

New Product Registration Procedure

Applicant User Guide

April 27, 2017

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1. Introduction

Ensuring the quality, safety, and effectiveness of health products is a complex task for national medicine regulatory authorities (NRAs), as is ensuring that these products meet and comply with international standards and guidelines. Regulation of medicines, vaccines, medical devices, and other health products involves pre-marketing evaluation, marketing authorization, and post-marketing surveillance, all of which require effective management of information systems.

Despite efforts to improve regulatory information management in low- and middle-income countries, many countries still face challenges in developing an information system (IS) for the entire pharmaceutical regulatory process, including registration, licensing, inspection, quality control, pharmacovigilance, and medicine information. Implementation of an information management system that supports regulatory business processes and information flow can lead to improved efficiency and transparency by making NRA databases available and by providing timely information to stakeholders.

2. What is PharmaDex?

PharmaDex is a web-based integrated IS solution that facilitates management, documentation, dissemination, and sharing of regulatory information. Key features include—

- **Designed as a web-based system**—allows for online application and information sharing with the regulated industry and consumers
- **Provides modular structure**—helps NRA departments integrate and coordinate their work, from product registration, licensing, pre- and post-marketing inspections, to quality control, pharmacovigilance, and administration
- **Includes built-in document tracking and management system**—facilitates archival, documentation, management, and retrieval of dossiers; and provides a platform to develop electronic document management systems
- **Supports submission in Common Technical Document (CTD) format**—allows dossiers to be submitted as non-eCTD electronic submissions
- **Uses international standard dictionaries**—provides standard terminologies and dictionaries with built-in International Nonproprietary Names (INN), Anatomical Therapeutic Chemical (ATC) classification system, and the Medical Dictionary for Regulatory Activities (MedDRA)
- **Provides one-stop access to regulatory approval package**—enables access to product approval history, approval letter, and approved product information.
- **Enhances performance monitoring**—monitors built-in key performance metrics and generates activity reports for the NRA
- **Provided as an open source platform and non-proprietary database** — PharmaDex is freely available for NRAs in developing countries.

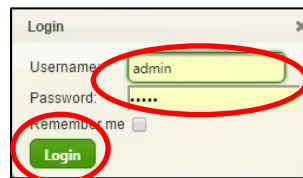
3. Accessing PharmaDex

3.1. Applicant Login

- To log in, go to the homepage and click on the door in the upper right corner.



- Enter in your username and password that was emailed to you and then click “Login”.



- Once you login, you will see your username in the upper right corner.



3.2. Changing User Settings

- Once logged in, you can change your password and language settings by clicking on “Settings” in the upper right corner.

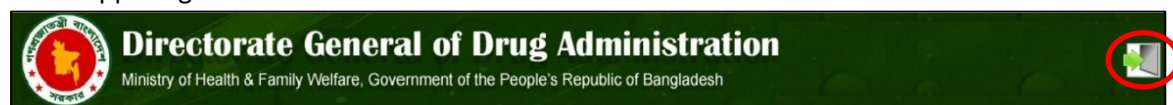


- Enter in your current password (the one that was emailed to you) and a new password. Click on “Submit” once finished.

- A message will displaying that your password has been successfully changed.

3.3. Resetting Password

- If you have forgotten your password, you can reset it. To do so, go to the homepage and click the door in the upper right corner.



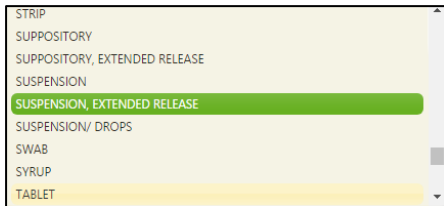
- Click on “Reset Password”.

- Enter in the email address you used when you registered for PharmaDex and click on “Reset”. A new password will be emailed to you. To change your password, follow the instructions in the above section on changing passwords.

