GOVERNMENT OF INDIA

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

THE DRUGS AND COSMETICS ACT AND RULES

THE DRUGS AND COSMETICS ACT, 1940

(23 OF 1940)

(As amended up to the 31st December, 2016)

and

THE DRUGS AND COSMETICS RULES, 1945

(As amended up to the 31st December, 2016)

150J. ***Renewal***. – On an application being made for renewal the approving authority may cause an inspection to be made and if satisfied that the conditions of the approval and the rules made under the Act are and shall continue to be observed shall issue a certificate of renewal in Form 38.

150K. ***Withdrawal and suspension of approvals*** – (1) The approving authority may, after giving the approved institution an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, withdraw an approval granted under this Part or suspend it for such period as he thinks fit either wholly or in respect of some of the categories of drugs or items of cosmetics to which it relates, if in his opinion the approved institution has failed to comply with any of the conditions of the approval or with any provisions of the Act or the Rules made thereunder.

(2) Any approved institution whose approval has been suspended or withdrawn may within three months of the date of the order, appeal to the State Government which shall dispose of the appeal in consultation with a panel of competent persons appointed by it in this behalf and notified in the Official Gazette.]

[1][PART XVI

MANUFACTURE FOR SALE OF AYURVEDIC (INCLUDING SIDDHA) OR UNANI DRUGS

151. ***Manufacture on more than one set of premises***.—If Ayurvedic (including Siddha) or Unani drugs are manufactured on more than one set of premises, a separate application shall be made and a separate licence shall be obtained in respect of each such set of premises.

152. *Licensing Authorities*.—For the purpose of this Part the State Government shall appoint such Licensing Authorities and for such areas as may be specified in this behalf by notification in the Official Gazette.

153. ***Application for licence to manufacture Ayurvedic (including Siddha) or Unani drugs*.—** (1) An application for the grant or renewal of a licence to manufacture for sale any Ayurvedic (including Siddha) or Unani drugs shall be made in Form 24-D to the Licensing Authority along with [2][a fee of rupees one thousand]:

Provided that in the case of renewal the applicant may apply for the renewal of the licence before its expiry or within one month of such expiry:

Provided further that the applicant may apply for renewal after the expiry of one month but within three months of such expiry in which case the [2][fee payable for renewal of such licence shall be rupees one thousand and two hundred plus an additional fee of rupees six hundred].

(ii) [2][A fee of rupees three hundred] shall be payable for a duplicate copy of a licence issued under this rule, if the original licence is defaced, damaged or lost.

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1. Parts XVI, XVII and XVII added by S.O. 642, dt. the 2-2-1970 (w.e.f. 21.2.1970)
2. Subs. by G.S.R 79 (E), dt. 14-2-2005.

[1] [**153A**. ***Loan Licence***.—(i) An application for the grant of renewal of a loan licence to manufacture for sale of any Ayurvedic (including Siddha) or Unani drugs shall be made in Form 25-E to the Licensing Authority along with [2][a fee of rupees six hundred.]

Explanation—For the purpose of this rule, a loan licence means a licence which a Licensing Authority may issue to an applicant who does not have his own arrangements for manufacture but intends to avail himself of the manufacturing facilities owned by a licence in Form 25-D:

Provided that in the case of renewal the applicant may apply for the renewal of the licence before its expiry or within one month of such expiry:

Provided further that the applicant may apply for renewal after the expiry of one month, but within three months of such expiry in which case [2][the fee payable for renewal of such licences shall be rupees six hundred plus an additional fee of rupees three hundred.]]

(ii) [2][A fee of rupees one hundred and fifty] shall be payable for a duplicate copy of a licence issued under this rule, if the original licence is defaced, damaged or lost.]

154. ***Form of licence to manufacture Ayurvedic (including Siddha) or Unani drugs.*** — (1) Subject to the conditions of rule 157 being fulfilled, a licence to manufacture for sale any Ayurvedic (including Siddha) or Unani drugs shall be issued in Form 25-D. The licence shall be issued within a period of three months from the date of receipt of the application.

(2) A licence under this rule shall be granted by the licensing authority after consulting such expert in Ayurvedic (including Siddha) or Unani Systems of medicine as the case may be, which the State Government may approve in this behalf.

