Form DA-2/88

Application Form of the Registration of Drugs (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 Drug:

2. Manufacturing Licence Number (for locally manufactured drugs):
   (a) Biological:
   (b) Non-Biological:

3. Name of the Drug:
   (a) Generic name (use INN name if included in INN List)
   (b) Name under which the Drug is proposed to be sold.

4. Product Data Sheet
   (Including Presentation, Uses, Dosage & Administration, Contra-indication, Use in pregnancy and lactation, Side-effects, Precautions, Warning, Drug Interaction, Absorption, Fate, Distribution, Exrertion, Elimination, Package Quantities, etc.)

5. Technical Data:
   (a) Composition/Formula;
   (b) Manufacturing Instruction;
   (c) Control Data for the Active Constituents;
   (d) Pharmacopoeial References or Control Data for other constituents;
   (e) Control data for Finished Product;
   (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 Data and Expiry Date).

Note :
1. Excipients should always be mentioned in generic/chemical name; but may be followed by brand name, if desired.
2. Overage to be shown separately in Composition/Formula, eg., 2.5% for antibiotics Capsule/Tablet, 5% for antibiotics Dry syrup/Injection, 10% for Vitamins, etc.
3. Capsule size to be mentioned by number; name/Monogram should be printed on capsule or engraved in tablet.
4. Coating material should be shown separately.

6. Pharmacological data:
   (a) Human Pharmacokinetics and metabolism;
   (b) Studies related to intended therapeutic activity;
   (c) Studies related to secondary pharmacological activity;
   (d) Drug interaction studies.

7. Toxicological Data :
   (a) Acute, sub-acute and chromic toxicity studies in animals;
   (b) Mutagenicity studies;
   (c) Studies on reproduction and teratogenicity;
   (d) Other studies.

8. Clinical Data:
   (a) Design and result of phase I and phase II clinical trials (mention name and address of investigators);
   (b) Studies on side-effects/adverse reactions in human subjects;
   (c) Reprints of publications on clinical and pharmacological studies.

9. (a) Number of manufacturer/importer already manufacturing/importing the product in Bangladesh;
   and
   (b) Estimated market of this product/product group in Bangladesh.

10. (a) Proposed Maximum Retail Price (MRP); and
    (b) Estimated Price-per dose; per day treatment; cost for the recommended course of treatment.

11. For locally manufactured drugs :
    Particulars of quality Control 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 Signature.

13. In case of imported drugs, the following additional information are to be provided
    (a) Name and address of the Indentor/or Manufacturer's authorised agent.
    (b) Registration status in the country of origin (including Free Sale Certificate)
    (c) Registration status in other countries (include Sale Certificates from atleast 2 other development countries)
    (d) Signature of the Indentor/or Manufacturer's authorised agent.

14. Date of submission :

15. Additional information (if any) :

Please Note : Information supplied if found wrong will lead to immediate cancellation of registration of the product.