4. Common Feature

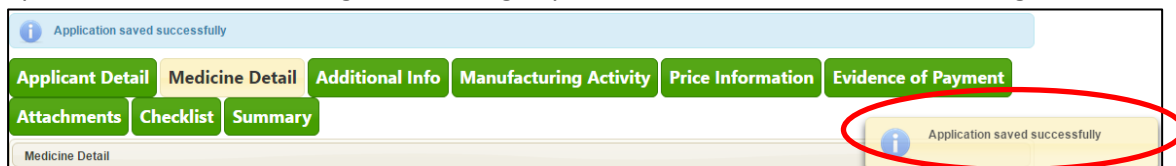
4.1. Search Option

- You need to write first alphabet of the word which you need to search:



4.2. Success Messages

- The system show success message after saving any new records as shown in the following screen:



4.3. Error Messages

- If you try to go without fill-in up any mandatory fields the following kind of message will arrive:

Medicine Detail

Application Type: Generic

Product Category * Human

Proprietary Name (Brand Name) *

Generic Name *

Dosage Form * TABLET

Dosage Unit * mg

Dosage Strength *

Route of administration * ORAL

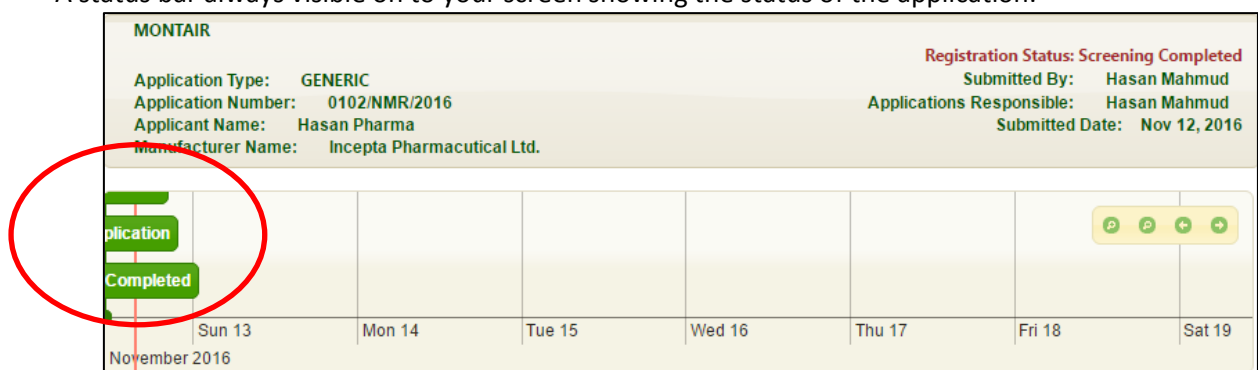
Age Group * Adult

Product Description and Physical Appearance *

☒ Select Product Type
☒ Enter Product Name
☒ Enter generic name
☒ Select dosage form from the drop down
☒ Select dosage form from the drop down
☒ Dosage Strength: Value required
☒ Value required
☒ Select Product Type

4.4. Timeline View of the Status

- A status bar always visible on to your screen showing the status of the application:



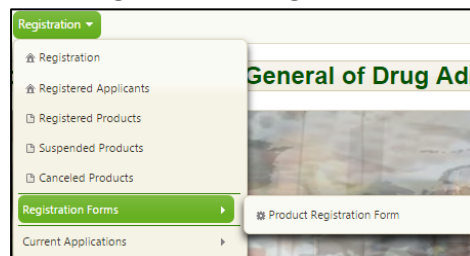
5. Registering Products

- In order to register a product, you must have a valid user name to access the system and you must be the person responsible for the applicant. After registering an applicant, you can begin to register products.
- To do so, go to the following menu options show below click on **“Registration” > “Registration Forms” > “Product Registration Form.”**



5.1. New Application Submission

- Need to log in as **“Applicant”** user -
- After putting your username and password the following screen has shown your logged in status on right side of the screen -
- Go to **Registration > Registration Forms > Product Registration Form** -



And the following screen will arrive –

5.2. Product Registration Application Entry Form

- You need to select one of the Application Type from the following combo – Generic/New Chemical Entity/Renewal or Variation

A screenshot of a web form showing a dropdown menu for 'Application Type *'. The dropdown is open, displaying four options: 'Generic', 'New Chemical Entity', 'Renewal', and 'Variation'. To the left of the dropdown is a green button labeled 'Verify Checklist'.

A screenshot of the 'Product Registration Application' form. The title 'Product Registration Application' is at the top. Below it, a message says: 'Please select the option below to find the total fees required for your application. If you have all the information about the product then you can click next to start the Product Registratrn Process.' Under 'Application Detail', there is a dropdown for 'Application Type *' with 'Generic' selected. At the bottom, there are two green buttons: 'Verify Checklist' and 'Product Registration Form'. The 'Product Registration Form' button is circled in red.

5.2.1. Application Detail

- After pressing Product Registration Form the following window will appear.
- Here you can see the applicant company's basic information only for viewing. Nothing need to do in this tab.

