FORM 24-D
(See Rule 153)

APPLICATION FOR THE GRANT/RENEWAL OF A LICENCE TO MANUFACTURE FOR SALE OF AYURVEDIC/SIDHA/UNANI DRUGS.

1. I/We_____of_____hereby apply for the grant/renewal of license to manufacture Ayurvedic (including Sidha) or Unani drugs on the at_____
_____

2. Name of drugs to be manufactured (with details).

3. Names, qualifications and experience of technical staff employed for manufacture and testing of Ayurvedic (including Sidha) or Unani drugs
_____
_____

4. A fee of rupees_____has been credited to the government under the head of account, 0210-Medical and Public Health, 01-Urban Health services, 800-other receipts, 09-Medical Examination and license fee for the year (Ayurveda) and the relevant Treasury Challan is enclosed herewith. Dated_____

Signature of Applicant
With full address.

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

PROFORMA FOR APPLICATION FOR LICENSE FOR MANUFACTURING OF AYURVEDIC/UNANI/HOMOEOPATHIC/SIDHA DRUGS.

1. Name of Sole proprietor/Firm Company/Co-op.Socieity etc. _____
2. Nature of Organization (Sole proprietor firm/company'co-op-Socieity etc.). _____
3. Registered Office/Head office. _____
4. Name(s) of Sole Proprietor Partner/ Member of Board of Directors/ Company. _____
   _____
   _____
   _____

5. (I) Authorized capital _____
   (II) Subscribed capital _____
   Permanent address _____
   _____
   _____
6. Name of Manager/Chief Executive: _____
7. Name & Permanent address of Technical person(s) Incharge of production: _____
8. Location of the factory: Place_____
   Gali_____-_____
   Plot_____
   Tehsil_____District_____
9. Building: i) Whether own building or rented_____
   ii) Total area of land/Plot _____
   iii) Total construction plinth area of building. _____-_____
   iv) Detail of rooms/halls _____

Sr.No.	Purpose for which to be used	Size of rooms/halls
I.		
II.		
III.		

V. Type of construction _____

VI. Specification of floor/room. _____

VII. Total estimated/actual cost of construction. _____

VIII. Annual rent, if rented (enclose Rent deal) _____

9. **Surrounding**

i) Distance from road _____

ii) Detail of other building & their use in North, South,East and West. _____

iii) Whether any public urinal, toilet, _____

Polluting agent present in the surrounding _____

(give detail). _____

iv) Source of Water: _____

v) Whether the water of other dirt is proposed to be discharged. _____

vi) Whether permission from water and _____

Air pollution control board obtained or not.

10. Name pf quality of toxic, inflammable or

license raw material to be used in products

during the process.

i) _____

ii) _____

iii) _____

iv) _____

11. Name of drugs proposed to be manufactured give

information .

12. Quantity of drugs proposed to be produced in first

two years _____

Name of drugs	Proposed quantity to be manufactured.

13. **<u>Quality Control</u>**

i) Laboratory facilities (give detail of equipment) _____

ii) Lab/test facilities proposed to be utilized from _____

outside. _____

iii) Details of tests to be conducted to access

quality of raw material/finished products. _____

iv) Parameters for testing quality of finished drugs _____

14. Has the drug been clinically tested in any hospital/ _____

Institution gives details. _____

15. Tupe of packing/size in which proposed to be _____

marketed.

16. **Detail of machinery/equipment**

Sl.No.	Name of machinery/equipment	Specification	Cost
1.			
2.			
3.			
4.			
5.			

(Attach additional sheet if necessary)

17. Technical staff proposed to be employed

Designation	Pay Scale	Essential qualifications

Other staff proposed to be employed..

18. **Details of record to be maintained regarding manufacture**

i) Manufacturing Register Name & Designation of person responsible manufacturing.

ii) Products and sale

iii) Raw material stock.

19. Whether the firm has taken CST/State Sales tax number

If so, give details _____

20. Loan raised/proposed to be raised

and sources. _____

21. Number of working days and holidays

Proposed to be observed. _____

22. Normal working hours of the factory _____

23. Whether registered under factory Act. _____

24. Connected electrical load K.Wattts. _____

25. Any other relevant information _____

I/We hereby certify that the information given the application is correct and nothing material concealed therein. I/We understand that if the license is granted/renewed on the basis of above information and if any information/part thereof is found incorrect/false the licensing authority may cancel/revoke/suspend the license.

II. I/We do hereby undertake to abide by all provide of the drugs and Cosmetics Act, 1940 and the rules made thereunder any other legislature enacted by the Central/State Gove. Or local authority relating to manufacture and sale of drugs.

III. I/We further undertake to abide by all direction of the Licensing Authority or any other officer authorized by him this behalf, relating to manufacture/quality control and sale of drugs.

Signature_____

Name of Applicant_____

Designation_____

Address for correspondence

Telephone No., if any.

