Side-effects:** Complete lack of immune-suppression has not been demonstrated. No information is available on the Safety and efficacy from the concurrent use of this vaccine with any other vaccine.	New	-	বাংলাদেশে ভ্যাকসিনটির ফিল্ড ট্রায়ালের মাধ্যমে কার্যকারিতা প্রমাণ সাপেক্ষে অনুমোদন করা যেতে পারে।	বাংলাদেশে ফিল্ড ট্রায়ালের মাধ্যমে কার্যকারিতা প্রমাণ সাপেক্ষে অনুমোদন করার সিদ্ধান্ত গৃহীত হয়।
27.	Incepta Vaccine Ltd. (Animal Vaccine Division)	Avian Influenza Type A Virus Strain H9N2 (Inactivated) NLT 10^{7} EID_{50} + Newcastle disease virus (Inactivated) NLT 10^{8} EID_{50} 500 ml, 1000 doses	Avian Influenza Type A Virus Strain H9N2 (Inactivated) NLT 10^{7} EID_{50} + Newcastle disease virus (Inactivated) NLT 10^{8} EID_{50}	Vaccine	For protection against Avian Influenza (strain H9N2) and Newcastle disease, recommended for broilers, layers and breeders to boost the immunity of flocks previously vaccinated with live vaccine (ND). Suggested for ideal protection to progeny against early infections. This vaccine has been developed for use in breeder hens to give broad protection against Avian Influenza type A virus strain H9N2 and Newcastle Disease. When injected, the vaccine produces a high level of circulating antibody (humoral immunity), which is maintained throughout the production	**Contraindications:** Temporary lameness may occur in birds following vaccination . While birds are going through the reaction period , keep them comfortable by providing adequate heat and good ventilation. This reaction should be self-limiting. **Side-effects:** Complete lack of immunosuppression has not been demonstrated. No	New	-	বাংলাদেশে ভ্যাকসিনটির ফিল্ড ট্রায়ালের মাধ্যমে কার্যকারিতা প্রমাণ সাপেক্ষে অনুমোদন করা যেতে পারে।	বাংলাদেশে ফিল্ড ট্রায়ালের মাধ্যমে কার্যকারিতা প্রমাণ সাপেক্ষে অনুমোদন করার সিদ্ধান্ত গৃহীত হয়।

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		Emulsion (Injection) (Vet)			cycle. This provides high levels of parental immunity in the progeny and confer protection to the chicks during the critical first few days of life.	information is available on the safety and efficacy from the concurrent use of this vaccine with any other vaccine.				
28.	Incepta Vaccine Ltd. (Animal Vaccine Division)	Avian Influenza Type A Virus Strain H9N2 (Inactivated) NLT 10^7 EID_{50} 500 ml, 1000 doses Emulsion (Injection) (Vet)	Avian Influenza Type A Virus Strain BP H9N2 (Inactivated) NLT 10^7 EID_{50}	Vaccine	For protection against Avian Influenza (strain H9N2), recommended for broilers, layers and breeders to boost the immunity of flocks. Suggested for ideal protection to progeny against early infections. This vaccine has been developed for use in breeder hens to give broad protection against Avian Influenza type A virus strain H9N2. When injected, the vaccine produces a high level of circulating antibody (humoral immunity), which is maintained throughout the production cycle. This provides high levels of parental immunity in the progeny and confer protection to the chicks during the critical first few days of life.	**Contraindications:** None **Side-effects:**Temporary lameness may occur in birds following vaccination. While birds are going through the reaction period, keep them comfortable by providing adequate heat and good ventilation .This reaction should be self-limiting.	New	-	বাংলাদেশে ভ্যাকসিনটির ফিল্ড ট্রায়ালের মাধ্যমে কার্যকারিতা প্রমাণ সাপেক্ষে অনুমোদন করা যেতে পারে।	বাংলাদেশে ফিল্ড ট্রায়ালের মাধ্যমে কার্যকারিতা প্রমাণ সাপেক্ষে অনুমোদন করার সিদ্ধান্ত গৃহীত হয়।
29.	Incepta Vaccine Ltd. (Animal Vaccine Division)	Avian Influenza Type A Virus Strain H9N2 (Inactivated) NLT $10^7 EID_{50}$ 250 ml, 500 doses	Avian Influenza Type A Virus Strain BP H9N2 (Inactivated) NLT 10^7 EID_{50}	Vaccine	For protection against Avian Influenza (strain H9N2), recommended for broilers, layers and breeders to boost the immunity of flocks. Suggested for ideal protection to progeny against early infections. This vaccine has been developed for use in breeder hens to give broad protection against Avian Influenza type A virus strain H9N2. When injected, the vaccine	**Contraindications:** None **Side-effects:**Temporary lameness may occur in birds following vaccination. While birds are going through the reaction period, keep them comfortable by providing adequate heat and good ventilation .This reaction	New	-	বাংলাদেশে ভ্যাকসিনটির ফিল্ড ট্রায়ালের মাধ্যমে কার্যকারিতা প্রমাণ সাপেক্ষে অনুমোদন করা যেতে	বাংলাদেশে ফিল্ড ট্রায়ালের মাধ্যমে কার্যকারিতা প্রমাণ সাপেক্ষে অনুমোদন করার সিদ্ধান্ত গৃহীত হয়।

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		Emulsion (Injection)			produces a high level of circulating antibody (humoral immunity), which is maintained throughout the production cycle. This provides high levels of parental immunity in the progeny and confer protection to the chicks during the critical first few days of life.	should be self-limiting.			পারে।	
30.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Amino Acids 5% in 100 ml Injectable Solution (Vet)	L-Isoleucine USP 0.352 gm, L-Leucine USP 0.490 gm, L-Lysine Hydrochloride USP 0.430 gm, L-Methionine USP 0.225 gm, L-Phenylalanine ~SP 0.533 gm, L-Threonine USP 0.250 gm, L-Tryptophan USP 0.090 gm, L-Valine USP 0.360 gm, L-Arginine	Amino acids (Vet)	Amino Acids helps in protein formation. It acts as building blocking agent for the development of meat production. It also uses to increase egg & milk production. For use as a supplemental source of dextrose, electrolytes, vitamins and amino acid in ali animals. Supporting therapy on the operation & after operation, convalescing, dehydration, weakness, vomiting, diarrhea, imbalance of electrolytes, ketosis, anaphylaxis, acidosis and hypoproteinemia.	**Contraindication:** Amino acid is contraindicated in patients with inborn errors of amino acids metabolism, irreversible liver damage and severe uremia. **Side-effects:** Amino acid is usually well tolerated. Nausea Occurs rarely. Vomiting, flushing and sweating have been observed during infusion of Amino acid at rates exceeding the recommended dose. Hypersensitivity reactions have been reported. As with all hypertonic infusion solution, thrombophlebitis may occur when peripheral veins are used..	New		আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			Hydrochloride USP 0.500 gm, L-Histidine Hydrochloride Monohydrate BP 0.250gm, L-Aspartic acid USP 0.250 gm, L-Glutamic Acid BP 0.075 gm, L-Alanine USP 0.200 gm, L-Cystine BP 0.010 gm, Glycine BP0.760 gm, L-Proline USP 0.100 gm,L-Serine USP 0.100 gm and L-Tyrosine USP 0.025 gm.in 100 ml							
31.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Amino Acids 5%) in 500 ml Injectable Solution (Vet)	L-Isoleucine USP 1.760 gm, L-Leucine USP 2.450 gm,	Amino acids (Vet)	Amino Acids helps in protein formation. It acts as building blocking agent for the development of meat production. It also uses to increase egg & milk production. For use as a supplemental source of dextrose, electrolytes, vitamins and	**Contraindication:** Amino acid is contraindicated in patients with in born errors of amino acids metabolism, irreversible liver damage and severe uremia.	New		আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			L-Lysine Hydrochloride USP 2.150 gm, L-Methionine USP 1.125 gm, L-Phenylalanine USP 2.665 gm, L-Threonine USP 1.250 gm, L-Tryptophan USP 0.450 gm, L-Valine USP 1.800 gm, L-Arginine Hydrochloride USP2.500 gm, L-Histidine Hydrochloride Monohydrate BP 1.250 gm, L-Aspartic acid USP 1.250 gm, L-Glutamic Acid BP 0.375 gm,		amino acid in ali animals. Supporting therapy on the operation & after operation, convalescing, dehydration, weakness, vomiting, diarrhea, imbalance of electrolytes, ketosis, anaphylaxis, acidosis and hypoproteinemia.	**Side-effects:** Amino acid is usually well tolerated. Nausea Occurs rarely. Vomiting, flushing and sweating have been observed during infusion of Amino acid at rates exceeding the recommended dose. Hypersensitivity reactions have been reported. As with all hypertonic infusion solution, thrombophlebitis may occur when peripheral veins are used..				

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			L-Alanine USP 1.000 gm, L-Cystine BP 0.050 gm, Glycine BP 3.800 gm, L-Proline USP 0.500 gm, L-Serine USP 0.500 gm and L-Tyrosine USP 0.125 gm.in 500 ml							
32.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Bromhexine Hcl 1 gm/100 ml solution	Bromhexine Hydrochloride BP 1 gm per 100 ml	Mucolytic (vet)	Bromhexine Hydrochloride solution is indicated for the treatment of respiratory disorders associated with viscid or excessive mucus or productive cough in dogs, cattle.	**Contraindication** Bromhexine Hydrochloride solution is contraindicated for use in animals with known hypersensitivity or idiosyncratic reaction to bromhexine hydrochloride (or any of the other ingredients in the product). **Side-effects:** Gastrointestinal side effects may occur with Bromhexine and a transient rise in serum amino-transferase values has been reported. Other reported adverse effect includes sweating, allergic reactions.	Bromhexine HCl 0.08gm/100ml Oral Solution Bromohexine HCl 10mg/gm Powder (Vet) DCC-240	-	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
33.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Levofloxacin 5000mg/50 ml injectable Solution	Levofloxacin Hemihydrate USP 5120 mg/50ml eq.to Levofloxacin 5000mg/50 ml	Antibiotic (vet)	It is very effective against various gram positive and gram negative bacteria, Mycolplasma, Staphylococci, Streptococci, E. coli, Salmonella, Hemophilus, Klebshiella and Pasteruella in poultry and cattle.	**Contraindications:** It should not be used in layer within 14 days prior to laying period. **Side effects**: is well tolerated for poultry at recommended dose. However, it may cause developmental cartilage abnormalities. **Withdrawal Period:** Meat : 4 days Egg : 7 days Milk : Not required	Levofloxacin 10 gm/100 gm Oral Powder (DCC-242)	-	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
34.	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	Levofloxacin 1000mg/10 ml injectable Solution (vet)	Levofloxacin Hemihydrate USP 1024 mg/10ml eq.to Levofloxacin 1000mg/10 ml	Antibiotic (vet)	It is very effective against various gram positive and gram negative bacteria, Mycolplasma, Staphylococci, Streptococci, E. coli, Salmonella, Hemophilus, Klebshiella and Pasteruella in poultry and cattle.	**Contraindications:** It should not be used in layer within 14 days prior to laying period. **Side effects**: is well tolerated for poultry at recommended dose. However, it may cause developmental cartilage abnormalities. **Withdrawal Period:** Meat : 4 days Egg : 7 days Milk : Not required	Levofloxacin 10 gm/100 gm Oral Powder (DCC-242)	-	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
35.	Al-Madina, Pharmaceutical	Methenamine95gm+ Vitamin B1 0.8 gm+	Methenamine BP 95gm+ Vitamin B1 BP 0.8gm+	Anti-infective	(i) It is a Diuretic which is indicated for the treatment of Oedema, Hepatitis, Ascites and Gout treatment in Poultry. (ii) Increase appetite, stimulate digestion	**Contra-indications:** Contraindicated in Birds those already have renal diseases or renal insuffiency	New	-	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No	Name of the Manufacturer	Name of the Product & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contra-indication & Side effect	Status (New Molecule /Existing)	USFDA/ UKMHRA/ BNF Reference	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
	s Ltd.,Tongi, Gazipur	Vitamin B2 0.1 gm+ Vitamin k3 (MSB) 0.2 gm/100 gm Powder(vet).	Vitamin B2 BP 0.1 gm+ Vitamin k3 (MSB) USP 0.2 gm/100 gm Powder.		and prevent paralysis from during different infection. (iii) Prevent kidney damage during Gumboro disease.	and Birds with severe Dehydration. **Side effects:** Most common side effects areupset stomach, diarrhea, abdominal cramps, painful or difficult urination, loss of appetite.				

Annex-E: Products List for Import (Veterinary)

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
1.	**Manufacturer:** Biomune Company 8906 Rosehill Road, Lenexa, Kansas 66215, USA **Local Agent:** (ACI Ltd.)	Ultifend IBD ND (Live, frozen vaccine) Suspension for S/C injection **(vet)**	Bursal Disease-Marek"s Disease-Newcastle Disease Antigen At least 2818 PFU/dose through expiration	Vaccine	For active immunization of healthy chickens and chick embryos against Newcastle disease caused by Newcastle disease virus, bursal disease caused by standard type infectious bursal disease virus and Marek's disease caused by Marek's disease virus.	**Contraindication:** No Contraindications are known. **Side effects:** No undesirable effects are known. Withdrawl period: 21 days	New	USA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
2.	**Manufacturer: Interchemie werken "De Adelaar" Eesti AS.** Vanapere tee 14, Viimsi vald, Harjumaa 74013**,** Estonia **Local Agent:** BIOLAB, House #10, Road # 3/A, Sector # 09, Uttara, Dhaka-1230	Dexon Super Powder **(vet)**	Potassium Peroxymonosulfate 50% + ulphamic acid 6% + Sodium dichloroisocyanurate dihydrate 1%	Disinfectant	Dexon Super is a highly concentrated per-oxygen based disinfectant. It is effective against a wide range of bacteria, viruses and fungi. Dexon Super rapidly destroys microorganisms causing important animal diseases.	Contraindication/precaution: Do not eat,drink or smoke when using this product.	New	Estonia	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
3.	**Manufacturer:** Lohmann Animal Health International, 375 China Road,	AviPro 108 FC3 Platinum Oil emulsion for subcutaneous	Quantity per Dose (0.25 ml): *Pasteurella multocida*, type 1	Vaccine	Recommended for the vaccination of chickens and turkeys as an aid in the prevention of fowl cholera caused by	**Contraindication:** Do not use in clinically ill or weakened animals. **Side Effects:**	New	USA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
	Winslow, Maine 04901 USA **Local Agent:** Elanco Bangladesh Limited Praasad Trade Center, 11th Floor),6 Kemal Ataturk Avenue, Banani Dhaka-1213 Bangladesh	or intramuscular injection**(vet)**	(X-73 strain) ≥ $10^{8.5}$ CFU + *Pasteurella multocida*, type 4 (P-1662 strain) ≥ $10^{8.5}$ CFU + *Pasteurella multocida*, type 3X4 (86-1913 strain) ≥ $10^{8.5}$ CFU		*Pasteurella multocida*, type 1 infection in chickens, and types 4 and 3X4 in turkeys. Onset of immunity for subcutaneous injection in chickens and turkeys: 2 weeks following 2nd vaccination Onset of immunity for intramuscular injection in chickens and turkeys: 3 weeks following 2nd vaccination	Mild local reactions may occur after subcutaneous injection. May cause processing plant lesions when injected in turkey breast muscle. **Withdrawal Period:** Do not vaccinate within 42 days before slaughter.				
4.	**Manufacturer:** Bios AgriCorp Ltd, Bulevardi 7, 00120 Helsinki, Finland (EU) **Local agent :** Farmers Agri Business Ltd. Adabor, Mohammadpur, Dhaka-1207.	**Biosoftt PC®** **Liquid(vet)**	Cationic Polymeric Compound 1%+ Acid pH Regulator 5% + Distilled Water 94%	Disinfectant	**Biosoftt PC®** is a polymer based versatile, water conditioners for various industries. Biosoftt improves the water quality for farm operations. **Biosoftt** comprises range of products and are designed to ensure high levels of food safety and security, facility hygiene, and animal hygiene.	NO	New	Finland	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
5.	**Manufacturer:** Bios AgriCorp Ltd, Bulevardi 7, 00120 Helsinki, Finland (EU) **Local agent :** Farmers Agri	**Bioscil®** Liquid**(vet)**	Cationic Polymeric Compound 10%+ Uv treated Distilled Water 90%	Disinfectant	**Bioscil®** is a polymer based versatile, water conditioners used in various industries. **Bioscil®** improves the water quality for farm operations. **Bioscil®** co mprises range of products and are designed to ensure high	NO	NEW	Finland	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
	Business Ltd. Adabor, Mohammadpur, Dhaka-1207.				levels of food safety and security, facility hygiene, and animal hygiene.					
6.	**Manufacturers:** Q-Vet Ltd. 17 Ffordd Caradog, Four Mile Bridge, Anglesey, LL652SX, UK **Local Agent:** M/s. Linkage International Pvt. Ltd, Chattogram	Q-CERYL WSP**(vet)**	Each gm contains Erythromycin Thiocyanate 35.0mg + Oxytetracycline Hydrochloride 50.0mg + Streptomycin Sulphate 35.0mg + Retinol-Acetate Powder (Vitamin A Acetate) 3,000 IU + Cholecalciferol Powder (Vitamin D3) 1,500 IU + □-Tocopherol Acetate (Vitamin E) 2.0mg + Thiamine Hydrochloride 2.0mg + Riboflavine 4.0mg + Pyridoxine Hydrochloride 2.0mg + Cyanocobalamin 10.0µg + Ascorbic Acid 20.0mg + Calcium Pantothenate 10.0mg + Menadione Sodium Bisulfite 2.0 mg + Nicotinamide 20.0mg + Inositol 1.0mg	Antibiotic+ Vitamin combinations	The vitamins supplement those in the normal rations during periods of diseases and stress and stimulate egg production and weight gains in calves, goats, poultry, sheep and swine. Prevents and treats a wide range of diseases caused by gastrointestinal, respiratory and urinary tract infections caused by both Gram-positive and Gram-negative bacteria; intestinal infections, C.R.D., infections coryza, infectious synovitis, fowl cholera, pullorosis, mycoplasmose, streptococcal and staphylococcal infections in calves, goats, poultry, sheep and swine.	Hypersensitivity to tetracyclines, macrolides, aminoglycocides. Administration to animals with a seriously impaired renal and/or hepatic function. Concurrent administration of bactericidal agents like penicillins. Administration to animals with an active microbial digestion.	New	-	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।*

