

Particulars to be furnished in connection with the application for the grant/renewal of manufacturing licence in Form 25-D for Ayurveda, Siddha and Unani drugs.

1. Application in Form 24-D dully filled up and Court Fee Stamp for Rs.2/- affixed on it.
2. Details of Technical Staff along with their qualification certificate, Council Registration certificate, Experience certificate, Bio data, ID Proof & Declarations obtained from technical staff to be notarized by the Notary public along with photo in non judicial paper to the value of Rs.20/-
3. List equipments/Purchase Invoices/Partnership Deed.
4. Plan of the Premises/ copy of Rent receipt /Tax Receipt/ Copy of Rental Agreement.
5. List of Medicine with ingredients (both botanical and S/A/U names) Authoritative Text Book reference from any one of the Text Books mentioned in the first Schedule to the drugs and Cosmetics Act 1940, method of manufacture, dose and the indications in Siddha/ Ayurveda/ Unani terminology (in triplicate)
6. Clinical Trial Report (Pilot Study) with IEC Certificate and CTRI Registration No. in duplicate duly mentioning the curable diseases in Siddha/Ayurveda/Unani terminology, if needed.
7. Labels/ Specimen Labels.
8. General Declaration & Drugs and Magic Remedies (objectionable Advertisement) Act, 1954 and Rules, 1955 (DMR) declaration.
9. Standards for raw materials.
10. Finished product specification.
11. List of books available - Authoritative books specified in the first schedule as applicable.
12. NOC – Local body, Fire.
13. Additional documents – Company Registration, GST Registration, Building Stability Certificate, Property Tax, Consent letter from AYUSH approved/ NABL Accredited Laboratory, etc.,
14. Batch Manufacturing Record, Distribution Register, Market Complaint Register & Adverse Drug Register.

**OFFICE OF THE STATE DRUG LICENSING AUTHORITY (IM),
ARUMBAKKAM, CHENNAI – 600 106.
LANDLINE: 044 – 26223653, EMAIL ID: statelicensing_authority@yahoo.com**

Fee details:

Payments should be made through treasury challan/ online transaction.

S.N o.	Type of Product	License fee (in Rs.)	Remarks
1.	Classical – New Applicants	2000	Any no. of products to encourage classical products
2.	Classical – Existing Applicants	1000	Any no. of products
3.	Patent and Proprietary – New product applicants	3000	First 10 Products
4.	Additional New P&P above first 10	@2000/product	
5.	Patent and Proprietary – existing applicants	1000	First 10 products
6.	Additional existing P&P above first 10	@1000/product	
7.	New GMP Certificate	5000	Validity 5 years
8.	Existing GMP certificate retention	1000	Validity 5 years

Online Payment Details:

Account Number : 30495199824
Name : The State Drug Licensing Authority IM
IFSC Code : SBIN0003273
Type : Regular Savings Bank Account
Branch : Aminjikai, Chennai
Bank : State Bank of India

Court fee stamp

“FORM 24D”

(See rule 153)

Application for the grant of a licence to manufacture for sale of Ayurvedic, Siddha or Unani drugs

1 . I / W e of..... hereby apply for the grant of a licence to manufacture Ayurvedic, Siddha or Unani drugs on the premises situated at.....

2. Names of drugs categorized according to Schedule T to be manufactured (with details)

3. Names, qualifications and experience of technical staff employed for manufacture and testing of Ayurvedic, Siddha or Unani drugs

4. A fee of rupees has been credited to the Government under the head of account and the relevant Treasury Challan/ online transaction slip is enclosed herewith.

Date.....

Signature

(applicant)

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

“FORM 24E-1

(See rule 153B)

Application for the Certificate of Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing units.

1 . I / W e of..... hereby apply for the grant of a Certificate of Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing on the premises situated at

2. A fee of rupees has been credited to the Government under the head of account and the relevant Treasury Challan/ online transaction slip is enclosed herewith.

Date.....

Signature

(applicant)

Note—The application should be accompanied by a Plan of the premises”.

General Declaration

From

To

**The State Licensing Authority (IM),
Tamil Nadu, Chennai 600106.**

Sir,

I / We do hereby declare that the following in respect of our application for Siddha, Ayurveda, Unani Manufacturing Licence and also Drugs and Cosmetics Act, 1940 and Rules made there under 1945

- 1. We will not violate any of the provisions of the Drugs and Cosmetics Act,1940 and the rules made thereunder, 1945**
- 2. We will not violate any of the provisions of the Drugs and Magic Remedies (Objectionable Advertisement Act) 1954 and the rules there under.**
- 3. The indications and claim submitted along with the applications for license will not be deviated at any time after obtaining the licence.**
- 4. Indications and testing of raw materials used in the preparations will be carried out wherever established tests are prescribed.**
- 5. No new ingredients other than shown in the product claim will be added after obtaining licence.**
- 6. Our products do not any way contravene provisions of Trade and Merchandise Act.**

Yours faithfully,

Name and address of the Licensed ASU Private Drug Testing Laboratories

1. **Cholayil Pvt Ltd, 31-A/24, SIDCO Industrial Estate, Ambattur, Chennai – 98.**
Phone Number: 044-66771600
2. **Captain Srinivasa Murthy Central Ayurveda Research Institute, Arignar Anna
Government Hospital of Indian Medicine Campus, Arumbakkam, Chennai-106.**
Phone Number: 044-26214823, 26207566
3. **CARISM (Center for Advanced Research in Indian System of Medicine), Unit of
Shanmugha Arts Science, Technology and Research Academy (SASTRA)
University, Thirumalaisamudram, Thanjavur – 613 401.**
Phone Number: 04362 304000 to 010 & 264101 & 108
4. **Regional Research Institute of Unani Medicine (CCRUM), No. 1, West Madha
Church Road, Royapuram, Chennai – 600 013.**
Phone Number: 044-25955519
5. **Asthagiri Herbal Research Foundation, 162-A, II Floor, Perungudi Industrial
Estate, Perungudi, Chennai 600 096.**
Phone Number: 044-24967645, 24967646
6. **Interdisciplinary Institute of Indian System of Medicine, SRM University, SRM
Nagar, Kattankulathur, Kancheepuram District – 603 203.**
Phone Number: 91-44-27455818, 98848 45887
7. **SMS Labs Services Private Limited, 39/6, Thiruvallur High Road,
Pudhuchatram Post, Thirumazhisai Via, Poonamallee Taluk, Chennai 600 124.**
Phone Number: 9884609199, 7338773269
8. **Sanjeev Biomedical Research Centre, 1/15, Kumaran Nagar, Keelkatalai,
Chennai 600 117. Phone Number: 9176049309**

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9. Bioscience Research Foundation, Sengadu Village & Post, Via Manavalanagar,
Kandamangalam, Kancheepuram 602 002.

Phone Number: 98400 33458, 044 27658298

e-mail: drselvan@brfchennai.com

10. T. Stanes and Company Limited, 1128, Trichy Road, Coimbatore – 641 018.

Phone Number: 0422 2221514, 2223515

e-mail: info@t-stanes.com

11. Chennai Mettex Lab Private Limited, Jothi Complex, 83, M.K.N. Road, Guindy,
Chennai 600 032.

Phone Number: 8939872544

e-mail: cro@mettexlab.com

Check list for GMP Certificate

- 1. Application in Form 24E-1**
- 2. Photo copy of GMP certificate**
- 3. Photo copy of original licence is form 25D and 26D**
- 4. List of equipments**
- 5. Plan of the premises**

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DMR Declaration in non Judicial paper to the value of Rs.50/-

**To
The State Licensing Authority (IM),
Arumbakkam, Chennai-106.
Tamil Nadu.**

Sir,

Sub: Declaration letter.

**We hereby undertake and declare that we will not advertise our product
in contravention of the provisions of the Drugs and Magic Remedies
(Objectionable Advertisement) Act, 1954.**

**We further declare that our product labels do not any way contravene the
Provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act,
1954 or any Rules made there under.**

Yours faithfully.

THE FIRST SCHEDULE

[See section 3(a)]

AYURVEDA

- 1 Arogya Kalpadruma
- 2 Arka Prakasha
- 3 Arya Bhishak
- 4 Ashtanga Hridaya
- 5 Ashtanga Samgraha
- 6 Ayurveda Kalpadruma
- 7 Ayurveda Prakasha
- 8 Ayurveda Samgraha
- 9 Bhaishajya Ratnavali
- 10 Brihat Bhaishajya Ratnakara
- 11 Bhava Prakasha
- 12 Brihat Nighantu Ratnakara
- 13 Charaka Samihita
- 14 Chakra Datta
- 15 Gada Nigraha
- 16 KupiPakva Rasayana
- 17 Nighantu Ratnakara
- 18 Rasa Chandanshu
- 19 Rasa Raja Sundara
- 20 Rasaratna Samuchaya
- 21 Rasatantra Sara Va Siddha Prayoga Sangraha—Part 1
- 22 Rasa Tarangini
- 23 Rasa Yoga Sagara
- 24 Rasa Yoga Ratnakara
- 25 Rasa Yoga Samgraha
- 26 Rasendra Sara Samgraha
- 27 Rasa Pradipika
- 28 Sahasrayoga
- 29 Sarvaroga Chikitsa Ratnam

