

Government of Pakistan
Ministry of Health

Islamabad, the 25th June, 2005

NOTIFICATION

S.R.O. 662 (I)/2005.- In exercise of the powers conferred by section 43 of the Drugs Act, 1976 (XXXI of 1976), the Federal Government is pleased to direct that the following further amendments shall be made in the Drugs (Licensing, Registering and Advertising) Rules, 1976, the same having been previously published as required by sub-section (3) of the said section, namely:-

In the aforesaid Rules, -

- (1) in rule 2, clause(a) shall be relettered as clause (aa) and before clause (aa) relettered as aforesaid, the following new clause shall be inserted, namely:-
“(a) “ Act” means the Drugs Act, 1976 (XXXI of 1976);
- (2) in rule 8,-
 - (a) in sub-rule (3), for the word “re-nomination” the words “nomination for a maximum of two consecutive terms” shall be substituted; and
 - (b) in sub-rule (5),-
 - (i) for the word “important” the word “urgent” shall be substituted; and
 - (ii) after the word “meeting” the words and comma “within a period of fifteen days,” shall be inserted;
- (3) in rule 10,-
 - (a) in sub-rule (2), after the word “inspection” ,at the end, the words “within a period of fifteen days” shall be added; and

(b) in sub-rule (4), after the word “issued”, at the end, the words and comma “within a period of thirty days,” shall be added;

(4) in rule 11, in sub-rule (2), at the end, the words and comma “However, all in process control protocols and required facilities shall be provided.” shall be added;

(5) in rule 12,

(a) in sub-rule (1), -

(i) the words “or fails to deposit the requisite amount of the Central Research Fund due from him” shall be omitted; and

(ii) for the full stop, at the end, a colon shall be substituted and thereafter the following proviso shall be added, namely:-

“Provided that in case of non-deposition of Central Research Fund, the manufacturing license may be suspended till the settlement of the Fund.” ;
and

(b) in sub-rule (2), after the comma “;”, occurring for the second time, the words “conduct an inquiry into the case and” shall be inserted;

(6) in rule 13, -

(a) the words “or otherwise reject the application and inform the licensee accordingly” shall be omitted; and

(b) after the full stop at the end, a colon shall be substituted and thereafter the following proviso shall be added, namely:-

“Provided that if directed by the Central Licensing Board, the licensee shall rectify the observations made during the inspection within a period which shall not be less than one month and more than three months from the date of receipt of orders in this regard and during this period the manufacturing in that particular area or the premises, as the case may be, shall remain suspended and, until after re-inspection the Board grants renewal of license, or otherwise rejects the application and inform the licensee accordingly.” ;

(7) rule 14 shall be omitted;

(8) in rule 15, in sub-rule (1),-

(a) in clause (c),-

(i) for the words and comma “, medicine, science with chemistry and chemical engineering” the words and commas “or chemical engineering or a masters degree in chemistry, with at least two years experience in basic or semi basic manufacturing,” shall be substituted;

(ii) for the word “ Ordinance” the word “Act” shall be substituted; and the commas and words “, and shall possess qualifications and experience which, in the opinion of the Central Licensing Board, is appropriate and adequate for the manufacture and handling of the drug to be, or being, manufactured” shall be omitted;

(b) in clause (d), after the word “manufacture” at the end, the words “and all in process control protocols and the required facilities shall be provided” shall be added; and

(c) in clause (e),-

(i) for the commas and words “, or a degree in science with chemistry, or a degree in medicine, microbiology, pharmacology or bacteriology” the words and commas “or chemical engineering or a masters degree in chemistry, with at least two years’ experience in basic or semi-basic manufacturing,” shall be substituted;

(ii) the words and semicolon “as the Central Licensing Board may deem fit for any particular unit;” shall be omitted; and

(iii) for the full stop at the end, a colon shall be substituted and thereafter the following proviso shall be added, namely:-

“Provided that for the testing of specialized products, relevant technical staff possessing a masters degree in microbiology or bacteriology shall be appointed.”.

