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

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Annexure – 8

FORM Title: Checklist for Source Validation Documents Review

Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F08-01	01	DEC' 21	DEC' 26		09.11.21	01 of 02

Sl. No.	Content	Submitted?	Remarks
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 product name)		

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9.	Authenticated pre-clinical, clinical completed study report and copy of clinical trial protocol approval by Drug regulatory authority (in case of biological/biosimilar API)		
10.	Manufacturing companies have to submit certifications registered from their local drug regulatory authorities in terms of their drug substances or drug products.		
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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Annexure-9						
	FORM Title: Check list for Registration Application of Vaccine & Biosimilar products as per CTD format Dossier.					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F09-01	02	DEC' 21	DEC' 26		09.11.21	01 of 04

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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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**
   i) Nomenclature
   ii) Structure
   iii) General properties (Physico-chemical properties)

b) **Manufacture**
   i) Name and address of Manufacturer

c) **Characterization of Active Ingredient**
   i) Host Cell/Master Seed/Cell line (from Bulk antigen manufacturer)
   ii) Elucidation of structure and other characteristics (from Bulk antigen manufacturer or from compendia) (applicable for Biosimilar product)
   iii) Impurities Profile (if applicable) (from Bulk antigen manufacturer)

d) **Control of drug substances**
   i) Specification
   ii) Analytical procedures
   iii) Validation/Verification of analytical procedures
   iv) Certificate of analysis

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v) Reference of specification for compendia Active Ingredient / Justification of 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:**
   i) Components of drug product (Bulk Antigen & Excipients)
   ii) Formulation development and Justification for overage (if any)
   iii) Manufacturing Process Development
   iv) Container closure system
   v) Microbiological attributes

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

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

e) **Control of FP**
   i) Product Specification
   ii) Analytical Procedures
   iii) Validation/verification of analytical procedures
   iv) Certificate of analysis
   v) Characterization of impurities/Impurities Profile (if applicable)
   vi) Reference of specification for compendial product/Justification of specification for non-compendial product

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Annexure-9						
	FORM Title: Check list for Registration Application of Vaccine & Biosimilar products as per CTD format Dossier.					
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f) Reference standard/ Reference materials/ Working standard
- i) Name of the Standards
- ii) Name of the Manufacturer
- iii) Source of the standard
- iv) Certificate of analysis

g) Container closure system
- i) Primary packaging material
- ii) Secondary packaging material

h) Stability study
- i) Accelerated Stability Study Data
- ii) 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:
- i) 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

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

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Annexure – 10

	FORM Title: Checklist for NOC to Import Host Cell/Cell line/Master cell					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F10-01	01	DEC' 21	DEC' 26		09.11.21	01 of 01

Sl. No.	Content	Submitted?	Remarks
1.	Host cell / cell line / master cell identification and characteristics document.		
2.	Certificate of analysis		

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Annexure – 11

	FORM Title: Checklist for Permission to Start Preclinical Study					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F11-01	01	DEC' 21	DEC' 26		09.11.21	01 of 01

Sl. No.	Content		Submitted?	Remarks
1.	Information about product development			
	1.1	Information about cell bank		
	1.2	Procedure to prepare working cell bank		
	1.3	Data generated from development of R&D batch, Manufacturing flowchart, Cell bank history, Preliminary characterization and manufacturing process in brief.		
	1.4	Analytical specifications		
	1.5	Comparability exercise (For Biosimilar products)		
2.	Information about pre-clinical study			
	2.1	Protocol for preclinical study for local study or NOC to send sample to overseas		
3.	Information about production of pre-clinical trial batch			
	3.1	Preclinical batch summary report		
	3.2	Analytical methods		
	3.3	Stability study of at least 3 months of development batch		

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Annexure – 12						
	FORM Title: Checklist for NOC/Permission to Start Clinical Study					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F12-01	01	DEC' 21	DEC' 26		09.11.21	01 of 01

Sl. No.	Content	Submitted?	Remarks
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		
10.	Test samples, COA and Summary protocol		

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Annexure – 13

	FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 1, 2 and 3					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
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APPLICATION ASSESSMENT CHECKLIST (ICH CTD – UPA AND IPA)

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 Technical Dossier (ICH CTD) format and assessment report of Module – 1, 2, 3 for UPA and IPA applications only.

