

FORM 5-E
[See rule 26 (1)]

APPLICATION FORM FOR THE REGISTRATION TO MANUFACTURE A
PATENTED DRUG

I / We of
hereby apply for registration of the drug, namely
details of which are enclosed.

Date
Place

Signed

ENCLOSURES OF THE APPLICATION FOR REGISTRATION OF A PATENTED
DRUG

Dosage Form: -----

- 1 - Name and address of the manufacturer (applicant).
- 2 - Name of the drug.
- 3- Chemical name(s) and , as appropriate and available, the established (generic) and synonyms, Chemical Abstracts Service (CAS) registry number and code number.
- 4- *Structural formula.* - Provide the chemical structure (including stereochemistry, where applicable), molecular formula, and molecular weight.
- 5- *Physical and chemical characteristics.*- Describe physiochemical characteristics including, where applicable, such information and description regarding solid- state form, solubility profile, melting point, pH, specific rotation, refractive index, etc.
- 6- *Elucidation of structure.*- Supply physical and chemical data collected to elucidate and confirm the chemical structure of the drug substance.
- 7- *Stability.*- Describe fully the studies on the stability of the new drug substance and include the results. Reference to stability, information from prior studies or from the

literature may be used to meet some or all of these requirements. Also, include information showing the stability, indicating analytical methods used therein.

8- *Manufacturer(s)*.- Provide the name and address of each facility, besides the applicant, that participates in manufacturing the drug substance (e.g., performs the synthesis, isolation, purification, testing, packaging or labeling). Describe the operation(s) that each will perform.

9- *Method(s)*.- of Manufacture and Packaging- Provide a full description of the materials and method(s) used in the synthesis, isolation and purification of the drug substance. This description should include a list of starting materials, reagents, solvents, and auxiliary materials with specifications or a statement of the quality of each. The description should include a diagrammatic flow chart of the synthesis and a detailed description of each step. Any alternate methods or variations in the synthesis should be included with an explanation of the circumstances under which they would be used. If the drug substance is prepared by fermentation or by extraction from natural sources (plant or animal), provide a full description of the process.

10- Strength of active ingredient(s) per unit, e.g. each tablet or 5 ml, etc. contains.

11-Pharmacological group.

12-In case of International availability, provide the following information, namely: -

- a. name of the drug;
- b. country where sold / registered; and
- c. name of company selling the drug or having registration to manufacture(including supporting documents).

15-Proposed route of administration.

16- Composition (actives & excipients) including statement of the quantitative composition, giving the weight or measure for each active substance used in the manufacture of the dosage form.

17- Detailed method of manufacture & packaging.

18- Name of equipments that will be used in the manufacture of the applied drug.

		cGMP	Compliant
1. _____	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
2. _____	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
3. _____	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
4. _____	Yes	<input type="checkbox"/>	No <input type="checkbox"/>

19-Persons under whose direct supervision and control the applied drug shall be manufactured with the following details, namely:-

- a. total number of technical staff; and
- b. name, qualification and designation of the persons directly supervising the manufacture of the drug applied for registration and any change shall be properly documented and record maintained by the manufacturer.

20- Name, qualification and designation of the persons who will be responsible for the quality control of the drug.

21- Description of the equipment to be used for the quality control of the active raw material and the finished products.

22- A full description of the specifications and analytical methods necessary to assure the identity, strength, quality, purity and homogeneity through out the shelf life of the drug product.

23-Labeling and prescribing information (to be mentioned on the pack/leaflet) specimen or draft shall be submitted.

24-Patent number & country where the first patent was applied for & granted (attach a certified copy of the Letter of Patent).

25- Patent number and date of grant of Patent in Pakistan (attach a certified copy of the Letter of Patent).

26-Expiry date of Patent in Pakistan.

27-Proposed shelf life of the drug.

28-Complete batch formula .

29-Proposed dosage.

30- Attach the last Inspection Report conducted by the Ministry of Health.

31. Clinical data (along with data of clinical trials conducted and safety data of the drug, with reported side effects and adverse drug reactions in the indigenous community).

32. Clinical justification.

33. Dosage form stability profile.

34-Any other relevant information that may be required by the Board.

UNDERTAKING

I / We hereby undertake that the above given information is true and correct to the best of my / our knowledge and belief.

Production Manager

Quality Control Manager.