(9) in rule 16,-

(1) in clause (c),-

(a) after the word “person” the words “being the production incharge” shall be inserted;

(b) in sub-clause (ii),-

(i) after the word “a”, occurring for the first time, the word “masters” shall be inserted; and

(ii).the words and commas “, for the time being, is working as incharge of licensed pharmaceutical manufacturing unit,” shall be omitted; and

(c) in sub clause (iii), for the third proviso at the end, the following shall be substituted, namely:-

“Provided that if a firm has more than one section, the manufacture shall be conducted under the active directions and personal supervision of competent technical staff which shall be at least one for each section and who shall be a whole-time employee with sufficient experience.” ; and

(2) in clause (e),-

(a) before the word “degree”, occurring for the second time, the word “masters” shall be inserted; and

(b) in the proviso, for the full stop, at the end a colon shall be substituted and thereafter the following further proviso should be added, namely.-

“Provided further that there shall be a separate incharge for the in-process control of the drugs being manufactured who shall possess a degree in pharmacy or a masters degree in chemistry, with sufficient experience.”;

(10) in rule 18, in clause (c), for the full stop the end, a semicolon and word “; and” shall be added and thereafter the following new clause shall be added, namely:-

“(d) all in process control protocols and required facilities shall be provided.”;

(11) in rule 19,-

(a) in sub-rule (11), after the word “directs” the words “in writing with reasons to be recorded therein after providing an opportunity of being heard” shall be inserted; and

(b) in sub-rule (13), for the word “sold” the words “stored at the licensed premises” shall be substituted;

(12) in rule 20, in clause (b),-

(a) for the words “two years ” the words “one year” shall be substituted; and

(b) the words and commas “and, in the case of other substances, for a period of five years from the date of manufacture” shall be omitted;

(13) in rule 24,-

(a) in sub-rule (2), after the word “Act” the words “for evaluation and report which shall be submitted before the date of the next meeting” shall be added;

(b) in sub-rule (3), after the word “case” the words “for the registration of a new drug molecule” shall be inserted;

(c) in sub-rule (5), after the word “Board” the words “or a person authorized on this behalf” shall be inserted; and

(d) after sub-rule (6), the following new sub-rules shall be added, namely:-

“(7) The registration letter along with per unit price be issued within sixty days of the decision taken by the Board.

(8).All policy decisions taken by the Registration Board in public domain shall be available on the Internet/Ministry of Health web site.

(9) Registration Board shall meet at least once in every month preferably in the last week of the month.

(10) A tentative schedule of meeting giving dates for each month for the complete calendar year shall be displayed on the official web site in the first week of January each year.

(11) All applications for the registration of the drug having the same active ingredient or salt thereof, therapeutic use, dosage form and route of administration that has already been approved by the Registration Board, which has not been withdrawn from sale for reasons of safety or effectiveness, received thirty days prior to the scheduled date of meeting, shall be included in the agenda of the meeting which be considered and decided upon in the same meeting.

(12) The agenda for a meeting shall be circulated to the members at least seven days prior to the meeting.

(13) In deciding applications for registration, first priority shall be given to the newly licensed units and their applications shall be decided in the first instance:

Provided, that for the registration of drugs containing psychotropic, narcotic and corticosteroids, a separate methodology for evaluation and registration shall be adopted as the Registration Board may deem fit.

(14) Prices of the drugs already registered 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 and have not been withdrawn from sale, for reasons of safety

or effectiveness, shall be granted on the basis of the ceiling prices already approved by the Government of Pakistan.

(15) The ceiling prices shall be made available on the Internet/ Ministry of Health web site.” ;

(14) in rule 26,-

(a) for sub-rule (1) the following shall be substituted, namely.-

“(1) An application for registration of a drug for the local manufacture of a drug substance having the same active ingredient or salt thereof, therapeutic use, dosage form and route of administration that has already been approved by the Registration Board and has not been withdrawn from sale for reasons of safety or effectiveness, shall be made in Form 5, for imported drugs on Form 5-(A), for new drug molecule on Form 5D for a new drug molecule having valid patent within Pakistan on Form 5-E and an electronic copy shall also be provided in the form of a CD in the Microsoft Word format in duplicate to the Registration Board addressed to its Secretary, and separate application shall be made for each drug.;

(b)in sub-rule (2), for the word “drug” the words “new drug molecule” shall be substituted;

(c) sub-rule (3) shall be omitted ; and

(d) sub-rule (4) shall be omitted ;

(15) in rule 27,-

(a) in the first proviso, after the word “years” at the end, the words “and a certificate to this effect shall be issued within one month” shall be added; and

(b) for the second proviso the following shall be substituted, namely:-

“provided further that in case of an imported drug, the renewal may be granted and a renewal certificated shall be issued, if in the opinion of the Registration Board it is necessary to do so in the public interest.”;

(16) in rule 29,-

(a) in sub-rule (1),-

(i) after the word “necessary” the words “in case of a new drug molecule” shall be inserted; and

(ii) for the full stop, at the end, a colon shall be substituted and thereafter the following proviso shall be added, namely.-

“ Provided that in case of a drug product 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 which has not been withdrawn from sale, for reasons of safety or effectiveness, the provision of the inspection report conducted within last twelve months, along with the application for registration shall be sufficient for evaluation.”;