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

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 document is not an accurate reflection of the original document.

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

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 ☐ indicate that the documents shown are not required for the selected application type and evaluation route.

Legend:

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

Product Name:

Application Date:

Annexure – 13

FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 1, 2 and 3

Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
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Module 1 – Administrative Information **Assessment Started on:**

Section	Documents	Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
			UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
			RT	EUA	RT	EUA			Yes	No	NA	
1.1	Module 1 table of contents		☐	☐	☐	☐	☐	☐	☐	☐	☐	
1.2	Application letter								☐	☐	☐	
1.3	Information about product								☐	☐	☐	
1.4	Product labelling and packaging information								☐	☐	☐	
1.4.1	Packaging insert								☐	☐	☐	
1.4.2	Patients' information leaflet								☐	☐	☐	
1.4.3	Labels (outer and inner)								☐	☐	☐	
1.5	Information about the experts								☐	☐	☐	
1.5.1	Name and qualification of head of Quality Assurance								☐	☐	☐	
1.5.2	Name and qualification of head of quality control								☐	☐	☐	
1.5.3	Name and qualification of head of product development or R&D								☐	☐	☐	
1.5.4	Name and qualification of head of production								☐	☐	☐	

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FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 1, 2 and 3

Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
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Section	Documents	Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
			UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
			RT	EUA	RT	EUA			Yes	No	NA	
1.6	Specific Requirements for Amendment Application of Registered Products		☐	☐	☐	☐	☐	☐	☐	☐	☐	
1.6.1	Literature based submissions								☐	☐	☐	
1.6.2	Variations/amendment								☐	☐	☐	
1.6.3	Copy of registration								☐	☐	☐	
1.7	Environmental risk assessment								☐	☐	☐	
1.8	Good Manufacturing Practices								☐	☐	☐	
1.8.1	Last date of inspection of each site								☐	☐	☐	
1.8.2	Inspection report or equivalent								☐	☐	☐	
1.8.3	Latest GMP certificate								☐	☐	☐	
1.8.4	Batch release procedure								☐	☐	☐	
1.8.5	Active pharmaceuticals ingredients								☐	☐	☐	
1.8.6	Finished product release control tests for imported products								☐	☐	☐	
1.8.7	Finished product release responsibility criteria for imported products								☐	☐	☐	

Adv. Sadiqur Rahman
Solicitor
Ministry of Health & Family Welfare
Date:
10 NOV 2021

Annexure – 13

FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 1, 2 and 3

Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F13-01	01	JUN' 22	JUN' 27		29.05.22	4 of 13

Section		Documents	Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
				UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
				RT	EUA	RT	EUA			Yes	No	NA	
1.8	1.8.8	Confirmation of contract		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	1.8.9	Certificate of pharmaceutical products								☐	☐	☐	
	1.8.10	Proof of current registration of responsible pharmacist								☐	☐	☐	
	1.8.11	Sample and documents								☐	☐	☐	
	1.8.12	Confirmation of submission of sample								☐	☐	☐	
	1.8.13	Batch manufacturing record of the sample								☐	☐	☐	
	1.8.14	Certificate of analysis of sample								☐	☐	☐	
	1.8.15	Certified copy of permit to manufacture								☐	☐	☐	
	1.8.16	Inspection flow diagram								☐	☐	☐	
	1.8.17	Organogram								☐	☐	☐	
1.9	1.9.1	list of the countries to which an application for the same product has been submitted								☐	☐	☐	
	1.9.2	information and signature of the manufacturers authorized agent								☐	☐	☐	
	1.9.3	number of manufacturer or importers already manufacturing/importing this product								☐	☐	☐	