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
7.	**Manufacturer:** Laboratorios Eurisko, SL, C/Mallor 249, 1^0 1^0, 08008-Barcelona, Spain. **Local Agent:** M/s. Linkage International Pvt. Ltd, Chattogram	MASTI EURO 4 Syringes (Intramammary Suspension) **(vet)**	(Erythromycin 75mg + Neomycin 100mg +Dexamethasone 0.50mg + Papain 5mg)/10gm (Topic Pomade)	Antibiotic	Sharp and chronic mamitis, mammary congestion and cutaneous infection.	It is not described.	New	Spain	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
8.	**Manufacturer**: M/S Choong Ang Vaccine Laboratories Co. Ltd. 1476-37 Yuseong-daero, Yuseong-gu, Daejeon,305-348, Republic of Korea. **Local Agent:** M/S Pharma & Firm 3/2, City Heart Building, 67, Naya Paltan, Dhaka-1000	PoulShot® Gumboro 500/1000/2000dose/Vial (administer by drinking water) **(vet)**	Live freeze-dried IBDV vaccine Each dose: Infectious bursal disease virus (IBDV,LZD 228-JAC3 strain----- $\geq 10^{2.0}$ $TCID_{50}$ Stabilizer------50%	Vaccine	For active immunization of chickens as an aid in the control and prevention of infectious bursal disease (Gumboro disease) caused by IBDV infection.	**Contraindication** -None **Side-effect** Temporary fever, inappetance, and lethargy, convulsion may occur. **Withdrawal period** -None	Infectious bursal disease virus (IBDV, Winterfield 2512 strain) $\geq 10^{2\cdot0}$EID **50** Stabilizer 25%	Korea	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
9.	**Manufacturer**: M/S Choong Ang Vaccine Laboratories Co. Ltd. 1476-37 Yuseong-daero, Yuseong-gu, Daejeon,305-348, Republic of Korea. **Local Agent:** M/S Pharma & Firm 3/2, City Heart Building, 67, Naya Paltan, Dhaka-1000	PoulShot® Lasota 1000/2000dose/Vial (dminister by drinking water) **(vet)**	Live freeze-dried Newcastle disease virus (NDV) vaccine Each dose: Newcastle disease virus (NDV, Lasota strain).------- $\geq 10^{6\text{-}0.}$ EID_{50} Stabilizer--q.s * EID50 = 50% Embryo infective dose	Vaccine	For active immunization of chickens as an aid in the control and prevention of Newcastle disease caused by NDV infection.	**Contraindication** -None **Side-effect** Temporary fever, inappetance, and lethargy, convulsion may occur. **Withdrawal period** -None	Newcastle disease virus, Live, Strain La Sota min. 106,0 EID50 - max.107,0 EID50*	Korea	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
10.	**Manufacturer**: M/S Choong Ang Vaccine Laboratories Co. Ltd. 1476-37 Yuseong-daero, Yuseong-gu, Daejeon,305-348, Republic of Korea. **Local Agent:** M/S Pharma & Firm 3/2, City Heart Building, 67, Naya Paltan, Dhaka-1000	PoulShot® NDO 1000dose/bottle Intramascular /subcutaneous Injection **(vet)**	Inactivated NDV vaccine. Each dose: Newcastle disease virus (NDV, Lasota strain).--- -----$\geq 10^{9.0.}$ EID_{50} Adjuvant ----- 70% Formalin---≤ 0.2%	Vaccine	For active immunization of chickens as an aid in the control and prevention of Newcastle disease caused by NDV infection.	**Contraindication** -None **Side-effect** Inappetance, coughing, sneezing and decreased egg production may occur. **Withdrawal period** -None	Newcastle disease virus, Live, Strain La Sota min. 106,0 EID50 - max.107,0 EID50*	Korea	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
11.	**Manufacturer**: M/S Choong Ang Vaccine Laboratories Co. Ltd. 1476-37 Yuseong-daero, Yuseong-gu, Daejeon,305-348, Republic of Korea. **Local Agent:** M/S Pharma & Firm 3/2, City Heart Building, 67, Naya Paltan, Dhaka-1000	PoulShot® B1+IB (Lypholized vaccine) **(vet)**	Live Freeze dried NDV & IBV combuned Vaccine. Each dose: Newcastle disease virus (NDV, B1 strain).------- $10^{6.0.}$ EID_{50} Infectious Bronchitis virus (IBV, H120 strain)------ - $\geq 10^{2.5}$ EID_{50} Stabilizer ----q.s Color additive (food red No. 3)- 0.04mg	Vaccine	For active immunization of chickens as an aid in the control and prevention of Newcastle disease and infectious bronchitis caused by NDV and IBV infection.	**Contraindication** -None **Side-effect** Loss of appetite, coughing, and sneezing may occur. Withdrawal period -None	**Himmvac IB-ND Combined oil vaccine** Inactivated IB virus (H-120) - 20% Inactivated ND virus (B1) – 15% Marcol 52 – 58% Montanide – 7%	Korea	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
12.	**Manufacturer :** Vaxxinova Japan K.K., Tochigi Laboratory, Address : 82-1 Kogura, Nikko-shi, Tochigi-ken, 321-1106, Japan **Local Agent:** Renata Limited Mirpur, Dhaka	VAXXON MG Live Solution **(vet)**	Live Mycoplasma gallisepticum strain K5831B-19, ≥ $10^{6.0}$CFU per dose	Vaccine	For active immunisation of chickens against loss in egg production due to Mycoplasma gallisepticum infections	Do not use in unhealthy chickens. Adverse Reactions : If any adverse reaction is observed, immediately have a veterinarian examine and diagnose the affected chicken(s). Withdrawal period: 0 days	Mycoplasma gallisepticum strains6 bacteril concentrate 23.02mg/dose	Japan	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
13.	**Manufacturer :** Laboratorios Syva, S.A.U., Address : Av Parroco Palbo Diez, 49-57, 24010, Leon, Spain	AMOXOIL RETARD Suspension for injection**(vet)**	Amoxicillin (as Trihydrate Ph. Euro) 150 mg /ml	Antibiotic	Infectious processes caused by microorganisms sensitive to amoxicillin located in: - digestive tract - respiratory tract - urogenital tract - skin and soft tissues	Do not use in case of hypersensitivity to the active substance, or to any of the excipients. Do not administer to horses, rabbits, guinea-pigs and hamsters due to	Amoxicillin 1.5gm/10 ml injection	Spain	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
	Local Agent: Renata Limited Mirpur, Dhaka				and also for bacterial complications sensitive to amoxicillin.	amoxicillin, as all aminopenicillins have an important action on the cecal bacterial population. withdrawal period: Meat: Cattle, Sheep-50days Milk: 04days				
14.	**Manufacturer** – SLS Lommel BVBA, Maatheide 90, 3920 Lommel Belgium **Parent company** – Pikoline BV Kruisdonk 56 Maastricht, Netherland Local agent – Eco Greentech Limited, Registered address – DCC 179 West Nakhalpara, Tejgaon, Dhaka - 1215	Pikodes H20 Super Concentrated A Liquid **(vet)**	Sodium Chlorite 1.3%	Disinfectant	Combat bacteria like E.coli, Salmonella, and Campylobacter etc. Give protection against virus like New castle disease virus, Infectious Bronchitis Virus, Infectious Bursal Disease Virus etc. Kill micro-organisms like yeast, fungi etc. Control Avian Influenza Virus – Bird Flu. It is developed for cleaning and disinfecting drinking water system in professional livestock farming.	Contra-indication – None Side-effect - None	New	Netherland	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
15.	**Manufacturer** – SLS Lommel BVBA, Maatheide 90, 3920 Lommel Belgium Parent company	Pikodes H20 Super Concentrated B Liquid **(vet)**	Sodium Hydrogen sulfate 31%)	Disinfectant	Combat bacteria like E.coli, Salmonella, and Campylobacter etc. Give protection against virus like New castle disease virus, Infectious Bronchitis Virus, Infectious Bursal Disease	Contra-indication – None Side-effect - None	New	Netherland	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
	– Pikoline BV Kruisdonk 56 Maastricht, Netherland **Local agent** – Eco Greentech Limited, Registered address – DCC 179 West Nakhalpara, Tejgaon, Dhaka - 1215				Virus etc. Kill micro-organisms like yeast, fungi etc. Control Avian Influenza Virus – Bird Flu. It is developed for cleaning and disinfecting drinking water system in professional livestock farming.					
16.	**Manufacturer :** Ewhapharmtek Corp. South Korea. **Local agent:** Fahat Trade International, Dhaka-1000, Bangladesh	Levocin 20 Oral Solution **(vet)**	Levofloxacin-200gm/Liter	Antibiotic	For the treatment against the following diseases by Susceptible bacteria(E.Coli,Salmonella,Mycoplasma,Pasteurella,Staphylococcus,Haemophilus)Chicken: Chronic Respiratory disease, Complex Chronic Respiratory disease ,Collibacillosis, Salmonellosis, Fowel Cholera,Infectious Coryza, Staphylococcosis.	Hypersensitivity to the active substance, any other quinolone. It is contraindicated during pregnancy.	Levofloxacin 10% Solution	Korea	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
17.	**Manufacturer :** Ewhapharmtek Corp. South Korea. **Local agent:** Fahat Trade International, Dhaka-1000, Bangladesh	Tegodor 73 Liquid**(vet)**	Formaldehyde KP 75g + Glutaraldehyde KP 50g + Benzalkonium chloride KP 60g + Citric acid KP 13g/ Kg	Disinfectant	● Disinfection for surfaces and rooms of livestock barns ●Cleaning & disinfections for vehicles. ● Spray disinfections for livestock house	Eyes: Irritating to the eyes. Skin: Irritating to skin. Ingestion: Toxic by ingestion. Inhalation: Irritating to the nose, throat and lungs. Chronic Exposure:	Benzalkonium Chloride 10% W/W + Glutaraldehyde 15-16% (DCC-245)	Korea	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
						Extreme or prolonged exposure will induce tearing of eye tissue, coughing, Difficulty in breathing, nausea, headache, or weakness.				
18.	Ewhapharmtek Corp. South Korea. **Local agent:** Fahat Trade International, Dhaka-1000, Bangladesh	CRD Forte Powder **(vet)**	Tiamulin hydrogen fumarate- 33.0g + Doxycyline hyclate hydrate-100.0g/Kg	Antibiotic	For the treatment of disease caused by Doxycycline and Tiamulin susceptible bacteria. Poultry: Chronic respiratory disease (Mycoplasma gallistpticum).	Contraindication can be described as a special circumstance or a disease or a condition wherein you are not supposed to use the drug or undergo particular treatment as it can harm the patient; at times, it can be dangerous and life threatening as well. allergic to any ingredient in doxycycline or to any other tetracycline antibiotic (eg, minocycline)	Tiamulin hydrogen fumarate 45% powder	Korea	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
19.	**Phibro Animal Health Corporation** Manufactured By: Bio Agri Mix LP, 52 Wellington Street, Mitcheel, ON NOK 1NO, Canada	Stafac 500 Powder **(vet)**	Virginiamycin	Antibiotic	It is indicated for the Control & treatment of Necrotic enteritis in poultry.	**Contraindication:** There is no known contraindication to the use of virginamycin. **Side-effect:** NO adverse effects on recommended dose. Withdrawal Period: Zero days	NEW	Canada	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
	Local Agent: Provet Resources Ltd. Afsana Tower, Plot# 18, Alaol Avenue, Sector-06, Uttara, Dhaka.									
20.	**Laboratorios Zotal S.L.** Ctra, Nacional 630, km, 809.41900 Camas (Sevilla) SPAIN **Local Agent:** Provet Resources Ltd. Afsana Tower, Plot# 18, Alaol Avenue, Sector-06, Uttara, Dhaka.	PREVIO FOAM Concentrated Liquid**(vet)**	Anionic surfactant <5% , Amphoteric surfactant <5%, Sequestering agent <5%, Sodium hydroxide 5-15%	Alkaline Detergent	It is indicated for cleaning of all types of Livestock poultry facilities.	**Contraindication:** There is no known contraindication. **Side-effect:** NO side effect on recommended direction.	New	Spain	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
21.	**Laboratorios Zotal S.L.** Ctra, Nacional 630, km, 809.41900 Camas (Sevilla) SPAIN **Local Agent:** Provet Resources Ltd. Afsana Tower, Plot# 18, Alaol Avenue, Sector-06, Uttara, Dhaka.	PREVIO EXTRA FOAM Concentrated Liquid **(vet)**	Anionic surfactant 5-15%, Sequestering agent <5%, Sodium hydroxide 5-15%	Alkaline Detergent	It is indicated for cleaning of all types of Livestock poultry facilities.	**Contraindication:** There is no known contraindication. **Side-effect:** NO side effect on recommended direction.	New	spain	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
22.	**Manufacturer:** Laboratoires Bovine, 3Rue De Lorraine, 62510 Arques, France **Local Agent:** Inter Agro BD Ltd. 718/A, 1st Floor, West Nakhalpara Tejgoan, Dhaka	Actiliver I Solution for Injection**(vet)**	(Menbutone 50mg + Sorbitol 250mg)/ml	Choleretic agent + Hyperosmotic laxative	The preparation can be used for all domestic animals whose digestion and all associated secretory processes need assistance. Cattle, sheep, goats Primary indigestions. After over feeding, particularly with easily digestible carbohydrates (ruminal acidosis), with contaminated and spoilt food (ruminal breakdown) and as a result of rapid changes in diet; Dogs Constipation, intestinal atony, exocrine pancreatic insufficiency. Stimulation of hepatic function by promoting bile secretion.	Contraindications: The use of Menbutone + Sorbitol is contraindicated in animals with a history of an allergic reaction to its. Adverse Reactions: Anal irritation;diarrhea; gas; nausea; stomach cramps.		France প্রয়োজন নেই বিধায় ডিসিসি ২৪৮তম সভায় আবেদন নামঞ্জুর করা হয়।	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
23.	**Manufacturer:** V.M.D. nv/sa, member of Inovet Hoge Mauw 900, 2370 Arendonk, Belgium **Local Agent:** Inter Agro BD Ltd. 718/A, 1st Floor, West Nakalpara Tejgoan, Dhaka	Diaziprim-48% Soluble powder **(vet)**	Sodium Sulfadiazine 420mg + Trimethoprim 80mg)/gm	Antibacterial	Treatment of infections caused by microorganisms susceptible to trimethoprim and/or sulfadiazine, such as gastro-intestinal,respiratory and urogenital tract infections and general infections in valves, pigs and poultry.	**Contraindications** The drug should not be administered to: • commercial laying hens • animals with severe liver and kidneyimpairment or blood dyscrasia • animals hypersensitive to sulfonamides **Side Effects:** None.	Sulphamethoxazole 400mg + Trimethoprim 80mg Tablet	Belgium & France	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
24.	**Manufacturer:** V.M.D. nv/sa, member of Inovet Hoge Mauw 900, 2370 Arendonk, Belgium **Local Agent:** Inter Agro BD Ltd. 718/A, 1st Floor, West Nakalpara Tejgoan, Dhaka	CTC-Oblets Tablet **(vet)**	Chlortetracycline Hydrochloride Ph. Eur. 1000mg	Antibacterial	Treatment of acute post-partum uterine infection caused by bacteria susceptible to chlortetracycline.	Do not use in animals with moderate to severe live and/or renal insufficiency. Do not use in case of known hypersensitivity to tetracyclines Withdrawal Period- Meat-3days Milk-4days	Chlortetracycline HCl 45gm Powder Chlortetracycline HCl 20gm/100 gm Powder	Belgium	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
25.	**Manufacturer:** Permix Phama Gyogyszergyarto Kft,H-8900 Zalaegerszeg, Eszaki Iparterulet, Kamilla u.3, Hungary. **Product License holder**: V.M.D. nv/sa, member of Inovet Hoge Mauw 900, 2370 Arendonk, Belgium **Local Agent:** Inter Agro BD Ltd. 718/A, 1st Floor, West Nakalpara Tejgoan, Dhaka	Univerm Total Tablet **(vet)**	Praziquantel 50mg + Pyrantel Embonate 144mg +Fenbendazole 200mg	Anthelmintics	Roundworm and tapeworm remedy for use in dogs. For the treatment of mixed infestations with roundworms and tapeworms caused by: Roundworms: Ascarids, Hookworms, Whipworms Tapeworms: Echinococcus ranulosus, Echinococcus multilocularis, Multiceps multiceps etc.	Contraindications: Do not use during the first two thirds of gestation in bitches. Do not exceed the dose. Do not administer concurrently with other anthelminthics. Side-effects: Side effects of caninethic Plus may be common but are usually mild and transient. Headache, dizziness and restlessness, transient abdominal pain and diarrhea have been reported most frequently. Hypertensitivity	New	Belgium and Hungary	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
						reactions like rashes, prutitus, fever, and anaphylaxis can occur. They may be due to death of the infecting parasites. Raised liver enzyme values have been reported rately.				
26.	**Manufacturer:** V.M.D. nv/sa, member of Inovet Hoge Mauw 900, 2370 Arendonk, Belgium **Local Agent:** Inter Agro BD Ltd. 718/A, 1st Floor, West Nakhalpara Tejgoan, Dhaka	Lincomycin-40s Water Soluble Powder **(vet)**	Lincomycin 400mg/gm Water Soluble Powder	Antibiotic	Broiler chikens, Layers & Turkeys: For the prevention and treatment of: • Necrotic enteritis (Clostridium perfringens) • Improvement of weight gain and reducing mortality • CRD & Airsacculitis (Mycoplasma spp.) • Infectious synovitis (Mycoplasma synoviae) • Dermatitis	Contraindication: Do not use in poultry producing eggs are for human consumption. Do not use in case of hypersensitivity to lincomycin or any of the excipients. Do not use in horses, hamsters, guinea pigs, or ruminants. **Withdrawal period** : Meat: 6 days	Lincomycin Hydrchloride USP 44gm/Kg	Belgium	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
27.	**Manufacturer:** Choong Ang Biotech Co., Ltd. Address: 271-30, Gangchon-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea. (477, Mokrae-dong, Ansan City, Kyoungki-Do, Korea)	Hemoplus Injection **(vet)**	Iron (Iron III hydroxide-dextran . complex) Cyanocobalamine (Vitamin B_{12}) Each ml contains: Iron (Iron III hydroxide-dextran . complex): 100 mg+ Cyanocobalamine (Vitamin B_{12}): 100 mcg . . .	Vitamin-mineral combination	Cattle, Sheep, Goat: · Hemo-Plus is indicated in cases of prevention and treatment of anemia, caused by lack of iron in calves. · Iron deficiency anemia occurs commonly, often within the first few days following birth, As body size and blood volume increase rapidly from the first few days following birth.	**Contraindication :** Contraindicated to animals with vitamin E deficiency,animals with diarrhea and in combination with tetracyclines, because of the interaction of iron with tetracyclines. **Side effects:** Muscle tissue is colored temporarily by this preparation.	New	South Korea	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
	Local Agent Shamim Pharma 112/A, 3rd Floor, Senpara Parbata, Mirpur 10, Dhaka-1216, Bangladesh. Phone: +88 01716405067					Leaking of injection fluid can cause a persistent discoloration of skin.				
28.	**Manufacturer:** Laprovet Hungary Veterinary Pharmaceuticals Ltd. 1107 Budapest, Horog u. 32-34, HUNGARY **Local agent:** Navana Ltd.	ITA NEW FLU H9 Injection **(vet)**	ITA NEW FLU H9 Inactivated vaccine contains type-A Avian Influenza virus, H9N2 sub-type and Newcastle Disease virus, LaSota strain, homogenized with oil adjuvant.	Vaccine	Recommended for active immunization of chickens against H9N2 sub-type of type A Avian Influenza and Newcastle Disease.	None	New	-	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
29.	**Manufacturer:** Korea Thumbvet Co. Ltd. 470-15 Seonhwa-ro, iksan-si, jeollabuk-do, South Korea (Registered No. – 034). **Local Agent:** Axon Animal Health 419/A, Yesmin Cottage,Nuruzzaman NazirSarok , Mohora, Chandgaon,	Enrotril max Injection **(vet)**	Enrofloxacin 100mg/ml	Antibiotic	Treatment of bacterial respiratory disease sensitive to Enrofloxacin. Cattle:Pasteurellosis(*Pasteurellahaemolytica,Pasteurellamultocida)* Haemophilus infection *(Haemophilussomnus)* Mycoplasmosis *(Mycoplasmaspp*	**Contraindication:** Contraindicated in small and medium breed dogs from 2-8 monthsof age. Quinolones are contraindicated in patients hypersensitive to them. **Side Effects:** GI distress (vomiting, anorexia). In dogs, rare incidences of elevated hepatic enzymes, ataxia, seizures, depression,	Enrofloxacin 10% Solution, Enrofloxacin 10 gm/100 gm Powder	Korea	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
	Chittagong, Bangladesh					lethargy, and nervousness have also been reported. **Withdrawal period** : Cattle: meat-14 days, milk-3 days				
30.	**Manufacturer:** Supers Diana S.L. Ctra. C-17, KM17, 08150 Partes del Valles, (Barcellona) Spain **Local Agent:** Axon Animal Health 419/A, Yesmin Cottage,Nuruzzaman NazirSarok , Mohora, Chandgaon, Chittagong, Bangladesh.	Lincosan 800 Powder **(vet)**	Lincomycin hydrochloride 800mg/g	Antibiotic	Broiler chikens, Layers & Turkeys: For the prevention and treatment of: • Necrotic enteritis (Clostridium perfringens) • Improvement of weight gain and reducing mortality • CRD & Airsacculitis (Mycoplasma spp.) • Infectious synovitis (Mycoplasma synoviae) • Dermatitis (Staphylococcus Infections)	**Contraindication:** Do not use in poultry producing eggs are for human consumption. Do not use in case of hypersensitivity to lincomycin or any of the excipients. Do not use in horses, hamsters, guinea pigs, or ruminants. **Side effects**: Occasionally, transient diarrhea or swelling of anus or vulva can occur. **Withdrawal period** : Meat: 6 days	Lincomycin Hydrchloride 44gm/Kg	Spain	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*
31.	**Manufacturer:** Korea Thumbvet Co. Ltd. 470-15 Seonhwa-ro, iksan-si, jeollabuk-do, South Korea (Registered No. – 034). **Local Agent:**	Super Flo-25 Oral Solution **(vet)**	Florfenicol 250gm/1L	Antibiotic	Poultry : Treatment of salmonellosis, colibacillosis Swine : Treatment of respiratory disease including pleural pneumonia, pasteurella pneumonia, mycoplasma pneumonia. Treatment of salmonellosis, streptococcosis	**Contraindication:** Not for use in animals intended for breeding purposes. Do not use in female dairy cattle 20 months of age or older. Do not use in calves to be processed for veal. **Side Effects:** None	Florfenicol 200gm/L Oral Solution	Korea	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	*প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।*

