MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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| No. | | | |
| 1. | Principal company profile (Attested by Bangladesh Embassy/Chamber of commerce) | | |
| 2. | A valid copy of principal company manufacturing license (Attested by Bangladesh Embassy/ Chamber of commerce) | | |
| 3. | Principal company registered office and factory address (Attested by Bangladesh Embassy /chamber of commerce) | | |
| 4. | GMP certificate issued by the licensing authority of the country concerned (Attested by Bangladesh Embassy/ chamber of commerce) | | |
| 5. | List of countries where companies export their produced raw materials (Attested by Bangladesh Embassy/ chamber of commerce) | | |
| 6. | Certificate of analysis mentioning specification of each product (Attested by Bangladesh embassy/ chamber of commerce) | | |
| 7. | Product list issued by the licensing authority of the country concerned (Attested by Bangladesh Embassy/ Chamber of commerce) | | |
| 8. | Form -9 (Signed by the manufacturer mentioning the | MINISTRY DAIN | |
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MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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| 9. | Authenticated pre-clinical, clinical completed study report | | |
|--------------------------------|---|--|------|
| | and copy of clinical trial protocol approval by Drug | | |
| e E R e ^{r W} e | regulatory authority (in case of biological/biosimilar API) | | |
| 10. | Manufacturing companies have to submit certifications | | da s |
| | registered from their local drug regulatory authorities in | | |
| | terms of their drug substances or drug products. | 20 00 00 00 00 00 00 00 00 00 00 00 00 0 | |
| 11. | List of local agents or drug manufacturing companies from | | |
| | Bangladesh along with their agreement have to be submitted | | |
| | to whom listed product/products will be sold. | | |
| 12. | As biological bulk product/products are sensitive, in that | | |
| | case proof are to be submitted regarding required facilities | | |
| | for transportation, storage and distribution of the mentioned | | |
| | products. Furthermore, readings of data logger have to be | | |
| | submitted during import of biological bulk product/products | | |
| | in Bangladesh. | | |
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DIRECTORATE GENERAL OF DRUG ADMINISTRATION MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only Annexure-9 FORM Title: Check list for Registration Application of Vaccine & Biosimilar products as per CTD format Dossier. Version No. Effective Date Review Date Date Page No. Authorized by Form No. 01 of 04 119.11.21 NRA-MA-013/F09-01 **DEC' 21 DEC' 26** 02

The following information should be included in CTD Dossier

Part-A: Administrative Information:

- 1. Name and address of the Manufacturer of the Drug:
- 2. Manufacturing License Number (for locally manufactured drugs):
 - a) Vaccine:
 - b) Biosimilar:
- 3. Name of the Drug:
 - a) Generic name (use INN name if included in INN List)
 - b) Name of the reference product (Innovator Brand)
 - c) Meeting reference of Drug Control Committee for approval (for existing product)
 - d) Name under which the drug is proposed to be sold (Optional)
- 4. Summary of Product characteristic (SmPC) as per WHO format (Annex-1):
 - a) Qualitative and quantitative composition
 - b) Dosage form
 - c) Clinical particulars
 - d) Pharmacological properties
 - e) MA holder name and address (In case of imported product)
- 5. Registration Status at USFDA, UKMHRA or included in BNF of the product (Only for locally manufactured of new/unintroduced product)

Documents for Registration status of the product by United Status Food & Drug Administration (USFDA) or United Kingdom Medicine & Health Product Regulatory Authority (UKMHRA) or inclusion in British National Formulary (BNF).

6. Particulars and signature of qualified personnel for locally manufacturing products (Only for locally manufactured of new/unintroduced product)

Particulars of (a) Head of Product Development/Research and Development (b) Head of Quality Assurance (c) Head of Production (Full name, Qualifications, Date of Joining in the applicant's company, Total experience in the Vaccine or Biosimilar or Pharmaceutical industries, PCB Registration Number (If any).

Application has to be duly signed by the above personnel.

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DIRECTORATE GENERAL OF DRUG ADMINISTRATION MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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7. Application for Importation of Product:

The following additional information are to be provided:

a) Name, address, E-mail address, Telephone number, Fax number of the authorized local agent of exporter (Authorization document has to be appended)

b) Registration status in the country of origin: Registration status in the country of origin (COPP of one of the countries has to be submitted).

c) Registration status of human products in advance countries: Registration status of at least one of the following seven countries with same brand name: USA, UK, Germany, France, Australia, Switzerland, Japan or EMA/ WHO PQ (case to case basis) (COPP of one of the countries has to be submitted)

