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FORM 24-D: APPLICATION FOR LICENCE TO MANUFACTURE AYURVEDIC, SIDDHA OR UNANI DRUGS

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ABSTRACT

The application for the manufacture of Ayurvedic, Siddha, or Unani drugs for sale or distribution is made in Form 24-D to the Licencing Authority appointed for this purpose by the State Government. The information to be filled in the application are - the name of the applicant and the name of the manufacturing unit with their address. The important information here to be disclosed is the list of drugs with their category as per Schedule T of Drug Rule 1945, fee detail, and information about technical persons. A licence is issued when the manufacturing unit is found in compliance with the conditions of the licence and Schedule T of Drugs Rules 1945.

Key words: Licencing Authority, Drugs, and Cosmetics Act, Drugs Rules, Competent Technical Staff

INTRODUCTION

The drugs are regulated through the Drugs and Cosmetics Act of 1940 (D&C Act). The rules made them under were the Drugs and Cosmetics Rules 1945. These acts and rules were covering drugs, medical devices, and cosmetics. Now, a separate one, the Cosmetics Rules 2020 has been published. As per Rule 71 and Schedule Thirteen of Cosmetics Rules 2020, the word "and Cosmetics" was omitted from the Drugs and Cosmetics Rules 1945. So, now for drugs, there is Drugs Rules 1945. For medical devices, the Medical Device Rules 2017, and for new drugs, the New Drugs and Clinical Trials Rules 2019. Recently a draft of the New Drugs, Medical Devices and Cosmetics Bill 2022 was published for suggestions/ comments /objections from the public/ stakeholders.

Like other drugs, Ayurveda, Siddha, and Unani (ASU) drugs are also regulated through the Drugs and Cosmetic Act and Drug Rules. In the Drugs and Cosmetic Act, sections 33-B to 33-O are the provisions relating to Ayurvedic, Siddha, and Unani drugs. Section 33EEB, section 33EEC, and section 33EED are about regulation and prohibition of manufacture for sale of ASU drugs. The definitions of ASU medicines are given in section 3 of the Drugs and Cosmetic Act. In Drugs Rules, Rules 151 to 160 are manufacture for sale of ASU drugs, Rules 160-A to 160-J are about the testing of finished goods and raw materials by external labs, Rule 161 and 161-A deals with labelling, packaging, and limits of alcohol in ASU drugs, Rule 161 B is about shelf life or date of expiry of medicines, Rule 162 to 167 is about government analysts and inspectors and Rule 168 to 169 is about the standard of Ayurvedic, Siddha, and Unani Drugs.

MATERIAL AND METHOD

Drugs and Cosmetics Act 1940, Drugs Rules 1945, Medical Device Rules 2017, New Drugs and Clinical Trial Rules 2019, Cosmetic Rules 2020, a draft of New Drugs, Medical Devices and Cosmetics Bill 2022, Drafts of Amendments for Drug and Cosmetics Rules, Government notifications, available official and other information were collected and reviewed.

APPLICATION FOR LICENCE TO MANUFACTURE

The manufacture for sale or distribution of ASU drugs is permitted under and in accordance with the conditions of a licence issued for such purpose. For the grant of a licence to manufacture for sale of ASU drugs, an application is made to the Licencing Authority (LA) appointed by the State Government for this purpose. It is mandatory to comply with all other relevant applicable laws and regulations in addition to Drug and Cosmetic Act like Goods and Service Tax (GST) registration, Consent to Establish (CTE) or Consent to Operate (CTO) from pollution control board (PCB), factory licence and so on. A check list for application to LA usually includes- Form 24-D, Form 24E-1 (application for GMP), declaration, site plant, key plan, ownership deed of the land, non-conviction affidavit, organization chart, authorized signatory, list of machineries, list of books, SOP, proof of premises, MOA and documents related to drugs. The documents on check list vary from state to state.