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
	Axon Animal Health 419/A, Yesmin Cottage, Nuruzzaman Nazir Sarok , Mohora, Chandgaon, Chittagong, Bangladesh					**Withdrawal Period:** Poultry - 5 days				
32.	**Manufacturer:** Korea Thumbvet Co. Ltd. 470-15 Seonhwa-ro, iksan-si, jeollabuk-do, South Korea (Registered No. – 34). **Local Agent:** Axon Animal Health 419/A, Yesmin Cottage, Nuruzzaman Nazir Sarok , Mohora, Chandgaon, Chittagong, Bangladesh	Diclasol-Hi Oral solution **(vet)**	Diclazuril 25g/1000ml	Anti-Coccidials	Poultry : Treatment of coccidiosis for *E.tenella, E.maxima and E.acervulina.* Calf : Treatment of coccidiosis for *Eimeira bovis, Eimeria zuernii.* Lamb : Treatment of coccidiosis for Eimeria crandallis , Eimeria ovinoidalis.	**Contraindication:** The drug is contraindicated in patients known to be hypersensitive to diclazuril. **Side effects**: None Withdrawal period : 1. Poultry : 5 days 2. Calf, Lamb : None	New	Korea	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
33.	**Manufacturer:** Fatro- Veterinary Pharmaceutical industry 40064 Ozzano Emilia (BO) Italy. **Local Agent:** SP Vet Care Limited 382/H/3, East Nakhalpara.	EDS-VAC Inactivated emulsion vaccine (Injection) **(vet)**	Inactivated Adenovirus of EDS (127 strain) not less than $80DP_{50}$/dose.	Vaccine	It prevents mortality,clinical signs and lesions of Egg Drop Syndrome (EDS) in breeding and laying hens.	**Contraindication:** No Side Effects: Special warning: Only healthy birds should be vaccinated. Withdrawl period: None	New	Italy	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
34.	**Manufacturer:** Seoul Vet Pharma Co. Ltd Korea, 81, Yongchon-gil, Memaengdong-myeon,Eumseong-gun,Chungcheongbuk-do,Korea. **Local Agent:** Address: SKL Animal health Co. Ltd., Plot-87, BNS Centre, 10th Floor, Road-05, Sector-07, Uttora, Dhaka.	Tilmo Solution **(vet)**	Timicosin Phosphate 200gm/L	Antibiotic	Prevention and treatment of respiratory diseases caused by sensitive bacteria to Tilmicosin as follows,Poultry-Mycoplasma galisepticum, Mycoplasma synoviae.	**Contraindication:** Safety in breeding or pregnant animal has not been established, **Side effects:** In cattle, tilmicosin is distributed into milk at effective antibacterial concentrations for susceptible pathogens, but detectable concentrations in milk are maintained for many weeks. tilmicosin should not be administered to lactating dairy cattle because of impractical. Withdrawal period: 07 days (poultry)	Tilmicosin 25% Oral Solution	Korea	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
35.	**Manufacturer:** THESEO 200 Avenue de Myenne, France **Local Agent :** Centry Agro Limited 55/2 West panthapath, Dhaka	Deterstorm Nf Solution**(vet)**	Anionic surfactant…...9.5% + Tensioactifs anioniques....9.5%+ Nonionic surfactant…….5.36 %+Tensioactifs non ioniques…….9.5% Ingredients Name: (Sulfonic acids , C 14-16- alkane hydroxy and C 14-16 alkene, Sodium salts- 5-	Degreasing and self foaming cleaner	Degreasing and Self foaming Cleaner for surfaces & equipment in breeding.	**Contraindication**: None **Side effect:** none	New	France	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
			10% D-Glucopyranose, Oligomers,decyl octyl glycosides,- 2-4% Amines, C12-14 (even numbered)-alkyl dimethyl, N-Oxides.-1-3% 2-(2-butoxyethoxy)ethanol-3-7% Sodium hydroxide-3-7% Alanine, N,N-bis (carbooxymethyl-sodium salts (1:3)-1-3% water-to 100%							
36.	**M/S. Biogénesis Bagó** Ruta Panamericana Km 38,5, Garín Prov de Bs. As Argentina Importer/Local agent: **M/S. S.S. Scientific Corporation** 107, Begum Rokeya Sarani, Mirpur-10, Dhaka-1216	Bagovac Rabies (vet) (Inactivated Rabies Vaccine) Injection**(vet)**	Each 1 ml contains ≥ 1 IU inactivated suspension of rabies virus (antigen) Vial containing 10ml where 10 doses of 1 mL 1 mL by subcutaneous injection at or about 3 months of age. Veterinary use only	Vaccine	Inactivation vaccine for the prevention of rabies in cats and dogs.	**Contraindication:** Contraindicated in sick, hyperthermia or stressed animals. **Use in pregnancy and lactation**: The safety of the veterinary medicinal product has not been established during pregnancy or lactation **Side Effects**: Systemic reactions include fever, depression, loss of appetite, lethargy and weakness. They usually appear within 1-2 days of vaccination	Inactivated Rabies Vaccine Each dose: Canine Rabies virus (Pasteur Strain)---------- ≥107.0 FAID50 Adjuvant …….. ..... 5% Inactivator ....≤1.0mM	Argentina (Country of Origin) and Singapore	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
37.	**Manufacturer:** THESEO Deutschland GmbH, Kolpingstrasse 4, 49835, Wietmarschen, Germany. **Local Agent:** Registered Address: Univet Limited H-1302, Plot 408/A, Shohor Khilgaon, Malibagh Chowdhurypara, Dhaka-1219, Bangladesh.	Aldecoc ® CMK. **(vet)**	Chlorocresol 25% as active ingredient	Disinfectant	Before you move the animals in (after every cycle) firstly clean stables and all equipment which come into contact with the animals. Then inject floors and walls (up to 1 m height) with a 3 %-**ALDECOC® CMK**-dilution. Coccidian, oocysts and ascaride eggs are often placed at covered, hard accessible places. Therefore it is very important to treat this places too (chinks, gaps, undersides of cages, equipment etc.	As Aldecoc® CMK is not intended for application on animals (dermal, oral) there are no contra Indications to be expected.	New	Germany	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***
38.	**Manufacturer** : Ningbo Sansheng Pharmacutical com. Ltd, China **Local agents:** Agro based technology center, 85/A tejkunipara, taejgaon, Dhaka	Compound GnRHA Liquid Injection Grade (Ovlin) (For fish use only) Injection	DOM 100mg+S-GnRHa 0.2mg/10ml	Hormone	It is used to induce breeding in both fresh water and marine water fish. It substitutes the pituitary with advantages of high estrus rate, shorten response time and decrease side-effects.	**Contraindications:** Not Known **Side effects:** Undetected		**China** প্রয়োজন নেই বিধায় ডিসিসি ২৪৬তম সভায় আবেদন নামঞ্জুর করা হয়।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
39.	**Manufacturer :** Ningbo Sansheng Pharmacutical com. Ltd, China **Local agents:** Agro based technology center, 85/A tejkunipara, taejgaon, Dhaka	Compound S-GnRHa Powder for Injection Grade (Ovupin) (For fish use only) Injection	DOM 100mg+S-GnRHa 0.2mg/Vial	Hormone	It is used to induce breeding in both fresh water and marine water fish. It substitutes the pituitary with advantages of high estrus rate, shorten response time and decrease side-effects.	**Contraindications:** Not Known **Side effects:** Undetected		**China** প্রয়োজন নেই বিধায় ডিসিসি ২৪৬তম সভায় আবেদন নামঞ্জুর করা হয়।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

Sl. No.	Name of the Manufacturer & Importer	Brand Name & Dosage Form	Generic Name & Strength	Therapeutic Class	Indication	Contraindication & Side-effect	Status (New/ Existing)	FSC/CPP	টেকনিক্যাল সাব কমিটির সভার সিদ্ধান্ত	ডিডিসি ২৫১ তম সভার সিদ্ধান্ত
40.	**Manufacturer** : Ningbo Sansheng Pharmacutical com. Ltd, China **Local agents:** Agro based technology center, 85/A tejkunipara, taejgaon, Dhaka	Human Chorionic gonadotrophin (HCG) for Injection (For fish use only) Injection	Human Chorionic gonadotrophin (HCG)	Hormone	Accelerate ovulation and formation of corpus luteum and to increase animal sexual desire. Also can be used for delay of ovulation, ovarian cyst, inducing estrus and breeding of cultured fish.	**Contraindications:** Not Known **Side effects:** Undetected		**China** প্রয়োজন নেই বিধায় ডিসিসি ২৪৬তম সভায় আবেদন নামঞ্জুর করা হয়।	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

Annex-: G Products for Locally Manufacture (Herbal)

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
1.	Drug International Ltd (Herbal Division)	Turmeric Powder Extract 1000mg Soft capsule	Turmeric is used for dyspeptic disorders particularly feelings of fullness after meals and regular abdominal distention due to gas. Other uses include headache, chest infections, amenorrhea, flushing, inflammation of the oral mucosa & skin conditions.	Contraindications: Turmeric should not be used by people with gallstones or bile duct obstruction. It should also not be used by patients with hyperacidity or gastrointestinal ulcers. Side effects: Stomach complaints, acute contact dermatitis	New	**PDR For Herbal Medicines s 4th edition.**	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
2.	Drug International Ltd. (Herbal Division)	Psyllium Husk (Ispaghula Husk) BP 65.00gm + Senna Extract BP 2.54gm Eqv. to Sennoside B 139.4mg / 100gm effervescent powder	It is used to treat constipation, Hemorrhoids or piles, bowl regulation for bed ridden patients.	Contra-indication: Contraindicated for patients with pathological narrowing in gastrointestinal tract, intestinal obstructions, difficult-to-control diabetes mellitus, actually inflamed intestinal diseases, e.g. Crohn's disease, ulcerative colitis, appendicitis and abdominal pain of unknown origin. Contraindicated for children under 12 years old. Side effects: Occasionally allergic reaction may occur. Chronic use may cause loss of electrolytes (Potassium) that will reverse upon discontinuation.	Existing as Ispaghula Powder 3.5g USP (Plantago Ovata) + Cinsidering 5.5% Sennoside –B content 2.54g BP(Cassia angustifolia	PDR For Herbal Medicines s 4th edition British pharmacopoeia: Volume- IV	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
3.	The IBN SINA Natural Medicine (Herbal Division)	Carica papaya leaf extract 250 mg Capsule **Generic :** Carica papaya leaf extract 250 mg	Indicated for Thrombocytopenia (low platelet count) associated with Dengue and Thrombocytopenia induced by chemotherapy.	Nausea, vomiting, abdominal pain, heartburn, dyspepsia	New	PDR For Herbal Medicines (4th Edition) (Page 627-628) **Reference Product** : Papaya leaf extract 300mg capsule, Pakistan Caripill syrup, India, Black Mores multi B tablet, India.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
4.	Incepta Herbal & Nutricare Ltd.	Lactobacillus Plantarum 299V 10 billion CFU capsule **Generic :** Lactobacillus Plantarum 299v INN 410 mg eq Lactobacillus Plantarum 299v 10 billion CFU	Hayfever. Taking 2 billion colony-forming units of lactobacillus daily for 5 weeks can improve quality of life by almost 18% in people with grass pollen allergy that doesn't respond to the anti-allergy drug loratadine. In children with allergies that persist throughout the year, taking 10 billion colony-forming units of lactobacillus for 12 weeks seems to improve itchy eye symptoms. Preventing diarrhea caused by antibiotics. Taking probiotics products containing lactobacillus strains helps prevent diarrhea caused by antibiotics in adults and children. The most well-studied strain of lactobacillus seems to reduce the chance of diarrhea by about 60% to 70% when started within 2 days of beginning antibiotic treatment and continued for at least 3 days after finishing the antibiotics. Eczema (atopic dermatitis). Most	**Contraindication:** None **Side-effects:** Pregnancy and breast-feeding: Lactobacillus is POSSIBLY SAFE when taken by mouth appropriately while pregnant and breastfeeding. Lactobacillus GG has been used safely in pregnant and breast-feeding women. The combinations of Lactobacillus rhamnosus or Lactobacillus paracasei with Bifidobacterium longum from 2 months before delivery until the breastfed infant was 2 months has been used safely. But other types of lactobacillus have not been studied during pregnancy. Weakened immune system: There is some concern that lactobacillus from supplements that contain live bacteria might grow too well in people WHOse immune systems are weakened. This	Bifidobacterium Animals + Bifidobacterium bifidum + Bifidobacterium Longum + Lactobabacillus Plantarum + Lactobacillus Acidophillus + Lactobacillus Casei + lactobacillus Reuteri +	PDR For Herbal Medicines s (4th Edition) (Page 996-999) **Reference Product** : Ideal bowel support	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			research shows that taking lactobacillus products can reduce eczema symptoms in infants and children. Research also shows that lactobacillus can help PREVENT eczema from developing. When taken by a mother during the last month of pregnancy and then given to the child for the first 1-2 years of life, lactobacillus probiotics can reduce the chance of the child developing eczema by about 11%. A condition associated with an increased risk for developing allergic reactions (atopic disease). Research shows that taking certain lactobacillus strains can prevent atopic disease, such as asthma, allergic rhinitis, and eczema, in infants with a family history of this condition. However, not all strains seem to work. Treating vaginal infections caused by bacteria (bacterial vaginosis). Researchers have found that lactobacillus suppositories and vaginal tablets may be effective in treating bacterial vaginosis. Researchers have also found that eating yogurt or using vaginal capsules containing lactobacillus can help prevent these infections from occurring again. Preventing diarrhea due to cancer treatment (chemotherapy). A chemotherapy drug called 5-	includes people with HIV/AIDS or people WHO have taken medicines to prevent rejection of a transplanted organ. Lactobacillus has caused disease (rarely) in people with weakened immune systems. Short bowel syndrome: People with short bowel syndrome might be more likely than other people to develop lactobacillus infections. If you have this condition, talk with your healthcare provider. Ulcerative colitis: People with ulcerative colitis that is severe enough to require hospitalization might be more likely than other people to develop lactobacillus infections. Damaged heart valves: Lactobacillus can cause an infection in the inner lining of the heart chambers and heart valve, but this is extremely rare. However, people with damaged heart valves might be more likely than other people to develop this type of infection, especially if they take lactobacillus before dental or invasive stomach and intestinal procedures. People with damaged heart valves should stop taking probiotics before dental procedures or invasive stomach and intestinal procedures such as an endoscopy	Lactobacillus Rhamnosus Capsule			

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			fluorouracil can cause severe diarrhea and other gastrointestinal (GI) side effects. There is some evidence that patients with cancer of the colon or rectum have less severe diarrhea, less stomach discomfort, shorter hospital care, and require fewer chemotherapy dose reductions due to GI side effects when they take lactobacillus.					
5.	Incepta Herbal & Nutricare Ltd.	Lactobacillus rhamnosus GG 10 billion capsules. **Generic :** Lactobacillus Rhamnosus GG containing Blend INN 250 mg contain Lactobacillus Rhamnosus GG 10 billion	Probiotics contain different types of micro-organisms such as yeast (saccharomyces boulardii) and bacteria (such as lactobacillus, bifidobacterium). Micro-organisms (flora) are naturally found in the stomach/intestines/vagina. Some conditions (such as antibiotic use, travel) can change the normal balance of bacteria/yeast. Probiotics are used to improve digestion and restore normal flora. Probiotics have been used to treat bowel problems (such as diarrhea, irritable bowel), eczema, vaginal yeast infections, lactose intolerance, and urinary tract infections.	**Contraindication** None. **Side-effects:** An increase in stomach gas or bloating may occur. If this effect persists or worsens, notify your doctor or pharmacist promptly. Tell your doctor right away if any of these unlikely but serious side effects occur: signs of infection (such as high fever, chills, persistent cough). A very serious allergic reaction to this product is rare. However, seek immediate medical attention if you notice any of the following symptoms of a serious allergic reaction: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.	Bifidobacterium Animals + Bifidobacterium bifidum + Bifidobacterium Longum + Lactobabacillus Plantarum + Lactobacillus Acidophillus + Lactobacillus Casei + lactobacillus Reuteri + Lactobacillus Rhamnosus Capsule	PDR For Herbal Medicines (4th Edition) (Page 996-999) **Reference product :** Culturelle probiotics	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
6.	Incepta Herbal & Nutricare Ltd.	Lactobacillus rhamnosus GG 10 billion per sachet **Generic :** Lactobacillus Rhamnosus GG containing blend INN 1 gm contain Lactobacillus Rhamnosus GG 10 billion	Probiotics contain different types of micro-organisms such as yeast (saccharomyces boulardii) and bacteria (such as lactobacillus, bifidobacterium). Micro-organisms (flora) are naturally found in the stomach/intestines/vagina. Some conditions (such as antibiotic use, travel) can change the normal balance of bacteria/yeast. Probiotics are used to improve digestion and restore normal flora. Probiotics have been used to treat bowel problems (such as diarrhea, irritable bowel), eczema, vaginal yeast infections, lactose intolerance, and urinary tract infections.	**Contraindication** None. **Side-effects:** An increase in stomach gas or bloating may occur. If this effect persists or worsens, notify your doctor or pharmacist promptly. Tell your doctor right away if any of these unlikely but serious side effects occur: signs of infection (such as high fever, chills, persistent cough). A very serious allergic reaction to this product is rare. However, seek immediate medical attention if you notice any of the following symptoms of a serious allergic reaction: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.	Bifidobacterium Animals + Bifidobacterium bifidum + Bifidobacterium Longum + Lactobabacillus Plantarum + Lactobacillus Acidophillus + Lactobacillus Casei + lactobacillus Reuteri + Lactobacillus Rhamnosus Capsule	PDR For Herbal Medicines (4th Edition) (Page 996-999) **Reference product :** Culturelle probiotics	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
7.	Incepta Herbal & Nutricare Ltd.	Undenatured type 2 Collagen 40 mg tablet **Generic :** Undenatured type 2 collagen INN 40 mg	Osteoarthritis. Early research shows that taking a specific product (AR7 Joint Complex by Robinson Pharma) containing collagen type II, methylsulfonylmethane (MSM), cetyl myristoleate, lipase, vitamin C, turmeric, and bromelain by mouth for 12 weeks reduces joint pain and tenderness in people with osteoarthritis. However, it does not seem to improve X-rays of affected joints. Rheumatoid arthritis (RA). Research on the effects of collagen type II in people with RA shows conflicting results. Some research shows that taking collagen type II by mouth for 3 months reduces joint pain, swelling, and time to walk 15 meters in people with RA. However, other research does not show these improvements when collagen type II is taken for longer periods of time or in higher doses. Also, other research suggests that collagen type II is less effective than the drug methotrexate for treating RA. Pain associated with joint pain after surgery, pain after injury, and back and neck pain.	**Contraindication** Hypersensitivity to the active substance or to any of the excipients **Side-effects:** Collagen type II is Possibly safe when taken by mouth in doses up to 2.5 mg daily for up to 24 weeks. Some people might have stomach problems after taking collagen type II. Headache, difficulty sleeping, dizziness, and liver problems have also occurred. But these events are uncommon.	Colchicine + Collagen II	PDR For Herbal Medicines (4^{th} Edition) **Reference Product :** UC-II as Tablet, USA.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
8.	Incepta Herbal & Nutricare Ltd.	Glucosamine HCl 150 mg,Chondroitin sulfate 120 mg,Undenatured type 2 collagen 40 mg tablet **Generic :** Glucosamine Hcl USP 150 mg,Chondroitin sulfate USP 120 mg & Undenatured type 2 collagen INN 40 mg	Glucosamine sulfate • Pain: Opinion is divided about the effectiveness of glucosamine sulfate on pain. In some studies, glucosamine improved pain from OA of the knee more than placebo (fake pills). However in other studies, pain improved about the same whether people took glucosamine or placebo. • Cartilage: there is some evidence that glucosamine sulfate can slow cartilage breakdown in the knee.Glucosamine hydrochloride • Studies suggest the hydrochloride form is not effective in relieving pain. The effect of glucosamine Hydrochloride on cartilage has not been tested. Chondroitin •Pain: there are mixed results from studies of chondroitin. Some studies have found chondroitin reduces pain more than placebo. However other studies have found no improvement in pain with chondroitin. •Cartilage: there is some evidence that chondroitin supplements slow	**Contraindication** Hypersensitivity to the active substance or to any of the excipients **Side-effects:** Shellfish allergy: most glucosamine supplements are made from shellfish although some made from non-shellfish sources are now available. Talk to your doctor or pharmacist, before taking it, about whether the supplement is safe for you. •Bleeding:people taking the blood thinning medicine warfarin should talk to their doctor before starting, stopping or changing their dose of glucosamine as it may interact with warfarin and make the blood less likely to clot. • Diabetes: glucosamine is a type of sugar so check with your doctor before taking glucosamine if you have diabetes. • Pregnant or breastfeeding women: there have not been enough long term studies to clearly say that glucosamine is safe for a developing baby. Pregnant women should talk to their doctor before taking glucosamine. • Other side effects: upset stomach (for example, diarrhoea), headaches, and skin reactions. Talk to your doctor or pharmacist about possible side effects	Existing as Colchicine + Collagen II	Mosby's Drug Consult (2006)(Page III-55,III-23) & PDR For Herbal Medicines (4th Edition)(Page129) **Reference Product :** Glucosamine & Chondroitin plus UC-II, USA.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			cartilage breakdown or repair damaged cartilage from knee OA.Combination glucosamine sulfate and chondroitin • Recent studies have shown that the combination of glucosamine sulfate and chondroitin may be effective in slowing the breakdown of cartilage in the early stages of knee OA. Research has also shown that the combination may help in reducing moderate to severe knee pain from OA.	before taking glucosamine. Chondroitin • Bleeding: people taking blood thinning medicines, such as warfarin, should talk to their doctor before taking chondroitin as it may increase the risk of bleeding.				
9.	Incepta Herbal & Nutricare Ltd.	Montmorency tart Cherries (Prunus lauroceras) 500 mg capsule **Generic :** Montmorency tart Cherries extract 500 mg	Muscle soreness after exercise. Some research shows that drinking sour cherry juice or taking a sour cherry supplement for 7 days before a long-distance race reduces muscle soreness after the race. Also, taking a sour cherry concentrate or a sour cherry supplement seems to reduce muscle soreness caused by weightlifting. But not all sour cherry products seem to be beneficial. Drinking a blend of sour cherry and apple juice doesn't seem to reduce soreness after exercise in runners or weight lifters. Exercise performance. Early research shows that taking sour cherry concentrate can improve jumping, agility, and recovery of	**Contraindication** People WHO are allergic to cherries should not ingest sour cherries or products derived from them. Anaphylaxis to cherries has been reported. **Side-effects:** The fruit of the sour cherry is LIKELY SAFE for most adults when eaten as food or used as medicine. It's not known if sour cherry stems or dietary supplements containing the sour cherry stems are safe. For most people taking sour cherry supplements or drinking sour cherry juice is well-tolerated. Some people have reported loose stools after taking	New	PDR For Herbal Medicines (4th Edition) (Page 188) **Reaference Product :** cherrypure.4, USA.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			muscle strength in athletes taking part in intensive exercise programs. Drinking a different juice blended from sour cherry and apple juice before and after running a marathon appears to decrease symptoms such as cough, sore throat, congestion, and sneezing after the race. Taking a sour cherry supplement before and after running a half-marathon can improve race time by 13% in long-distance runners. Fibromyalgia. Early research shows that taking a sour cherry concentrate twice daily for 14 days does not improve pain or muscle strength in women with fibromyalgia WHO follow an exercise program. High blood pressure. Early research shows that taking a sour cherry concentrate decreases systolic blood pressure (the top blood pressure number) but not diastolic blood pressure (the bottom number) for 1-3 hours after it is taken. It's not known if this product decreases blood pressure when taken long-term in people WHO have high blood pressure. It doesn't appear to lower blood pressure in people WHO do not have high blood pressure.	sour cherry products.				

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			Insomnia. Some early research shows that taking a sour cherry juice concentrate, which contains a small amount of melatonin, improves sleep time when used for 1 week. Other early research shows that drinking a blend of sour cherry and apple juice daily for 14 days improves the severity of insomnia and the amount of time awake after falling asleep in older people withlong-term insomnia. But this product does not appear to help decrease the amount of time it takes to actually fall asleep in these people. Osteoarthritis. Some early research shows that drinking a blend of sour cherry and apple juice twice daily for 6 weeks does not improve arthritis symptoms or the need for rescue pain medicine in people with osteoarthritis. Gout. Improving digestion. Increasing urination. Other conditions.					