8. Maximum Retail Price (MRP) or Indicative Price: (Mention the proposed maximum retail rice (MRP) or Indicative Price)

Part-B: Quality Information

- 9. Active Ingredient:
 - a) General Information
 - Nomenclature i)
 - ii) Structure
 - General properties (Physico-chemical properties) (iii
 - b) Manufacture
 - Name and address of Manufacturer i)
 - c) Characterization of Active Ingredient
 - Host Cell/Master Seed/Cell line (from Bulk antigen manufacturer) i)
 - Elucidation of structure and other characteristics (from Bulk antigen ii) manufacturer or from compendia) (applicable for Biosimilar product)
 - Impurities Profile (if applicable) (from Bulk antigen manufacturer)
 - d) Control of drug substances
 - Specification i)
 - Analytical procedures ii)
 - Validation/Verification of analytical procedures iii)
 - Certificate of analysis

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DIRECTORATE GENERAL OF DRUG ADMINISTRATION MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH Authorized Personnel Only

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- Reference of specification for compendia Active Ingredient / Justification of v) specification for non-compendia Active Ingredient
- e) Reference/working standards of Active Ingredient
- f) Container closure system of Active Ingredient
- g) Stability data of the Active Ingredient (From Bulk antigen manufacturer)

10. Finished Product (FP):

- a) Description and composition
- b) Product Development:
 - Components of drug product (Bulk Antigen & Excipients)
 - Formulation development and Justification for overage (if any) ii)
 - Manufacturing Process Development iii)
 - Container closure system iv)
 - Microbiological attributes

c) Manufacture

- Batch size with formula (Proposed Commercial Batch)
- Manufacturing process and process control (Process flow, Manufacturing ii) steps, process control)
- Control of critical steps and intermediates iii)
- Process validation (During submission of application manufacturer will give commitment letter that process validation will be done for first three iv) commercial batches and will submitted to DGDA immediately after completion)

d) Control of excipients

- Specification for excipients (Pharmacopeia reference has to be mentioned for compendial excipients, for non-compendial it is needed)
- Analytical procedures used for testing excipients ii)
- Excipients of human or animal origin (TSE/BSE) iii)
- Novel excipients (if any) iv)

Control of FP

- **Product Specification** i)
- ii)
- iii)
- iv)
- oduct Special Proceduce /alidation/verification of and Sertificate of analysis Characterization of impurities/Impurities Reference of specification for compension specification for non-compendial product specification for non-compendial produ v) vi)

DIRECTORATE GENERAL OF DRUG ADMINISTRATION MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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f) Reference standard/ Reference materials/ Working standard

- Name of the Standards i)
- Name of the Manufacturer ii)
- Source of the standard iii)
- Certificate of analysis iv)
- Container closure system
 - Primary packaging material
 - Secondary packaging material ii)
- h) Stability study
 - Accelerated Stability Study Data i)
 - Long term stability data

(3-month data at the time of submission and six months before registration with commitment for long-term study)

Part-C: Toxicological Information (For new product/unintroduced products in Bangladesh for DCC):

- 11. a) Acute, sub-acute and chronic toxicity studies in animals
 - b) Mutagenicity studies
 - c) Studies on reproductive system and teratogenicity;
 - d) Other studies

Part-D: Clinical Information: (For new generic/unintroduced products)

12. a) Clinical study reports:

- Full clinical study
- b) Tabular listing and presentation of all clinical studies:
 - i) Pharmacokinetics and Pharmacodynamics (In case of Biosimilar)
 - ii) Studies related to intended therapeutic activity (In case of Biosimilar)
 - iii) Studies related to secondary pharmacological activity (In case of Biosimilar)
 - iv) Studies on side-effects/adverse reactions in human subjects

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SSREADS: CONTRACTOR OF STREET Please Note: Information supplied if found wrong will lead to immediate cancellation of application the product.

MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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| 1. | Host cell / cell line / master cell identification and characteristics | | |
| | document. | | 7 . 7 |
| 2. | Certificate of analysis | | |



MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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| 1. | Content | | | ** |
| 0. | | | | |
| | | duct development | | |
| 1. | Information a | bout product development | | |
| + | 1.1 | Information about cell bank | | |
| | 1.2 | Procedure to prepare working cell bank | | |
| | | Data generated from development of R&D batch, | | |
| | 1.3 | Manufacturing flowchart, Cell bank history, | | |
| | | Preliminary characterization and manufacturing | | - u |
| | | process in brief. | | |
| | 1.4 | Analytical specifications | | |
| | 1.5 | Comparability exercise (For Biosimilar products) | ji | 8 DA |
| | 9 = 2 | | | |
| 2. | Informatio | n about pre-clinical study | 8 | |
| | 2.1 | Protocol for preclinical study for local study or | | |
| | 2.1 | NOC to send sample to overseas | | |
| 3. | Informati | on about production of pre-clinical trial batch | | 50 To 10 To |
| ٠. | · Imoza | | | |
| | 3.1 | Preclinical batch summary report | | |
| | 3.2 | Analytical methods Stability study of at least 3 months of development | it | |
| | 3.3 | batch | | |

