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.
(Or Attach a Bank Draft in the Name of Director Ayurveda,Kasumpti,Shimla-9, for Rs.1100/- payable at Shimla)
Dated_____

Signature of Applicant
With full address.

Note: The application should be accompanied by a Site 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. Society etc. _____

2. Nature of Organization (Sole proprietor firm/company'co-op-Society 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. **<u>Surrounding</u>**

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. **Quality Control**

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. Type of packing/size in which proposed to be _____

marketed.

16. **Detail of machinery/equipment**

Sr.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& Phone No.

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 license 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 Performa.

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 at least one person, who is a whole-time employee and who possesses the following qualifications to be attached :-
   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.

HELP LINES:- 0177-2623066, 2624427,2623978 Directorate Ayurveda, Shimla.

Do and not to do-

Please do and insure the following :-

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 in your Manufacturing unit.

v) The worker should be provided with clean uniforms and ensure that all the workers should wear the uniform.

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

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.

Please note that if at the time of inspection, it is observed that the conditions of the License and the provisions of the Drugs & cosmetics Act, 1940 and the Rules made there under are not being complied with, the license shall be cancelled and necessary legal action can be taken against you.

Do not do

A) Technical Staff:-

1) An Expert in Ayurveda or Siddha or Unani (BAMS) medicine who possesses a degree qualification recognized under Schedule II of Indian Medicine Central Council Act, 1970; should be engaged or appointed. Other will not be entertained.

2) A person who possesses at least Bachelor Degree in Science or Pharmacy OR Pharmacy (Ayurveda) awarded by a recognized University; OR a Botanist (Pharmacognosist), who possesses at least bachelor Degree in Science (Medical) or Pharmacy or Pharmacy (Ayurveda) awarded by a recognized University should also be engaged or appointed. Do not engage any B .Sc. degree holder with the subject of Agriculture. Do not engage any Diploma holder in Ayurveda Pharmacy.

B) Registration:-

Do no engage/appoint any Ayurvedic Expert (B.A.M.S.) who has not registered himself with the H.P. Ayurvedic and Unani Board, Shimla. No expert who is registered out side the Himachal Pradesh should be appointed to manufacture the Ayurvedic Medicine.

Do not engage/appoint any Ayurvedic Expert who is already working/ engaged by any other manufacturing Unit. An expert should be appointed for whole time.

GMP- It is the abbreviated word for Good Manufacturing Practices.

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 undermentioned 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 24-E
(See Rule 154-A)

Application for Grant or Renewal of a Loan License 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:

PROFORMA FOR INSPECTION OF PRIVATE AYURVEDIC PHARMACIES AS PER THE PROVISION OF G.M.P.

1. Name and address of pharmacy: _____

_____

_____

2. Manufacturing No. _____

3. Date of Renewal _____

4. Any other address for cprrespondence

5. Name of Proprietor _____

_____

_____

6. Date of Establishment of unit _____

7. Total covered area of
8. pharmacy complex(Sq.feet) _____

8. Location of Pharmacy 1-1(A)
(a)Whether chances of Contamination from open Sewerage drain,public lavatory Or obnoxious odour of fumes Produced by another factory Yes No

(b) Whether premises compatible with other manufacturing of operations in same building. Yes No

(c)Whether adequately provided with working space to avoid the risk of mix up between different drugs.. Yes No

(d)Whether premises designed, Constructed and maintained to prevent entry of insects. Yes No

(e)Whether walls, floors, ceilings of premises smooth. Yes No

9. **BUILDING OF PHARMACY: 1.1(B)**

(a)Whether permit production of Drugs under hygienic condition. Yes No

(b)Whether provision of light and Ventilation. Yes No

(c)Whether floor and walls having dampness. Yes No

(d)Furnish information regarding office. L W H

(e)Map of office buildings. (Please attach as Annexure-(1)

(f)Whether provided with proper drainage system. Yes No

(g)Whether sanitary fitting and electrical fixtures proper and safe. Yes No

(h)Whether Bhatti section covered with tin roof,proper ventilation. Yes No

(i)Whether fire safety measures and proper exits provided. Yes No

10. **WATER SUPPLY: (1.1)(c)**

(a)Whether adequate provision of water for washing the premises. Yes No

(b)Whether water used of pure and of potable quality. Yes No

11. **DISPOSAL OF WASTES: 1.1(D)**

(a)Whether waste water and residues produced during manufacturing processes prejudicial to the workers or public health Yes No

(b)If yes, then whether the NOC from Pollution Control Board obtained. Yes No

12. **CONTAINER CLEANING:-1.1(E)**

(a)Whether adequate arrangements for

Washing, cleaning and drying of containers being used in premises. Yes No

13. **STORES;-(F)**

(a)Whether stores having proper entilation & free from dampness. Yes No

(I)Raw-Materialstore:-1.1(F)(A)

(a)Furnish information regarding Length Width, Height in feet to handle the Following different categories of raw-Materials.

(i)Raw material of metallic origen	L	W	H
(ii)Raw material of mineral origen	L	W	H
(iii)Raw material from animal source	L	W	H
(iv)Fresh herbs	L	W	H
(v)Dry herbs/raw material of all types	L	W	H
(vi)Expectants	L	W	H
(vii)Plant extracts Exudates	L	W	H

(b)Whether quality of raw material having Dampness and insects infestation. Yes No

(c)Whether raw material stores properly Labelled. Yes No

(d)Whether labelled drugs indicates source of Supply, status of material(South as under test Please attach annexure as above table.