The application for the grant of licence to manufacture for sale ASU drugs are required to be made through the portal e-AUSHADHI (www.e-aushadhi.gov.in). Initially, a maximum of six months period was given for the online and offline application process from the commencement of Drugs (4th Amendment) Rules 2021 which was published on 1st October 2021. On 4th April 2022, the period for online and offline applications was extended for a maximum of eighteen months. The application for the grant of licence to manufacture for sale ASU drugs is made in Form 24-D **(Fig. 1)** which comes under Rule 153 of Drug Rules 1945. In addition to the name of the applicant and name along with the address of manufacturing units, the information to be filled here are - list of drugs and their category according to Schedule T for which a licence is requested, information about the technical staff *i.e.*, name, qualification and experience of technical staff and fee detail. In order to fill up the form, it is required to know what the drug is, who are the technical staff and what is the fee structure for obtaining a manufacturing licence.

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 the manufacture and testing of Ayurvedic, Siddha, or Unani drugs .....
4. A fee of rupees ..... has been credited to the Government under the head of the 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.

Fig-1: Form 24D

Drugs and Authoritative Books

The definition of Ayurveda, Siddha, and Unani Drugs are given in section 3 of the Drugs and Cosmetics Act. Clause (a) of section 3 says- *Ayurvedic, Siddha or Unani drug includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation, or prevention of disease or disorder in human beings or animals and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha and Unani Tibb systems of medicine, specified in the First Schedule.* The medicines define are of textual reference which is commonly called classical medicine of Ayurveda, Siddha, and Unani system. Sub-clause (i) of clause (h) of Section 3 of the Drugs and Cosmetics Act defines the Patent or Proprietary medicines of the ASU system. In relation to Ayurveda, Siddha, and Unani system, patent or proprietary medicine include *all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha, or Unani Tibb systems of medicine specified in the First Schedule but does not include a medicine which is administered by the parenteral route and also a formulation included in the authoritative books as specified in clause (a).* For licencing purposes, the Drugs and Cosmetics Rules further categories the patent or proprietary medicine into four categories- (a) Patent or Proprietary medicine, (b) Balya/ Poshak/ Muqawi/ Unavuporutkal/ Positive health promoter, (c) Saundarya Prasadak (Husane Afza)/ Azhagh-sadhan, and (d) Aushadh Ghana (Medicinal Plant Extract- dry/wet).

The first schedule of the Drugs and Cosmetics Act is a list of authoritative books of Ayurveda, Siddha, or Unani Tibb systems of medicine. The schedule list 58 books for Ayurveda (Table 1), 31 books for Siddha (Table 2), and 14 books for Unani (Table 3) system of medicine.

Table-1: Authoritative Books of Ayurveda System	
Sl. No.	Books
1.	Arogya Kalpadruma
2.	Arka Prakasha
3.	Arya Bhishak
4.	Ashtanga Haridaya
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 Samhita
14.	Chakra Datta
15.	Gada Nigraha
16.	Kupi Pakva Rasayana
17.	Nighantu Ratnakara
18.	Rasa Chandanshu
19.	Rasa Raja Sundara
20.	Rasaratna Samuchaya
21.	Rasatantra Sara Va Siddha Prayoga Sangraha—Part1
22.	Rasatantra Sara Va Siddha Prayoga Sangraha—PartII (Edition 2006)
23.	Rasa Tarangini
24.	Rasa Yoga Sagara
25.	Rasa Yoga Ratnakara
26.	Rasa Yoga Samgraha
27.	Rasendra Sara Samgraha
28.	Rasa Pradipika
29.	Sahasrayoga
30.	Sarvaroga Chikitsa Ratnam
31.	Sarvayoga Chikitsa Ratnam
32.	Sharangadhara Samhita
33.	Siddha Bhaishajya Manimala
34.	Siddha Yoga Samgraha
35.	Sushruta Samhita
36.	Vaidya Chintamani
37.	Vaidyaka Shabda Sindu
38.	Vaidyaka Chikitsa Sara
39.	Vidya Jiwan
40.	Vasava Rajeeyam
41.	Yoga Ratnakara
42.	Yoga Tarangini
43.	Yoga Chintamani
44.	Kashyapasamhita
45.	Bhelasamhita
46.	Vishwanathachikitsa
47.	Vrindachikitsa
48.	Ayurvedachintamani
49.	Abhinavachintamani
50.	Ayurveda-Ratnakara
51.	Yogaratnasangraha

52.	Rasamrita
53.	Dravyagunanighantu
54.	Rasamanjari
55.	Bangasena
56.	Ayurvedic Formulary of India and its Parts
57.	Ayurveda Sara Samgraha
58.	Ayurvedic Pharmacopoeia of India and its Parts.