A screenshot of the 'Product Registration Application' form, specifically the 'Applicant Detail' tab. The tab is highlighted with a red border. The form displays the following information:

- Applicant Name *** ESKAYEF BANGLADESH LIMITED
- Address *** Tongi, Gazipur
- Country *** Bangladesh
- Applicant Type *** Manufacturer
- Manufacturing License #** 449&215
- Phone Number: *** +59228802981
- Fax Number:**
- Email:**
- Website:**
- Postal Code:**

Below this, there is a section for 'Person Responsible/Authorized to communicate with DGDA.' with the following information:

- Name: *** Mahmudul Islam Sohel
- Address *** 21/15 babor Road
- Country *** Bangladesh
- Phone Number:**
- Email: *** spsbdhelp@msh.org
- Fax Number:**
- Postal Code:**

At the bottom left is a green button labeled 'Cancel' with a small icon. At the bottom right is a green button labeled 'Next' with a right arrow icon.

- The following window will appear and you need to press “Next” button for going to next “Medicine Detail” tab.

5.2.2. Medicine Detail

Product Registration Application

Applicant Detail **Medicine Detail** Additional Info Manufacturing Activity Price Information Evidence of Payment

Attachments Checklist Summary

Medicine Detail

Application Type: Generic

Product Category *

Proprietary Name (Brand Name) *

Generic Name *

Dosage Form *

Dosage Unit *

Dosage Strength *

Route of administration *

Age Group *

Product Description and Physical Appearance *

- On the **“Medicine Detail”** tab, fill in the required fields describe below as much information as possible and click **“Next”** to continue.
- Select the following fields from the combos - Product Category*/Dosage Form*/Dosage Unit*/Route of Administration* and Age Group*
- You also need to fill in up the following fields - Proprietary Name (Brand Name)*/Generic Name*/Dosage Strength*/Product Description and Physical Appearance*
- After filing the above fields Medicine Detail tab look like as follows:

Medicine Detail

Application Type: New Chemical Entity

Product Category * Human

Proprietary Name (Brand Name) * ALBEN DS

Generic Name * ALBENDAZOLE

Dosage Form * TABLET

Dosage Unit * mg

Dosage Strength * 400

Route of administration * ORAL

Age Group * Adult

Product Description and Physical Appearance *

Alben-Ds Tablet is a medicine that is used for the treatment of Infections Caused By Pinworm, Infections Caused By Roundworm, Infections Caused By Tapeworm and other conditions. The complete list of uses and indications for Alben-Ds Tablet is as follows:
Infections Caused By Pinworm
Infections Caused By Roundworm
Infections Caused By Tapeworm

5.2.3. Additional Info

- After pressing “Next” button the following window will appear:

- If you want to assign ATC code, press “ATC Lookup” check box.

- After searching the ATC Name, the ATC Code will have displayed as shown in the following window. Then you need to click on “Add” to add the ATC Code.

- After added the ATC Code the ATC Lookup window will look like as follows:

Pharmacotherapeutic group	No ATC code has been assigned: <input checked="" type="checkbox"/> ATC Lookup	
	ATC Code	ATC Name
	A02A	ANTACIDS
		Delete

5.2.4. Add Active Ingredients

- To add active ingredients you need to click on **“Add”** button and the following window will arrive -

Add Active Substances

INN Name *

Dosage Strength *

Dosage Unit *

Manufacturer Name *

Address*

Postal Code

Country*

Manufacturing License #

Pharmacopoeial Reference

Phone Number: *

Fax Number:

Email

Is GMP Inspection done? ☐

GMP Certificate Number

GMP Inspection Date

[Add](#)
[Cancel](#)

- Begin typing in the INN, and a list will automatically populate based on what you type. Select the correct INN name, and enter in the strength (i.e. how much of that active substance), followed by the dosage unit (g, mg, etc.) and the pharmacopeia reference that was used (USP, BP, etc.).
- Fill in the details of Manufacturer of the active substance. If GMP inspection is done for the manufacturing facility, provide the GMP details also.
- After filled in you need to press **“Add”** button and the pop-up screen will go off and information saved.

Add Active Substances

INN Name *

Dosage Strength *

Dosage Unit *

Manufacturer Name *

Address*

Postal Code

Country*

Manufacturing License #

Pharmacopoeial Reference

Phone Number: *

Fax Number:

Email

Is GMP Inspection done? ☒

GMP Certificate Number

GMP Inspection Date

[Add](#)
[Cancel](#)

- You can add more INN using the **“Add”** button.
- In the same way you can also add Inactive Ingredients.

