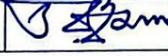


**DIRECTORATE GENERAL OF DRUG ADMINISTRATION**  
**MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH**

*Authorized Personnel Only*

Annexure-8						
	<b>FORM Title: Checklist for Source Validation Document Review</b>					
Form No.	Version No.	Effective Date	Review Date	Approved by	Date	Page No.
NRA-MA-013/F08-02	06	JAN' 25	JAN' 29		10.12.24	01 of 01

Sl No	Content	Submitted	Remarks
<b>Module - 1</b>			
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)		
9	Manufacturing companies have to submit certifications registered from their local drug regulatory authorities in terms of their drug substances or drug products.		
10	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.		
<b>Module-2</b>			
11	Summary of M-3,4,5		
<b>Module - 3</b>			
12	CMC data of biological/biosimilar API		
<b>Module-4</b>			
13	Authenticated pre-clinical completed study report		
<b>Module-5</b>			
14	Authenticated Clinical completed study report and copy of clinical trial protocol approved by Drug regulatory authority		