

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

APPLICATION FORM FOR REGISTRATION OF AN IMPORTED DRUG

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

Date Signed
Place

ENCLOSURES OF THE APPLICATION FOR REGISTRATION OF AN IMPORTED DRUG

Dosage Form:-----

- 1- Name and address of the indentor or agent.
- 2- Name and address of manufacturer of the drug.
- 3- Brand (Proprietary) name of the drug.
- 4- The chemical name(s) and , as appropriate and available, the established (generic) and synonyms of the drug.
- 5- Strength of active ingredient(s) per unit, e.g., each tablet or 5ml, etc. contains.
- 6- Country from where the drug is proposed to be imported.
- 7- The names of the countries, other than Pakistan, wherever the drug is registered and sold. Specify the brand name(s), if other than the brand name applied for.
(Free sale certificate of country of import to be attached.)
- 8- Pharmacological group.
- 9- Proposed route of administration.
- 10- Composition (actives & excepients) including statement of the quantitative composition, giving the weight or measure for each active substance used in the manufacture of the dosage form.
- 11- Recommended clinical use.
- 12- Out line of method of manufacture.
- 13- 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.

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

15- Proposed dosage.

16- Proposed shelf life of the drug.

17- Unit price of the drug, e.g. per tablet, per capsule, per 5ml, etc.

18- Proposed storage conditions of the finished product.

19- Persons under whose direct supervision and control the drug applied for registration 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, and any change shall be properly documented and recorded and maintained by the manufacturer.

20- 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"/>

21- Production capacity of the manufacturer per shift for the drug applied.

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

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

24- Facility of the water processing, with specifications.

25- Environment control processing with details.

26- Attach the last Inspection Report conducted by the concerned Regulatory Authorities.

27- 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).

28. Clinical justification.
29. Dosage form stability profile.
- 30-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.

Signature of the authorized importer