LIST OFDOCUMENTS FOR THE GRANT OF DRUG MANUFACTURING LICENCE

1. **Application** Form-24/24-A/24-B and/or 27/27-A-in original
2. **Challan** for Rs. 7500 (application and inspection fee) per application and fee for the additional @ Rs.300 per Product (excluding first 10 products per Section) proposed to be manufactured to be deposited separately in Government Treasury Account as per the treasury codes corresponding to the area of operation.
3. **Constitution** of the company/firm: Memorandum & Article of Association/ Partnership deed/Partnership deed
4. **Authorization**/Resolution on behalf of the partnership firm/company in favour of person/applicant, applying for the grant of licenses.
5. Power of Attorney/ Resolution/ Declaration of the **person(s) responsible for the conduct of the business and day to day activities of the firm/ company**
6. **Photo IDs** (Adhaar, PAN, DIN), of the promoters, applicant and/or persons (as referred in S.No.4 and 5)
7. **Affidavit** on behalf of the applicant duly verified by the oath commissioner (as per the prescribed language) *-regarding non conviction and person responsible for manufacturing and testing of drugs, conditions of the licenses etc. as required under the Drugs and Cosmetics Act, 1940.*
8. **Affidavit** on behalf of the applicant duly verified by the oath commissioner (as per the prescribed language) - *regarding proposed formulation and claim thereof.*
9. Site/location plan and floor wise layout plan (to the scale) of the proposed premises clearly indicating size and definition of the area, duly drawn and certified by the competent authority- (2-copies).
10. List of the **production** machinery installed with their nos. indicating model, make and capacity.
11. List of the machinery installed in **utilities** viz. Water System, HVAC System, Boiler, Electrical, etc.
12. List of the **laboratory** instruments/equipment with their nos. indicating model, make and capacity.
13. List of the **products** proposed to be manufactured, section wise and category wise (as prescribed in Schedule C and C1 and other than those prescribed in Schedule C and C1) – *as per the format attached*.
14. **Proof of ownership**: Registration papers of the land, rent/lease deed etc.-attested photocopy
15. **Certificate of registration** issued by the Industry Department, Himachal Pradesh-attested photocopy
16. **NOC** issued by the Pollution Control Board, Himachal Pradesh - attested photocopy

**Competent person(s) responsible for manufacturing and testing of drugs-** for each person (minimum three person) responsible for Production, Quality Assurance and Quality Control.

1. **Medical fitness** certificate clearly indicating freeness from contagious disease. Penicillin sensitivity is additionally required in case of penicillin (Beta lactum category) drugs are to be manufactured-photocopy
2. **Appointment** letter of the employee clearly indicating job profile and extent of responsibility- photocopy
3. **Affidavit** on behalf of the appointed competent person responsible for manufacturing/testing (as per the prescribed language) - in original
4. **Qualification** certificates- degree/ diploma/ matriculation -attested photocopy(ies)
5. **Certificate of approval** as Competent Technical Person by the Drug authority-attested photocopy
6. **Experience certificate** on the letter pad bearing licence Nos. of the issuing firm-original copy
7. **Photo IDs** (Adhaar, PAN, DIN) and Passport size photographs- 1 attested and 4 plain

**NOTE: all the documents are required to be countersigned by the applicant**

**FORM-24**

***Application for the grant of or renewal of a licence to manufacture for the sale or for distribution of drugs other than those specified in Schedule C and C(1) and X***
**(See Rule 69)**

1. I/We _____ of _____ hereby apply for the GRANT/ RENEWAL of a licence on the premises situated at _____

   the following drugs being the drugs other than those specified in Schedule C and C(1) and X of the Drugs and Cosmetics Rules, 1945.

2. Names of drugs categorized according to Schedule M. _____

3. Names, qualification and experience of the technical staff employed for manufacturing and testing.

| Name of the competent person: | Qualification | Experience |
|---|---|---|
| For manufacturing | | |
| | | |
| For testing | | |
| | | |

4. A fee of rupees _____ (Rupees _____ ) has been credited to the Government account.

| Major: 0210 | Sub major: 01 | Minor: 107 | Sub head: 01 |
|---|---|---|---|

Date; _____ Signature

**FORM-27**

***Application for the grant of or renewal of a licence to manufacture for the sale or for distribution of drugs specified in Schedule C and C(1)(excluding those specified in Part X-B and Schedule X)***

(See Rule 75)

1. I/We _____ of _____ hereby apply for the GRANT/ RENEWAL of a licence on the premises situated at _____

   the under mentioned drugs, being the drugs specified in Schedule C and C(1) excluding those specified in Schedule. X to the Drugs and Cosmetics Rules, 1945.

