

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

Authorized Personnel Only

Annexure-4						
	Title: COVER SHEET (to be completed by the sponsor)					
Form No.	Revision No.	Effective Date	Review Date	Approved by	Date	Page No.
NRA-CT-002/F04	02	JUN' 24	JUN' 29		19.06.24	01 of 01

IMPORTATION AND RELEASE OF INVESTIGATIONAL MEDICINAL PRODUCTS	
Fees (if applicable)	
Study title and phase of the study	
Protocol Number	
Study Drug	
Name of the GMP certificate issued NRA	
Unique code number	
NDA approval number of clinical trial/IND No	
NDA reference number(s) of comparator drug(s) (if applicable)	
NDA reference number(s) of concomitant drug(s) (if applicable)	
Sponsor	
Applicant	
Trial site(s)	
Sponsor Contact Person: Address Telephone number Fax number Cell number E-mail address	
Batch number(s) and expiry date: Study drug Comparator drug(s)	
Quantities	
Blinding done or not	
Recommended storage temperature	

	Submitted by (Sponsor)	Reviewed by (DGDA)	Approved/Authorized by (DGDA)
NAME			
DESIGNATION			
SIGN & DATE			

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Annexure-6						
	Title: Application Form of Import of IMPs/ Placebo					
Form No.	Revision No.	Effective Date	Review Date	Approved by	Date	Page No.
NRA-CT-002 /F06	02	JUN' 18	JUN' 29		19.06.24	01 of 01

To
Director General
Directorate General of Drug Administration

Attention: Head of Clinical Trial Cell

Subject: Application of bringing IMPs for NOC application.

In reference to approved entitled "....." and protocol approval letter no....., I hereby apply to bring IMPs/placebo. Required treasury chalan/ bank draft copy and relevant documents have been duly filled and attached herewith. It is to be noted that study of PI, sponsor....., study site/sites

Thanking you,

Name:

designation:

Address:

Signature

Date:

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Annexure-7						
	Title: Checklist for NOC for IMPs					
Form No.	Revision No.	Effective Date	Review Date	Approved by	Date	Page No.
NRA-CT-002 /F07	02	JUN' 18	JUN' 29		19.06.24	01 of 01

Checklist for NOC for IMPs:

- 1) GMP Certificate
- 2) Certificate of analysis
- 3) IND certificate of IND product from country of origin
- 4) Protocol approval letter
- 5) Name of PI, sponsor, trial site in application for NOC
- 6) NOC fees