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
10.	Incepta Herbal & Nutricare Ltd.	White Kidney bean (Phaselous vulgaris) Extract 500 mg tablet **Generic :** White Kidney bean extract 500 mg	1) White Kidney Bean Extract Helps Weight Loss Because the first commercial bean extracts had low α-amylase blocker activity, a concentrate (6 to 8x more carbohydrate-blocker content) was developed. It broke down the α-amylases from the mouth and small intestine and reduced intestinal α-amylase activity and starch digestion (Infusion of 2-5 mg/ml at 5 ml/min and 5-10 g, RCT with 7 and 4 subjects) . Daily intake of Phase 2 extract before a carbohydrate-rich meal reduced body weight, body mass index, fat mass, fatty tissue thickness, and waist, hip, and thigh sizes while maintaining lean body mass (445 mg for 30 days, DB-RCT of 60 overweight subjects) . Phase 2 with a low-calorie diet (1,800 cals) and exercise had no effect on weight loss. However, the Phase 2 individuals WHO had the most carbohydrates lost more weight and waist circumference (1 g 2x/day for 4 weeks, DB-RCT of 25 healthy overweight individuals) [R]. In a study of 123 overweight subjects, 2 x 500 mg Phase 2 tablets 3x/day before meals on a low-	**Contraindication** None **Side-effects:** An increase in stomach gas or bloating may occur. If this effect persists or worsens, notify your ectins are carbohydrate-binding proteins that recognize specific cells and proteins. Common bean varieties contain different types of lectins, which are responsible for many toxic symptoms [R, R]. The carbohydrate-binding capacity of lectins is a likely cause of their toxicity. Lectins may bind to the gut lining and interfere with the function of digestive enzymes [R, R]. Because approximately 15% of a bean's proteins are lectins, they can cause several harmful effects in lectin-sensitive individuals, such as: Leaky gut Increased sensitivity to some food components Autoimmune diseases Reduced nutrient digestion and absorption Among bean lectins, the most relevant one to human health is phytohemagglutinin. Red kidney beans contain the highest concentration of phytohemagglutinin and white kidney	New	PDR For Herbal Medicines (4th Edition) (Page 69) **Reference product :** Phase 2, USA.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			calorie diet for 12 weeks reduced weight compared to the control group (weight-loss phase). 73% of the 49 subjects that continued taking Phase 2 for 12 additional weeks with a non-restrictive diet maintained their weight (weight maintenance phase) . In two studies with healthy and obese rats, intake of the α-amylase blocker (either purified or raw beans) reduced body fat without reducing lean body weight . 2) White Kidney Bean Extract Reduces Blood Sugar and Insulin In two experiments, subjects WHO took 1,500 mg and 750 mg of Phase 2 with their meal absorbed 1/3 and 2/3 of the carbohydrates, respectively, compared to the control group (DB-RCT of 11 and 7 subjects) . However, in another study, only a high dose of 3,000 mg of Phase 2 reduced blood sugar levels following a meal (crossover study of 13 healthy individuals) Intake of 50 g of starch and 4-10 g of purified white kidney bean α-amylase blocker reduced blood sugar and insulin level rises after meals (DB-RCT of 8 non-insulin-	beans have approximately ⅓ of that amount Poisoning by excessive intake of phytohemagglutinin is common and can have the following symptoms : Nausea Vomiting Diarrhea Stomach pain Bowel inflammation Reduced nutrient absorption in the bowel Defective liver function In rats, phytohemagglutinin intake caused the excessive growth of small intestine bacteria, which may contribute to gut disorders Phytohemagglutinin is broken down when the beans are soaked and properly cooked. Therefore, avoid consuming raw beans and improperly processed white kidney extract to prevent poisoning.				

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			dependent diabetics) [R]. In three rat studies, intake of a white kidney bean α-amylase blocker (purified or raw beans) significantly reduced blood sugar levels . 3) White Kidney Bean Extract Curbs Appetite Beanblock (100 mg), taken with a meal after a 12 hour fast, reduced appetite, production of the hunger hormone ghrelin, and glucose and insulin rises in the blood (DB-RCT of 12 healthy individuals) . A combination of bean and artichoke extracts reduced appetite and blood sugar levels after meals (2-month DB-RCT of 39 overweight subjects) [R]. Beanblock supplementation reduced appetite, body weight, waist size, and oxidative damage (50 mg 2x/day for 12 weeks, DB-RCT of 60 overweight individuals) [R]. In two rat studies and one mice study, intake of Beanblock reduced food consumption [R, R, R]. 4) White Kidney Bean Extract Reduces Fatty Molecule Levels in the Blood Phase 2 (two 150 mg capsules, a 3x/day for 9 months) increased the elimination of fats (triglycerides) in					

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			feces and reduced the levels of cholesterol and the protein that carries it to the blood vessels (LDL) in the blood (DB-RCT of 62 overweight and obese individuals) . Phase 2 (1,500 mg, 2x/ day for 8 weeks) had no effect on weight loss but reduced blood triglyceride levels (DB-RCT of 27 obese subjects). 5) White Kidney Bean Extract Helps Prevent Cavities and Bleeding Gums The α-amylases produced by the salivary glands have the following effects in the mouth [R, R]: They begin the digestion of complex carbohydrates, thus increasing the availability of simple sugars. The α-amylases bind to mouth bacteria (such as Viridans streptococci) and help them break down carbohydrates into simple sugars that they use as a food source. Bacteria produce acids, which dissolve tooth enamel and form cavities. They bind to enamel and promote the formation of teeth plaque by bacteria. Plaque buildup can lead to bleeding gums and cavities. By blocking α-amylases, white kidney bean extract may help					

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			prevent cavities and bleeding gums. 6) White Kidney Bean Extract May Help Prevent Colon Cancer Non-digested starch may act similarly to fiber in the large intestine and thus help prevent colon cancer . Rats given a cancer-causing compound had lower incidences of colon cancer and multiplying tumor cells when fed a diet containing beans compared to rats on a regular diet [R]. A purified white kidney bean lectin prevented cancer cell growth and increased cell death (skin and liver cancer cell lines) . 7) White Kidney Bean Extract May Reduce the Risk of Blood Clots Bean extract reduced the clumping of platelet cells. White kidney bean extract may thus reduce the formation of blood clots, although studies in humans are needed to verify these findings					

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
11.	Incepta Herbal & Nutricare Ltd.	White Kidney bean Extract 500 mg capsule **Generic :** White Kidney bean extract 500 mg	1) White Kidney Bean Extract Helps Weight Loss Because the first commercial bean extracts had low α-amylase blocker activity, a concentrate (6 to 8x more carbohydrate-blocker content) was developed. It broke down the α-amylases from the mouth and small intestine and reduced intestinal α-amylase activity and starch digestion (Infusion of 2-5 mg/ml at 5 ml/min and 5-10 g, RCT with 7 and 4 subjects) . Daily intake of Phase 2 extract before a carbohydrate-rich meal reduced body weight, body mass index, fat mass, fatty tissue thickness, and waist, hip, and thigh sizes while maintaining lean body mass (445 mg for 30 days, DB-RCT of 60 overweight subjects) . Phase 2 with a low-calorie diet (1,800 cals) and exercise had no effect on weight loss. However, the Phase 2 individuals WHO had the most carbohydrates lost more weight and waist circumference (1 g 2x/day for 4 weeks, DB-RCT of 25 healthy overweight individuals) [R]. In a study of 123 overweight subjects, 2 x 500 mg Phase 2 tablets 3x/day before meals on a low-	**Contraindication** None **Side-effects:** An increase in stomach gas or bloating may occur. If this effect persists or worsens, notify your ectins are carbohydrate-binding proteins that recognize specific cells and proteins. Common bean varieties contain different types of lectins, which are responsible for many toxic symptoms [R, R]. The carbohydrate-binding capacity of lectins is a likely cause of their toxicity. Lectins may bind to the gut lining and interfere with the function of digestive enzymes [R, R]. Because approximately 15% of a bean's proteins are lectins, they can cause several harmful effects in lectin-sensitive individuals, such as: Leaky gut Increased sensitivity to some food components Autoimmune diseases Reduced nutrient digestion and absorption Among bean lectins, the most relevant one to human health is phytohemagglutinin. Red kidney beans contain the highest concentration of phytohemagglutinin and white kidney	New	PDR For Herbal Medicines (4th Edition) (Page 69) **Reference product :** phase 2, USA.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			calorie diet for 12 weeks reduced weight compared to the control group (weight-loss phase). 73% of the 49 subjects that continued taking Phase 2 for 12 additional weeks with a non-restrictive diet maintained their weight (weight maintenance phase) . In two studies with healthy and obese rats, intake of the α-amylase blocker (either purified or raw beans) reduced body fat without reducing lean body weight. 2) White Kidney Bean Extract Reduces Blood Sugar and Insulin In two experiments, subjects WHO took 1,500 mg and 750 mg of Phase 2 with their meal absorbed 1/3 and 2/3 of the carbohydrates, respectively, compared to the control group (DB-RCT of 11 and 7 subjects) . However, in another study, only a high dose of 3,000 mg of Phase 2 reduced blood sugar levels following a meal (crossover study of 13 healthy individuals) Intake of 50 g of starch and 4-10 g of purified white kidney bean α-amylase blocker reduced blood sugar and insulin level rises after meals (DB-RCT of 8 non-insulin-	beans have approximately ⅓ of that amount Poisoning by excessive intake of phytohemagglutinin is common and can have the following symptoms : Nausea Vomiting Diarrhea Stomach pain Bowel inflammation Reduced nutrient absorption in the bowel Defective liver function In rats, phytohemagglutinin intake caused the excessive growth of small intestine bacteria, which may contribute to gut disorders Phytohemagglutinin is broken down when the beans are soaked and properly cooked. Therefore, avoid consuming raw beans and improperly processed white kidney extract to prevent poisoning.				

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			dependent diabetics) [R]. In three rat studies, intake of a white kidney bean α-amylase blocker (purified or raw beans) significantly reduced blood sugar levels . 3) White Kidney Bean Extract Curbs Appetite Beanblock (100 mg), taken with a meal after a 12 hour fast, reduced appetite, production of the hunger hormone ghrelin, and glucose and insulin rises in the blood (DB-RCT of 12 healthy individuals) . A combination of bean and artichoke extracts reduced appetite and blood sugar levels after meals (2-month DB-RCT of 39 overweight subjects) [R]. Beanblock supplementation reduced appetite, body weight, waist size, and oxidative damage (50 mg 2x/day for 12 weeks, DB-RCT of 60 overweight individuals) [R]. In two rat studies and one mice study, intake of Beanblock reduced food consumption [R, R, R]. 4) White Kidney Bean Extract Reduces Fatty Molecule Levels in the Blood Phase 2 (two 150 mg capsules, a 3x/day for 9 months) increased the elimination of fats (triglycerides) in					

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			feces and reduced the levels of cholesterol and the protein that carries it to the blood vessels (LDL) in the blood (DB-RCT of 62 overweight and obese individuals) . Phase 2 (1,500 mg, 2x/ day for 8 weeks) had no effect on weight loss but reduced blood triglyceride levels (DB-RCT of 27 obese subjects). 5) White Kidney Bean Extract Helps Prevent Cavities and Bleeding Gums The α-amylases produced by the salivary glands have the following effects in the mouth [R, R]: They begin the digestion of complex carbohydrates, thus in7creasing the availability of simple sugars. The α-amylases bind to mouth bacteria (such as Viridans streptococci) and help them break down carbohydrates into simple sugars that they use as a food source. Bacteria produce acids, which dissolve tooth enamel and form cavities. They bind to enamel and promote the formation of teeth plaque by bacteria. Plaque buildup can lead to bleeding gums and cavities. By blocking α-amylases, white kidney bean extract may help					

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			prevent cavities and bleeding gums. 6) White Kidney Bean Extract May Help Prevent Colon Cancer Non-digested starch may act similarly to fiber in the large intestine and thus help prevent colon cancer . Rats given a cancer-causing compound had lower incidences of colon cancer and multiplying tumor cells when fed a diet containing beans compared to rats on a regular diet [R]. A purified white kidney bean lectin prevented cancer cell growth and increased cell death (skin and liver cancer cell lines). 7) White Kidney Bean Extract May Reduce the Risk of Blood Clots Bean extract reduced the clumping of platelet cells. White kidney bean extract may thus reduce the formation of blood clots, although studies in humans are needed to verify these findings					

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
12.	Incepta Herbal & Nutricare Ltd.	Ispaghula Husk Powder (Dried) 3.5 gm & Lactulose 10 gm Per Sachet **Generic :** Ispaghula Husk Powder (Dried) 3.5 gm & Lactulose 10 gm	Used in chronic idiopathic constipation I adult patient	**Contraindication** None **Side-effects:** May cause flatulence or intestinal cramp which are usually transient.A small amount of abdominal distension occur.	Existing as Ispaghula Husk	PDR For Herbal Medicines (4th Edition) (Page 669-670) BNF 76 **Reference Product :** Bulkose, India.	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
13.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	β-sitosterol 2.5mg/gm Ointment β-sitosterol 2.5mg/gm **Generic :** Source- Soy bean (Glycime soja)	First-degree burns, Second degree burns, Donor site to decrease pain, control infection and expedite healing, Surgical wounds including obstetrical wounds	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side-effect:** The ointment is of pure herbal origin. No side effects to the product have been reported so far, except for rare allergic reactions to sesame oil.	New	PDR For Herbal Medicines (fourth edition) page-765 Herbal drugs & phytopharmacuticals (third edition) page-191-192,623-624, 664 **Reference product :** Mebo, UAE	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
14.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Probiotic Composite Blend 500mg Capsule **Generic :** (Lactobacillus acidophilus 2.25 billion + Lactobacillus bulgaricus 75 million + Lactobacillus casei 2.25 billion + Lactobacillus lactis Ph. Grade 2.10 billion + Bifidobacterium bifidum 450 million + Bifidobacterium infantis	Indicated for the management of gastrointestinal problems e.g. IBS, constipation, flatulence, indigestion, etc.	**Contra-indication:** Probiotics are contraindicated in those WHO are hypersensitive to any component of a probiotic-containing product. **Side-effect**: The most common adverse reactions with use of probiotics are gastrointestinal and include flatulence and constipation. Probiotics are generally well tolerated.	New	PDR for Herbal Medicines, Page# 627,765. **Reference Product :** progut, Singapore.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		1.50 billion + Bifidobacterium longum 75 million + Streptococcus thermophilus 300 million + Fructo-Oligosaccharides 50mg + Soy Fiber & Papaya extract 140mg) Probiotic Composite Blend 500mg (Lactobacillus acidophilus 2.25 billion + Lactobacillus bulgaricus 75 million + Lactobacillus casei 2.25 billion + Lactobacillus lactis Ph. Grade 2.10 billion + Bifidobacterium bifidum 450 million + Bifidobacterium infantis 1.50 billion + Bifidobacterium longum 75 million + Streptococcus thermophilus 300 million + Fructo-Oligosaccharides 50mg + Soy Fiber & Papaya extract 140mg)						