Add

Inactive ingredients

Excipient Name	Dosage Strength	Dosage Unit	Function	Pharmacopoeial Reference	Manufacturer Name		
albandazole monooxygenase	10	mg			Eskayef Bangladesh Limited		

Pharmacotherapeutic group

No ATC code has been assigned: ☒ ATC Lookup

ATC Code	ATC Name

[Delete](#)

- After that you need to fill in up other fields:

Proposed Indication for Use *

It is effective first-line of treatment against:

Flatworms
Flukes/trematodes
Fasciolosis
Tapeworm/cestodes
Cysticercosis[8]
Echinococcosis[8][9]

Proposed Posology and Method of Administration *

Alben-Ds Tablet improves the patient's condition by performing the following functions:
Keeping away the worm from absorbing sugar.

Product Type

Pharmaceutical

Formulary National Medicine (FNM)

Shelf Life (in Months) *

24

Pack Size *

20

Container/Closure Type *

Blister

Storage Conditions/Climate Zone *

Normal Temperature

Use Category *

☐ Scheduled Narcotic
☐ Psychotropic
☒ Prescription only
☐ Over the counter (OTC)

Cancel **Save**

- After adding Active Ingredients, Inactive Ingredients and other fields you need to press **“Save”** button to save data then press **“Next”** button to for going to next **“Manufacturing Activity”** tab.

5.2.5. Manufacturing Activity

Applicant Detail **Medicine Detail** **Additional Info** **Manufacturing Activity** **Price Information** **Evidence of Payment**

Attachments **Checklist** **Summary**

Manufacturing Activity

i Application saved successfully

Enter all entities involved in Manufacturing, Packaging, and Quality Control of finished product and API.

Add*

Manufacturer Name	Country	Manufacturer Type	Phone Number:
Eskayef Bangladesh Limited	Bangladesh	API Manufacturer	+88029812592
Eskayef Bangladesh Limited	Bangladesh	API Manufacturer	+88029812592
Eskayef Bangladesh Limited	Bangladesh	Excipient manufacturer	+88029812592

Cancel **Save**

Back **Next**

- You can add Manufacturing, Packaging, Quality Control, Finished Product or API manufacturer details in this tab.
- Press the **“Add”** button and fill the all necessary fields as shown in the following window:

Manufacturing Activity Details

Manufacturer Name * Phone Number: *

Address* Fax Number:

Postal Code Email

Country* Is GMP Inspection done? ☒

Manufacturing License # GMP Certificate Number

GMP Inspection Date

Company Type *

- ☒ Finished Product Manufacturer
- ☐ Bulk Manufacturer
- ☐ Primary Packager
- ☐ Secondary Packager
- ☐ Finished Product Release Controller
- ☐ Finished Product Release Responsibility
- ☐ Toll/Contract Manufacturer

- You have to enter at least one record containing “Company Type” of “Finished Product Manufacturer” or “Toll/Contract Manufacturer”.
- Without selecting one of these two “Finished Product Manufacturer” or “Toll Contractor Manufacturer” if you try to save the following error will show:

Applicant Detail **Medicine Detail** **Additional Info** **Manufacturing Activity** **Price Information** **Evidence of Payment**

Attachments **Checklist** **Summary**

Manufacturing Activity

Please specify the Finished Product Manufacturer or Toll/Contra. Please, specify only one Product Manufacturer (Finished Product Manufacturer or Toll/Contract Product Manufacturer)

Application saved successfully

Enter all entities involved in Manufacturing, Packaging, and Quality Control of finished product and API.

Manufacturer Name	Country	Manufacturer Type	Phone Number:	
Dhaka Pharma Ltd.	Bangladesh	Primary Packager	324	<input type="button" value="Delete"/>
Square Pharmaceuticals Limited	Bangladesh	API Manufacturer	00801819295651	

- After selection of “Manufacturing Activity” the following screen will arrive:

Manufacturing Activity

Application saved successfully

Enter all entities involved in Manufacturing, Packaging, and Quality Control of finished product and API.

Manufacturer Name	Country	Manufacturer Type	Phone Number:	
Eskayef Bangladesh Limited	Bangladesh	Finished Product Manufacturer	+88029812592	<input type="button" value="Delete"/>
Eskayef Bangladesh Limited	Bangladesh	API Manufacturer	+88029812592	
Eskayef Bangladesh Limited	Bangladesh	API Manufacturer	+88029812592	
Eskayef Bangladesh Limited	Bangladesh	Excipient manufacturer	+88029812592	

- If the applicant company have multiple manufacturing activities need to add those types as shown in the above screen.
- Need to press “Save” button to save data then press “Next” for going to next “Price Information” tab.

