FORM 5

[See rule 26(1)]

APPLICATION FOR REGISTRATION OF A DRUG FOR LOCAL MANUFACTURE

having the same active ingredient or salt thereof, therapeutic use, dosage form and route of administration that has already been approved by the ministry of health, already on sale in local and/or international market.

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 A DRUG FOR LOCAL MANUFACTURE

Dosage Form: ----------

1- Name and address of the manufacturer (applicant):
2- Brand (Proprietary) name of Drug.
3- The chemical name(s) and, as appropriate and available the established (generic) names and synonyms of the drug.
4- Strength of active ingredient(s) per unit, e.g. each tablet or 5 ml, etc. contains.
5- Pharmacological group.
6- Recommended clinical use.
7- Proposed route of administration.
8- Proposed dosage.
9- Proposed shelf life of the drug.
10- Proposed storage conditions of finished product.
11- Unit price of the drug, e.g. per tablet, per capsule, per 5ml, etc.
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 (include supporting documents/proof of International registration.

13- Brand name(s) of drug available in Pakistan.

14- Name(s) of company(s) manufacturing in Pakistan.

15- 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.

16- Outline of method of manufacture.

17- Persons under whose direct supervision and control the drug is 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.

18- Name of equipments that will be used in the manufacture of the drug applied for registration:

		cGMP Compliant	
1.	_____	Yes ☐	No ☐
2.	_____	Yes ☐	No ☐
3.	_____	Yes ☐	No ☐
4.	_____	Yes ☐	No7 ☐

19- Full descriptions 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.

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- Labeling and prescribing information (to be mentioned on the pack/leaflet) specimen or draft shall be submitted for the following class as of drugs, namely:-

a. C.N.S. stimulants;
b. drugs affecting uterine motility;
c. drugs inhibiting hormonal production;
d. hormones and other steroidal preparation excluding preparations for external and topical use;
e. narcotic drugs as per Single Convention on Narcotic Drugs 1961; and
f. psychotropic substances mentioned as per convention on psychotropic substances, 1971.

(Specimen of label to be submitted as soon as production starts)

23- Facility of water processing with specifications.

24- Environment control processing with details.

25- Type of container/packaging.

26- A copy of last Inspection Report conducted by the Ministry of Health.

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**";