CHECK LIST FOR GRANT OF NEW LICENCE

1. Application on prescribed Form no. 24-D.
2. Fee of Rs.1100/-(Rs.1000 + Rs.100) against TR-5 receipt or through Bank Draft payable at Punjab National Bank,Kasumpati, Shimla-9 in the name of Director of Ayurveda, Himachal Pradesh or through treasury challan under Head of Account " 0210-Medical & Public Health Services, 01-Urban Health Services, 800-other receipts, 08-License Fee (Ayurveda)".
3. Subject to the conditions of Rule 157 being fulfilled the licence will be issued Form 25-D which will be valid for a period of three years from date of issue.
4. Requirement of schedule 'T' are to be fulfilled for which Departmental Inspection Team will conduct the inspection and submit its report on the prescribed proforma.
5. Inspection team will inspect the premises with regard to:-
   Location and surroundings, buildings, water supply, disposal of container's cleaning, Stores, raw material, packing material, finished goods store, working space, Health(clothing sanitation and hygiene of workers, medical services, and equipment's, quality control section etc. Documents in respect of competent technical staff consisting of atleast one person, who is a whole-time employee and who possesses the following qualifications:-

   a) Expert in Ayurveda or Siddha or Unani medicine who possesses a degree qualification recognized under Schedule II of Indian Medicine Central Council Act, 1970;
   b) Chemist, who shall possess at least Bachelor Degree in Science or Pharmacy or Pharmacy (Ayurveda) awarded by a recognized University; and
   c) Botanist (Pharmacognosist), who shall possess at least bachelor Degree in Science (Medical) or Pharmacy or Pharmacy (Ayurveda) awarded by a recognized University.

6. Attested copies of final professional examination marks sheet alongwith degree & latest registration renewal certificate with the H.P. Ayurvedic Board of the Ayurvedic doctor to be employed.
7. Attested copies of two person with Bachelor qualification in Botany/chemistry/Pharmacy who could be employed on part-time or contractual basis.
8. Site Plan of the premises.
9. Attested copy of No Objection Certificate from Pollution Control Board.
10. Power Availability Certificate from HPSEB,
11. Copy of Registration as a S.S.I Unit
12. List of Machinery/Lab. Equipments.
13. List of medicine to be manufacture.
14 Project Report.
15 Certificate of measurement & weighing.
16 Ownership proof.

FORM 26-D
(SEE RULE-155)

CERTIFICATE OF RENEWAL OF LICENSE TO MANUFACTURE FOR SALE OF AYURVEDIC, SIDHA OR UNANI DRUGS.

1. Certified that License No. _____ granted on Form No. 25-D to M/S _____ for the manufacture of Ayurvedic, Sidha or Unani Drugs at the premises situated at _____ has been renewed from_____ to_____.

2. **Name of Technical Staff.**

1._____

2._____

3._____

4._____

2. Name of each items to be separately specified in License No._____ dated_____.

Signature

FORM No. 25-D

(See Rule -154)

License to manufacture for sale of Ayurvedic (Including Siddha) or Unani Drugs.

No. of License_____

1. _____ is/are hereby licensed to manufacture the following Ayurvedic medicines on the premises situated at _____ _____under the direction and supervision on the following technical staff:-

(a) Technical Staff(Name)

(b) Names of drugs (each item to be specified.

2. The license shall be in force from_____ to _____

3. The license is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date of Issue _____

Signature_____

Designation _____

Conditions of License

1. The license and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2 Any change in the technical staff named in the license shall be reported forthwith to the Licensing Authority.

3 This license shall be deemed to extend to such additional items as the licensee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.

4 The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the license. Where any change in the constitution of the Firm takes place, the current license shall be deemed to be valid for a maximum period of three months from the Date on which the change takes place unless, in the meantime a fresh license has been taken from the Licensing Authority in the name of the firm with the changed constitution.

DEPARTMENT OF INDIAN SYSTEMS OF MEDICINE AND HOMOEOPATHY,
HIMACHAL PRADESH.

No.Ay.H (A) (3) - / - Dated, Shimla-9, the

To

M/S_____

_____

_____

Subject: - Grant of License for the manufacturing of Ayurvedic Medicines.

Dear Sir,

Reference your application dated_____ on the above-mentioned subject.

Enclosed herewith please find license No._____ on Form No.25-D prescribed under the Drugs and Cosmetics Act/Rules, 1945 for the manufacturing of Ayurvedic Medicines.

This license is valid from the date of issue to_____.

The drug manufactured should be labeled as required under Rule 161 of the Drugs and Cosmetics Act/Rules, 1945, provision of Rules 158 and Schedule T should be strictly adhered to.

This license is further subject to the fulfillment of the following conditions: -

i) The walls of the manufacturing premises should be painted with washable paint.

ii) Entry to premises should be doubled doored.

iii) Washing facilities to the workers should provide before entry into premises.

iv) There should be proper arrangement for identification and testing of the raw herbs/materials.

v) The worker should be provided with clean uniforms.

vi) The manufacturing premises should not be used for residential purposes.

vii) The syrup section should have wire gauze doors and windows.

viii) Water used in the syrup should be free from pathogenic organisms.

ix) For filtration of syrups, proper filter press should be provided.

If on the inspection it is observed that the conditions of the License and the provisions of the Drugs & cosmetics Act, 1940 and the Rules made thereunder are not being complied with, the license shall be cancelled and necessary legal action will be taken against you.

