

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

Authorized Personnel Only

Annexure-2						
	FORM TITLE: Application Form of the Registration of APIs / Drug substance (which are not Included as monographs)					
Form No.	Version No.	Effective Date	Review Date	Approved by	Date	Page No.
NRA-MA-027/F2-00	00	OCT'2024	OCT'2029		20.10.24	01 of 02

Application Form of the Registration of APIs / Drug Substances (which are not Included as monographs in BP/BPC/USP-NF/Int,Ph.or are not Introduced In Bangladesh)

1. Name and address of the Manufacturer of the API / Drug Substance:
2. Manufacturing License Number (for locally manufactured APIs / Drug Substances):
 - (a) Biological:
 - (b) Non-Biological:
3. Name of the API / Drug Substance:
 - (a) Generic name (use INN name if included in INN List)
4. Key starting materials/key intermediates:
 - (a) Name of the Manufacturer
 - (b) Characterization of Key starting materials/key intermediates
 - (c) Control data of Key starting material/key intermediate
 - (g) Certificate of Analysis
5. General Raw materials:
 - (a) Name of General Raw materials (should be mentioned by chemical names) but may be followed by brand name, if desired)
 - (b) Control Data of general raw materials.
 - (c) Function of each general raw material
6. Chemical Reference Standards:
 - (a) Name of the Standards
 - (b) Name of the Manufacturer
 - (c) Source of the CRS
 - (d) Certificate of Analysis



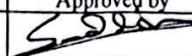
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Issued by: 

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

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7. Product Development:

- (a) Protocol of Product Development
- (b) Accelerated Stability Study Data
- (c) Process Validation Status
- (d) Analytical Method Validation /Verification Data

8. Real Time Stability Data:

9. Therapeutic Class & Use

10. Technical Data:

- (a) Composition/Formula
- (b) Manufacturing Instructions
- (c) Control data for Finished API
- (e) Proposed shelf life (must be expressed on Finished Product in the form of manufacturing Dato and Expiry Dato)

11. (a) Number of manufacturer/importer already manufacturing/importing the product in Bangladesh; and

- (b) Estimated market of this product n Bangladesh.

13. (a) Proposed Maximum Retail Price (MRP) or Indicative Price

14. For locally manufactured APIs / Drug Substances:

Particulars of (a) Factory manager (b) Quality Assurance manager (c) Production manager (d) Quality Control manager. (Full name, Qualifications, Date of Joining in the applicant's company, Total experience in the pharmaceutical industries, Registration Number and Signature).

15. Date of submission:

16. Additional information (if any):

Please Note:

- i. Information supplied if found wrong will lead to immediate cancellation of registration of the product.
- ii. Registration will be given as conditional subject to submission APIMF/DMF/ASMF (Annexure 5 & 7 as relevant) including 6 months accelerated and real time stability data



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ADMINISTRATION (DGDA)**
MINISTRY OF HEALTH AND FAMILY WELFARE,
BANGLADESH



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