(II)**PACKING MATERIAL STORE:-1.1(F)(B)** L W H

(a)Whether containers used properly cleaned and dried before packing the products. Yes No

(III) **FINISHED GOODS STORE;-(F)(c)** L W H

(a)Whether quality control lab. and experts Checked the correctness of finished goods. Yes No

(b)Detail of medicine manufactured during last three years.
Please attach annexure as above table.

(c)Sale of Medicines in open market during last 3 years

Please attach annexure as above table.

(d)Sale of medicine for Govt. supply during last 3 years

Please attach annexure as above table.

14.(a) List of Medicines being manufactured at the time of Inspection

Please attach annexure as above table

(c) List of medicines not being prepared according to the formula approved

Please attach annexure as above table

(d) Whether medicines prepared have been labeled and packed as per the drug and Cosmetic Act-1945 i.e.(list of ingredients with qty. indication, dose, net weight of packed medicines, batch no. Manufacturing license number, date of manufacturing, best before use) Yes No

15. **WORKING SPACE;- 1.1(G)**

(a) Whether working space sufficient for orderly placement of equipments and for carrying out various processes. Yes No

16. HEALTH CLOTHING SANITATION AND HYGIENCE OF WORKING:- 1.1(H)

(a) Whether workers employed free from contagious disease. Yes No

(b) Whether proper uniform provided to workers. Yes No

(c) Whether provision for clean towel, soap provided Yes No

(d) Whether lavatories provided for men located at places separately from processing rooms. Yes No

(e) Whether lavatories provided for women located at places separately from processing rooms. Yes No

(f) Whether workers provided with change rooms, if Yes, then furnish information. Yes No

17. **MEDICAL SERVICES:-1.1(I)**

(a) Whether adequate facility for first aid provided. Yes No

Whether medical examination of workers conducted at the time of employment. Yes No

Whether periodical check-up by a physical once a year conducted Yes No

Whether record of periodical check-up by a Physician maintained. Yes No

18. **EQUIPMENTS:-1.1(J)**

(a) Whether equipment's properly installed and m maintained. Yes No

(b) Whether proper standard operational Procedures (Sops) for cleaning, maintaining and Performance of every machine maintained. Yes No

(C) INFORMATION REGARDING MACHINERY

Please attach annexure as per above table.

INFORMATION REGARDING EQUIPMENTS:-

Please attach annexure as per above table.

19. **BATCH MANUFACTURING RECORDS:-1.1(K)**

(a) Whether manufacturing record of each Batch maintained. Yes No

(b) Whether daily observation registered regarding details of manufacturing processes i.e. stage by stage process of manufacturing processes maintained. Yes No

(c) Whether classical tests like taste/ colour/Physical characteristics during various stages of manufacturing conducted. Yes No

(d) Whether chemical tests as may have been necessary conducted. Yes No

(e) Whether raw material approved by the the laboratory. Yes No

(f) Whether finished drug approved by the Drug Testing Laboratory. Yes No

(g) Details of quality control in laboratory, If any. Yes No

(h) Whether raw material register maintained. Yes No

(i) Whether finished material register maintained. Yes No

(j) Whether provision of library/manual. Yes No

20. **DISTRIBUTION** RECORD**:-1.1(L)**

(a) Whether record of sale and distribution Of each batch of medicine maintained. Yes No

21. **RECORD OF MARKET COMPLAINTS;-1.1(**M)

(a) Whether record of market complaints Regarding product sold on a separate Register maintained. Yes No

(b) Whether manufacturer submitted the Record of such complaint to the Licensing authority once in a period Of six months. Yes No

22. **QUALITY CONTROL:-1.1(N)**

(a) Whether provision of Govt. approved Testing laboratory. Yes No

(b) If yes, name of the approved testing Laboratory. _____

_____

© Whether quality control section provided In own premises. Yes No

(d) If provided in own premises then furnish Information. L W H

(e) Whether standards of identity, purity and Strength followed as given in Yes No

(f) Whether quality control section having One officer with degree qualification In Ayurveda as per Schedule-II CCIM Act,1970 alongwith the registration No. Yes No

(e) Whether Bachelor of Pharmacy, Pharmacogonosy And Chemistry associated with quality control Section. Yes No

23. REQUIREMENT FOR STERILE PRODUCTS (3.0)

(a) Whether provision for sterile products exists Yes No

24. **ELECTRICITY DETAILS**:- _____

_____

25. **HERBAL GARDEN:-**
(if any) furnish information. _____

26. Name and qualification of Supervisory Technical Officers for manufacturing purpose under Drug and Cosmetic Act-1945.
Please attach annexure-as above table.

27. **LIST OF SKILLED WORKERS**

Section wise/Ministerial Staff.
Please attach annexure as above table.

28. **LIST OF UNSKILLED WORKERS**
Please attach annexure as above table.

(a) Whether attendance register of workers Maintained. Yes No

1. Whether unit deployed less than ten workers In the premises.
Yes No

(a) If no, then registration under rule No. 99 of Factory Act-1948 _____

_____

_____

2. Certification of weighing equipments. _____

3. List of total number of licensed medicines. _____

4. List of total number of licensed medicines not being manufactured with reason thereof. _____

Please attach annexure.

33. TAX DETAIL FOR PAST THREE YEARS:-

(a) Sale tax _____
_____

Signature of owner

Remarks by Inspection Committee