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
15.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Biotin 1 mg soft gel capsule **Generic :** Biotin 1 mg	For healthy hair, skin and nails Aids in the body's energy and metabolic processes Eczema & dermatitis	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side-effect:** Well tolerated in recommended dose. No toxicity has been reported in individuals supplements with as much as 200 mg orally or 20 mg intravenously per day.	Existing as Biotin Tablet Biotin 1000mcg	USP-38 NF-33, Volume-2 Page-2440. Japanese Pharmacopeia Page no: 510. USP-Dietary supplements Compendium Page- 914-915. **Reference Product :** Biotin, USA.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
16.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Biotin 2.5 mg soft gel capsule **Generic :** Biotin 2.5 mg	For healthy hair, skin and nails Aids in the body's energy and metabolic processes Eczema & dermatitis	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side-effect:** Well tolerated in recommended dose. No toxicity has been reported in individuals supplements with as much as 200 mg orally or 20 mg intravenously per day.	Existing as Biotin Tablet Biotin 2500mcg	USP-38 NF-33, Volume-2 Page-2440. Japanese Pharmacopeia Page no: 510. USP-Dietary supplements Compendium Page- 914-915. **Reference Product :** Biotin, USA.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
17.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Tocotrienol & Tocopherol Complex (Tocotrienol 35.71% & Tocopherol 9.64%) 140 mg (eqv. to Tocotrienol 50 mg & Tocopherol 13.5 mg) Soft gel Capsule **Generic :** Tocotrienol & Tocopherol Complex (Tocotrienol 35.71% & Tocopherol 9.64%) 140 mg (eqv. to Tocotrienol 50 mg & Tocopherol 13.5 mg) Source- pumpkin seed	Powerful Antioxidant Activity Supports Healthy Hair & Skin Helps Maintain Healthy Blood Lipids and Blood Vessel Tone Supports Brain Health and Cognitive Function	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effects:** No side effects are known.	New	The Complete German Commission E Monographs (Page: 52,193,391). PDR For Herbal Medicines 4th edition (Page: 234,235, 675-677). Herbal drugs and pharmaceuticals, 3rd edition (Page: 163-165, 620-622). **Reference product :** EVNol Supra Bio, USA.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
18.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	D-Alfa Tocopherol 147.06mg (eqv. to 200IU) Soft Gel Capsule **Generic :** D-Alfa Tocopherol 147.06mg (eqv. to 200IU)	Powerful antioxidant activity Supports healthy hair & skin	**Contra-indication:** Not known contraindications found. **Side effects:** Well tolerated in recommended dose.	New	The Complete German Commission E Monographs (Page: 193, 211) PDR For Herbal Medicines 4th edition (Page:228, 255, 618, 800) **Reference Product :** Vitamin E 200IU	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
19.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	D-Alfa Tocopherol 294.12mg (eqv. to 400IU) Soft Gel Capsule **Generic :** D-Alfa Tocopherol 294.12mg (eqv. to 400IU)	Powerful antioxidant activity Supports healthy hair & skin	**Contra-indication:** No known contraindications found. **Side effects:** Well tolerated in recommended dose.	New	The Complete German Commission E Monographs (Page: 193, 211) PDR For Herbal Medicines 4th edition (Page:228, 255, 618, 800) **Reference Product :** Vitamin E 200IU	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
20.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Astaxanthin 5% 40mg (eqv. to Astaxanthin 2mg) Soft Gel Capsule **Generic :** Astaxanthin 5% 40mg (eqv. to Astaxanthin 2mg)	Astaxanthin is indicated as a strong antioxidant in following indications: Cardiovascular health Brain and central nervous system health Silent inflammation (C-reactive protein) Eye health Arthritis Strength and endurance & immune system Internal beauty and skin improvement Internal sunscreen	**Contra-indication:** Astaxanthin is contraindicated in those hypersensitive to any component of an Astaxanthin containing supplement. **Side effects:** No reports have been found regarding Astaxanthin.	New	USP Dietary Supplements Compendium 2019 (Page: 4735-4737) Martindale, The Complete Drug Reference, Volume: A, 39th Edition (Page:2206) **Reference Product :** Astaxanthin 2mg Soft gel, USA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
21.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Astaxanthin 5% 80mg (eqv. to Astaxanthin 4mg) Soft Gel Capsule **Generic :** Astaxanthin 5% 80mg (eqv. to Astaxanthin 4mg)	Astaxanthin is indicated as a strong antioxidant in following indications: Cardiovascular health Brain and central nervous system health Silent inflammation (C-reactive protein) Eye health Arthritis Strength and endurance & immune system Internal beauty and skin improvement Internal sunscreen	**Contra-indication:** Astaxanthin is contraindicated in those hypersensitive to any component of an Astaxanthin containing supplement. **Side effects:** No reports have been found regarding Astaxanthin.	New	USP Dietary Supplements Compendium 2019 (Page: 4735-4737) Martindale, The Complete Drug Reference, Volume: A, 39th Edition (Page:2206) **Reference Product :** Astaxanthin 4mg Soft gel, USA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
22.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Omega 3 Oil 1000mg Soft Gel Capsule **Generic :** Omega 3 Oil 1000mg	Hypertriglyceridemia Post Myocardial infarction	**Contra-indication:** Omega-3- is contraindicated in patients WHO exhibit hypersensitivity to it or any component of this medication. **Side effects:** Adverse events are rarely reported such as enlarged abdomen, body odor, chest pain, chills, fever, generalized edema, hypertension, anorexia, constipation, dry mouth, gastritis dizziness etc.	New	ABC clinical guide to herbs (Page no: 146&150). **Reference product:** Ultra omega-3, Norway	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
23.	Square Pharmaceuticals Ltd., (Herbal Division), BSCIC, Pabna	Vitamin K1 60 mcg + Vitamin K2- MK7 (from Olive Oil) 30 mcg + Vitamin D3 400 IU Soft Gelatin Capsule **Generic :** Vitamin K1 60 mcg + Vitamin K2- MK7 (from Olive Oil) 30 mcg + Vitamin D3 400 IU	Contribute to normal absorption and utilization of calcium and phosphorous in the body Contribute to the maintenance of normal bones Support for cardiovascular health Contribute to normal blood clotting	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the ingredients. **Side effects:** Well tolerated in recommended dose.	New	Mosby's DRUG consult Pacge 2251-2253, USP, Dietary supplement compendium- Page 7943-44 **Reference product :** Kcomplex + Vit D3, UK	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
24.	**UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur.**	Capsule BIOTIN 1000 mcg capsule **Generic :** Biotin1000 mcg	Hair loss, brittle nails, skin rash in infants (seborrheic dermatitis), diabetes, Diabetic nerve pain and mild depression.	**Contraindication:** Biotin is contraindicated in those hypersensitive to any component of a biotin – containing product **Side effect:** There is no report of adverse reaction associated with biotin in the literature.	Existing Biotin Tablet Biotin 1000mcg	PDR for Nutritional supplements 2nd Edition Page: 84-89 Japanese pharmacopoeia (Page 510) **Product Name :** Total Biotin 1000 mcg Tablet	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
25.	**UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur.**	Capsule BIOTIN 2500 mcg **Generic :** Biotin 2500 mcg	Hair loss, brittle nails, skin rash in infants (seborrheic dermatitis), diabetes, Diabetic nerve pain and mild depression.	**Contraindication:** Biotin is contraindicated in those hypersensitive to any component of a biotin – containing product **Side effect:** There is no report of adverse reaction associated with biotin in the literature.	Existing Biotin Tablet Biotin 2500mcg	PDR for Nutritional supplements 2ndEdition: Page: 84= 89 Japanese pharmacopoeia (Page 510) **Product Name :** Total Biotin 2500 mcg Tablet	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
26.	**UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur.**	Capsule BIOTIN 5000 mcg **Generic :** 5000 mcg Biotin	Hair loss, brittle nails, skin rash in infants (seborrheic dermatitis), diabetes, Diabetic nerve pain and mild depression.	**Contraindication:** Biotin is contraindicated in those hypersensitive to any component of a biotin – containing product **Side effect:** There is no report of adverse reaction associated with biotin in the literature.	Existing Biotin Tablet Biotin 5000mcg	PDR for Nutritional supplements 2nd Edition: Page: 84-89 Japanese pharmacopoeia (Page 510) **Product Name :** Total Biotin 5000 mcg Tablet	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
27.	**UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur.**	Cranberries Syrup **Generic :** Each 5 ml syrup contains 300.0 mg Cranberry extract(*Vaccinium microcarpum*L)	#Treatment & Prevention of Urinary tract infection# Remove Kidney stone,	**Contra- indication**: Potential Contraindication of cranberry may be present with renal insufficiency and persons with the potential for developing uric acid or calcium oxalate.**Side Effect:** Well tolerated in recommended dose. Occasional gastrointestinal discomfort or upset or diarrhea may be occurred at high dose.	New	PDR For Herbal Medicines s 4thEdition: Page: 238-241 The ABC clinical Guide to Herbs by Mark Blumenthal. Page :73=83 **Reference Product :** MARNYS® – MARTÍNEZ NIETO,S.A,Spain. CISTOMAR liquid	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
28.	**UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur**	Justicia adhatoda Syrup (Basok Leaf extract) Each 5 ml syrup **Generic :** containsStandardized Basok Leaf extract (*Adhatoda vasica)* adhatoda powder : 210 mg [Equivalent to 2.5 ml Basok leaf liquid extract (1:1){soak into 4% alcohol}]	For acute and chronic bronchial infection, catarrhs of upper respiratory tract and as an expectorant and to alleviation cough	**Contra- indication**: There is no evidence available on contraindication but it may happen in-patient WHO is hypersensitive to any of its ingredients **Side Effect:** Well tolerated in recommended dose. Occasional gastrointestinal discomfort or upset or diarrhea may be occurred at high dose.	Existing as Vasaka (Justicia adhatoda) 500mg/Capsule	a) PDR For Herbal Medicines- 4thedition Page:552-553 **Reference Product :** Honeybas,	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
29.	**UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur (Under licensing from ADM Protexin Limited, UK)**	Probiotic Preparation Capsule (Protexin Balance) **Generic :** Ready to fill Probiotic & Prebiotic mixture- 180.00 mg (Total Viable count: 5.5 x 10^8 CFU/g; 1.00 x 10^8 CFU/capsule – 5.58 mg **Content of Probiotic Concentrate:-**	# Prevention and treatment of diarrhea. # Alleviation of Lactose Intolerance. # Prevention and Treatment of Vaginal infection # Enhancement of the immune system #Treatment of allergic condition	**Contra-indication:** Contains soya and milk, used in the fermentation process. Content of milk is at a level that would not affect lactose intolerance sufferer. **Side-effect :** Not Known	New	a) PDR For Herbal Medicines s- 4th edition. Page:996-998 b) PDR for Nutritional supplements 2nd Edition. Page :512-515:517-522 **Reference Product :** Protexin Balance Capsule. ADM Protexin, UK	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		Lactobacillus casei *Lactobacillus rhamnosus* *Streptococcus thermophilus* *Lactobacillus acidophilus* *Bifidobacteriumbreve* *Bifidobacterium longum* *Lactobacillus bulgaricus* Content of Prebiotic Fructooligosaccharide (FOS)- 173.52 mg)				***NCIMB** (National Collections of Industrial, Food and Marine Bacteria) is an internationally recognized bacterial culture collection *Registered trademark of ADM Protexin Ltd. UK		
30.	**UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur (Under licensing from ADM Protexin Limited, UK)**	**Probiotic Preparation Capsule (Protexin Balance +)**Each Capsule Contains Ready to fill Probiotic & Prebiotic mixture with Vitamin supplement- 180.00 mg (Total Viable count: 5.5 x 10^8 CFU/g; 1.00 x 10^8 CFU/capsule- 9.054 mg **Generic :** **<u>Content of Probiotic Concentrate:-</u>** *Lactobacillus casei* *Lactobacillus rhamnosus* *Streptococcus thermophilus* *Lactobacillus acidophilus* *Bifidobacteriumbreve* *Bifidobacterium longum* *Lactobacillus bulgaricus*	# Prevention and treatment of diarrhea. # Alleviation of Lactose Intolerance. # Prevention and Treatment of Vaginal infection # Enhancement of the immune system #Treatment of allergic condition	**Contra-indication:** Contains soya and milk, used in the fermentation process. Content of milk is at a level that would not affect lactose intolerance sufferer. **Side-effect :** Not Known	New	a) PDR For Herbal Medicines s- 4th edition. Page:996-998 b) PDR for Nutritional supplements 2nd Edition. Page :512-515:517-522 **Reference Product :** Protexin Balance + Capsule. ADM Protexin, UK ***NCIMB** (National Collections of Industrial, Food and Marine Bacteria) is an internationally recognized bacterial culture collection *Registered trademark of ADM Protexin Ltd. UK	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		Content of Prebiotic **Fructooligosaccharide (FOS**) – 110.124 mg **Contains of Vitamin Supplement-** Vitamin C (Ascorbic acid)- 41.742 mg Vitamin E (DL-alpha-tocopheryl) – 13.483 mg Vitamin A(Retinol acetate)- 4.65 mg						
31.	**UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur**	Probiotic Preparation Capsule (Protexin Bio-Kult) **Generic :** Each Capsule Contains Ready to fill Probiotic Preparation- 160.00 mg (Total Viable count: >1 x 10^{10} CFU/g; 2 x 10^{9} CFU/capsule- 70.40 mg **Content of Probiotic Concentrate:-** *Lactobacillus casei* *Lactobacillus plantarum* *Lactobacillus rhamnosus* *Bacillus subtilis* *Bifidobacteriumbifidum* *Bifidobacteriumbreve* *Bifidobacterium longum* *Lactobacillus acidophilus*	# Prevention and treatment of diarrhea. # Alleviation of Lactose Intolerance. # Prevention and Treatment of Vaginal infection # Enhancement of the immune system #Treatment of allergic condition	**Contra-indication:** Contains soya and milk, used in the fermentation process. Content of milk is at a level that would not affect lactose intolerance sufferer. **Side-effect :** Not Known	New	a)PDR For Herbal Medicines s- 4th edition. Page:996-998 b) PDR for Nutritional supplements 2nd Edition. Page :512-515:517-522 **Reference Product :** Protexin Bio-Kult Capsule. ADM Protexin, UK ***NCIMB** (National Collections of Industrial, Food and Marine Bacteria) is an internationally recognized bacterial culture collection *Registered trademark of ADM Protexin Ltd. UK **Reference Product :** Protexin Balance + Capsule. ADM Protexin,	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		*Lactococcuslactis*ssp.*lactis* *Streptococcus thermophilus* *Bifidobacteriuminfantis* *Lactobacillus delbrueckiissp bulgaricus* *Lactobacillus helveticus* *Lactobacillus salivarius*				UK		
32.	**UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur (Under licensing from ADM Protexin Limited, UK)**	**Probiotic Preparation Sachet (Protexin Restore)** Each sachet Contains Ready to fill Probiotic & Prebiotic – 1 g (Total Viable count: 1 x 10^9 CFU/g; 1.00 x 10^9 CFU/Sachet – 42.00 mg **Generic :** **Content of Probiotic Concentrate:-** *Lactobacillus casei* *Lactobacillus rhamnosus* *Streptococcus thermophilus* *Lactobacillus acidophilus* *Bifidobacteriumbreve* *Bifidobacterium longum* *Lactobacillus bulgaricus* **Content of Prebiotic Fructooligosaccharide (FOS)** – 958.00 mg	# Prevention and treatment of diarrhea. # Alleviation of Lactose Intolerance. # Prevention and Treatment of Vaginal infection # Enhancement of the immune system #Treatment of allergic condition	**Contra-indication:** Contains soya and milk, used in the fermentation process. Content of milk is at a level that would not affect lactose intolerance sufferer. **Side-effect :** Not Known	New	a) PDR For Herbal Medicines s- 4th edition. Page:996-998 b) PDR for Nutritional supplements 2nd Edition. Page :512-515:517-522 **Reference Product :** Protexin Restore , ADM Protexin, UK ***NCIMB** (National Collections of Industrial, Food and Marine Bacteria) is an internationally recognized bacterial culture collection *Registered trademark of ADM Protexin Ltd. UK	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
33.	**UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur (Under licensing from ACM Laboratoire Dermatologique , France)**	**Amino acids, vitamins, Mineral and plant based silicon Premix Capsule (Novophane Capsule)** **Generic :** Each capsule contains premix- 555.00 mg Contain of premix: L-Cystine 100 mg L-Methionine 100 mg L- Arginine 5.00 mg Vitamin C (L-ascorbic acid) 30.00 mg Vitamin E (DL- alpha – tocopheryl acetate) 5.00 mg Vitamin B5 (D-pantothenate Calcium) 3.00 mg Vitamin B6 (Pyridoxine Hydrochloride) 0.70 mg Vitamin B2 (Riboflavin) 0.80 mg Vitamin B3 (Niacin) 8.00 mg Biotin (D- Biotin) 225.00 µg Iron Gluconate 6.25 mg Zinc Gluconate 5.00 mg Magnesium Oxide 28.50 mg Copper Gluconate 0.50 mg Horsetail Herbs extract (Equlsteum arvense L) 25.00 mg	Temporary or seasonal hair loss, hair damage, fragile, soft and brittle nail.	**Contra-indication:**This capsule is contraindicated in those hypersensitive to any component of product**.** **Side-effect :** Not Known		a) PDR For Herbal Medicines , 4th edition.Page:458-459 b) PDR for Nutritional Supplement, 2nd edition. Page: 84-89: 161-164: 324-331,333-339;351-352; 404-412, 441-449,479-489 547-553;634-644 654-669;682-703,730-737: **Reference Product :** ACM, France. .	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
34.	**UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur (Under licensing from ACM Laboratoire Dermatologique , France)**	**Melon extract plus Vitamin & Mineral Tablet (Vitix)** **Each Tablet Contains** premix- 740.00 mg **Generic :** **Content of Premix** Melon Extract (*Cucumis melo* L) 10.00 mg Vitamin C (L-ascorbic acid) 40.00 mg Vitamin E (DL- alpha – tocopheryl acetate) 10.00 mg Vitamin B9(Folic acid) 100.00 µg Vitamin B12 (Cynocobalamine) 1.00 µg Selenium 40.00 µg Copper Gluconate 1000.00 µg Zinc Gluconate 5.00 mg	Vitix is a product range dedicated to persons suffering from Vitiligo and which offers concrete and effective solutions. A genuine relief for individuals concerned**.**	**Contra-indication:**This tablet contraindicated in those hypersensitive to any component of product**.** **Side-effect :** Not Known		a) PDR for Nutritional Supplement, 2nd edition. Page : 161-164;225-237; 563-570;644-654;682-703;730-73 b)) Pharmacognostical and Pharmacological Review of Cucumis melo L melo L. Including Unani Medicine Perspective by International Journal of Pharmacognosy and Chinese Medicine c) ACM LaboratoireDermatologique web page :https://www.labo-acm.com/en/ **Reference Product :** Tablet Vitix,ACM Laboratoire Dermatologique France	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
35.	**UniMed UniHealth Pharmaceuticals (Herbal Division) B.K.Bari, Gazipur**	**Turmeric (*Curcuma longa* Linn.) Plus Piperine Capsule** **Generic :** Dried Turmeric Powder (Curcuma longa L) 500 mg Piperine (*Piper longum*) 5 mg	# Dyspeptic complaints # Loss of appetite # Arthritis # Pain	**Contra-indication:**People with obstructed biliary duct should not use the drug; those with gallstones should take it only under the supervision of a physician. **Side-effect:** Health risks or side effects following the proper administration of designated therapeutic dosages are not recorded. Stomach complaints can occurs following extended use or in the case of overdose **Side-effect :** Not Known		PDR For Herbal Medicines s, 4th Edition Page:864-867 For piperine b) PDR for Nutritional Supplements, 2nd edition. Page:167-172,503-505 **Reference Product :** Turmeric extract with piperine	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
36.	Renata Limited (Herbal Division) Kashor, Hobirbari, Bhaluka, Mymensingh.	L-5 Hydroxytryptophan (*Griffonia simplicifolia*) 100mg + Powdered Valerian Extract (Valeriana officinalis) 100mg Capsule	**ACTIONS:** 5-HTP works in the brain and central nervous system by increasing the production of the chemical serotonin. Serotonin can affect sleep, appetite, temperature, sexual behavior, and pain sensation. Since 5-HTP increases the synthesis of serotonin, it is used for several diseases where serotonin is believed to play an important role. **INDICATIONS:** Depression Fibromyalgia Migraine headache Obesity	**Contra-indication :** Contraindicated during pregnancy or lactation. **Side effect :** Heartburn, stomach pain, nausea, vomiting, diarrhea, drowsiness, sexual problems, and muscle problems.	New	PDR For Herbal Medicines + ABC Clinical Guide to Herbs (P 351), (P 3-6) **Reference Product :** 5-HTP **Company Name :** Holland & Barrett, UK	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
37.	Renata Limited (Herbal Division) Kashor, Hobirbari, Bhaluka, Mymensingh.	Acai (*Euterpe oleracea*) Fruit Extract 500mg Tablet	**ACTIONS:** Has potent in vitro antioxidant activity against superoxide and peroxyl radical. Inhibits cyclooxygenase (COX) 1 & 2; Mild antioxidant activity against peroxynitrite and hydroxyl radical. **INDICATIONS&USES:** Weight loss Obesity Hypercholesterolemia	**Contra-indication :** Insufficient data. **Side effect :** Insufficient data.	New	Dietary supplement; 4th Edition; Page: 01. **Reference Product :** Acai **Company Name :** Holland & Barrett, UK	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
38.	Renata Limited (Herbal Division) Kashor, Hobirbari, Bhaluka, Mymensingh.	Garlic Powder (*Allium sativum*) 385mg Capsule	**ACTIONS:** Increasing the availability and activities of nitric oxide, inhibiting ACE thereby reducing a number of pathways that are known to decrease plasma volume and vasoconstriction, and lastly, increasing the production of H2S that results in hyperpolarization of vascular smooth muscle cells. Thus garlic helps to lower the blood pressure and maintain a good cardiovascular health. **INDICATIONS:** Hypertension peripheral arterial occlusive disease Hyperlipidemia	**Contra-indication :** None known. **Side effect :** Bad odor from breath and skin.	1. Garlic Oil USP/BP 10mg, 2. Garlic Cap 300mg 3. Garlic Oil 10mg Cap DCC-243	PDR For Herbal Medicines + ABC Clinical Guide to Herbs (P 351), (P 3-6) USP- DSC; 4th Edition; **Reference Product :** Odorless Garlic 500 **Company Name :** GNC Herbal Plus, USA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
39.	Renata Limited (Herbal Division) Kashor, Hobirbari, Bhaluka, Mymensingh.	Garlic Powder (*Allium sativum*) 500mg Capsule	**ACTIONS:** Increasing the availability and activities of nitric oxide, inhibiting ACE thereby reducing a number of pathways that are known to decrease plasma volume and vasoconstriction, and lastly, increasing the production of H2S that results in hyperpolarization of vascular smooth muscle cells. Thus garlic helps to lower the blood pressure and maintain a good cardiovascular health. **INDICATIONS:** Hypertension peripheral arterial occlusive disease Hyperlipidemia	**Contra-indication :** None known. **Side effect :** Bad odor from breath and skin.	1. Garlic Oil USP/BP 10mg, 2. Garlic Cap 300mg 3. Garlic Oil 10mg Cap DCC-243	The ABC Clinical Guide to Herbs. Page: 153-170 **Reference Product :** **Odorless Garlic 500** **Company Name :** GNC Herbal Plus, USA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
40.	Renata Limited (Herbal Division) Kashor, Hobirbari, Bhaluka, Mymensingh.	Hydrolysed Collagen 500mg Tablet	**ACTIONS:** Stimulates collagen synthesis in the chondrocytes. Presence of collagen fractions in cultures of osteoclasts inhibits bone resorption while concomitantly stimulating collagen synthesis. Can increase both firmness and flexibility in connective tissue and increase cartilage mass. **INDICATIONS&USES:** Osteoarthritis Skin health Joint pain	**Contra-indication :** None known. **Side effect :** Bad taste in the mouth, heartburn and fullness.		Dietary Supplement; 4th Edition (P110) **Reference Product :** Marine Collagen **Company Name :** Holland & Barrett, UK .	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
41.	Renata Limited (Herbal Division) Kashor, Hobirbari, Bhaluka, Mymensingh.	Hydrolysed Collagen 500mg/gm Powder	**ACTIONS:** Stimulates collagen synthesis in the chondrocytes. Presence of collagen fractions in cultures of osteoclasts inhibits bone resorption while concomitantly stimulating collagen synthesis. Can increase both firmness and flexibility in connective tissue and increase cartilage mass. **INDICATIONS&USES:** Osteoarthritis Skin health Joint pain	**Contra-indication :** None known. **Side effect :** Bad taste in the mouth, heartburn and fullness.		Dietary Supplement;4th Edition (P110) **Reference Product :** Marine Collagen 1000mg **Company Name :** Holland & Barrett, UK	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
42.	Renata Limited (Herbal Division) Kashor, Hobirbari, Bhaluka, Mymensingh.	Hydrolysed Collagen 1000mg/gm Powder	**ACTIONS:** Stimulates collagen synthesis in the chondrocytes. Presence of collagen fractions in cultures of osteoclasts inhibits bone resorption while concomitantly stimulating collagen synthesis. Can increase both firmness and flexibility in connective tissue and increase cartilage mass. **INDICATIONS&USES:** Osteoarthritis Skin health Joint pain	**Contra-indication :** None known. **Side effect :** Bad taste in the mouth, heartburn and fullness.		Dietary Supplement;4th Edition (P110) **Reference Product :** Marine Collagen 1000mg **Company Name :** Holland & Barrett, UK	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
43.	Renata Limited (Herbal Division) Kashor, Hobirbari, Bhaluka, Mymensingh.	Hydrolysed Collagen 1000mg/gm Tablet	**ACTIONS:** Stimulates collagen synthesis in the chondrocytes. Presence of collagen fractions in cultures of osteoclasts inhibits bone resorption while concomitantly stimulating collagen synthesis. Can increase both firmness and flexibility in connective tissue and increase cartilage mass. **INDICATIONS&USES:** Osteoarthritis Skin health Joint pain	**Contra-indication :** None known. **Side effect :** Bad taste in the mouth, heartburn and fullness.		Dietary Supplement; 4th Edition (P110) **Reference Product :** Marine Collagen 1000mg Company Name : Holland & Barrett, UK	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
44.	Renata Limited (Herbal Division) Kashor, Hobirbari, Bhaluka, Mymensingh.	L-Arginine Hydrochloride 725.58mg equivalent to L-Arginine 600mg/gm Powder	**ACTIONS:** L-arginine is converted in the body into a chemical called nitric oxide. Nitric oxide causes blood vessels to open wider for improved blood flow. Thus it can reduce blood pressure in pregnant women with pre-eclampsia. L-arginine also seems to keep pregnant women from developing pre-eclampsia. **INDICATIONS:** Pre-eclampsia	**Contra-indication :** Contraindicated in people with guanidinoacetatemethyltransferase deficiency. **Side effect :** It may cause abdominal pain, bloating, diarrhea, gout, allergies, worsening of asthma, and low blood pressure.		Dietary Supplement;4th Edition. (P 24) **Product Name** : GNC L-Arginine **Company Name :** GNC, USA	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
45.	Radiant Nutraceuticals Limited (Herbal Division) B-34,BSCIC I/A, Tongi, Gazipur-1710, Dhaka	Chaste berry 20mg Capsule *(Vitex agnus-castus)*	Irregular menstruation Premenstrual syndrome such as lower abdominal pain, sleep disturbance, cyclic mastalgia, acne, headache and mood swing Hyperprolactinemia Mastodynia	Side Effects: Generally well tolerated in recommended dose. Side effects are rare, occasionally may occur nausea, gastrointestinal discomfort, urticaria and headache. Contraindications: Contraindicated for patient with known hypersensitivity to Chaste berry.	New	PDR For Herbal Medicines (4th Edition; Page-176) & The American Botanical Council Clinical Guide to Herbs (Page-61) USP Dietary Supplement Compendium (USP30-NF25; Page-904) **Reference Product :** Zeller premen	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
46.	Radiant Nutraceuticals Limited (Herbal Division) B-34,BSCIC I/A, Tongi, Gazipur-1710, Dhaka	Pelargonium 20mg/ Tablet *(Pelargonium sidoides)*	Common cold Upper respiratory tract infection symptoms such as cough, runny nose, sore throat Acute and chronic bronchitis Acute sinusitis Acute tonsillitis Tonsillopharyngitis Rhinopharingitis Rhinosinusitis	Side Effects: Generally well tolerated in recommended dose. Occasionally gastrointestinal discomfort and allergic skin reaction may occur. Contraindication: Contraindicated in patient with known hypersensitivity to Pelargonium. Contraindicated for patients those WHO are suffering from severe hepatic disease.	New	E/S/C/O/P Monographs, The Scientific Foundation for Herbal Medicinal Products & The American Botanical Council Clinical Guide to Herbs (HerbalGram, Page-35)	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
47.	Radiant Nutraceuticals Limited (Herbal Division) B-34,BSCIC I/A, Tongi, Gazipur-1710, Dhaka	Pelargonium 20mg Capsule *Pelargonium sidoides*	Common cold Upper respiratory tract infection symptoms such as cough, runny nose, sore throat Acute and chronic bronchitis Acute sinusitis Acute tonsillitis Tonsillopharyngitis Rhinopharingitis Rhinosinusitis	Side Effects: Generally well tolerated in recommended dose. Occasionally gastrointestinal discomfort and allergic skin reaction may occur. Contraindication:Contraindicated in patient with known hypersensitivity to Pelargonium. Contraindicated for patients those WHO are suffering from severe hepatic disease.	New	E/S/C/O/P Monographs, The Scientific Foundation for Herbal Medicinal Products & The American Botanical Council Clinical Guide to Herbs (HerbalGram, Page-35)	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
48.	Radiant Nutraceuticals Limited (Herbal Division) B-34,BSCIC I/A, Tongi, Gazipur-1710, Dhaka	Tart cherry 500mg/Capsule *Prunus cerasus*	Gout Chronic hyperuricemia Arthritis Exercise induced pain, muscle damage Joint Inflammation and pain Muscle soreness	Side Effects: Generally well tolerated in recommended dose. Contraindications: Contraindicated to the patient with known hypersensitivity to Tart cherry.	New	The American Botanical Council Clinical Guide to Herbs (HerbalEGram; Vol-15) USP Dietary Supplement Compendium (USP30-NF25; Page-1099) **Reference Product :** Tart cherry 500mg, USA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
49.	Radiant Nutraceuticals Limited (Herbal Division) B-34,BSCIC I/A, Tongi, Gazipur-1710, Dhaka	Lutein 10mg + Zeaxanthin 2mg Chewable Tablet **Generic :** *Lutein and Zeaxanthin from Marigold (Calendula officinalis)* Flower	Blurry vision Vision impairment Eye fatigue Eye color change Cognitive Performance Oxidative stress	Side Effects: No adverse side effects have been reported. Contraindications: No toxicities have been reported in the scientific literature for Lutein and Zeaxanthin at doses up to 40mg for 2 months. High doses of carotenoids supplement have been associated with carotenodermia.	Existing	PDR For Herbal Medicines (Page-497) & The Complete German Commission E Monographs Therapeutic Guide To Herbal Medicines USP Dietary Supplement Compendium (USP30-NF25; Page-958) Reference Product : vitalux advanced chewable	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
50.	Radiant Nutraceuticals Limited (Herbal Division) B-34,BSCIC I/A, Tongi, Gazipur-1710, Dhaka	Menaquinone-7 (as Vitamin K2) 75mcg + Calcium Carbonate 264mg (from Red Algae Extract) + Vitamin D3 5mcg (200IU) (from Lichen Extract) Chewable Tablet **Generic :** Red Algae (*Algas calcareas)* + Menaquinone-7 *(as Vitamin K2)* fermented by *Bacillus subtilis + Lichen* (as Vitamin D3)	Osteoporosis Prevention of Vitamin K2, Calcium and Vitamin D deficiency Bone health Heart health Dental health	Side Effects: Generally well tolerated in recommended dose. Occasionally constipation or stomach upset may occur. Contraindications: Contraindicated in patient with known hypersensitivity to Menaquinone-7 (Vitamin K2) or Red Algae Extract (Calcium) or Lichen Extract (Vitamin D3).	New	PDR For Herbal Medicines USP Dietary Supplement Monographs (USP30-NF25; Page-7096) **Reference Product :** Triangle Fort, Germany	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
51.	Radiant Nutraceuticals Limited (Herbal Division) B-34,BSCIC I/A, Tongi, Gazipur-1710, Dhaka	Menaquinone-7 (as Vitamin K2) 75mcg + Calcium Carbonate 264mg (from Red Algae Extract) + Vitamin D3 5mcg (200IU) (from Lichen Extract) granules for solution/ Sachet **Generic :** Red Algae (*Algas calcareas)* + Menaquinone-7 *(as Vitamin K2)* fermented by *Bacillus subtilis + Lichen* (as Vitamin D3)	Osteoporosis Prevention of Vitamin K2, Calcium and Vitamin D deficiency Bone health Heart health Dental health	Side Effects: Generally well tolerated in recommended dose. Occasionally constipation or stomach upset may occur. Contraindications: Contraindicated in patient with known hypersensitivity to Menaquinone-7 (Vitamin K2) or Red Algae Extract (Calcium) or Lichen Extract (Vitamin D3).	New	Herbal Medicines Compendium – USP Dietary Supplement Monographs (USP30-NF25; Page-7096, 1742) & Mosby's Drug Consult (Page-iii-118) **Reference Product :** Triangle Fort, Germany	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
52.	Radiant Nutraceuticals Limited (Herbal Division) B-34,BSCIC I/A, Tongi, Gazipur-1710, Dhaka	Ubidecarenone USP (Co-enzyme Q10) 200mg Capsule *Co-enzyme Q10*	Infertility Myopathy Muscular Dystrophy Ataxia Parkinson's Disease Alzheimer's Disease Genetic Neuromuscular Disease Migraine Heart Protection During Surgery Cardiomyopathy Angina Congestive Heart Failure (CHF) Hypertension	Side Effects: Ubidecarenone seems to be safe and relatively well tolerated in recommended dose. Occasionally gastrointestinal discomfort, dizziness and skin rash may occur but these tend to with higher doses. Contraindication: None known.	Existing as Coenzyme Q 10 50mg Cap	Herbal Medicines Compendium USP Dietary Supplement Monographs (USP30-NF25; Page-986) & Mosby's Drug Consult (Page-iii-25) **Reference Product :** Co. Q- 10, 200mg	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
53.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Fruit Momordica 500 mg capsule **Generic :** Fruit Momordica 500 mg	Diabetes, Prediabetes, Reduce blood sugar levels, Vairous stomach, Intestinal disorders including gastrointestinal upset, Ulcers, colitis, constipation, intestinal worms, kidney stones, psoriasis, liver disease.	Be cautious with this combination POSSIBLY SAFE for most people when taken by mouth short-term (up to 3 months). Bitter melon may cause an upset stomach in some people.	New	WHO monographs on selected medicinal plants, Volume 4. Page-192-206	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
54.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Fruit Momordica 500 mg Tablet. **Generic :** Fruit Momordica 500 mg	Diabetes, Prediabetes, Reduce blood sugar levels, Vairous stomach, Intestinal disorders including gastrointestinal upset, Ulcers, colitis, constipation, intestinal worms, kidney stones, psoriasis, liver disease.	Be cautious with this combination POSSIBLY SAFE for most people when taken by mouth short-term (up to 3 months). Bitter melon may cause an upset stomach in some people.	New	WHO monographs on selected medicinal plants, Volume 4. Page-192-206	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
55.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Fructus Agni Casti 500 mg capsule **Generic :** Fructus Agni Casti 500 mg	It naturally prevents female infertility, Regulates menstrual activities & finally eases the way for sperm to reach the ovaries. It helps menstrual disorders, Restoring normal ovulatory activity, hormonal imbalacce	Vitex agnus castus should not be used during pregnancy. Adverse events include fa-tigue, hair loss, increased intraocular pressure, palpitations, polyurea, sweating and vaginitis.	New	WHO monographs on selected medicinal plants, Volume 4. Page-9-30 **Reference Product :** premeeze 500mg capsule. UK	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
56.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Silymarin (Silybum marianum) 180 mg capsule **Generic :** Silymarin (Silybum marianum) 180 mg	Preparations of Milk Thistle herb are used as a stimulant, for functional disorders of liver and gallbladder including jaundice, gallbladder colic and diseases of the spleen. The herb was formerly used as a malaria treatment, emmenagogue and for uterine complaints.	The concomitant use of silymarin and butyrophenones or phenothiazines results in a reduction of lipid peroxidation (Palasciano, 1994). Silymarin has an atagonistic effect with yohimbine and phentolamine when given siflffulaneously (Di Carlo, 1993).	Exisisting	PDR For Herbal Medicines s 2nd edition. Page-516	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
57.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Silymarin (Silybum marianum) 500 mg Capsule **Generic :** Silymarin (Silybum marianum) 500 mg	Preparations of Milk Thistle herb are used as a stimulant, for functional disorders of liver and gallbladder including jaundice, gallbladder colic and diseases of the spleen.	The concomitant use of silymarin and butyrophenones or phenothiazines results in a reduction of lipid peroxidation (Palasciano, 1994). Silymarin has an atagonistic effect with yohimbine and phentolamine when given siflffulaneously (Di Carlo, 1993).	Existing as Silymarin Cap 70mg	PDR For Herbal Medicines s 2nd edition. Page-516 **Reference Product :** Natures plus 500mg capsule, USA.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
58.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Silymarin (Silybum marianum) 500 mg Tablet **Generic :** Silymarin (Silybum marianum) 500 mg	Preparations of Milk Thistle herb are used as a stimulant, for functional disorders of liver and gallbladder including jaundice, gallbladder colic and diseases of the spleen. The herb was formerly used as a malaria treatment, emmenagogue and for uterine complaints.	The concomitant use of silymarin and butyrophenones or phenothiazines results in a reduction of lipid peroxidation (Palasciano, 1994). Silymarin has an atagonistic effect with yohimbine and phentolamine when given siflffulaneously (Di Carlo, 1993). Silymarin herbs The cholagogue effect of the Drug has not been documented.	Existing as Silymarin Cap 70mg	PDR For Herbal Medicines s 2nd edition. Page-516 **Reference Product :** Natures plus 500mg Tablet, USA.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
59.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Silymarin (Silybum marianum) 540 mg Tablet **Generic :** Silymarin (Silybum marianum) 540 mg	Preparations of Milk Thistle herb are used as a stimulant, for functional disorders of liver and gallbladder including jaundice, gallbladder colic and diseases of the spleen. The herb was formerly used as a malaria treatment, emmenagogue and for uterine complaints.	The concomitant use of silymarin and butyrophenones or phenothiazines results in a reduction of lipid peroxidation (Palasciano, 1994). Silymarin has an atagonistic effect with yohimbine and phentolamine when given siflffulaneously (Di Carlo, 1993). Silymarin herbs The cholagogue effect of the Drug has not been documented.	New	PDR For Herbal Medicines s 2nd edition. Page-516 **Reference Product :** Euro Pure 540mg Tablet, USA.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
60.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Rhizoma Picrorhizae 500 mg Capsule. **Generic :** Rhizoma Picrorhizae 500 mg	**Uses described in pharmacopoeias and well-established documents** Used orally to treat fever, immune disorders and skin diseases (1, 2). While two studies have suggested a possible role of the rhizome for the treatment of bronchial asthma (17, 18) and viral hepatitis (19), no randomized controlled clinical trials	with this combination Rhizoma Picrorhizae possible safe form most people, when taken by mouth for up to one year. It can cause vomiting, rash, anorexia, diarrhea and itching.	New	WHO monographs on selected medicinal plants, Voume 4. Page-258-270	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			have been performed. WHO monographs on selected medicinal plants **Uses described in traditional medicine** Used orally to treat anaemia, asthma, diarrhea, dyspepsia, fever, headaches, obesity, and stomach ache. Also used as an anti-inflammatory agent, a cathartic, a cholagogue and an emmenagogue & over weight.					
61.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Rhizoma Picrorhizae 500 mg Tablet. **Generic :** Rhizoma Picrorhizae 500 mg	**Uses described in pharmacopoeias and well-established documents** Used orally to treat fever, immune disorders and skin diseases (1, 2). While two studies have suggested a possible role of the rhizome for the treatment of bronchial asthma (17, 18) and viral hepatitis (19), no randomized controlled clinical trials have been performed. WHO monographs on selected medicinal plants **Uses described in traditional medicine** Used orally to treat anaemia, asthma, diarrhea, dyspepsia, fever, headaches, obesity, and stomach ache. weight.	Be cautious with this combination Rhizoma Picrorhizae possible safe form most people, when taken by mouth for up to one year. It can cause vomiting, rash, anorexia, diarrhea and itching.	New	WHO monographs on selected medicinal plants, Voume 4. Page-258-270	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
62.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Ginkgo Biloba (Ginseng) 505 mg capsule. **Generic :** American Ginseng 505 mg	Lack of stamina Ginseng is used internally for fatigue and debility, and for a decrease capacity for work and concentration. Unproven Uses: In Folk medicine, Ginseng is used for loss of appetite, cachexia, anxiety, impotence and sterility, neuralgia and insomnia. Chinese Medicine, Ginseng is used for hemoptysis, gastric disturbances, and vomiting.	Diabetic Agents/Insulin---Caution should be taken when taking an anti-diabetic agent or insulin to lower blood glucose. Caution should be taken in patients with cardiovascular disease or diabetes. Hypertension resulting from Ginseng Abuse Syndrome is associate with prolonged high dose Ginseng with concomitant use of caffeine (Siegel, 1979,Siegel, 1980). General adverse effects include insomnia, epistaxis, headache, nervousness, and vomitting	Existing as Ginkgo Biloba Tablet 40mg (Ginkgo Biloba Extract)	PDR For Herbal Medicines 2nd edition. Page-598-603	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
63.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Fructus Tribuli 500 mg Capsule. **Generic :** Fructus Tribuli 500 mg	Orally for the treatment of cough, headache and mastitis (1). Although clinical trials have assessed the use of the crude drug for the symptomatic treatment of angina pectoris and male infertility, randomized controlled clinical trials are needed before the use of the crude drug can be recommended for the treatment of these conditions.	There don't appear to any interactions between tribulus. Taking tribulus as supplement for a short time is probably safe	New	WHO monographs on selected medicinal plants, Volume 4. Page-323-334	প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা হল।***
64.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Fructus Tribuli 500 mg Tablet. **Generic :** Fructus Tribuli 500 mg	**Uses described in pharmacopoeias and well-established documents** Orally for the treatment of cough, headache and mastitis (1). Although clinical trials have assessed the use of the crude drug for the symptomatic treatment of angina pectoris and male infertility,	There don't appear to any interactions between tribulus. Taking tribulus as supplement for a short time is probably safe	New	WHO monographs on selected medicinal plants, Volume 4. Page-323-334	প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা হল।***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			randomized controlled clinical trials are needed before the use of the crude drug can be recommended for the treatment of these conditions. **Uses described in traditional medicine** Orally for the treatment of abdominal distension, diarrhea, kidney stones, nosebleeds and vitiligo. Also used as an aphrodisiac, diuretic, galactagogue, general tonic and uterine tonic..					
65.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Bilberry 125 mg capsule. **Generic :** Bilberry 125 mg	Uses: Bilberry has been used in Diabetes Mellitus (for prevention and treatment), complaints of the gastrointestinal tract, kidney and urinary tract,, arthritis, gout and dermatitis. External uses include inflammation of the oral mucosa, eye inflammation, burns and skin diseases. BILBERRY FRUIT Diarrhea Inflammation of the mouth and pharynx Internally, Bilberry is used for nonspecific, acute diarrhea (particularly in light cases of enteritis). Externally the berry is used for mild inflammation of the mucous membranes of mouth and throat.	No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages. Digestive complaints due to the high tannin content are possible. Adverse events include fa-tigue, hair loss, increased intraocular pressure, palpitations, polyurea sweating and vaginitis.	Existing as Bilberry fruit Extract Vaccinium myrtilfus 80 mg Capsule	PDR For Herbal Medicines 2nd edition. Page-75-77	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			Uses: Well constructed clinical studies in humans that give conclusive support for use of Bilberry in the treatment of diabetic retinopathy or as a treatment for inproving night vision are not available. There is moderate support in animal model trials that support the vasoprotective and anti-edema properties of Bilberry. The literature also demonstrates efficacy in animal models for the treatment of diabetes, hyperlipidemia and gastric ulcers. Folk medicine uses include internal use for vomiting, bleeding and hemorrhoids and external use for poorly healing skin ulcers and wound healing.					
66.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Bilberry 160 mg Tablet. **Generic :** Bilberry 160 mg	Uses: Bilberry has been used in Diabetes Mellitus (for prevention and treatment), complaints of the gastrointestinal tract, kidney and urinary tract,, arthritis, gout and dermatitis. External uses include inflammation of the oral mucosa, eye inflammation, burns and skin diseases. BILBERRY FRUIT Diarrhea Inflammation of the mouth and pharynx Internally, Bilberry is used for	No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages. Digestive complaints due to the high tannin content are possible. Adverse events include fa-tigue, hair loss, increased intraocular pressure, palpitations, polyurea sweating and vaginitis.	Existing as Bilberry fruit Extract Vaccinium myrtilfus 80 mg Capsule	PDR For Herbal Medicines s 2nd edition. Page-75-77 WHO monographs one seleceted midicinal plants. **Reference Product :** Bilberry 160 mg Tablet. UK	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			nonspecific, acute diarrhea (particularly in light cases of enteritis). Externally the berry is used for mild inflammation of the mucous membranes of mouth and throat. Uses: Well constructed clinical studies in humans that give conclusive support for use of Bilberry in the treatment of diabetic retinopathy or as a treatment for inproving night vision are not available. There is moderate support in animal model trials that support the vasoprotective and anti-edema properties of Bilberry. The literature also demonstrates efficacy in animal models for the treatment of diabetes, hyperlipidemia and gastric ulcers. Folk medicine uses include internal use for vomiting, bleeding and hemorrhoids and external use for poorly healing skin ulcers and wound healing.				
67.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Bilberry 310 mg capsule. **Generic :** Bilberry 310 mg	Uses: Bilberry has been used in Diabetes Mellitus (for prevention and treatment), complaints of the gastrointestinal tract, kidney and urinary tract,, arthritis, gout and dermatitis. External uses include inflammation of the oral mucosa, eye inflammation, burns and skin	No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages. Digestive complaints due to the high tannin content are possible.	Existing as Bilberry fruit Extract Vaccinium myrtilfus 80 mg Capsule	PDR For Herbal Medicines s 2nd edition. Page-75-77 WHO monographs one seleceted midicinal plants. **Reference Product :** Bilberry 310 mg	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			diseases. BILBERRY FRUIT Diarrhea Inflammation of the mouth and pharynx Internally, Bilberry is used for nonspecific, acute diarrhea (particularly in light cases of enteritis). Externally the berry is used for mild inflammation of the mucous membranes of mouth and throat. Uses: Well constructed clinical studies in humans that give conclusive support for use of Bilberry in the treatment of diabetic retinopathy or as a treatment for inproving night vision are not available. There is moderate support in animal model trials that support the vasoprotective and anti-edema properties of Bilberry. The literature also demonstrates efficacy in animal models for the treatment of diabetes, hyperlipidemia and gastric ulcers. Folk medicine uses include internal use for vomiting, bleeding and hemorrhoids and external use for poorly healing skin ulcers and wound healing.	Adverse events include fa-tigue, hair loss, increased intraocular pressure, palpitations, polyurea sweating and vaginitis.		Tablet. UK		