   Name of the drugs: _____

2. Names of drugs categorized according to Schedule M. _____

3. Names, qualification and experience of the expert staff responsible for manufacturing and testing of the above mentioned drugs.

| Name of the competent person: | Qualification | Experience |
|---|---|---|
| For manufacturing | | |
| | | |
| For testing | | |
| | | |

4. The premises and plan are ready for the inspection/ will be ready for the inspection on _____.
5. A fee of rupees _____ (Rupees _____ ) has been credited to the Government account.

| Major: 0210 | Sub major: 01 | Minor: 107 | Sub head: 01 |
|---|---|---|---|

Date; _____ Signature

**DRUGS MANUFACTURING LICENCE** **GRANT**

Contents of affidavit from a *proprietor/ partner/ director/GPA holder etc. as prescribed under S.No.7*

I _____ son/daughter/wife of Shri _____ age ___ years, permanent resident of village/town _____ P.O. _____ Tehsil. _____ Distt._____ of Himachal Pradesh do hereby solemnly affirms and declare as under:

1. That I am Managing Director/ managing partner/ sole proprietor/authorised person of the company/ firm named as M/S._____ situated at _____ town/village _____P.O._____ Tehsil. _____ Distt. _____ of Himachal Pradesh. Following are the partners of the said firm:
   1. _____ 2. _____
2. That the above said firm is hereby applying for the grant of manufacturing of drugs for sale and distribution on FORM-24/ 24-A and/or Form-28/ 28-A for the first time.
3. That I am never been convicted/ I have and any of the director/partners of the said firm has never been convicted under any provision of the Drugs and Cosmetics Act, 1940 anytime and anywhere.
4. That I am person responsible for the day to day activities of the firm/company and is responsible for the conduct of business as defined under the provisions of the Drugs and Cosmetics Act 1940 and Rules 1945 made there under.
5. That I am/ company/ firm is absolute owner of the proposed land and building premises/ that shri Shri/Smt. _____ son/ wife of Shri_____ is legal owner of the proposed premises, who is resident of village: _____, PO _____ Tehsil: _____ Distt. _____ of Himachal Pradesh and has agreed upon to rent out the said premises in my favour/ in favour of firm/company for manufacturing drugs for sale and/ or distribution and possesses an area as per the map being submitted along with the application located at the aforesaid location and address duly authorised by the competent authority and is free from any kind of encumbrance.
6. That Sh./Smt./Ms._____son/daughter of Shri _____ age _____ permanent resident of village/town _____ Tehsil. _____ Distt. _____ is full time appointed competent person of the above said firm responsible for manufacturing of drugs for sale and/ or distribution, who possesses qualification as prescribed under Rule 71(1)(a) or 71(1)(b) and 76(1)(a) or 76(1)(b) of the Drugs and Cosmetics Rules 1945 and he/she is not engaged anywhere else in any kind of service or business to the best of my knowledge.
7. That Sh./Smt./Ms._____son/daughter of Shri _____ age _____ permanent resident of village/town _____ Tehsil. _____ Distt. _____ is full time appointed competent person of the above said firm responsible for testing of all substances to be used for or incorporated in the drugs for sale and/ or distribution, who possesses qualification as prescribed under Rule 71(4-A) and/ or 76(4-A) of the Drugs and Cosmetics Rules 1945 and he/she is not engaged anywhere else in any kind of service or business to the best of my knowledge
8. That manufacturing and testing of the drugs, shall be affected under personal supervision of the competent persons as detailed in Para 5 and 6 above only. In case if any one leaves the said firm I shall intimate the Licensing Authority immediately and appoint a fresh person at least before one month of such change with prior permission of the Licensing Authority.
9. That I shall strictly observe the condition of the license as prescribed under Rule 71 and 76 of the Drugs and Cosmetics Rules 1945.
10. That I shall maintain proper purchase, manufacturing, testing and sale or distribution records in accordance with the Schedule M, Schedule U etc. of the Drugs and Cosmetics Rules,1945.
11. That I shall strictly observe the Good Manufacturing Practices as detailed in Schedule M and as amended from time to time.
12. That I shall inform the Licensing Authority at least three months before closing the business.
13. That I shall abide by all the instructions issued under the provisions of the Drugs and Cosmetics Act, 1940 and Rules, 1945 made there under as amended from time to time.
14. That in case there will be any change or alteration in the premises or name of the firm or constitution of the firm. I shall obtain a fresh license within the period of three months of such change.

DEPONENT

Verification: I the above said deponent further state on oath that the contents of the above affidavit are true to the best of my knowledge and nothing relevant has been concealed there from and as such I verify the same.

