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

Authorized Personnel Only

Annexure – 11

FORM Title: Checklist for Permission to Start Preclinical Study

Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
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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		

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

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Issue date: