

CITIZEN CHARTER

DEPARTMENT OF AYUSH

DRUGS ADMINISTRATION & LICENSING AUTHORITY (AYURVEDA) DRUGS LICENSING SYSTEM OF AYURVEDA SYSTEM OF MEDICINE

S.No.	Name of the officer	Designation & Address	Phone No.
1.	Additional Director (Ayur), Drug Controller & Licensing Authority	Office of the Commissioner, Dept of AYUSH, T.S., Hyderabad.	040 – 24758331
2.	Drugs Inspector (Ayur) (Telangana Region)	Office of the Commissioner, Dept of AYUSH, T.S., Hyderabad.	040 – 24758331

S. No.	Service	Duration	Required Documents
1.	Issue of Fresh Manufacturing License & GMP Certificate	3 Weeks From the Date of Inspection	Necessary Documents 1. Form 24 – D 2. Challan for Rs. 1000/-. 3. Covering Letter. 4. Attested Copy of Plan of the Premises With Partitions & Measurements. 5. Attested Copies of Ownership documents of the Building. 6. Declaration of Proprietor or Managing Partner. 7. List of manufacturing & Analytical equipments. 8. Appointment letter of Fulltime Technical Supervisor. 9. Declaration / Consent letter of Fulltime Technical Supervisor (FTS). 10. Academic Qualification & Registration Certificate, Bio-data & Experience Certificate of the Fulltime Technical Supervisor (FTS). 11. List of Shastric Medicines Xerox Copies of the Concerned Pages of reference book duly signed by FTS with samples. 12. (2) Passport size photos each of Proprietor & FTS. 13. (2) Sales packed draft labels for each drug as per D & C Rules with different names if any. 14. (10) Samples for each drug with sales pack draft labels with different sizes if any. 15. Self addressed envelop with sufficient postal stamps for Registered Post. 16. Clinical Trial Reports from (3) institutionally qualified.

1 APPLICATION FOR GRANT / RENEWAL OF LICENCE FORM – 24 D
(SEE RULE 153)

Application for the Grant / Renewal of License to Manufacture for sale of
Ayurveda Drugs.

..... I/We
.....
..... of M/s.
..... hereby apply for
the Grant / Renewal of License to manufacture Ayurvedic / Unani Drugs in the premises situated at
.....
.....
.....

- 2. Name & Qualifications and experience to Technical Staff employees for manufacture and testing of Ayurvedic / Unani Drugs.
- 3. Name of the Drugs
- 4. A fee of Rs. Has been credited Government under Head of Account
.....
.....
.....

And the relevant Treasury Challan is enclosed herewith.

Signature

Application Dated:

DECLARATION

1. Proprietor /
Managing Director /Managing Partner hereby declare that the words “Ayurveda / Unani /
Preparatory Medicine” shall be printed premisenently each label of Ayurvedic/Unani Medicine
which will be manufactured by M/s.
.....

2. Certified that there is no resemblance of the product of M/s.
.....
.....

With other drugs of any system of medicine and there is no drug in the market with the same
name and also does not bear any resemblance to any other brand name.

3. Certified that I will adide by the D & C Act, 1940 and D&C Rules, 1945 and I will not a violate
the DMR & Objectionable Advertisement Act 1954 and follow G.M.P guidelines.

4. Certified that, the information given in this application is true and correct to the best of my
knowledge and I have not furnished any false information with view to obtain Ayurveda / Unani
Drug Manufacturing Licence.

Signature

Proprietor/Managing Partner/Managing Director

CHECKLIST FOR APPLICATION FOR GRANT OF LICENCES IN FORM 24 D

1. Covering Letter
2. Form 24 – D
3. Challan for **Rs. 1,000/-**
4. **Rs.1200/-** for Renewal up to **January, 31st**
5. From **1st February** to **March 31st Rs. 1200/- + 600/- = 1800/-**

0210 - Medical & Public Health

03 - Medical Education, Training & Research

200 - Other Systems of Medicine

81 - Other Charges

001 - Other Receipts

PAO CODE NO. 2500

DDO CODE NO. 25000 906044

6. Plan of the premises with partitions and measurement specification etc.
7. Attested copies of documents related to the ownership rent/lease/allotment of the site of building, along with proof of ownership.
8. Declarations of Proprietor / Managing Partner/managing Director and attested copies of partnership deed/Memorandum and articles of Association as the case may be.
9. Detailed list of manufacturing and Analytical equipment as required for formulations applied.
10. Appointment letter to Full Time Technical Supervisor (F.T.S).
11. Attested copies of certificates of Academic qualification, experience certificate Bio-dated Medical Registration Certificate and declarations of Technical Staff in the prescribed proforma with photo duly attested.
12. List of Sastric Medicines and Xerox copies of concerned pages of reference book duly signed by F.T.S with samples.
13. (2) Passport size photos each of proprietor and F.T.S.
14. (2) Sales packed draft labels for each drug as per D & C Rules with different names if any.

15. (10) Samples for each drug with sales pack draft labels with different sizes if any.
16. Self addressed envelop with sufficient postal stamps for Registered Post.
17. Clinical trial reports from (3) institutionally qualified Ayurvedic/Unani Parctioners as the may be on at least 30 patients for each drug used orally as per the proforma guidelines.
18. Drug Information in the Quadruplicate in the following lines for Anubhutha Yogams (Patent Drugs) duly signed by the Proprietor and F.T.S.
 - a. Name of the Product.
 - b. Formula, shall contain Shastric/Tibbi Name part used and quantity.
 - c. Detailed method of preparation.
 - d. Purification of drugs wherever required.
 - e. Indications (in Ayurveda/Unani terminology).
 - f. Passage Schedule in detail.
 - g. Contra – Indications.
 - h. Side effects.
 - i. Anti – dates Diet restriction, if any.