[1][**154A.** ***Form of loan licence to manufacture for sale of Ayurvedic (including Siddha) or Unani drugs***.—

(1) A loan licence to manufacture for sale of any Ayurvedic (including Siddha) or Unani drugs shall be issued in Form 25E.

(2) A licence under this rule shall be granted by the Licensing Authority after consulting such expert in Ayurvedic (including Siddha) or Unani systems of medicine, as the case may be, which the State Government may approve in this behalf.

(3) The Licensing Authority shall, before the grant of a loan licence, satisfy himself that the manufacturing unit has adequate equipment, staff, capacity for manufacture and facilities for testing, to undertake the manufacture on behalf of the applicant for a loan licence.]

155. ***Certificate of renewal***—The certificate of renewal of a licence in Form 25-D shall be issued in Form 26-D.

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1. Ins. by G.S.R. 376(E), dt. 20-7-1978.
2. Subs. by G.S.R 79 (E), dt. 14-2-2005.

[1] [**155A.** ***Certificate of renewal of a loan licence***.—The certificate of renewal of a loan licence in Form 25-E shall be issued in Form 26-E.]

[2][**155B.** ***Certificate of award of G.M.P. of Ayurveda, Siddha and Unani Drugs***.— [3][(1)]The certificate of Good Manufacturing Practices to manufacturers of Ayurveda, Siddha or Unani drugs shall be issued to licensees who comply with the requirements of Good Manufacturing Practice of Ayurveda, Siddha and Unani drugs as laid down in Schedule T.]

[4][(2) The certificate referred to in sub-rule (1) shall be issued for a period of five years from the date of issuance of the license.]

156. ***Duration of licence***—An original licence in Form 25-D or a renewed licence in Form 26-D, unless sooner suspended or cancelled shall be [5][valid for a period of [6][five years] from the date of its issue]:

Provided that if the application for the renewal of a licence is made before its expiry or within one month of its expiry after payment of the additional fee of rupees thirty, the licence shall continue to be in force until orders are passed on the application. The licence shall be deemed to have expired, if the application for its renewal is not made within three months of its expiry.]

[1] [**156A**. ***Duration of loan licence***.—An original loan licence in Form 25-E or a renewed loan licence in Form 26-E, unless sooner suspended or cancelled, shall be valid up to the 31st December of the year following the year in which it is granted or renewed:

Provided that if the application for the renewal of a loan licence is made in accordance with rule 153-A, the loan licence shall continue to be in force until orders are passed on the application. The licence shall be deemed to have expired, if the application for its renewal is not made within three months of its expiry.]

157. ***Conditions for the grant or renewal of a licence in Form 25-D***.—Before a licence in Form 25-D is granted or renewed in Form 26-D the following conditions shall be complied with by the applicant, namely: —

(1) The manufacture of Ayurvedic (including Siddha) or Unani drugs shall be carried out in such premises and under such hygienic conditions as are specified in Schedule T.

[2][(IA) For issuing of the certificate of Good Manufacturing Practices, the Licensing Authority shall verify the requirements as per schedule T and issue the Good Manufacturing Practices certificate in form 26 E-I, simultaneously along with grant or renewal of licence in form 25D].

[7][(IB) No manufacturer shall use any prefix or suffix with the name of any Ayurvedic, Siddha or UnaniTibb drug falling under clause (a) of section 3 of the Act, except as described in the authoritative books specified in the First Schedule to the Act:

Provided that a formulation without any specific name, described in the authoritative books may be named on the basis of the ingredients of the formulation.

(IC) The name of any Ayurvedic, Siddha or UnaniTibb drug falling under clause (a) of section 3 of the Act shall not be used for naming any patent or proprietary medicine relating to Ayurvedic, Siddha or UnaniTibb systems of medicine referred to in sub-clause (i) of clause (h) of the said section:

Provided that this rule shall not be applicable for single plant-ingredient based Ayurvedic, Siddha or UnaniTibb formulation licensed or to be licensed as patent or proprietary medicine under sub-clause (i) of clause (h) of section 3 of the Act.]