5.2.6. Price Information

- After pressing to “Next” the following window will appear:

Applicant Detail **Medicine Detail** **Additional Info** **Manufacturing Activity** **Price Information** **Evidence of Payment**

Attachments **Checklist** **Summary**

General Price Information

Application saved successfully

Proposed Maximum Retail Price (MRP)/Indicative Price: Pack Size: 20

Estimated Price per Dose:

Estimated Price per day of Treatment:

Estimated Cost for recommended course of Treatment:

Price Comparison Information

[Add](#)

Name of marketed drugs which have the same indications	Approved Maximum Retail Price (MRP)/Indicative Price
No records found.	

[Cancel](#) [Save](#)

[Back](#) [Next](#)

- Here you need to put all new Products pricing information as shown in the above screen.
- Need to press **“Save”** button to save data then press **“Next”** for going to next **“Evidence of Payment”** tab.

5.2.7. Evidence of Payment

- After pressing to **“Next”** the following window will appear:

Applicant Detail **Medicine Detail** **Additional Info** **Manufacturing Activity** **Price Information** **Evidence of Payment**

Attachments **Checklist** **Summary**

Evidence of Payment

Confirm payment for this Product application

Name of the Bank *

Receipt Number

Fee Submission Date * [📅](#)

[Cancel](#) [Save](#)

[Back](#) [Next](#)

- Here you need to put payment details as shown in the above screen.
- Need to press **“Save”** button to save data then press **“Next”** for going to next **“Attachment”** tab.

5.2.8. Attachments

- Here you need to attach necessary files like label of the product, Images of the product using **“Add Document”** button. .

Applicant Detail **Medicine Detail** **Additional Info** **Manufacturing Activity** **Price Information** **Evidence of Payment**

Attachments **Checklist** **Summary**

Please attach the soft copy of the following documents: CPP, Label, Payment Receipt, Method of Analysis.
Attachments have a 4mb size limit.

[Add Document](#)

Title	File Name	Upload Date	Uploaded By	Registration Status		
Packet Label	Alben-DS_tabs.jpg	Mar 29, 2017	Mahmudul Islam Sohel	Saved	Download	🗑️

[Cancel](#) [Save](#)

[Back](#) [Next](#)

- Need to press **“Save”** button to save data then press **“Next”** for going to next **“Checklist”** tab.

5.2.9. Checklist

- After pressing to “Next” the following window will appear:

Applicant Detail

Medicine Detail

Additional Info

Manufacturing Activity

Price Information

Evidence of Payment

Attachments

Checklist

Summary

Checklist

Please confirm that the items listed below are enclosed as part of the application by checking the box next to it.

		Module Number	
1	Letter of application *	Module 1	Yes No N/A
1.1	Comprehensive table of content (module 1) *	Module 1	Yes No N/A
1.2	Application - Hasan *	Module 1	Yes No N/A
1.3	Bangladesh labelling and packaging *	Module 1	Yes No N/A
1.4	Information about the experts *	Module 1	Yes No N/A
1.5	Specific requirements for different types of application *	Module 1	Yes No N/A
1.6	Environmental risk assessment *	Module 1	Yes No N/A
1.7	Good manufacturing practice *	Module 1	Yes No N/A
1.8	Foreign regulatory status *	Module 1	Yes No N/A
1.9	Pharmacovigilance plan *	Module 1	Yes No N/A
1.1	Details of compliance with screening outcomes *	Module 1	Yes No N/A
1.11	Bioequivalence trial information *	Module 1	Yes No N/A
1.12	Information on price	Module 1	Yes No N/A
1.13	Paediatric development program *	Module 1	Yes No N/A
1.14	Risk management plan *	Module 1	Yes No N/A
2.1	CTD Table of contents (Modules 2 to 5) *	Module 2	Yes No N/A
2.2	CTD introduction *	Module 2	Yes No N/A
2.3	Quality overall summary *	Module 2	Yes No N/A
2.4	Nonclinical overview *	Module 2	Yes No N/A
2.5	Clinical overview *	Module 2	Yes No N/A
2.6	Nonclinical written and tabulated summaries *	Module 2	Yes No N/A
2.7	Clinical summary *	Module 2	Yes No N/A
3.1	Table of contents of Module 3 *	Module 3	Yes No N/A
3.2	Body of Data *	Module 3	Yes No N/A
3.3	Literature references *	Module 3	Yes No N/A
4.1	Table of contents of Module 4 *	Module 4	Yes No N/A
4.2	Study reports *	Module 4	Yes No N/A
4.3	Literature references *	Module 4	Yes No N/A
5.1	Table of contents of Module 5 *	Module 5	Yes No N/A
5.2	Tabular listings of all clinical studies *	Module 5	Yes No N/A
5.3	Clinical study reports *	Module 5	Yes No N/A
5.4	Literature references *	Module 5	Yes No N/A

