

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



Authorized Personnel Only

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Issue date: 27 NOV 2021

**Annexure-4**

**FORM Title: Checklist for Renewal of MA and Assessment**

Form No. NRA-MA-017/F04-01	Version No. 00	Effective Date DEC' 21	Review Date DEC' 26	Authorized by <i>[Signature]</i>	Date 22.11.2021
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Assessment Started on:

Section	Documents	Documents Availability			Submitted?			Assessment Outcome
		Yes		No		NA		
		Yes	No	Yes	No	Yes	No	
1.	Annual Product Quality Review (APQR) report for last 01 year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	DGDA Screening
2.	Summary of Periodic Safety Update Report (PSUR) for last 01 year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.	GMP certificate of Country of origin for manufacturer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.	Summary of AEFI/ADR reports for last 01 year (if available)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.	Summary of all market complaint reports or recall for last 01 year (if applicable)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.	Real time stability data of finished product for last 01 year (Ongoing)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7.	Summary of post market variation for last 05 years (if applicable)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8.	Latest version of SmPC (if revised)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Assessment Completed on		Total Duration						

Assessment Summary	Assessment Done By/Date
Recommendation of Head of Vaccine and Biologics	Head of Vaccine & Biologics Sign/Date