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| No. | | | |
| 1. | DGDA approval certificate for CRO | | |
| 2. | Approved protocol by BMRC | | |
| 3. | Investigator's Brochure | | |
| 4. | Informed consent form | | |
| 5. | Copy of signed agreement with sponsor | | |
| 6. | CV of principle investigator and his/her team members | | |
| 7. | GCP training | | |
| 8. | List of SOPs | | |
| 9. | GMP certificate of manufacturing plant | | 40 |
| 10. | Test samples, COA and Summary protocol | | |



MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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| A | FORM Title: Applic | FORM Title: Application Assessment Checklist for ICH CTD | st for ICH CTD Dossi | Dossier Module 1, 2 and 3 | | 0 |
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APPLICATION ASSESSMENT CHECKLIST (ICH CTD - UPA AND IPA)

Technical Dossier (ICH CTD) format and assessment report of Module - 1, 2, 3 for UPA and IPA applications only. This Application Assessment Checklist should be used to ensure the submission of a complete dataset for Module - 1, 2, 3 (CMC part) in the ICH Common

Colour scanned copies of the original documents should be submitted and original hard copies of documents are not required.

document is not an accurate reflection of the original document. However, DGDA reserves the rights to request for the original or certified true copy of submitted documents if there is any doubt that a submitted scanned

information/documents during evaluation. The acceptance of the application after screening including assessment does not preclude requests by DGDA for additional documents or changes to the

This Checklist should be completed by checking each item against the dossier according to the application type.

Note

- Cells with] indicate that the documents shown are mandatory for the selected application type and evaluation route.
- Cells without \square indicate that the documents shown are not required for the selected application type and evaluation route.

Legend:

| Evaluation route EUA | RT | IMP | Application type IND | IPA | UPA |
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| Emergency Use Authorization | Routine MA pathway | Imported | Indigenous or locally developed | Introduced Product Application | UPA Unintroduced Product Application |

Product Name:

Application Date:

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| Name and qualification of head of production | Name and qualification of head of product development or R&D | Name and qualification of head of quality control | Name and qualification of head of Quality Assurance | e experts | Labels (outer and inner) | Patients' information leaflet | insert | Product labelling and packaging information | oduct | | itents | | | Documents | | Module 1 – Administrative Information | 01 | Version No. | FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 1, 2 and 3 | |
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| Finished product release responsibility criteria for imported products | product release control tests | Active pharmaceuticals ingredients | se procedure | certificate | Inspection report or equivalent | Last date of inspection of each site | ractices | sessment | stration | nendment | Literature based submissions | | Specific Requirements for Amendment Application of Registered | | Documents | | 01 | Version No. | FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 1, 2 and 3 | |
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MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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| number of manufacturer or im- manufacturing/importing this product | the manu | list of the countries to which an application for the same product has been submitted | n | low diagram | Certified copy of permit to manufacture | Certificate of analysis of sample | Batch manufacturing record of the sample | Confirmation of submission of sample | documents | Proof of current registration of responsible pharmacist | Certificate of pharmaceutical products | of contract | (Manual) | | Documents | | | 01 | Version No. | FORM Title: Application Assessment Checklist for ICH CTD D | |
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| 1.12.2 Paediatri Risk mar | \$1.12.1 | Information on price | Details of compliance | Pharmacovigilance plan | 1.9.7 Data set of similarities | 7.9.6 Proreign pres | 1.9.5 Registration | 1.9.4 Estimated In Bangladesh | 0- | 190 | Passi | | NRA-MA-013/F13-01 | FOIHI NO. | Form No. | |
| the recommended course of treatment c development program agement plan | Proposed maximum retail price or indicative price Estimated price per dose, per day treatment and cost of | | Details of compliance with screening outcomes | an | imilarities | Foreign prescribing and patient information | Registration certificates or marketing authorization | Estimated market for this product/product Bangladesh | | | Documents | | C F | 01 | Version No. | FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 1, 2 and 3 |
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| 3.2.S.2.5 | Process validation and/or evaluation | | | | | | | 3 | | | | | |
| 3.2.S.2.6 N | Manufacturing process development | | | | | | | | | | | | |
| 3.2.S.3 Characterization | on | | | 17 | | | | | | | | | |
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| A. S. | (3.2.P.3.2 Batch formula | 3.2.P.3 Manufacture 3.2.P.3 Manufacturer | 3.2.P.2.6 Compatibility | 3.2.P.2.5 Microbiological attributes | 3.2.P.2.4 | 3.2.P.23 Manufacturing process development | ************************************** | 3.2.P.2.2.2 Overages | _\/ | 3 70 Fipal pharmaceutical product | Active pharmaceutical substitution | Component of pharmaceutical product | Pharmaceuti | Course | Section | | INICATION | NR A-MA-013/F13-01 01 | Form No. Version No. | | FORM Title: Application | | |
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Note: 1. Estimated Time duration for Dossier assessment is 05 Months through Routine MA pathway.