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Annexure – 13

FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 1, 2 and 3

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Section	Documents	Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
			UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
			RT	EUA	RT	EUA			Yes	No	NA	
1.9	1.9.4 Estimated market for this product/product group in Bangladesh		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	1.9.5 Registration certificates or marketing authorization								☐	☐	☐	
	1.9.6 Foreign prescribing and patient information								☐	☐	☐	
	1.9.7 Data set of similarities								☐	☐	☐	
1.10	Pharmacovigilance plan								☐	☐	☐	
1.11	Details of compliance with screening outcomes								☐	☐	☐	
1.12	Information on price								☐	☐	☐	
	1.12.1 Proposed maximum retail price or indicative price								☐	☐	☐	
	1.12.2 Estimated price per dose, per day treatment and cost of the recommended course of treatment								☐	☐	☐	
1.13	Paediatric development program								☐	☐	☐	
1.14	Risk management plan								☐	☐	☐	

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Annexure – 13

FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 1, 2 and 3

Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
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Module 2 – Quality Overall Summary

Section	Documents	Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
			UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
			RT	EUA	RT	EUA			Yes	No	NA	
2.1	Module Table of Contents								☐	☐	☐	
2.2	Background of the quality overall summary								☐	☐	☐	
2.3	Body data of quality overall summary								☐	☐	☐	
2.3.S	**Active pharmaceutical ingredients**								☐	☐	☐	
	2.3.S.1 General information								☐	☐	☐	
	2.3.S.2 Manufacture (Name and address of the manufacturer)		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	2.3.S.3 Characterization								☐	☐	☐	
	2.3.S.4 Control of active pharmaceutical ingredients								☐	☐	☐	
	2.3.S.5 Reference standards or materials								☐	☐	☐	
	2.3.S.6 Container closure system								☐	☐	☐	
	2.3.S.7 Stability								☐	☐	☐	

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Annexure – 13

FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 1, 2 and 3

Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
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Section	Documents		Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
				UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
				RT	EUA	RT	EUA			Yes	No	NA	
	2.3.P.4	Control of inactive pharmaceutical ingredient								☐	☐	☐	
	2.3.P.5	Control of pharmaceutical products								☐	☐	☐	
	2.3.P.6	Reference standards or materials								☐	☐	☐	
	2.3.P.7	Container closure system								☐	☐	☐	
	2.3.P.8	Stability								☐	☐	☐	
2.3.A		Appendices		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	2.3.A.1	Facilities and equipment								☐	☐	☐	
	2.3.A.2	Adventitious agent safety evaluation								☐	☐	☐	
	2.3.A.3	Novel excipients								☐	☐	☐	
	2.3.A.4	Regional information								☐	☐	☐	

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Annexure – 13

FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 1, 2 and 3

Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
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Module 3 – Quality (CMC Part)

Section	Documents		Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
				UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
				RT	EUA	RT	EUA			Yes	No	NA	
3.1	Module Table of contents									☐	☐	☐	
3.2	Body of data									☐	☐	☐	
3.2.S	Active pharmaceutical ingredients									☐	☐	☐	
3.2.S.1	General information									☐	☐	☐	
	3.2.S.1.1	Nomenclature								☐	☐	☐	
	3.2.S.1.2	Structure								☐	☐	☐	
	3.2.S.1.3	General properties								☐	☐	☐	
3.2.S.2	Manufacture									☐	☐	☐	
	3.2.S.2.1	Name and address of the manufacturer		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	3.2.S.2.2	Description of manufacturing process and process control								☐	☐	☐	
	3.2.S.2.3	Control of materials								☐	☐	☐	
	3.2.S.2.4	Control of critical steps and intermediates								☐	☐	☐	
	3.2.S.2.5	Process validation and/or evaluation								☐	☐	☐	
	3.2.S.2.6	Manufacturing process development								☐	☐	☐	
3.2.S.3	Characterization									☐	☐	☐	
	3.2.S.3.1	Elucidation of structure and other characteristics								☐	☐	☐	