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
68.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Cortex Granati 500 mg capsule **Generic :** Cortex Granati 500 mg	Used orally to treat dyspepsia, sore throat, menorrhagia, leucorrhoea and ulcers.	Hypersensitivity or allergy to the bark. Common adverse events observed in humans include dizziness, visual disturbances, weakness, calf spasms and tremors.	New	WHO monographs on selected medicinal plants, Volume 4. Page-108-115	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
69.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Cortex Granati 500 mg Tablet. **Generic :** Cortex Granati 500 mg	Used orally to treat dyspepsia, sore throat, menorrhagia, leucorrhoea and ulcers.	Hypersensitivity or allergy to the bark. Common adverse events observed in humans include dizziness, visual disturbances, weakness, calf spasms and tremors.	New	WHO monographs on selected medicinal plants, Volume 4. Page-108-115	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
70.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Ginkgo biloba 80 mg capsule. **Generic :** Ginkgo biloba 80 mg	Well constructed clinical studies in humans that give conclusive support for use of Bilberry in the Approved by Commission E: Symptomatic relief of organic brain dysfunction Intermittent claudication Vertigo (vascular origin) Tinnitus (vascular origin) The Commission E approvals listed are limited to special standard extracts of Ginkgo. Unproven Uses: The drug is used for disturbed brain functions that result in dizziness and headache with emotional lability and anxiety. Ginkgo has been demonstrated to	The drug is contraindicated in patients known to be hypersensitive to Ginkgo biloba preparations. Patients with known risk factors for intracranial hemorrhage (systematic arterial hypertension, diabetes amyloid senile plaques) should avoid the use of Ginkgo biloba due to a recent case report of subarachnoid hemorrhage associated with the herb (Value, 1998) Health risks or side effects following the proper administration of designated therapeutic dosages are not recorded. Mild gastrointestinal complaints could occur as side effects (Cohen,1998). Also blood pressure problems, allergic	Existing as Ginkgo Biloba Capsule 120mg (Ginkgo Biloba Extract)	PDR For Herbal Medicines s 2nd edition. Page-342-346	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
			improve concentration and memory deficits as a result of peripheral arterial occlusive disease. Chinese Medicine: Among traditional Chinese uses for Ginkgo biloba are asthma, tinnitus, hypertonia and angina pectoris.	reaction and phlebitis have occasionally been documented after parenteral administration. Allergic skin reactions have been observed on extremely tare occasions. The possible hypersensitibity reactions consist of occurrence of spasms and cramps and, in cases of acute toxicity, atonia and adynamia.				
71.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Ginkgo biloba 125 mg capsule. **Generic :** Ginkgo biloba 125 mg	Well constructed clinical studies in humans that give conclusive support for use of Bilberry in the Approved by Commission E: Symptomatic relief of organic brain dysfunction Intermittent claudication Vertigo (vascular origin) Tinnitus (vascular origin) The Commission E approvals listed are limited to special standard extracts of Ginkgo. Uses: The drug is used for disturbed brain functions that result in dizziness and headache with emotional lability and anxiety. Ginkgo has been demonstrated to improve concentration and memory deficits as a result of peripheral arterial occlusive disease. Chinese Medicine: Among traditional Chinese uses for Ginkgo biloba are asthma, tinnitus, hypertonia and angina pectoris.	The drug is contraindicated in patients known to be hypersensitive to Ginkgo biloba preparations. Patients with known risk factors for intracranial hemorrhage (systematic arterial hypertension, diabetes amyloid senile plaques) should avoid the use of Ginkgo biloba due to a recent case report of subarachnoid hemorrhage associated with the herb (Value, 1998) Health risks or side effects following the proper administration of designated therapeutic dosages are not recorded. Mild gastrointestinal complaints could occur as side effects (Cohen,1998). Also blood pressure problems, allergic reaction and phlebitis have occasionally been documented after parenteral administration. Allergic skin reactions have been observed on extremely tare occasions. The possible hypersensitibity reactions consist of occurrence of spasms and cramps and, in cases of acute toxicity, atonia and adynamia.	Existing as Ginkgo Biloba Capsule 120mg (Ginkgo Biloba Extract)	PDR For Herbal Medicines s 2nd edition. Page-342-346	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
72.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Ginkgo biloba 260 mg capsule. **Generic :** Ginkgo biloba 260 mg	Well constructed clinical studies in humans that give conclusive support for use of Bilberry in the Approved by Commission E: Symptomatic relief of organic brain dysfunction Intermittent claudication Vertigo (vascular origin) Tinnitus (vascular origin) The Commission E approvals listed are limited to special standard extracts of Ginkgo. Uses: The drug is used for disturbed brain functions that result in dizziness and headache with emotional lability and anxiety. Ginkgo has been demonstrated to improve concentration and memory deficits as a result of peripheral arterial occlusive disease. Chinese Medicine: Among traditional Chinese uses for Ginkgo biloba are asthma, tinnitus, hypertonia and angina pectoris.	The drug is contraindicated in patients known to be hypersensitive to Ginkgo biloba preparations. Patients with known risk factors for intracranial hemorrhage (systematic arterial hypertension, diabetes amyloid senile plaques) should avoid the use of Ginkgo biloba due to a recent case report of subarachnoid hemorrhage associated with the herb (Value, 1998) Health risks or side effects following the proper administration of designated therapeutic dosages are not recorded. Mild gastrointestinal complaints could occur as side effects (Cohen,1998). Also blood pressure problems, allergic reaction and phlebitis have occasionally been documented after parenteral administration. Allergic skin reactions have been observed on extremely tare occasions. The possible hypersensitibity reactions consist of occurrence of spasms and cramps and, in cases of acute toxicity, atonia and adynamia.	Existing as Ginkgo Biloba Capsule 120mg (Ginkgo Biloba Extract)	PDR For Herbal Medicines s 2nd edition. Page-342-346	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
73.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division	Aloe vera 500 mg capsule **Generic :** Aloe vera 500 mg	*Unproven Uses:* The drug is used for evacuation relief in the presence of anal fissures after recto-anal operations. In European folk medicine the drug is employed for its ability to influence digestion. *Chinese Medicine:* The most common use in Chinese medicine is for treatment of fungal diseases. *Indian Medicine:* Uses in Indian medicine include stomach tumors, constipation, colic, skin diseases, amenorrhea, worm infestation, and infections.	Aloe is contraindicated in cases of intestinal obstruction, acutely inflamed intestinal diseases (e.g., Crohn's disease, ulcerative colitis), appendicitis and abdominal pain of unknown origin. If cramping of the gastrointestinal tract after single dosing occurs, the dosage should be reduced. Spasmodic gastrointestinal complaints are a side effect to the drug's purgative effect.	New	PDR For Herbal Medicines 3rd edition. Page-16-20	প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা হলো।***
74.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Brown Kelp 150 mg capsule **Generic :** Brown Kelp 150 mg	*Unproven Uses:* Folk medicine uses include weight reduction. The drug is used as a commercial pharmaceutical preparation in the U.S. for anemia in pregnancy. In Japan the drug is used for hypertension.	Brown Kelp should not be used by individuals with a familial disposition to thyroid illness or hyperthyroidism. No health hazards are known in conjunction with the proper administration of designated therapeutic dosages.	New	PDR For Herbal Medicines s 2nd edition. Page-342-346	প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা হলো।***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
75.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Arnica 500 mg capsule **Generic :** Arnica 500 mg	• Fever and colds • Inflammation of the skin • Cough/bronchitis • Inflammation of the mouth and pharynx • Rheumatism • Common cold • Blunt injuries • Tendency to infection	Hypersensitivity or allergy to the bark Arnica is **POSSIBLY SAFE** when taken by mouth in the amounts commonly found in food or when applied to unbroken skin short-term.	New	PDR For Herbal Medicines 2nd edition. Page-41-43	প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা হলো।***
76.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	Asa Foetida 240 mg capsule **Generic :** Asa Foetida 240 mg	*Unproven Uses:* The drug is used for chronic gastritis, dyspepsia and irritable colon.*Chinese Medicine:* In China, the drug is used for infestation with intestinal parasites. *Indian* **Asthma.** **Bronchitis.** **Convulsions.** **Corns and calluses.** **Hysteria.** **Intestinal gas.** **Irritable colon.** **Menstrual problems.** **Nerve disorders.** **Stomach upset.**	Asafoetida might slow blood clotting. Taking asafoetida along with medications that also slow clotting might increase the chances of bruising and bleeding. When taken by mouth: Asafoetida is LIKELY SAFE for most people in the amounts typically found in foods. There is some evidence that asafoetida is POSSIBLY SAFE when taken by mouth as medicine.	New	PDR For Herbal Medicines s 2nd edition. Page-47-48	প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা হলো।***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
77.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division)	American Ginseng Tea 3 gm Powder **Generic :** American Ginseng Tea 3 gm	Lack of stamina Ginseng is used internally for fatigue and debility, and for a decrease capacity for work and concentration. *Unproven Uses:* In Folk medicine, Ginseng is used for loss of appetite, cachexia, anxiety, impotence and sterility, neuralgia and insomnia. *Chinese Medicine:* In Chinese medicine, Ginseng is used for hemoptysis, gastric disturbances, and vomiting.	Diabetic Agents/Insulin — Caution should be taken when taking an antidiabetic agent or insulin to lower blood glucose. Caution should be taken in patients with cardiovascular disease or diabetes. Hypertension resulting from Ginseng Abuse Syndrome is associated with prolonged high dose Ginseng with concomitant use of caffeine (Siegel, 1979; Siegel, 1980). General adverse effects include insomnia, epistaxis, headache, nervousness, and vomitting.	New	PDR For Herbal Medicines s 2nd edition. Page-598-603	প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা হলো।***
78.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division	Noni 500 mg capsule **Generic :** Noni 500 mg	Immunity Booster. Rich source of polysaccharides & phytonutrient. Helps to strengthen the Immune system. Support overall Healthy & well-being.	Hypersensitivity or allergy to the bark Noni is POSSIBLY SAFE when the fruit is consumed as food	New	PDR For Herbal Medicines s 2nd edition. Page-544	প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা হলো।***
79.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division	Noni 500 mg Tablet **Generic :** Noni 500 mg	Immunity Booster. Rich source of polysaccharides & phytonutrient. Helps to strengthen the Immune system. Support overall Healthy & well-being.	Hypersensitivity or allergy to the bark Noni is POSSIBLY SAFE when the fruit is consumed as food	New	PDR For Herbal Medicines 2nd edition. Page-544	প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা হলো।***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
80.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division	Coenzyme Q10 150 mg capsule **Generic :** Coenzyme Q10 150 mg	Coenzyme Q10 is most commonly used for conditions that affect the **heart** such as **heart** failure and fluid build up in the body (congestive **heart** failure or CHF), chest pain (angina), and high blood pressure. It is also used for preventing migraine headache, Parkinson disease, and many other conditions. Improve the health of your heart over time. Coenzyme Q-10 is a powerful antioxidant. Neutralizing harmful free radicals plays an important role in helping cells produce energy.	CoQ10 may lower blood sugar levels and blood pressure Although not all side effects are known, Coenzyme Q10 is thought to be likely safe for most adults when used as directed.	Existing	PDR For Herbal Medicines s 3rd edition. Page-936-937	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
81.	Bexter Herbal & Nutraceuticals Matidali, 2nd Bypass Road, Manikchock, Bogura (Herbal Division	Aloe vera Shampoo **Generic :** Aloe vera Shampoo	Holland and Barrett' – 'Dr Organic **Aloe Vera Shampoo**' is a gentle and mild **shampoo**. It is ideal for both normal and dry **hair** and for all scalp types. Use as often as possible. It can protect **hair**, prevent split ends and nourishes the scalp leaving both scalp and **hair** hydrated, soft and manageable. *Chinese Medicine:* The most common use in Chinese medicine is for treatment of fungal diseases. *Indian Medicine:* Uses in Indian medicine include skin diseases, amenorrhea, worm infestation, and infections	Aloe is contraindicated in cases of intestinal obstruction, acutely inflamed intestinal diseases (e.g., Crohn's disease, ulcerative colitis), appendicitis and abdominal pain of unknown origin Skin irritation, dry skin, oily or dry hair/scalp, or temporary hair loss may occur.	New	PDR For Herbal Medicines 3rd edition. Page-16-20	প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় তথ্যাদির ঘাটতি থাকায় আবেদন নামঞ্জুর করা হল।***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
82.	Total Herbal & Nutraceuticals	Lactobacillus acidophilus +Bifidobacterium longum +Streptococcus thermphilus +Xylo-oligosaccharide (prebiotic) +Inulin (prebiotic) **Capsule** **Generic :** Lactobacillus acidophilus 10 billion .eqv to 50mg+ Bifidobacterium longum 10 billion.eqv to 60mg+ Streptococcus thermphilus 25 billion.eqv to 80mg+ Xylo-oligosaccharide (prebiotic) 60 mg +Inulin (prebiotic) 60 mg	a) Probiotics support for kidney care naturally. b) Naturally occurring microbes that target and metabolize various nitrogenous wastes that diffuse from the blood-stream into the bowel. c) Clinically tested to reduce nitrogenous waste metabolites in the bowel and also stabilize healthy gut flora	Probiotics are contraindicated in those hypersensitive to any component of a probiotic-containing product.	Existing	**Reference Pharmacopeia: -** PDR For Herbal Medicines ; 4th edition. – Page:996-1001 **Reference Products**: Brand : **Renadyl-** Kibow Biotech, Inc. (USA) 4781 West Chester Pike, Newtown Square, PA, 19073, USA, P. P +1.610.353.5130	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
83.	Total Herbal & Nutraceuticals	Lactobacillus acidophilus +Lactobacillus plantarum + Lactobacillus casei + Lactobacillus paracasei + Lactobacillus reuteri + Lactobacillus rhamnosus + Lactobacillus salivarius + Lactobacillus helveticus + Lactobacillus bulgaricus + Lactobacillus gasseri + Bifidobacterium lactis + Bifidobacterium longum + Bifidobacterium bifidum + Bifidobacterium infantis + Bifidobacterium breve + Sodium Citrate+ Potassium	a) Classic oral rehydration salts combination for severe diarrhea application b) Zinc combined formulation	Probiotics are contraindicated in those hypersensitive to any component of a probiotic-containing product.	Existing	**Reference Pharmacopeia: -** PDR For Herbal Medicines ; 4th edition. - P.996-1001 **Reference Products**: Biotic Restore BIOGROWING CO, LTD. No.26, lane 118, Yonghe Road, Jingan District, Shanghai, China, 200072, PRC.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		Chloride + Sodium Chloride + Zinc gluconate + Glucose **Sachet** **Generic :** Lactobacillus acidophilus 0.1billion (0.55 mg) + Lactobacillus plantarum 1.55billion (8.25 mg)+ Lactobacillus casei 1.65 billion (8.25 mg) + Lactobacillus paracasei 1.1billion (5.5 mg) + Lactobacillus reuteri 0.1billion (0.55 mg) + Lactobacillus rhamnosus 1.65 billion (8.25 mg)+ Lactobacillus salivarius 0.1billon (0.55 mg) + Lactobacillus helveticus 0.1billion (0.55 mg) + Lactobacillus bulgaricus 0.055 billion (0.55 mg) + Lactobacillus gasseri 1billion (5.5 mg) + Bifidobacterium lactis 2.2billion (11 mg)+ Bifidobacterium longum 0.1 billion (0.55 mg)+ Bifidobacterium bifidum 0.1billion (0.55 mg) + Bifidobacterium infantis 0.075billion (0.55 mg)+						