Place: _____

Date; _____ DEPONENT

**DRUGS MANUFACTURING LICENCE** **GRANT**

(Contents of additional affidavit from a proprietor/ partner/ GPA holder etc. as prescribed under S.No.8)

I _____ son/daughter/wife of Shri _____ age ___ years, permanent resident of village/town _____ P.O. _____ Tehsil. _____ Distt._____ do hereby solemnly affirms and declare as under:

1. That I am sole proprietor/ managing partner/ director/ authorized person of the firm/company named as M/S._____ situated at _____ town/village _____P.O._____ Tehsil. _____ Distt. _____ of Himachal Pradesh. Following are the partners of the said firm:
   1. _____ 2. _____
2. That the above said firm is hereby applying for the grant of manufacturing of drugs for sale and distribution on Form-24/ 24-A and/or Form-28/ 28-A and propose to manufacture drugs as per the contents of the list attached herewith only.
3. That patent and proprietary name/ brand name as mentioned in the list does not resemble same to the patent/ proprietary name of any other firm already available in the market to the best of my knowledge. In case if there is any such coincidence I undertake to withdraw the same.
4. That product presentation i.e. packing style, as proposed to be used for packing the drug does not resemble in any way to any firm already available in the market to the best of my knowledge. In case if there is any such coincidence I undertake to withdraw the same.
5. That every drug including patent and proprietary medicines, the said firm propose to manufacture for sale or distribution;
   - I. Contains the constituent ingredients in therapeutic/ prophylactic quantities as determined in relation to the claims or condition for which the medicines are recommended for use or claimed to be useful.
   - II. Are safe for use in the context of the vehicles, excipients, additives and pharmaceutical aids used in formulations, and under the conditions in which the formulation for administration and use are recommended.
   - III. Are stable under the condition of storage recommended; and
   - IV. Contain such ingredients and in such quantities for which there is therapeutic justification.
6. That I and my firm shall not undertake manufacture of any drug other than as approved by the Licensing Authority, in any form, with alteration or modification without the approval and necessary permission of the Drugs Licensing Authority.
7. That I undertake hereby to withdraw any drug completely from the market, in case of any such instructions from the Licensing Authority
8. That the proposed list of drugs as submitted for approval does not include any new drug as defined in the Rule 122-E of the Drugs and Cosmetics Rules 1945 to the best of my knowledge. In case of any such coincidence I under take to withdraw the same at any time.
9. That in case the firm propose to manufacture any new drug as defined under Rule 122-E of the Drugs and Cosmetics Rules, 1945. I shall obtain the necessary No Objection Certificate for the same from the Central Licensing Authority, under intimation to the State Drugs Licensing Authority.

DEPONENT

Verification: I the above said deponent further state on oath that the contents of the above affidavit are true to the best of my knowledge and nothing relevant has been concealed there from and as such I verify the same.

Place: _____
Date; _____ DEPONENT

**DRUGS MANUFACTURING LICENCE** **GRANT**

Contents of affidavit from the competent person responsible for Production, Quality Control and Quality Assurance as prescribed at S.No.3.

I _____ son/daughter/wife of Shri _____ age ___ years, permanent resident of village/town _____ P.O. _____ Tehsil. _____ Distt._____ of do hereby solemnly affirms and declare as under:

1. That I am full time paid employee of the firm named as M/S._____ situated at _____ town/village _____P.O._____ Tehsil. _____ Distt. _____ of Himachal Pradesh from _____(date) and Shri _____prop,/ managing partner of the firm, is my employer.

2. That I have never been convicted under any provision of the Drugs and Cosmetics Act, 1940 and Rules., 1945 made thereunder anytime and anywhere.

3. That I am the competent person responsible for manufacturing/ testing of the drugs for sale and/ or distribution of the above said firm, and possesses qualification as prescribed under 71(1)(a) or 71(1)(b) and 76(1)(a) or 76(1)(b) / Rule 71(4-A) and/ or 76(4-A) of the Drugs and Cosmetics Rules 1945 i.e. B.Pharmacy, M.Sc./ B.Sc./ other, and is not engaged anywhere else in any kind of service or business. I possesses ___ years working experience with M/S. _____ situated at _____ from _____ to _____ ( mention in chronological order).

4. That manufaturing / testing of the drugs, the firm entitled to manufacture, shall be affected under my personal supervision only.

5. That I shall intimate the Drugs Licensing Authority, Swasthya Sadan, Shimla-9 at least one month before leaving the firm without any failure.

6. That I shall maintain proper record in accordance with the provisions given in the Drugs and Cosmetics Rules, 1945, especially as prescribed under schedule M.

7. That I shall strictly observe the Good Manufacturing Practices as detailed in Schedule M and as amended from time to time.

8. That I shall abide by all the instructions issued under the provisions of the Drugs and Cosmetics Act, 1940 and Rules, 1945 made there under as amended from time to time.

DEPONENT

Verification: I the above said deponent further state on oath that the contents of the above affidavit are true to the best of my knowledge and nothing relevant has been concealed there from and as such I verify the same.

Place: _____
Date; _____ DEPONENT