Table-2: Authoritative Books of Siddha System

Sl. No.	Books
1.	Siddha Vaidya Thirattu
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.	Bala Vagadam
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.	Agasthiyar Vallathi (600)
29.	Therayar Thaila Varkam
30.	Siddha Formulary of India (Part I)
31.	Siddha Formulary of India and its Parts

Table-3: Authoritative Books of Unani System	
Sl. No.	Books
1.	Karabadin Qadri
2.	Karabadin Kabir
3.	Karabadin Azam
4.	Ilaj-ul-Amraz
5.	Al Karabadin
6.	Biaz Kabir 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 Medicine
14.	Unani Pharmacopoeia of India

Table-4: Categories of Ayurvedic & Siddha Medicines according to Schedule T	
Sl. No.	Category
1.	Anjana/Pisti
2.	Churna / Nasya /Manjan / Lepa / Kwath Churn
3.	Pills / Vati / Gutika / Matirai and tablets
4.	Kupi pakava/Ksara/Parpati/ Lavana Bhasma Satva / Sindura Karpu/Uppu / Param
5.	Kajal
6.	Capsules
7.	Ointment/Marham Pasai
8.	Pak/Avaleh/Khand/ Modak/Lakayam
9.	Panak, Syrup / Pravahi Kwath Manapaku
10.	Asava / Arishta
11.	Sura
12.	Ark / Tinir
13.	Tail/Ghrit/Ney
14.	Aschyotan / Netra Malham Panir/Karn Bindu/Nasa- bindu

Categories of Drugs according to Schedule T

The guideline for Good Manufacturing Practice (GMP) for ASU drugs are described in Schedule T of Drugs Rules 1945. Schedule T is described in Part-I and Part-II. Part-I is Good Manufacturing Practice whereas Part-II is further divided as – (A) a List of recommended machinery, equipment, and minimum manufacturing premises required for the manufacture of various categories of Ayurvedic, Siddha system of medicines, (B) a List of recommended machinery, equipment, and minimum manufacturing premises required for the manufacture of various categories of Unani system of medicines, (C) List of equipments recommended for Quality Control section, and (D) Supplementary guidelines for the manufacturing of Rasaushadhies or Rasmarunthukal and Kushatajat (herbo-mineral-metallic componds) of ASU medicine.

Schedule T categories Ayurvedic and Siddha medicines in 14 categories mainly on the basis of their dosage form (Table-4). Unani medicines are placed in 13 categories (Table-5).

Table-5: Categories of Unani Medicines according to Schedule T	
Sl. No.	Category
1.	Itrifal Tirya/majoon/ Laooq/Jawarish/ Khamiras
2.	Arq.
3.	Habb (Pills) and tablets
4.	Sufoof (Powder)
5.	Raughan (Oils) (Crushing and boiling)
6.	Shiyaf, Surma, Kajal
7.	Marham, Zimad (Ointment)
8.	Qurs. (Tab.)
9.	Kushta
10.	Murabba
11.	Capsule
12.	Sharbat and Joshanda
13.	Qutoor-e-chashm and Marham (Eye drops, eye ointment)