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		Bifidobacterium breve 0.12 billion (1.1 mg) + Sodium Citrate 725 mg+ Potassium Chloride 375 mg + Sodium Chloride 650 mg + Zinc gluconate 71.5 mg+ Glucose 3375 mg						
84.	Total Herbal & Nutraceuticals	Lactobacillus acidophilus +Lactobacillus plantarum + Lactobacillus paracasei + Bifidobacterium lactis + Bifidobacterium longum +Bifidobacterium infantis +Lactobacillus bulgaricus +Streptococcus thermphilus **Capsule** **Generic :** Lactobacillus acidophilus 5billion (25 mg) +Lactobacillus plantarum 10 billion (50 mg)+ Lactobacillus paracasei 4 billion (20 mg) + Bifidobacterium lactis 10 billion (50 mg) + Bifidobacterium longum 0.5 billion (5 mg) +Bifidobacterium infantis 0.5 billion (10 mg) +Lactobacillus bulgaricus 0.25 billion (5 mg) +Streptococcus thermphilus 1 billion (5 mg) **Capsule**	a) Irritable Bowel Syndrome Relief. b) Gastrointestinal Flora Balance.	Probiotics are contraindicated in those hypersensitive to any component of a probiotic-containing product.	Existing	**Reference Pharmacopeia: -** PDR For Herbal Medicines ; 4th Edition. - P.996-1001 **Reference Products**: Brand name: IBS Care, BIOGROWING CO, LTD. No.26, lane 118, Yonghe Road, Jingan District, Shanghai, China, 200072, PRC.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
85.	Total Herbal & Nutraceuticals	Wild Yam Extract (Dehydroepiandrosterone) **Tablet** **Generic :** Wild Yam Extract (Dehydroepiandrosterone) 200 mg eqv to ext 25 mg	1) Diminished Ovarian Reserve (DOR). 2) Premature ovarian failure 3) Premature ovarian aging 4) Enhance female fertility 5) Poor response to IVF	Side effects reported for the use of DHEA in preparation for IVF were oily skin, acne.	New	**Reference Pharmacopeia:** 1) PDR for Herbal Medicines, 4th Edition, Page- 817 **Reference Products:** DHEA 25 mg Quality Supplement & Vitamin, Inc. Florida, USA	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
86.	Total Herbal & Nutraceuticals	Wild Yam Extract (Dehydroepiandrosterone) **Tablet** **Generic :** Wild Yam Extract (Dehydroepiandrosterone) 400 mg eqv to ext 50 mg	1) Diminished Ovarian Reserve (DOR). 2) Premature ovarian failure 3) Premature ovarian aging 4) Enhance female fertility 5) Poor response to IVF	Side effects reported for the use of DHEA in preparation for IVF were oily skin, acne.	New	**Reference Pharmacopeia:** 1) PDR for Herbal Medicines, Fourth Edition, Page- 817 **Reference Products:** Brand: **DHEA50mg** Rexall Sundown Inc. Baca Raton.Fl 33487, USA.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
87.	Total Herbal & Nutraceuticals	Alpha Ketoanalogue **tablet** **Generic :** Alpha Ketoanalogue 850 mg are (Calcium-3-methyl-2-oxo-valerate (α-ketoanalogue to isoleucine , calcium salt) 67 mg + Calcium-4-methyl-2-oxo-valerate (α-ketoanalogue to leucine , calcium salt) 101 mg + Calcium-2-oxo-3-	Low Protein Diet for (a) Kidney dysfunction (b) Chronic Kidney Disease (c) Diabetic Nephropathy	Contraindications − Hypersensitivity to the active substances or to any of the excipients − Hypercalcaemia − Disturbed amino acid metabolism	New	**Reference Pharmacopeia:** 1) United States Pharmacopeia- DSC-2015, PageNo:1215-1216, 1226,1322-1323,1456-1457, 2112-2113,1244-1245,1431-1432,1439-1441,1202-1203,1445-1446 **Reference Products:** Brand: NefroGard-**Centaur Pharmaceuticals Pvt. ltd.**	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হল।***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		phenylpropionate (α-ketoanalogue to phenylalanine , calcium salt) 68 mg + Calcium-3-methyl-2-oxo-butyrate (α-ketoanalogue to valine , calcium salt) 86 mg+ Calcium-dl-2-hydroxy-4(methylthio) butyrate (α-hydroxyanalogue to methionine , calcium salt) 59 mg + Lysine acetate u.s.p.(eq to lysine 75 mg.) 105 mg + L-threonine u.s.p. 53 mg + L-tryptophan u.s.p. 23 mg + L-histidine u.s.p 38 mg + L-tyrosine u.s.p. 30 mg)				**India** Ketosteril - Fresenius Kabi, Germany		
88.	Total Herbal & Nutraceuticals	Magnesium Tablet **Generic :** Magnesium Oxide 400mg	a) Osteoporosis, b) Leg cramps, c) Migraines, d) Fatigue, e) PMS, F) Preeclampsia, g) Pre-term labor, h) Heart attack, i) High blood pressure, j) Serum lipids, k) Diabetes	Side effects include indigestion or nausea. Possible reaction if allergic to shellfish	New	**Reference Pharmacopeia:** 1) United States Pharmacopeia- DSC-2015, Vol-1, Page No -1254. 2) Korean Pharmacopeia (Herbal & Supplement) .Page-:KPX 767 **Reference Products:** Brand : Magox /Magnesium 400 mg, a) Akorn Consumer Health, USA. / b) Windmill Health Products- USA	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
89.	Total Herbal & Nutraceuticals	L-Carnitine + Maca + Grape Seed Extract +Asian Ginseng+ Coq10 + Vitamine A + Vitamin C + Vitamin D3 + Vitamin E + Vitamin K + Thiamin Hcl + Riboflavin + Vitamin B6 + Folic Acid + Vitamin B12 + Pantothenic Acid + iodine +Zinc + Selenium + Copper + Manganese + Chromium **Capsule** **Generic :** L-Carnitine 350.00 mg, + Maca 300.00 mg + Grape Seed Extract 100.00 mg +Asian Ginseng 100.00 Mg + Coq10 50.00 Mg+ Vitamine A 5000.00 IU + Vitamin C 250.00 mg + Vitamin D3 400.00 IU + Vitamin E 150.00 IU + Vitamin K 80.00 mcg + Thiamin Hcl 1.50 mg + Riboflavin 1.70 mg + Vitamin B6 2.00 mg + Folic Acid 500.00 mcg + Vitamin B12 25.00 mcg + Pantothenic Acid 10.00 mg + iodine 150.00 mcg +Zinc 30.00 mg + Selenium 100.00 Mg + Copper 2.00 Mg + Manganese 2.00mg + Chromium 120.0 0 Mcg	1) Improve overall male reproductive Health 2) Sperm parameters such Increase Sperm Count 3) Increase Sperm motility (movement) and morphology (shape) 4) Infertility formulation support for men	No interactions have been reported.	New	**Reference Pharmacopeia:** United States Pharmacopeia- DSC-2015, Page No. Page No: 1226-1227,139-146, 1183-1185, 889-890, 1445-1446, 906-907, 879-880, 1497-1503, 1462-1463, 1268 ,1427-1428, 1359-1360, 1348-1349, 1643-1644, 1052-1053, 967-968, 1214, 1715-1717, 1398-1399, 1038-1039,1262-1263,1031-1032. **Reference Products:** FertilAid for Men Fairhaven Health, LLC 1410 11th St.Bellingham, WA 98225, USA.	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
90.	Total Herbal & Nutraceuticals	Red Clover Leaf 4:1 extract+ PABA + Eleuthero Root 5:1 extract + Chaste Tree Fruit 4:1 extract + Ginkgo Leaf Extract + Vitamin A + Vitamin C + Vitamin D3 + Vitamin + Thiamin + Riboflavin + Niacin + Vitamin B6 + Folic Acid + Vitamin B12 + Pantothenic Acid + Iron +Iodine +Magnesium: as magnesium oxide + as magnesium Chloride + Zinc + Selenium + Copper **Capsule** **Generic :** Red Clover Leaf 4:1 extract 225 mg + PABA200 mg + Eleuthero Root 5:1 extract 125 mg + Chaste Tree Fruit 4:1 extract 40 mg + Ginkgo Leaf Extract 30 mg + Vitamin A 4000 IU + Vitamin C 85mg + Vitamin D3 400 IU + Vitamin E 100 IU + Thiamin 1.5mg + Riboflavin 1.7 mg +	1) Help to women conceive naturally, an effective alternative to invasive /Expensive infertility treatment. 2) Provides optimal nutritional support for trying to conceive women. 3) Particularly helpful of those with irregular cycles for conditions such as PCOS	No interactions have been reported.	New	**Reference Pharmacopeia:** United States Pharmacopeia-DSC-2015, Page No: 1350-1353, 2461, 1085, 1013,1156,1460,879,1020, 1462,1427,135,1305,1348, 958,1052,966,1215,1214,1 252,1252,1248,1715,1398, 2470,1038. **Reference Products:** FertilAid for Women Fairhaven Health, LLC 1410 11th St.Bellingham, WA 98225, USA.	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
		Niacin 20 mg + Vitamin B6 2 mg + Folic Acid 600 mg + Vitamin B12 6 mcg + Pantothenic Acid 10 mg + Iron 18 mg + Iodine 245 mg +Magnesium: as magnesium oxide 320 mg + as magnesium Chloride 75 mg + Zinc 15 mg + Selenium 70 mcg + Copper 2 mg						
91.	Total Herbal & Nutraceuticals	Maca (Root) + Withania + Sombifera (Root) + Pannax Ginseng Root + Mucuna Puriens Extract (Seed) + d-Ribose + CoQ10 + L-lutathione Reduced + Vitamin C + Riboflavin+ Niacin + Vitamin B12 **Capsule** **Generic :** Maca (Root) 100 mcg + Withania Sombifera (Root) 50 mg + Pannax Ginseng Root 50 mg + Mucuna Puriens Extract (Seed) 50 mg + d-Ribose 50 mg + CoQ10 50 mg + L-lutathione Reduced 50 mg + Vitamin C 500 mg + Riboflavin15 mg + Niacin 25 mg + Vitamin B12 100 mcg	1) Increase sperm count for male 2) Increase sperm mobility for male 3) Support overall productivity for male	No interactions have been reported. Safe, non-prescription formula	New	**Reference Pharmacopeia:** United States Pharmacopeia- DSC-2015, PageNo, Vol-2- Page: 139-144, 19-22. USP-DSC-Vol-1 Page: 881-883, 882-806, 1445-1447, 1174, 880, 1359, 1306, 1052. **Reference Products:** Count Boost for Men Fairhaven Health, LLC 1410 11th St.Bellingham, WA 98225, USA.	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
92.	Total Herbal & Nutraceuticals	Trigonella foenumgraceum ext (Fenugreek seed) + Shatavari root (Asparagus recemosus) + Cowherb seed + *Silybum marianum* ext + Turmeric rhizome (Curcuma Longa)+ Black Piper (Piper nigrum) **Tablet** **Generic :** Trigonella foenumgraceum (Fenugreek seed) 333.00 mg ext + Shatavari root (Asparagus recemosus) 400.00 mg. + Cowherb seed 333.00 mg + *Silybum marianum* 37.33 mg ext + Turmeric rhizome (Curcuma Longa) 50 mg+ Black Piper (Piper nigrum) 10.75	1) Help improve the overall quantity of breast milk produced. 2) Help stimulate breasts to release milk. 3) Help improve nutrient content or consistency of production.	This combination product is not known to have any side effects if taken as per the prescribed dosage by your physician.	New	**Reference Chinese Pharmacopeia:** Page no: 466-767,57-58,473,426 **Reference Products**: ProLactation Max Biocare Pty Ltd, Suite 19, Level 3, Como Centre, 299 Australia,	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
93.	Total Herbal & Nutraceuticals	Shatavari (Asparagus recemosus) + Vidharikand (Pueraria tuberose)+ Ashwagandha (Withania somnifera)+ Lasuna (Allium sativum) + Methi Seeds (Trigonella foenum graecum) + Jivanti (Leptadenia reticulata) + Doodhi (Euphorbia hirta) **Capsule** **Generic :** Shatavari (Asparagus recemosus) 150 mg eq. to ext 15mg + Vidharikand ext (Pueraria tuberose) 250 mg eq. to ext 25mg + Ashwagandha (Withania somnifera) 100 mg eq. to ext 10mg + Lasuna (Allium sativum) 50 mg eq. to ext 5mg + Methi Seeds (Trigonella foenum graecum) 100 mg eq. to ext 10mg + Jivanti (Leptadenia reticulata) 150 mg eq. to ext 15mg + Doodhi (Euphorbia hirta) 50 mg eq. to ext 5mg	a) Lactating Mother Milk Enhancement support. b) Help improve nutrient content or consistency of production	This combination product is not known to have any side effects if taken as per the prescribed dosage by your physician.	New	**Reference Pharmacopeia:** *Indian Pharmacopeia-IP 2007,Vol-3*, (Herbal Section) Page-No-1427-1428,1387-1388,1411-1412, Page-CXI-CXII. *Indian Pharmacopoeia-IP 2010, Vol-III*, Page no-2523-2425. *Chinese Pharmacopeia, Page no:* 187, 380 **Reference Products:** *LACTOGIN*, Unijules Life Sciences Ltd. Survey No. 338 (P-38), Nagpur-441501, (M.S) India.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
94.	Total Herbal & Nutraceuticals	Gokhru (tribulus terrestries). + Kaunch beej (Mucuna pruriens). **Capsule** **Generic :** Gokhru (tribulus terrestries) 500 mg eqv.to extract 50 mg + Kaunch beej (Mucuna pruriens) 2 gm eqv.to extract 200 mg	a) Supplement to improve alertness during work & pleasure	**Interactions with other drugs:** None reported. **Side effects:** This combination product is not known to have any side effects if taken as per the prescribed dosage by your physician.	New	**Reference Pharmacopeia:-** a) Indian Pharmacopoeia (IP)-2018, Page-3815-3816, Indian Pharmacopoeia (IP)-2010, Page-2500-2501. **Reference Products:** VALIDO Capsule Unijules Life Sciences Ltd. Survey No. 338 (P-38), Dist: Nagpur-441501, (M.S) India	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
95.	Total Herbal & Nutraceuticals	Ashok chhal (Saraca indica) + Lodhra chhal (Symplocos racemosa)+ Shatavari (asparagus racemosus)+ Ashwagandha (Withania somnifera) **Capsule** **Generic :** Ashok chhal (Saraca indica) 500 mg eqv.to extract 50 mg + Lodhra chhal (Symplocos racemosa) 500 mg eqv.to extract 50 mg + Shatavari (asparagus racemosus) 500 mg eqv.to extract 50 mg + Ashwagandha (Withania somnifera) 100 mg eqv.to extract 10 mg	1) Irregular menstrual cycle. 2) Dysfunctional uterine bleeding. Menorrhagia, dysmenorrhea, metrorrhagia and associated depression. 3) Premenstrual syndrome.	**Interactions with other drugs:** None reported. **Side effects:** This combination product is not known to have any side effects if taken as per the prescribed dosage by your physician.		**Reference Pharmacopeia:-** (a) Indian Pharmacopoeia-2018 (IP), Page no-3745-3746, 3744-3745,3823-3824,3862-3865 **Reference Products:** U-GYANETONE Capsule Unijules Life Sciences Ltd., Survey No. 338(P-38), Dist: Nagpur-441501, (M.S) India.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
96.	Total Herbal & Nutraceuticals	Sharapunkha (tephrosia purpurea) + Latakaranja (Caesalpinia bonducella) +Haridra (Curcuma longa). + Shatapushpa/Dill (Anethum sowa). + Shatavari (Asparagus recemosus). +Trikatu - Sounth, Marich, Pippali (Zingiber officinale ,Piper nigrum,Piper longum) +Tankan Bhasma (Borax). **Capsule** **Generic :** Sharapunkha (tephrosia purpurea) 250 mg eqv.to extract 25 mg + Latakaranja (Caesalpinia bonducella) 250 mg eqv.to extract 25 mg +Haridra (Curcuma longa) 500 mg eqv.to extract 50 mg + Shatapushpa/Dill (Anethum sowa) 500 mg eqv.to extract 50 mg + Shatavari (Asparagus recemosus) 500 mg eqv.to extract 50 mg +Trikatu - Sounth, Marich, Pippali (Zingiber officinale , Piper nigrum,Piper longum) 500 mg eqv.to extract 50 mg +Tankan Bhasma (Borax) 50 mg	a) Remedy for Poly Cystic Ovarian Syndrome, b) Scanty menses and associated symptoms.	**Interactions with other drugs:** None reported. **Side effects:** This combination product is not known to have any side effects if taken as per the prescribed dosage by your physician.		**Reference Pharmacopeia:-** (a) Indian Pharmacopeia–IP-2018, Page no: 3800, 3800, 3862-3865, 3869-3870, 3829, 3846. 650-651, 42-45. (b) PDR For Herbal Medicines s 4th Edition-Page no-253 **Reference Products**: OvaCid Capsule, Unijules Life Sciences Ltd,.Dist.: Nagpur - 441501,(M.S) India.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
97.	Total Herbal & Nutraceuticals	Centella asiatica + Bacopa monnieri **Capsule** **Generic :** Centella asiatica 250 mg eqv.to extract 25 mg + Bacopa monnieri 250 mg eqv.to extract 25 mg	a) Treatment as a brain toner. b) Enhances memory and restores coordination between mind and body in children and elderly people.	This combination product is not known to have any side effects if taken as per the prescribed dosage by your physician	New	**Reference Pharmacopeia:-:** Indian Herbal Pharmacopoeia (IP) - 2018, Page no – 3765-3766, 3827-3728 **Reference Products:** RECALIT Capsule, Unijules Life Sciences Ltd., Survey No. 338(P-38), Dist: Nagpur-441501, (M.S) India.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
98.	Total Herbal & Nutraceuticals	Momordica charantia + Azadirachta indica + Ocimum sanctum . + Picrorhiza kurroa + Zingiber officinale **Capsule** **Generic :** Momordica charantia 2500 mg eqv.to extract 250 mg + Azadirachta indica 200 mg eqv.to extract 20 mg + Ocimum sanctum 100 mg eqv.to extract 10 mg + Picrorhiza kurroa 100 mg eqv.to extract 10 mg + Zingiber officinale 100 mg eqv.to extract 10 mg	Anti-diabetic support as taken as a prophylactic and also therapeutically to improve carbohydrate metabolism and managing blood sugar level, reducing weight and complications of diabetes.	This combination product is not known to have any side effects if taken as per the prescribed dosage by your physician		**Reference Pharmacopeia:-** WHO Monographs on selected medicinal plants. Vol-IV, Page no-192-207. Indian Pharmacopoeia (IP) – 2018- Page no-3837, 3875.3818, 3869. **Reference Products:** Karnim Plus, Unijules Life Sciences Ltd., Survey No. 338(P-38), Dist: Nagpur-441501, (M.S) India.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
99.	Total Herbal & Nutraceuticals	*Lactase* ***Tablet*** **Generic :** *Lactase* 300 mg eqv to 9000 FCC	**(**a) Bloating. (b) Diarrhea, (c) Excessive wind, (d) Stomach Pain/ Cramp, (e) Urgency to go to toilet.	This medication usually has very few side effects. If you have any unusual effects from taking this medication contact your doctor or pharmacist promptly	New	**Reference Pharmacopeia:-** United States Pharmacopeia- DSC-2015, Page No. Page No: 1225-1226. **Reference Products:** Lactase Complex, Lamberts Health Care Ltd. UK,	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
100.	Total Herbal & Nutraceuticals	*Lactase* ***drop*** **Generic :** *Lactase* 100 ml eqv to 3000 FCC	**(**a) Bloating. (b) Diarrhea, (c) Excessive wind, (d) Stomach Pain/ Cramp, (e) Urgency to go to toilet.	This medication usually has very few side effects. If you have any unusual effects from taking this medication contact your doctor or pharmacist promptly	New	**Reference Pharmacopeia:-** United States Pharmacopeia- DSC-2015, Page No. Page No: 1225-1226. **Reference Products:** Lactase Drop Seeking Health, Bellingham, USA.	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
101.	Total Herbal & Nutraceuticals	Alpha Lipoic Acid + Chromium as Picolinate + Zinc + Selenium + Vitamin E + Vitamin B5 + Vitamin B6 + Vitamin B1 + Vitamin H Biotin **tablet** **Generic :** Alpha Lipoic Acid 600 mg+ Chromium as Picolinate 100 mcg + Zinc 10 mg + Selenium 50 mcg + Vitamin E 15 mg + Vitamin B5 9 mg + Vitamin B6 3 mg + Vitamin B1 2 mg + Vitamin H Biotin 100 mcg	a) Neurotropic b) Anti-Inflammatory c) Antioxidant d) Altered Nervous Tropism e) Oxidative Stress.	Women WHO are pregnant or WHO could become pregnant should not use this supplement. There have been no reports of significant drug interactions	New	**Reference Pharmacopeia:-** United States Pharmacopeia- DSC-2015, Page No. Page No: 1225-1226. **Reference Products:** Nevralip, RIVER PHARMA s.r.l. Viale Stazione n. 6 | 26863 Orio Litta (LO) – Italy	প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজন নেই বিধায় আবেদন নামঞ্জুর করা হলো।***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
102.	Total Herbal & Nutraceuticals	Neem oil Soap **Generic :** Neem oil (Azadirachta) 2% + Castor oil 1%	Itching, Anti Acne, Anti Lice, Scabies	There have been no reports of significant drug interactions	New	**Reference Pharmacopeia:-** PDR Herbal Medicines, 4th edition, Page -539-540, 158-160. **Reference Products:** Neem Bath Bar The Himalaya Drug Company, Makali, Bengaluru – 562162	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
103.	Total Herbal & Nutraceuticals	Coal Tar Oil +Alpha Hydroxy Acid (Salicylic Acid) Soap **Generic :** Coal Tar Oil 1% +Alpha Hydroxy Acid 3% (Salicylic Acid) Soap bar	a) Seborrheic dermatitis, b) Dandruff. c) Pityriasisversicolor d) Itching e) Scaling f) Flaking & redness	Women WHO are pregnant or WHO could become pregnant should not use There have been no reports of significant drug interactions	New	**Reference Pharmacopeia:-** 1)USP-United States Pharmacopeia Page-1111, **Products Reference:** SELKOL Soap MARS Medi Soap, 54/B/2 Changodar Ind. Estate, Ahmedabad, Gujarat, India.	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***
104.	Total Herbal & Nutraceuticals	Coal Tar Oil Shampoo **Generic :** Coal Tar Oil 2% Shampoo	a) Seborrheic dermatitis, b) Dandruff. c) Pityriasisversicolor d) Itching e) Scaling f) Flaking & redness	Women WHO are pregnant or WHO could become pregnant should not use	New	**Reference Pharmacopeia:-** USP- United States Pharmacopeia –USP Vol-1, Page-1111. **Products Reference:** Redwin Coal Tar Shampoo Pharmacare Laboratories Australia. Product Name: Redwin Sensitive Skin Coal Tar Shampoo	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল।***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
105.	Alien Pharma (Herbal)	Wild Yam Extract (Dehydroepiandrosterone) **Tablet** **Generic :** Wild Yam Extract (Dehydroepiandrosterone) 200 mg eqv to ext 25 mg	a) Diminished Ovarian Reserve (DOR), b) Premature ovarian failure, c) Premature ovarian aging d) Enhance female fertility e) Poor response to IVF	**Contra-indication:** Safe, No Interaction. **Side Effect:** Currently, No side effects. Possible side effects in Allergy at high doses.	New	**Reference Pharmacopeia:** 1) PDR for Herbal Medicines. Page: 817, **Reference Product :** Women DHEA F 25mg, **Company Name:** Natures Sunsine Products Inc. USA. **Reference Product :** DHEA 25mg. **Company Name:** Quality Supplements & Vitamins Inc. USA.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
106.	Alien Pharma (Herbal)	Wild Yam Extract (Dehydroepiandrosterone) **Tablet** **Generic :** Wild Yam Extract (Dehydroepiandrosterone) 400 mg eqv to ext 50 mg	a) Diminished Ovarian Reserve (DOR), b) Premature ovarian failure, c) Premature ovarian aging d) Enhance female fertility e) Poor response to IVF	**Contra-indication:** Safe, No Interaction. **Side Effect:** Currently, No side effects. Possible side effects in Allergy at high doses.	New	**Reference Pharmacopeia:** 1) PDR for Herbal Medicines. Page: 817, **Products Reference:** Sundown Natural DHEA 50mg, **Company Name:** Rexall Sundown Inc. USA.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
107.	Alien Pharma (Herbal)	Coal Tar **Shampoo** **Generic :** Coal Tar 2.0%	a) Eczema, b) Psoriasis, c) Seborrheic dermatitis, d) Dandruff other skin disorders.	**Contra-indication:** Safe, No Interaction. **Side Effect:** Currently, No side effects.	New	**Reference Pharmacopeia:** a) British Herbal Pharmacopoeia 2016-Volume-2; Page no.: 991. **Products Reference:** Redwin Sensitive Skin Coal Tar Fragrance Shampoo. **Company Name:** Pharmacare Laboratories Australia. **Reference Product :** Energy Coal Tar Shampoo **Company Name:** Energy Cosmetics UAE.	প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হলো।***
108.	Alien Pharma (Herbal)	Turmeric **Soap/Bar** **Generic :** Turmeric 2.0%	a) Skincare b) Skin health and beauty c) Anti-inflammatoryd)Antibacterial	**Contra-indication:** Safe, No Interaction. **Side Effect:** Currently, No side effects.	New	**Reference Pharmacopeia:** a) PDR Herbal Medicine. Page: 775-777. **Products Reference:** Turmeric Soap, **Company Name:** Morvin, India.	সাবান হিসাবে প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা যেতে পারে।	***সাবান হিসাবে প্রয়োজনীয় রেফারেন্স নেই বিধায় আবেদন নামঞ্জুর করা হল***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
109.	Alien Pharma (Herbal)	Aloe Vera + Tea Tree Oil + Wheat Germ + Charcoal **Body Wash** **Generic :** Aloe Vera (Aloe barbadensis) 5.0% + Tea Tree Oil (Melaleucae Alternifoliae) 1.0% + Wheat Germ (Wheat Bran) 2.0% + Charcoal 0.24% (Activated Charcoal)	a) Antibacterial b) Moisturizing effect c) Good Cleanser	**Contra-indication:** Safe, No Interaction. **Side Effect:** Currently, No side effects.	New	**Reference Pharmacopeia:** a) USP-Dietary Supplement Compendium- DSC, Pages: 861-862, 1008-1009, 1704-1706 b) WHO monographs on Selected Medicinal Plants, Pages: 172-178. **Reference Product :** Herbal Body Wash, **Company Name:** Mantra Organics of India. **Reference Product :** Tea Tree Oil **Company Name:** Natural Riches of USA.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
110.	Alien Pharma (Herbal)	Neem + Coconut Oil + Australia Tea Tree Oil **Shampoo** **Generic :** Neem (Folium Azadirachti) 2.0% + Coconut Oil (Cocos Nucifera) 3.0% + Tea Tree Oil (Melaleuca Alternifolia) 1.0%	a) Killed lice and lice eggs b) Treat Hair Loss and Balding c) Good hair cleanser d) Anti Dandruff e) Hair grows longer, thicker, and faster.	**Contra-indication:** Safe, No Interaction. **Side Effect:** Currently, No side effects.	New	**Reference Pharmacopeia:** a) WHO monographs on Selected Medicinal Plants, Pages: 88-99, 172-178 b) USP DSC-2015, Pages: 1785-1786. **c)** **Products Reference:** Lice-Nil, **Company Name:** Sujanil Chemo industries, India.	ফর্মুলেশনে ভুল থাকায় আবেদন নামঞ্জুর করা যেতে পারে।	***ফর্মুলেশনে ভুল থাকায় আবেদন নামঞ্জুর করা হল।***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
111.	Alien Pharma (Herbal)	Neem + Aloe Vera Herbal Hand Wash **Generic :** Neem (Folium Azadirachti) 2.0% + Aloe Vera (Aloe barbadensis) 3.0%	a) Anti-bacterial b) Moisturizing effect c) Good hand Cleanser	**Contra-indication:** Safe, No Interaction. **Side Effect:** Currently, No side effects.	New	**Reference Pharmacopeia:** a) WHO monographs on Selected Medicinal Plants, Pages: 88-99 b) USP DSC-2015, Pages: 861-862. **Products Reference:** Aloe Vera & Neem Hand Wash. **Company Name:** Space Life Science, India. **Reference Product :** Neem & Aloe Vera 3X, **Company Name:** Jainsons Herbo Labs Pvt. Ltd., India. Protection.	আবেদন অনুমোদন করা যেতে পারে।	আবেদন অনুমোদন করা হল।
112.	Alien Pharma (Herbal)	Tea Tree Oil **Foot Lotion** **Generic :** Tea Tree Oil (Melaleuca Alternifolia)2.0%	a) Eliminating foot odor, b) Deodorant	**Contra-indication:**Safe, No Interaction. **Side Effect:**Currently, No side effects.	New	**Reference Pharmacopeia:** a) WHO monographs on Selected Medicinal Plants, Pages: 172-178 ` **Products Reference:** (Therapeutic Soothing Lotion Foot & Body Care. **Company Name:** Oleavine TheraTree, USA.	**Foot Lotion** হিসাবে মনোগ্রাফে উল্লেখ না থাকায় আবেদন নামঞ্জুর করা যেতে পারে।	***Foot Lotion হিসাবে মনোগ্রাফে উল্লেখ না থাকায় আবেদন নামঞ্জুর করা হল।***

