Grant & Renewal of Drugs manufacturing Licenses in Form 20 & 28

Step 1:

Submit following document at Office of Drug Controller-Chandigarh, Sector 34, Chandigarh.

- Application Form 24 & 27..
- Treasury Challan Rs. 7500/- for each form (Total Rs. 15,000/-) to be deposited in Bank through Draft in favour of PMO, U.T., Chandigarh.
- Site Plan of proposed premises with location plan.
- Proof regarding possession of premises e.g. documents regarding premises ownership or rental or other basis.
- List of Machinery & Equipments installed for manufacturing of drugs.
- List of Testing Equipments installed, chemicals and Reference Standards for analysis of drugs.
- Self declaration or Affidavit of Proprietor, Partners, Authorised Signatory, and Directors as the case may be.
- Self declaration or Affidavit of Technical Staff (Manufacturing Chemists & Analytical Chemists) responsible for the activities and proof of approval of technical staff.
- Copies of Qualification Certificates, Experience Certificates and approval letters of the technical staff.
- Residential and identity proof of Proprietor/Partners/Authorised Signatory/Directors or technical staff.
- In case of Pvt. Ltd. & Ltd. company:-

  a) List of Directors with address.

  b) Copy of Resolution of board of Directors.

  c) Memorandum of Article.

  d) Form 32 regarding status of Directors.

  e) In case of Partnership concern, copy of partnership deed.

- NOC of Chandigarh Pollution control Board.
- NOC of explosives/Fire Safety for Bulk Drugs manufacturer.
- Water Analysis report of potable water to be used.
- List of drugs to be manufactured.
- Power of Attorney, if the application through Attorney Holder
- Dissolution Deed/the sale deed in case of transfer of business.
- Previous Drugs Licenses in cases of application for grant of license due to change of Constitution or transfer of business or change of Premises.
- List of Official books e.g. Drugs & Cosmetics Act 1940 and Rule 1945, IP, BP, etc.
- Facility required as per Schedule M and fulfillments of conditions of the Drugs & Cosmetics Rules, 1945 for grant of licenses.

Note: All documents shall be in duplicate. All photocopies shall be attested by Gazetted Officer /Notary.

Step 2:

- Scrutiny by Office clerk

Step 4:

- Site visit by Concerned Inspector.

Step 5:

- Forwards recommendations to Director Health Services-cum-Drug Controller for allotment of registration.

Step 6:

- Allotment of Registration Certificate/Renewal.

- Time period for approval/renewal- 60 days

FORM 24
(See Rule 69)

Application for grant of renewal of a licence to manufacture for sale and or for distribution of drugs other than those specified in schedule C & C(1)& X

1. I/We.....
of.....
hereby apply for the grant/renewal of a licence to manufacturer on the premises situated at .....the following drugs being drugs other than those specified in schedule C and C(1) and X of the Drugs and Cosmetics Rules, 1945.

2. Name of Drugs categorized according to Schedules M.

3. Names, qualifications and experience of technical staff, employed for manufacture and testing.

4. A fee of rupees.....of rupees has been credited to Government under the Head of Account vide Treasury receipt attached.

Date.....

Signature

Note:- The application should be accompanied by a plan of the premises.

FORM 27

[See rule 75(1)]

Application for grant or renewal of a licence to manufacture for sale [or for distribution of] drugs specified in Schedules C and C(1) [2][excluding those specified in [3](part XB and) Schedule X]

1. I/We.....hereby apply for the grant/renewal of a licence to manufacture on the premises situated at.....
.....
.....the under mentioned drugs, being drugs specified in Schedules C and C(1), [2][excluding those specified in [3](part XB and) Schedule X] to the Drugs and Cosmetics Rules, 1945.

2. The names, qualifications and experience of the expert staff responsible for the manufacture and testing of the above-mentioned drugs:

   (a) Name(s) of staff responsible for test.....

   (b) Name(s) of staff responsible for manufacture.....

3. The premises and plan <u>are ready for inspection</u>
   will be ready for inspection on

3. A fee of rupees.....and an inspection fee of rupees.....has been credited to Government under the head of account.....

Date.....

Signature.....
Designation.....

Note: The application shall be accompanied by a plan of the premises.

Grant and Renewal of Homeopathic Drugs manufacturing Licenses in form 25-C

Step 1:

Submit following document at Office of Drug Controller-Chandigarh, Sector 34, Chandigarh.

- Application Form 24-C.
- Receipt Challan Rs. 300/- for grant & Rs. 250/- for renewal to be deposited in Bank through Draft in favour of PMO, U.T., Chandigarh.
- Site Plan of proposed premises with location plan.
- Proof regarding possession of premises e.g. documents regarding premises ownership or rental or other basis.
- List of Machinery & Equipments installed for manufacturing of drugs.
- List of Testing Equipments installed, chemicals and Reference Standards for analysis of drugs.
- Self declaration of Proprietor, Partners, Authorised Signatory, and Directors as the case may be.
- Self declaration of Technical Staff (Manufacturing Chemists & Analytical Chemists) responsible for the activities and proof of approval of technical staff.
- Copies of Qualification Certificates, Experience Certificates and approval letters of the technical staff.
- Residential and identity proof of Proprietor/Partners/Authorised Signatory/Directors or technical staff.
- In case of Pvt. Ltd. & Ltd. company:-

  a) List of Directors with address.

  b) Copy of Resolution of board of Directors.

  c) Memorandum of Article.

  d) Form 32 regarding status of Directors.

  e) In case of Partnership concern, copy of partnership deed.

- NOC of Chandigarh Pollution control Board.
- NOC of explosives/Fire Safety if required.
- Water Analysis report of potable water to be used.
- List of drugs to be manufactured.
- Power of Attorney, if the application through Attorney Holder
- Dissolution Deed/the sale deed in case of transfer of business.
- Previous Drugs Licenses in cases of application for grant of license due to change of Constitution or transfer of business or change of Premises.
- List of Official books e.g. Drugs & Cosmetics Act 1940 and Rule 1945, IP, BP, etc.
- Facility required as per Schedule M and fulfillments of conditions of the Drugs & Cosmetics Rules, 1945 for grant of licenses.

Note: All documents shall be in duplicate. All photocopies shall be attested by Gazetted Officer /Notary.

Step 2:

- Scrutiny by Office clerk

Step 4:

- Site visit by Concerned Inspector.

Step 5:

- Forwards recommendations to Director Health Services-cum-Drug Controller for allotment of registration.

Step 6:

- Allotment of Registration Certificate/Renewal.

- Time period for approval /renewal- 60 days

[FORM 24-C

[*See*]

Application for the grant or renewal of a licence to manufacture for sale [or for distribution] of Homoeopathic medicines or a licence to manufacture potentised preparations from back potencies preparation by licensees holding licence in

[I. I/we..... of..... holder of licence No..... in hereby apply for grant/renewal of licence to manufacture the under mentioned Homoeopathic Mother Tincture/Potentised and other preparations on the premises situated at .....

Names of the Homoeopathic preparations

.....

.....

.....

.....

(Each item to be separately specified).]

2. Names, qualifications and experience of technical staff employed for manufacture and testing of Homoeopathic medicines.

3. A fee of rupees ..... has been credited to Government under head of account.....

Date..... Signature.....

Note 1. *Delete* whichever portion is not applicable.

2. The application should be accompanied by a plan of the premises.