

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

Authorized Personnel Only

Annexure-1						
	FORM TITLE: Application Form for the Registration APIs/Drug Substances					
Form No.	Version No.	Effective Date	Review Date	Approved by	Date	Page No.
NRA-MA-027/F1-00	00	OCT'2024	OCT'2029		20.10.2024	01 of 02

Application Form for the Registration of APIs / Drug Substances

Application Form for the Registration of APIs / Drug Substances (which are included as monographs in BP/BPC/USP-NF/Int.Ph. or are already 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. Therapeutic class and Use
5. Technical Data:
 - (a) Composition/Formula
 - (b) Manufacturing Instruction
 - (c) Control Data for the Key starting materials/key intermediates
 - (d) Control data for General Raw Materials
 - (e) Control data for Finished API
 - (f) Stability data (if not done, then to be submitted at the time of inclusion)
 - (g) Proposed shelf life (must be expressed on Finished Product in the form of Manufacturing Dat and Expiry Date).

Note: 1. Raw materials should be mentioned by chemical names.

6. (a) Number of manufacturer/importer already manufacturing/importing the product in Bangladesh; and
(b) Estimated market of this product Bangladesh.
7. Proposed Maximum Retail Price (MRP) or Indicative Price
8. For locally manufactured APIs / Drug Substances:
Particulars of Quality Control manager/Quality Assurance Manager and Factory/Production manager.
Full name, Qualifications, Date of Joining in the applicant's company; Total experience in the pharmaceutical industries, Registration Number and Signatures.
9. Date of submission:
11. Additional Information (If any):

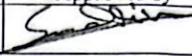


Issued by: 

Issue date: 22 OCT 2024

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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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Issue date:

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