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	FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 1, 2 and 3					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
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Section	Documents		Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
				UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
				RT	EUA	RT	EUA			Yes	No	NA	
3.2.S.3	3.2.S.3.2	Impurities								☐	☐	☐	
3.2.S.4	Control of active pharmaceutical ingredients									☐	☐	☐	
	3.2.S.4.1	Specifications								☐	☐	☐	
	3.2.S.4.2	Analytical procedures								☐	☐	☐	
	3.2.S.4.3	Validation of analytical procedures								☐	☐	☐	
	3.2.S.4.4	Batch analysis								☐	☐	☐	
	3.2.S.4.5	Justification for specifications		☐	☐	☐	☐	☐	☐	☐	☐	☐	
3.2.S.5	Reference standards or materials									☐	☐	☐	
3.2.S.6	Container closure system									☐	☐	☐	
3.2.S.7	Stability									☐	☐	☐	
	3.2.S.7.1	Stability summary and conclusions								☐	☐	☐	
	3.2.S.7.2	Post approval stability protocol and stability commitment								☐	☐	☐	
	3.2.S.7.3	Stability data								☐	☐	☐	
3.2.P	Pharmaceutical product									☐	☐	☐	
3.2.P.1	Description and composition of the pharmaceutical product									☐	☐	☐	

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10 NOV 2021

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				UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
				RT	EUA	RT	EUA			Yes	No	NA	
3.2.P.2	Pharmaceutical development									☐	☐	☐	
	3.2.P.2.1	Component of pharmaceutical product								☐	☐	☐	
		3.2.P.2.1.1 Active pharmaceutical substances								☐	☐	☐	
		3.2.P.2.1.2 Inactive pharmaceutical ingredients or excipients								☐	☐	☐	
	3.2.P.2.2	Final pharmaceutical product								☐	☐	☐	
		3.2.P.2.2.1 Formulation development								☐	☐	☐	
		3.2.P.2.2.2 Overages								☐	☐	☐	
		3.2.P.2.2.3 Physicochemical and biological properties								☐	☐	☐	
	3.2.P.2.3	Manufacturing process development								☐	☐	☐	
	3.2.P.2.4	Container closure system								☐	☐	☐	
	3.2.P.2.5	Microbiological attributes								☐	☐	☐	
	3.2.P.2.6	Compatibility								☐	☐	☐	
3.2.P.3	Manufacture									☐	☐	☐	
	3.2.P.3.1	Manufacturer								☐	☐	☐	
	3.2.P.3.2	Batch formula								☐	☐	☐	

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				UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
				RT	EUA	RT	EUA			Yes	No	NA	
3.2.P.3	3.2.P.3.3	Description of manufacturing process and process control								☐	☐	☐	
	3.2.P.3.4	Control of critical steps and intermediates								☐	☐	☐	
	3.2.P.3.5	Process validation and/or evaluation								☐	☐	☐	
3.2.P.4	Control of inactive pharmaceutical ingredients									☐	☐	☐	
	3.2.P.4.1	Specifications								☐	☐	☐	
	3.2.P.4.2	Analytical procedures								☐	☐	☐	
	3.2.P.4.3	Validation of analytical procedures								☐	☐	☐	
	3.2.P.4.4	Justifications for specifications		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	3.2.P.4.5	Excipients of human or animal origin								☐	☐	☐	
	3.2.P.4.6	Novel excipients								☐	☐	☐	
3.2.P.5	Control of pharmaceutical products									☐	☐	☐	
	3.2.P.5.1	Specifications								☐	☐	☐	
	3.2.P.5.2	Analytical procedures								☐	☐	☐	
	3.2.P.5.3	Validation of analytical procedures								☐	☐	☐	
	3.2.P.5.4	Batch analysis								☐	☐	☐	

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Section	Documents		Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
				UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
				RT	EUA	RT	EUA			Yes	No	NA	
3.2.P.5	3.2.P.5.5	Characterization of impurities		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	3.2.P.5.6	Justifications for specifications								☐	☐	☐	
3.2.P.6	Reference standards or materials									☐	☐	☐	
3.2.P.7	Container closure system									☐	☐	☐	
3.2.P.8	Stability									☐	☐	☐	
	3.2.P.8.1	Stability summary and conclusion								☐	☐	☐	
	3.2.P.8.2	Post-approval stability protocol and stability commitment								☐	☐	☐	
	3.2.P.8.3	Stability data								☐	☐	☐	
3.2.A	Appendices									☐	☐	☐	
	3.2.A.1	Facilities and equipment								☐	☐	☐	
	3.2.A.2	Adventitious agent safety evaluation								☐	☐	☐	
	3.2.A.3	Novel excipients								☐	☐	☐	
	3.2.A.4	Regional information								☐	☐	☐	