(b) in sub-rule (5A),-

(i) after the word “drug” occurring for the first time, the words “ or molecule” shall be inserted; and ,

(ii) after the word “drug”, at the end , the words “or molecule “ shall be added;

(c) in sub-rule (6), after the word “drug”, occurring twice, the words “ or molecule” shall be inserted;

(d) in sub-rule (7), after the word “drug” the words “ or molecule with a slight change in chemical formula /salt with the same therapeutic indications as of the already registered molecule” shall be inserted; and

(e) in sub-rule (9), after the word “writing”, at the end , the words “within a period not exceeding thirty days” shall be added;

(17) in rule 30, after sub-rule (14), the following new sub-rules shall be added, namely.-

“(14) For a change in pack size of oral drugs, no prior approval shall be required.

(15) For any change in the quantity of the exceptient(s) except for those exceptient(s) in which a duty drawback is claimed, no prior permission shall be required, whereas, in case of any addition, deletion or substitution of exceptient (s), it shall be sufficient to inform an authorized officer of the Ministry of Health along with stability data and technical information in writing for which acknowledgement shall be obtained for record.”; and

(18) in schedule A-

(a) for Form 5, the following shall be substituted, namely:

“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 & excipients) 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	
		Yes	No
1.		<input type="checkbox"/>	<input type="checkbox"/>
2.		<input type="checkbox"/>	<input type="checkbox"/>
3.		<input type="checkbox"/>	<input type="checkbox"/>
4.		<input type="checkbox"/>	<input type="checkbox"/>

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”;

(b) for Form A, the following new form shall be substituted, namely:

“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
Place

Signed

**ENCLOSURES OF THE APPLICATION FOR REGISTRATION OF AN IMPORTED
DRUG**

Dosage Form:-----

- 1- Name and address of the indenter 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 & excipients) 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 No

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”;

(c) for Form 5-B, the following new form shall be substituted, namely:-

“FORM 5-B
[See rule 26 (3A)]

APPLICATION FORM FOR RENEWAL OF REGISTRATION OF ALL KINDS OF DRUGS

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

Date

Signed

Place

ENCLOSURES OF THE APPLICATION FOR RENEWAL OF REGISTRATION OF A DRUG

Dosage Form:-----

- 1- Brand (Proprietary) name of the drug.
- 2- Strength of active ingredient(s) per unit, e.g., each tablet or 5ml, etc. contains.
- 3- Name and address of the manufacturer.
- 4- Name and address of the agent or indentor in case of imported drug.
- 5- Whether the drug is registered for local manufacture or import.
- 6- Patent number in Pakistan & its expiry date.

7- Name of the registered drug with its registration number and date of initial registration and last renewal.

8- Changes, if any, in information furnished at the time of initial registration or last renewal.

9- If withdrawn from the market anywhere:

- (i) the name of the country; and
- (ii) the reasons thereof.

UNDERTAKING

We hereby give this undertaking that the above mentioned information is true and correct to the best of our knowledge.

Production Manager

Quality Control Manager.”;

(d) after Form 5(C), the following new forms shall be added, namely:-

“FORM 5-D
[See rule 26 (1)]

APPLICATION FORM FOR REGISTRATION OF A DOSAGE FORM CONTAINING
A NEW DRUG MOLECULE OR A NEW COMBINATION / DOSAGE FORM, FOR
LOCAL MANUFACTURE.

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 NEW DRUG
OR A NEW COMBINATION / DOSAGE FORM

Dosage Form:-----

- 1- Name and address of the manufacturer.
- 2- Brand (Proprietary) name of the drug.
- 3- The chemical name(s) and, as appropriate and available, the established (generic) 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- Proposed route of administration.
- 7- 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.
- 8- Out line of method of manufacture.
- 9- Recommended clinical use.
- 10- Full description of the specifications and analytical methods necessary to assure the identity, strength, quality, purity and homogeneity throughout the shelf life of the drug product.
- 11- Labeling and prescribing information (to be mentioned on the pack/leaflet) specimen or draft shall be submitted.

12- Proposed dosage.

13- Proposed shelf life of the drug.

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

15- Proposed storage conditions of finished product.

16- 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 applied for registration, and any change shall be properly documented and record maintained by the manufacturer.

17. 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"/>

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

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

20- Facility of the water processing with specifications.

21-Environment control processing with details.

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

23-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).

24. Clinical justification.

25. Dosage form stability profile.

26-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.”;

‘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"/>
		<input type="checkbox"/>	<input type="checkbox"/>

3. _____ Yes No
4. _____ Yes No

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.”.

[NO.F.8-1/2004-AU9VOL-III]

(DR.FARNAZ MALIK)
Drugs Controller (Regn.)