- 30 SarvayogaChikitsaRatnam
- 31 Sharangadhara Samhita
- 32 Siddha Bhaishajya Manimala
- 33 Siddha Yoga Samgraha
- 34 Sushruta Samhita
- 35 Vaidya Chintamani
- 36 Vaidyaka Shabda Sindu
- 37 Vaidyaka Chikitsa Sara
- 38 Vidya Jiwan
- 39 Vasava Rajeeyam
- 40 Yoga Ratnakara
- 41 Yoga Tarangini
- 42 Yoga Chintamani
- 43 Kashyapasamhita
- 44 Bhelasamhita
- 45 Vishwanathachikitsa
- 46 Vrindachikitsa
- 47 Ayurvedachintamani
- 48 Abhinavachintamani
- 49 Ayurveda-Ratnakara
- 50 Yogaratnasangraha
- 51 Rasamrita
- 52 Dravyagunanighantu
- 53 Rasamanjari
- 54 Bangasena
- 55 Ayurvedic Formulary of India (Part-I) and its Parts
- 56 Ayurveda Sara Samgraha
- 57 Ayurvedic Pharmacopoeia of India
- 58 Ayurvedic Pharmacopoeia of India and its Parts

Siddha

- 1 Siddha VaidyaThirattu
- 2 Therayar Maha Karisal
- 3 Brahma Muni Karukkadai (300)
- 4 Bhogar (700)
- 5 Pulippani (500)
- 6 Agasthiyar Paripuranam (400)
- 7 Therayar Yamagam
- 8 Agasthiyar Chenduram (300)
- 9 Agasthiyar (1500)
- 10 Athmarakshamrutham
- 11 Agasthiyar Pin (80)
- 12 Agasthiyar Rathna Churukkam
- 13 Therayar Karisal (300)
- 14 Veeramamuni Nasa Kandam
- 15 Agasthiyar (600)
- 16 Agasthiyar Kanma Soothiram
- 17 18 Siddar's Chillarai Kovai
- 18 Yog Vatha Kaviyam
- 19 Therayar Tharu
- 20 Agasthiyar Vaidya Kaviyam (1500)
- 21 BalaVagadam
- 22 Chimittu Rathna (Rathna) Churukkam
- 23 Nagamuni (200)
- 24 Agasthiyar Chillarai Kovai
- 25 Chikicha Rathna Deepam
- 26 Agasthiyar Nayana Vidhi
- 27 Yugi Karisal (151)
- 28 AgasthiyarVallathi (600)
- 29 Therayar Thaila Varkam
- 30 The Siddha Formulary of India (Part I) and its Parts
- 31 The Siddha Pharmacopoeia of India and its Parts

UNANI TIBB SYSTEM

- 1 Karabadin Qadri**
- 2 Karabadin Kabir**
- 3 Karabadin Azam**
- 4 Ilaj-ul-Amraz**
- 5 Al Karabadin**
- 6 BiazKabir Vol. II**
- 7 Karabadin Jadid**
- 8 Kitab-ul-Taklis**
- 9 Sanat-ul-Taklis**
- 10 Mifta-ul-Khazain**
- 11 Madan-ul-Aksir**
- 12 Makhzan-ul-murabhat**
- 13 National Formulary of Unani India and its Parts**
- 14 Unani Pharmacopoeia of India and its Parts**

Procedure to register in e-aushadhi:

- 1. Open the portal e-aushadhi.gov.in.**
- 2. Click on Login/ Registration.**
- 3. In Registration form select Tamil Nadu and Licensee/ Applicant.**
- 4. In the “Name of the Company/Firm” text box, type the name of your company. .**
- 5. There will be two addresses that a Licensee/Applicant has to enter a. Registered office address b. Premises Address**
- 6. In Registered office address area, type Address line 1, Address line 2, Address line 3, Village/Town/City name and pin code.**
- 7. State will be displayed as per the state selected by the Licensee/Applicant on the previous screen.**
- 8. List of the districts will be populated as per the selected State.**
- 9. Select the district of registered office.**
- 10. Same as Registered office address, fill the premises address.**
- 11. Type the name, designation, Tel No with STD, 10 digit mobile no., fax number, email Id. These will be the details of primary Authorized Signatory. Email id of primary Authorized signatory will be used as the user name to login to this portal. All the emails and messages (SMS) from this portal will be sent to this email id and mobile number.**
- 12. To enter more than one Authorized Signatory, Click on “Add Row” button. New blank row will be added where user can add details of another authorized signatory. To remove the authorized signatory details, click “Delete Row” button.**
- 13. Primary Contact details are mandatory to fill and cannot be deleted.**
- 14. In the PAN No. text box, type the PAN NO. of the Firm.**
- 15. In the GST No. Text box, Type the GST No. of the firm.**
- 16. In the Website Address, type the Website Address of the firm if exists.**
- 17. Enter the Company certification details ((i) Company incorporation certification details – Company registration details, (ii) Details of IE (Import Export) Code) if exists.**
- 18. From the purpose of applying, there are two options 1. New 2. Existing Manufacturers. Who are already registered and have got license, will select**

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“Existing”. New Manufacturers will select “New”. Enter the captcha code and clicks submit.

- 19. Once submitted, request will be forwarded to the State Licensing Authority. Currently user will be inactive and won't be able to login. Licensing Authority will review your registration and approve or reject the same. When Licensing Authority accepts the registration, an email will be sent to the Licensee/Applicant and user can login to the portal.**
- 20. If any queries, contact the Office of the State Drug Licensing Authority (IM).**