Cancel

Save

- Here you have to select any of the 3 options against each checklist item- **Yes, No or N/A**. Each checklist item represents one item from the application submitted physically. If you have submitted the document, select Yes, if you have not select No. If the checklist item does not apply for your application – select N/A.
- Need to press “**Save**” button to save data then press “Next” for going to next “**Summary**” tab.

5.2.10. Summary

- On the “**Summary**” tab, you can view all of the information you have provided. After checking all entered information here you need to press “**Save**” button to save and press “**Submit**” button to submit the new application.

Applicant Detail
Medicine Detail
Additional Info
Manufacturing Activity
Price Information
Evidence of Payment

Attachments
Checklist
Summary

Summary

Proprietary Name (Brand Name)
ALBEN DS

Product Category
Human

Generic Name
ALBENDAZOLE

Application Type
New Chemical Entity

Dosage Form
TABLET

Dosage Strength
400

Dosage Unit
mg

Route of administration
ORAL

Age Group
Adult

Pharmacological Classification

Product Description and Physical Appearance

Alben-Ds Tablet is a medicine that is used for the treatment of Infections Caused By Pinworm, Infections Caused By Roundworm, Infections Caused By Tapeworm and other conditions. The complete list of uses and indications for Alben-Ds Tablet is as follows: Infections Caused By Pinworm Infections Caused By Roundworm Infections Caused By Tapeworm

Proposed Indication for Use
It is effective first-line of treatment against: Flatworms Flukes/trematodes Fasciolosis Tapeworm/cestodes Cysticercosis[8] Echinococcosis[8][9]

Proposed Posology and Method of Administration
Alben-Ds Tablet improves the patient's condition by performing the following functions: Keeping away the worm from absorbing sugar.

Product Type
PHARMACEUTICAL

Formulary National Medicine (FNM)

Shelf Life (in Months)
24

Pack Size
20

Container/Closure Type
Blister

Storage Conditions/Climate Zone
Normal Temperature

Use Category
Prescription only

Applicant Name
Country
Applicant Type
Phone Number:

Eskayef Bangladesh Limited	Bangladesh	Finished Product Manufacturer	+88029812592
Eskayef Bangladesh Limited	Bangladesh	API Manufacturer	+88029812592
Eskayef Bangladesh Limited	Bangladesh	API Manufacturer	+88029812592
Eskayef Bangladesh Limited	Bangladesh	Excipient manufacturer	+88029812592

Cancel
Save
Submit

- After pressing “**Submit**” button the following “**Terms and Conditions**” window will appear:

TERMS AND CONDITIONS OF CONTRACT

I the undersigned certify that all the information in the accompanying documentation concerning an application for a marketing authorization for:

Proprietary Name (Brand Name):
MONTAIR

Generic Name:
SINGULAIR

Dosage Form
TABLET

Dosage Strength:
10

Dosage Unit
mg

Product Description and Physical Appearance
Montelukast is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene CysLT1 receptor. Cysteinyl leukotrienes and leukotriene receptor occupation have been correlated with the pathophysiology of asthma (such as, airway edema, smooth muscle contraction and altered cellular activity associated with the inflammatory process, which contribute to the signs and symptoms of asthma).

Applicant
Hasan Pharma

Manufacturer Name
Incepta Pharmaceutical Ltd.

is correct and true, and reflects the total information available. I further certify that I have examined the following statements and I attest to their accuracy.