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APPLICATION ASSESSMENT CHECKLIST (ICH CTD - OFA AND IFA)

should be submitted and original hard copies of documents are not required. This Application Assessment Checklist should be used to ensure the submission of a complete dataset for Module – 3 (Testing Part) in the ICH Common Technical Dossier (ICH CTD) format and assessment report of Module – 3 for UPA and IPA applications only. Colour scanned copies of the original documents

item against the bossier according to the application type. document is not an accurate reflection of the original document. The acceptance of the application after screening including assessment does not preclude However, DGDA reserves the rights to request for the original or certified true copy of submitted documents if there is any doubt that a submitted scanned requests by DGDA for additional documents or changes to the information/documents during evaluation. This Checklist should be completed by checking each

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APPLICATION ASSESSMENT CHECKLIST (ICH CTD – UPA AND IPA)

submitted and original hard copies of documents are not required. This Application Assessment Checklist should be used to ensure the submission of a complete dataset for Module 4 & 5 in the ICH Common Technical Dossier (ICH CTD) format and assessment report of Module 4 & 5 for UPA and IPA applications only. Colour scanned copies of the original documents should be

document is not an accurate reflection of the original document. The acceptance of the application after screening including assessment does not preclude requests by pGDA for additional documents or changes to the information/documents during evaluation. However, DGDA reserves the rights to request for the original or certified true copy of submitted documents if there is any doubt that a submitted scanned

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| | | 4.2.3.6 | Local Tolerance | | | | | | | | | | |
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| 5.3.4 Reports of F | Reports of Pharmacodynamic (PD) Studies | | | | | 22 |] eg | + |] \{ |
| | Reports of Efficacy and Safety Studies | 3 | | | | | |)] [| ם כ |
| For RT, | For RT, study reports of ALL clinical trials (including the appendices and tables) should be submitted. | ials (including the itted. | | | | | | | |
| For EUA should be only upo | For EuAstudy reports of pivotal or relevant clinical trials should be submitted (appendices and tables are required only upon request by DGDA). | want clinical trials ables are required | | | | | | | |
| ASSECTION. | The clinical trials should be conducted using the drug product formulation submitted in the application and in the appropriate patient population for the indication(s) and/or dosing regimen(s) as requested in the application. | d using the drug lication and in the dication(s) and/or plication. | | | | | | | |
| differs from the studies, bioph section 5.3.1) | If the commercial formulation for the Bangladesh market differs from the clinical trial formulation used in the pivotal studies, biopharmaceutic study reports are required (see section 5.3.1). | ingladesh market sed in the pivotal are required (see | | | | | | | |

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| Other Supporting Documents | Risk management plan (RMP) documents as separate attachment. | List of Key Literature References | Case Report Forms and Individual Patient Listings (required upon request by DGDA) | Reports of Post-marketing Experience | Phase III, confirmatory, randomised, controlled pivotal trials conducted in compliance with Good Clinical Practice (GCP) are required to support each requested indication and downg regimen, unless adequately justified. Active-controlled studies should use relevant active comparators that are locally registered, unless adequately justified. | If the information on the comparability between the clinical trial formulation and the proposed commercial formulation is not available in the clinical study reports or the Clinical Overview/Summaries, a separate declaration letter should be submitted to confirm that the clinical trial formulation is the same as the commercial formulation proposed for registration in Bangladesh. | | Documents | | |
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Assessment Summary Recommended to Allsham **Assessment Completed on** NRA-MA-013/F15-01 Form No. FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 4 and 5 Version No. 01 Effective Date JUN' 22 Annexure – 15 Review Date JUN' 27 Assessment Done By/Date **Total Duration** Authorized by 29.05.22 Date Authorized Personnel Only Page No. 7 of 7

Note: 1. Estimated Time duration for Dossier assessment is 05 Months through Routine MA pathway.

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2. Estimated Time duration for Dossier assessment is 05 days through EUA pathway.