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Annexure – 13

	FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 1, 2 and 3					
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Assessment Completed on		**Total Duration**	
Assessment Summary		**Assessment Done By/Date**	
Recommendation		**Head of Vaccine & Biologics Sign/Date**	

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

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

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	FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 3 (Testing Part)					
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APPLICATION ASSESSMENT CHECKLIST (ICH CTD – UPA AND IPA)

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

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 document is not an accurate reflection of the original document. The acceptance of the application after screening including assessment does not preclude requests by DGDA for additional documents or changes to the information/documents during evaluation. 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 ☐ indicate that the documents shown are not required for the selected application type and evaluation route.

Legend:

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

Product Name:

Application Date:

10 NOV 2021

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FORM Title: Application Assessment Checklist for ICH CTD Dossier Module 3 (Testing Part)

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Module 3 – Laboratory Testing Part

Assessment Started on:

Section	Documents		Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
				UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
				RT	EUA	RT	EUA			Yes	No	NA	
3.2.P.4	Control of inactive pharmaceutical ingredients									☐	☐	☐	
	3.2.P.4.1	Specifications								☐	☐	☐	
	3.2.P.4.2	Analytical procedures								☐	☐	☐	
	3.2.P.4.3	Validation of analytical procedures								☐	☐	☐	
	3.2.P.4.4	Justifications for specifications								☐	☐	☐	
	3.2.P.4.5	Novel excipients								☐	☐	☐	
3.2.P.5	Control of pharmaceutical products			☐	☐	☐	☐	☐	☐	☐	☐	☐	
	3.2.P.5.1	Specifications								☐	☐	☐	
	3.2.P.5.2	Analytical procedures								☐	☐	☐	
	3.2.P.5.3	Validation of analytical procedures								☐	☐	☐	
	3.2.P.5.4	Batch analysis								☐	☐	☐	
	3.2.P.5.5	Characterization of impurities								☐	☐	☐	
	3.2.P.5.6	Justifications for specifications								☐	☐	☐	
3.2.P.6	Reference standards or materials									☐	☐	☐	

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Section	Documents		Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
				UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
				RT	EUA	RT	EUA			Yes	No	NA	
3.2.P.7	Stability			☐	☐	☐	☐	☐	☐	☐	☐	☐	
	3.2.P.8.1	Stability summary and conclusion								☐	☐	☐	
	3.2.P.8.2	Post-approval stability protocol and stability commitment								☐	☐	☐	
	3.2.P.8.3	Stability data								☐	☐	☐	

Assessment Completed on		**Total Duration**	
Assessment Summary		**Assessment Done By/Date**	
Recommendation		**Head of Vaccine & Biologics Sign/Date**	

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

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

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APPLICATION ASSESSMENT CHECKLIST (ICH CTD – UPA AND IPA)

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 submitted and original hard copies of documents are not required.

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

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

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- Cells without ☐ indicate that the documents shown are not required for the selected application type and evaluation route.

Legend:

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

Product Name:

Application Date:

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Module 4 – Non-clinical Study Reports

Assessment Started on:

Section	Documents			Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
					UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
					RT	EUA	RT	EUA			Yes	No	NA	
4.1	Module 4 Table of Contents										☐	☐	☐	
4.2	Study Reports										☐	☐	☐	
	4.2.1	Pharmacology									☐	☐	☐	
		4.2.1.1	Primary Pharmacodynamics								☐	☐	☐	
		4.2.1.2	Secondary Pharmacodynamics								☐	☐	☐	
		4.2.1.3	Safety Pharmacology								☐	☐	☐	
		4.2.1.4	Pharmacodynamic Drug Interactions								☐	☐	☐	
	4.2.2	Pharmacokinetics									☐	☐	☐	
		4.2.2.1	Analytical Methods and Validation Reports								☐	☐	☐	
		4.2.2.2	Absorption								☐	☐	☐	
		4.2.2.3	Distribution								☐	☐	☐	
		4.2.2.4	Metabolism								☐	☐	☐	
		4.2.2.5	Excretion								☐	☐	☐	
		4.2.2.6	Pharmacokinetic Drug Interactions (non-clinical)								☐	☐	☐	