Technical Staffs

It is required that the manufacture of ASU drugs shall be conducted under the direction and supervision of at least one competent technical staff, who is a whole-time employee. The qualification for technical staff include– (1) a degree in Ayurveda or Ayurvedic pharmacy, or Siddha or Unani system of medicine, as the case may be, (2) a diploma in Ayurveda, Siddha, or Unani system of medicine, (3) graduate in Pharmacy or Pharmaceutical Chemistry or Chemistry or Botany with at least 2 years' experience in the manufacture of ASU drugs, (4) Registered Vaid or Hakim with at least 4 years' experience in the manufacture of ASU drugs, or (5) Pharmacist in ASU with NLT 8 years' experience as may be recognized by Central Government. Every licensee is also required to provide a facility for a quality control section on his own premises or through Government approved testing laboratory. The quality control section will have a minimum of- (1) an Expert in Ayurveda or Sidha or Unani medicine having degree qualification recognized under Schedule II of Indian Medicine Central Council Act 1970, (2) a Chemist having a bachelor's degree in science or Pharmacy or Pharmacy (Ayurveda), (3) Botanist (Pharmacognosist) having at least Bachelor's Degree in science (Medical) or Pharmacy or Pharmacy (Ayurveda). The requirement of technical persons and their qualification for manufacturing sections are in sub-Rule (2) of Rule 157 of Drug Rules 1945. As per the draft Drugs and Cosmetics (Amendment) Rules, 2021 published for objection/ suggestion on 2nd July 2021, sub-Rule (2) of Rule 157 is under the amendment.

Fee structure for a licence to manufacture ASU medicines

The fee for a licence to manufacture any number of classical medicines is Rs 2000/-. The fee for the first 10 patents or proprietary medicine is Rs 3000/- and then Rs 2000/- per product for additional patent or proprietary medicine.

Inspection and issue of license

After the application, the manufacturing establishment is inspected by one or more drug inspectors with or without an expert. The inspectors examine all areas-the premises, plant, and appliance. The inspector also inspects the process of manufacture, means for standardization and testing of drugs, and enquiry into the professional qualification of technical staff. They examine and verify the statements made in the application in regard to and capability of the applicant to comply with all the requirements including **Schedule T.** After completion of the inspection, the inspector forwards a detail report of his findings on each aspect of the inspection along with his recommendation to the LA. On the inspection report, the LA may make further enquiry, if any as he may consider necessary. If the LA is satisfied that the conditions of the licence (Schedule T and other provisions) have been complied with, he shall grant a Licence to manufacture for sale of Ayurvedic, Siddha, or Unani drugs in Form 25D

through the e-AUSHADHI portal or the means applicable. If the LA is not satisfied with the requirements for a license, he shall issue a memorandum of shortcomings, the conditions which shall be satisfied, and a copy of the inspection report to the applicant. The applicant within two months of the issue of such memorandum shall reply the same. On non-submission of requirement, the LA shall reject the application and shall inform the applicant, of the reason for such rejection

DISCUSSION

There is an increasing interest in Ayurveda, Siddha, and Unani medicines due to a number of factors. The increasing interest has widened the scope in all areas such as diagnosis and treatment, the inclusion of modern and advance techniques, the upgradation of teaching curriculum, and so on. The increasing interest in Ayurveda and other system of medicine cannot be separated from the increasing demand for Ayurveda products including medicinal preparation. There is wide opportunity in manufacturing Ayurveda, Siddha, and Unani Medicine for sale or distribution. For the manufacturing license Form 24-D is submitted. A checklist of documents usually varies from place to place. Form 24-D requires information such as a list of drugs along with their categories, and information about technical staff. The fee for manufacturing licence of any number of medicine of clause (a) of section 3 of the Drugs and Cosmetic Act is Rs2000/-, the fee for upto 10 patent or proprietary is Rs 3000/- and then Rs 2000/- per addition patent or proprietary. Before the issuance of a licence, the manufacturing unit is inspected against the conditions of the licence as per Schedule T and other requirements. The manufacturing licence is issued in Form 25-D. Vaidyas and Hakims who manufacture Ayurvedic, Siddha, or Unani drugs for the use of their own patient do not require Form 24-D.

CONCLUSION

The application for the manufacturing licence for the sale or distribution of Ayurvedic, Siddha, or Unani drugs are made to the Licencing Authority appointed by State Government for this purpose in Form 24-D along with the applicable fee. The information to be filled in Form 24-D include a list of drugs along with their category as specified in Schedule T and information about technical staff.

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