নং	প্রস্তুতকারকের নাম	ঔষধের নাম ও জেনেরিক নাম	নির্দেশনা	Contra-indication & Side effect	Status (New Molecule/ Existing)	Reference	টেকনিক্যাল সাব কমিটির সিদ্ধান্ত	ডিসিসি ২৫১ তম সভার সিদ্ধান্ত
113.	Alien Pharma (Herbal)	Myo-inositol + D Chiro Inositil + Qutrefolic **Sachet** **Generic :** Myo-inositol 2000mg + D Chiro Inositil 50mg + Qutrefolic 400mcg	a) Polycystic ovary syndrome(PCOS),b) Women Infertility, c) Premenstrual syndrome (PMS), d) Menopausal complaints	**Contra-indication:** Safe, No Interaction. **Side Effect:** Currently, No side effects.	New	**Reference Pharmacopeia:** 1) USP DSC-2015, Page- 2068-2069, 1118. **Products Reference:** `HUMUS` **Company Name:** Nutrabiotic National Life Science, Pakistan. **Reference Product :** Inofem, **Company Name:** Establo Pharma, Poland.	D Chiro Inositil এর প্রয়োজনীয় রেফারেন্স না থাকায় আবেদন নামঞ্জুর করা যেতে পারে।	***D Chiro Inositil এর প্রয়োজনীয় রেফারেন্স না থাকায় আবেদন নামঞ্জুর করা হল।***