Kindly acknowledge receipt of this letter and license.

Yours faithfully,

Director of Ayurveda-cum-
Licensing Authority, H.P.

FROM 25-E

(See Rule 154-A)

Loan license to manufacture for sale Ayurvedic (Including Sidha) or Unani Drugs

1. Number of license_____
2. _____ _____ is hereby granted a loan license to manufacture for sale Ayurvedic(Including Siddha) and Unani drugs, on the premises situated at _____

   C/O_____ under the direction and supervision of the following expert technical staff.

   (a) Technical Staff (Names)_____

   (b) Name of drugs (each item to be separately specified).

3. The license shall be in force from _____to _____
4. The license is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

   Date of issue_____

Signature_____

Designation_____

Conditions of License

1. The license and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector, appointed under the Drugs and Cosmetics Act, 1940
2. Any change in the technical staff names in the license shall be reported forthwith to the licensing authority.
3. This license shall be deemed to extend to such additional items as the licensee may intimate to the licensing authority from time to time, and as may be endorsed by the licensing authority.
4. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under license. Where any change in the constitution of the firm takes place, the current license shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless in the meantime a fresh license has been taken from the licensing authority in the name of the firm with the changed constitution.

DEPARTMENT OF INDIAN SYSTEMS OF MEDICINE AND HOMOEOPATHY,
HIMACHAL PRADESH.

No.Ay.H (A)(3)- / - Dated, Shimla-9, the

To

M/S_____
_____
_____

Subject: - Grant of Loan License for the manufacturing of Ayurvedic Medicines.

Dear Sir,

Reference your application-dated _____on the above-mentioned subject.

Enclosed herewith please find license No._____ on Form No. 25-E prescribed under the Drugs and Cosmetics Act/Rules, 1945 for the manufacturing of Ayurvedic Medicines.

This license is valid from the date of issue to_____.

The drug manufactured should be labeled as required under Rule 161 of the Drugs and Cosmetics Act/Rules, 1945, provision of Rules 158 A and Schedule T should be strictly adhered to.

This license is further subject to the fulfillment of the following conditions.

i) The license in Form 25-E shall be deemed to be cancelled or suspended, if the license owned by the licensee in Form 25-D whose manufacturing facilities have been availed of by the licensee is cancelled or suspended, as the case may be, under these rules.

ii) The licensee shall comply with the provisions of the Act and of the rules and such further requirements if any, as may be specified in any rules subsequently made under Chapter IV-A of the Act, provided that where such further requirements are specified in the rules, these would come into force four months after publication in the Official Gazette.

iii) The licensee shall maintain proper records of the details of manufacture and of the tests, if any, carried out by him or any other person on his behalf, of the raw materials and finished products.

iv) The licensee shall allow an Inspector appointed under the Act to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may required for the purpose of ascertaining whether the provisions of the Act and the rules have been observed.

v) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.

If on the inspection it is observed that the conditions of the License and the provisions of the Drugs & Cosmetics Act, 1940 and the Rules made thereunder are not being complied with, the license shall be cancelled and necessary legal action will be taken against you.

Kindly acknowledge receipt of this letter and license.

Yours faithfully,

Director of Ayurveda-cum-
Licensing Authority, H.P

FORM 24-C

(See Rule 85-B)

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 by licensees holding licence in Form 20-C

1. I/We_____ of _____ holder of licence No._____in Form 20-C 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: The application should be accompanied by a plan of the premises.

FORM 26-C
(See Rule 85- G)

CERTIFICATE OR RENEWAL OF LICENSE TO MANUFACTURE FOR SALE OF HOMOEOPATHIC MEDICINES

1. Certified that license No. _____granted on Form 25-C to _____for the manufacture for sale of the Homoeopathic mother tinctures/potentised preparations at the premises situated at _____has been renewed for a period from _____.

2. Name of technical staff:

Servshri/Shrimat

3. Name of the Drugs (as per list of items for which license is already granted).

Licensing Authority,
Himachal Pradesh.

FORM 24-E
(See Rule 154-A)

Application for Grant or Renewal of a Loan Licence to Manufacture for sale Ayurvedic (including Siddha) or Unani Drugs

1. I/We*_____ of_____

_____ hereby apply for the grant/renewal of a loan licence to manufacture Ayurvedic (including Siddha) or Unani Drugs on the premises situated at_____

C/O*_____.

2. Names of drugs to be manufactured (with details).

3. The names, qualifications and experience of technical staff actually connected with the manufacture and testing of Ayurvedic (including Siddha) or Unani drugs in the manufacturing premises.

4. I/We enclose

(a) A true copy a letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilized by me/us.

(b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their competent technical staff, equipment and premises for the manufacture of each item required by me/us and that they shall maintain the registers of raw materials and finished products separately in this behalf.

(C) Specimen of labels, cartons of the drugs proposed to be manufactured.

5. A fee of Rs._____ has been credited to Government under the head of Account_____ and the relevant Treasury Challan is enclosed herewith.

Signature_____ (applicant)

Date: