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

Authorized Personnel Only

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)		

DIRECTORATE GENERAL OF DRUG ADMINISTRATION (DGDA) 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 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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Issue date: 10 NOV 2021