- The current edition of the WHO guideline on "Good manufacturing practices for pharmaceutical products" Guideline, is applied in full in all premises involved in the manufacture of this product.
- The formulation per dosage form correlates with the master formula and with the batch manufacturing record forms.
- The manufacturing procedure is exactly as specified in the master formula and batch manufacturing record forms.
- Each batch of all starting materials is either tested or certified against the full specifications in the accompanying documentation and comply fully with those specifications before it is released for manufacturing purposes.
- All batches of active pharmaceutical ingredient(s) are obtained from the source(s) specified in the accompanying documentation.
- No batch of active pharmaceutical ingredient will be used unless a copy of the batch certificate established by the active ingredient manufacturer is available.
- Each batch of the container/closure system is tested or certified against the full specifications in the accompanying documentation and complies fully with those specifications before it is released for manufacturing purposes.
- Each batch of the finished product is either tested, or certified, against the full specifications in the accompanying documentation and complies fully with the release specifications before it is released for sale.
- The person releasing the product for sale is an authorized person as defined by the WHO guideline "Good manufacturing practices: Authorized person - the role, functions and training".
- The procedures for control of the finished product have been validated for this formulation.
- The market authorization holder has a standard operating procedure for handling adverse reaction reports on its products.
- The market authorization holder has a standard operating procedure for handling batch recalls of its products.
- All the documentation referred to in this certificate is available for review during a GMP inspection.
- All clinical trials including BE study were conducted according to WHO's "Guidelines for good clinical practice (GCP) for trials on pharmaceutical products"

Yes
No

- After pressing “Yes” button the submitted “**New Application**” will appear in the screen:

ALBEN DS		Registration Status:		New Application	
Application Type:	NEW_CHEMICAL_ENTITY	Submitted By:	Mahmudul Islam Sohel		
Application Number:	0138/NMR/2017	Applications Responsible:	Mahmudul Islam Sohel		
Applicant Name:	ESKAYEF BANGLADESH LIMITED	Submitted Date:	Mar 29, 2017		
Manufacturer Name:	Eskayef Bangladesh Limited				

Application									
	Thu 30	Fri 31	Sat 1	Sun 2	Mon 3	Tue 4	Wed 5		
March 2017			April 2017						

Application submitted successfully.

Application Information		Letters	
Proprietary Name (Brand Name):	ALBEN DS	Product Category:	Human
Generic Name:	ALBENDAZOLE	Application Type:	New Chemical Entity
Dosage Form	TABLET	Dosage Strength	400
Dosage Unit	mg	Route of administration	ORAL
Age Group	Adult	Pharmacological Classification	
Product Description and Physical Appearance	Alben-Ds Tablet is a medicine that is used for the treatment of Infections Caused By Pinworm, Infections Caused By Roundworm, Infections Caused By Tapeworm and other conditions. The complete list of uses and indications for Alben-Ds Tablet is as follows: Infections Caused By Pinworm Infections Caused By Roundworm Infections Caused By Tapeworm		
Medicine Detail	Click here		

5.2.11. Generate Acknowledgement Letter

- After submitting the application the system give you option to generate Acknowledgement Letter under **Letters** tab.
- To generate Acknowledgement Letter you need to click on **“Create Acknowledgement Letter”** under Letters tab.

Application Information

Letters

Create Acknowledgement Letter

Title	File Name	Upload Date	Uploaded By	Registration Status	
No records found.					


- A pop-up window will arrive to put Dossiers submission date. After putting the date click on **“Create”** button.


New letter has been created ✕


File number

0133/NMR/2017

Dossiers received *



 Create

 Cancel

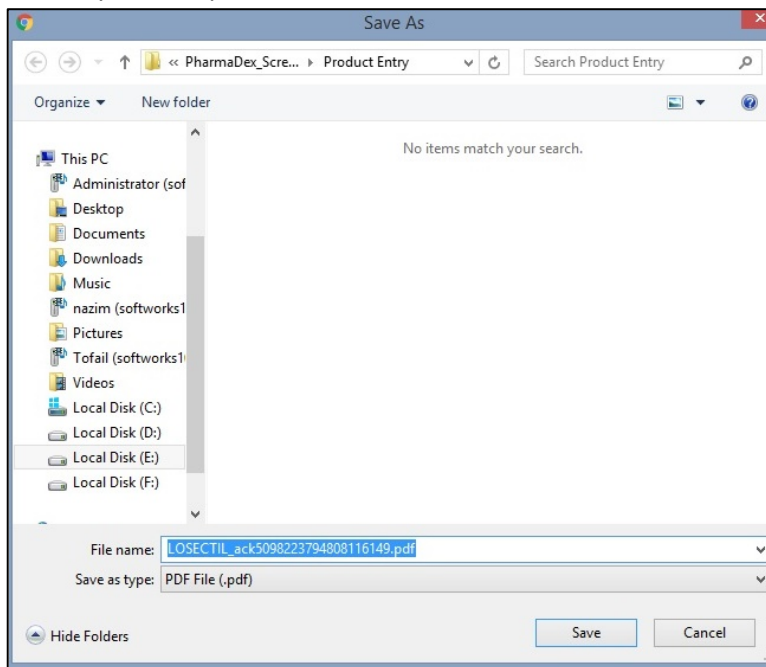
- You will see the following screen –

Application Information Letters

Create Acknowledgement Letter

Title	File Name	Upload Date	Uploaded By	Registration Status	
Acknowledgment letter	LOSECTIL_ack5098223794808116149.pdf	Apr 20, 2017	SoftWorks	New Application	Download

- To print the Acknowledgement Letter you need to click on **“Download”** button and save the file in a drive of your computer -



- The following printable view will generated as PDF format –



**Government of the Peoples Republic of Bangladesh
Directorate General of Drug Administration (DGDA)
Aushad Bhaban, Mohakhali, Dhaka-1212**

Dossier Acknowledgement Letter

Memo No: _____

Date: _____

Hasan Pharma
21/15 Babar Road, Mohammadpur
Attention: Hasan Mahmud

Subject: Acceptance Letter

Application Reference Number: 0102/NMR/2016

Trade name MONTAIR

Generic name(s) SINGULAIR

Strength(s) per dosage unit 10 mg

Dosage form TABLET

Your application has been accepted for evaluation. It is anticipated that the evaluation will be completed by approximately 1 year from the date of submission. The anticipated date of completion of the evaluation has been provided for your convenience and it is an estimate only.

If you have any queries as to the meaning of this letter, you should contact the undersigned immediately.

Yours faithfully

Director General,
Directorate General of Drug Administration
&
Licencing Authority (Drugs)
Government of the People's Republic of Bangladesh

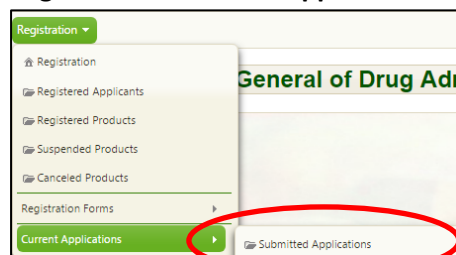
6. Viewing Status of Applications

- To view the status of applications you have submitted, log in and click on **“Application Status”**. From here, you can view submitted and saved applications as well as any products that have already been registered.



6.1. Submitted Product Application View

- After that you can view your submitted application by going to submitted applications from the menu **Registration > Current Application > Submitted Application**



- The submitted **“New Application”** will appear in the screen:

Submitted Applications						
Product Name ⚙	Generic Name	Application Number	Registration Status	Product Category	Date Submitted ⚙	Manufacturer Name
Vass	Atorvastatin	201411/0048	New Application	Human	Nov 8, 2014	
Clofenac DT	Diclofenac Free Acid	201411/0049	New Application	Human	Nov 8, 2014	
crestor	rosuvastatin	201411/0051	Screening Completed	Human	Nov 11, 2014	
hgih	gbmn	201411/0052	Screening Completed	Veterinary	Nov 12, 2014	
newdrug2	newdrug2	201503/0057	Screening Completed	Human	Mar 18, 2015	
newproduct	newproduct	201503/0058	Follow Up	Human	Mar 24, 2015	
RIXIT	GEN 50	0083/06/2016	New Application	Human	Jun 12, 2016	ACI Ltd
MSH ACYCLOVIR 5% CREAM	ACYCLOVIR	0086/06/2016	New Application	Human	Jun 21, 2016	MSH pharmaceutical Co. LTD.
TEST ACYCLOVIR 400MG TABLET	ACYCLOVIR	0087/08/2016	Follow Up	Human	Aug 9, 2016	ABC Pharma
NEW MEDICINE-1	NEW GENERIC	0092/10/2016	Follow Up	Human	Oct 4, 2016	Moon Pharma
MONTAIR	SINGULAIR	0102/NMR/2016	New Application	Human	Nov 12, 2016	Incepta Pharmaceutical Ltd.
(2 of 2) ⏪ ⏩ 1 2 ⏪ ⏩ 20 ▼						

- You can continue to register other products by repeating the same steps above.

6.2. Viewing Saved Applications

- During the process of filling out the product registration information you can save the information and access it at a later point. You will have to login to the system and go to the registration page or access the menu **Registration > Current Application > Saved Application**