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Section	Documents			Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
					UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
					RT	EUA	RT	EUA			Yes	No	NA	
4.2		4.2.2.7	Other Pharmacokinetic Studies		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	4.2.3	Toxicology									☐	☐	☐	
		4.2.3.1	Single-Dose Toxicity								☐	☐	☐	
		4.2.3.2	Repeat-Dose Toxicity								☐	☐	☐	
		4.2.3.3	Genotoxicity								☐	☐	☐	
		4.2.3.4	Carcinogenicity								☐	☐	☐	
		4.2.3.5	Reproductive and Developmental Toxicity								☐	☐	☐	
		4.2.3.6	Local Tolerance								☐	☐	☐	
		4.2.3.7	Other Toxicity Studies								☐	☐	☐	
4.3	List of Literature References										☐	☐	☐	

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Module 5 – Clinical Study Reports

Section	Documents	Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
			UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
			RT	EUA	RT	EUA			Yes	No	NA	
5.1	Module 5 Table of Contents								☐	☐	☐	
5.2	Tabular Listings of All Clinical Studies								☐	☐	☐	
5.3	Clinical Study Reports								☐	☐	☐	
	5.3.1 Reports of Biopharmaceutic Studies ▪ For EUA, information on the comparability between clinical trial (pivotal studies) and commercial formulations should be available in the Clinical Overview/Summary. If the commercial formulation for the Bangladesh market differs from the clinical trial formulation used in the pivotal studies, the final study report(s) of biopharmaceutic studies to establish bioequivalence between the commercial product formulation and the clinical trial formulation used in pivotal studies should be submitted. ▪ For RT, all biopharmaceutic study reports are required.		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	5.3.2 Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials								☐	☐	☐	
	5.3.3 Reports of Pharmacokinetic (PK) Studies								☐	☐	☐	

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Section		Documents	Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
				UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
				RT	EUA	RT	EUA			Yes	No	NA	
5.3	5.3.4	Reports of Pharmacodynamic (PD) Studies		☐	☐	☐	☐	☐	☐	☐	☐	☐	
	5.3.5	Reports of Efficacy and Safety Studies								☐	☐	☐	
		▪ For RT, study reports of ALL clinical trials (including the appendices and tables) should be submitted.								☐	☐	☐	
		▪ For EUA, study reports of pivotal or relevant clinical trials should be submitted (appendices and tables are required only upon request by DGDA).								☐	☐	☐	
		▪ 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.								☐	☐	☐	
		▪ 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).								☐	☐	☐	

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Section	Documents		Submitted By (Sign & Seal)	Application Type & Evaluation Route						DGDA Screening			DGDA Assessment
				UPA		IPA		IND	IMP	Submitted?			Assessment Outcome
				RT	EUA	RT	EUA			Yes	No	NA	
5.3	5.3.5	▪ 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.		☐	☐	☐	☐	☐	☐	☐	☐	☐	
		▪ Phase III, confirmatory, randomised, controlled pivotal trials conducted in compliance with Good Clinical Practice (GCP) are required to support each requested indication and dosing regimen, unless adequately justified. Active-controlled studies should use relevant active comparators that are locally registered, unless adequately justified.								☐	☐	☐	
	5.3.6	Reports of Post-marketing Experience								☐	☐	☐	
	5.3.7	Case Report Forms and Individual Patient Listings (required upon request by DGDA)								☐	☐	☐	
5.4	List of Key Literature References									☐	☐	☐	
5.5	Risk management plan (RMP) documents as separate attachment.									☐	☐	☐	
5.6	Other Supporting Documents									☐	☐	☐	

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Assessment Completed on		**Total Duration**	
Assessment Summary		**Assessment Done By/Date**	
Recommendation		**Head of Vaccine & Biologics Sign/Date**	

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

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

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MINISTRY OF HEALTH AND FAMILY WELFARE