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1. Ins. by G.S.R. 376 (E),dt. 20-7-1978.
2. Subs. by G.S.R. 376 (E),dt. 3-5-2010. Earlier Ins. by G.S.R. 198 (E), dt. 7-3-2003.
3. Rule 155B renumbered as sub-rule (1) by G.S.R. 376 (E),dt. 3-5-2010.
4. Ins. by G.S.R. 376 (E),dt. 3-5-2010.
5. Subs. by G.S.R 79 (E), dt. 14-2-2005.
6. Subs. by G.S.R. 376 (E),dt. 3-5-2010.
7. Ins. by G.S.R. 390 (E),dt. 18.5.2015.

(ID) Notwithstanding the period for renewal of licence provided in rules 156 and 156 A, the licensee of the Ayurvedic, Siddha or UnaniTibb drug, which is not in conformity with sub-rules (1B) and (1C), shall seek renewal of the licence with appropriate name of the drug within a period of one year from the date of commencement of Drugs and Cosmetics (4th Amendment) Rules, 2015:

Provided that this rule shall not be applicable to any batch of Ayurvedic, Siddha or UnaniTibb drugs manufactured prior to the date of commencement of the Drugs and Cosmetics (4th Amendment) Rules, 2015.

(IE) Whoever contravenes the provisions of rules (IB) to (ID) shall be punishable under section 33-I of the Act.]

(2) The manufacture of Ayurvedic (including Siddha) or Unani drugs shall be conducted under the direction and supervision of competent technical staff consisting at least of one person, who is a whole time employee and who possesses the following qualifications, namely:–

(a) A degree in Ayurveda or Ayurvedic Pharmacy, Siddha or Unani system of medicine, as the case may be, conferred by a University, a State Government or Statutory Faculties, Councils and Boards of Indian Systems of Medicines recognized by the Central Government or a State Government for this purpose, or

(b) a diploma in Ayurveda, Siddha or Unani system of medicine granted by a State Government for this purpose, or

(c) a graduate in Pharmacy or Pharmaceutical Chemistry or Chemistry or Botany of a University recognized by the Central Government with experience of at least two years in the manufacture of drugs pertaining to the Ayurvedic or Siddha or Unani systems of medicines, or

(d) a Vaid or Hakim registered in a State Register of Practitioners of indigenous systems of medicines having experience of at least four years in the manufacture of Ayurvedic or Siddha or Unani drugs, or

(e) a qualification as Pharmacist in Ayurvedic (including Siddha) or Unani systems of medicines, possessing experience of not less than eight years in the manufacture of Ayurvedic or Siddha or Unani drugs as may be recognized by the Central Government.

(3) The competent technical staff to direct and supervise the manufacture of Ayurvedic drugs shall have qualifications in Ayurveda and the competent technical staff to direct and supervise the manufacture of Siddha drugs and Unani drugs shall have qualification in Siddha or Unani, as the case may be.

[3][**157A. Maintaining of records of raw material used by licensed manufacturing unit of Ayurveda, Siddha and Unani drugs in the preceding financial year.-** Each licensed manufacturing unit of Ayurveda or Siddha or Unani drugs shall keep a record of raw material used by each licensed manufacturing unit of Ayurveda, Siddha or Unani drugs as the case may be in the proforma given in Schedule TA in respect of all raw materials utilized by that unit in the manufacture of Ayurveda or Siddha or Unani drugs in the preceding financial year, and shall submit the same by the 30th day of June of the succeeding financial year to the State Drug Licensing Authority of Ayurveda, Siddha and Unani drugs and to the National Medicinal Plants Board or any agency nominated by the National Medicinal Plant Board for this purpose.]

158. ***Conditions of licence***.—A licence in Form 25D shall be subject to the conditions stated therein and to the following further conditions, namely:–

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

(b) The licensee shall allow an Inspector appointed under the Act to enter any premises where the manufacture of a substance in respect of which the licence is issued is carried on, to inspect the premises, to take samples of the raw material as well as finished the products, and to inspect the records maintained under these rules.

[1][(c) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.]

[2][**158-A.** *Condition of loan licence*.—A licence in Form 25E shall be subject to the conditions stated therein and to the following conditions, namely:—

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

(b) The licensee shall comply with the provisions of the Act and of the rules and with 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.

(c) 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.

(d) 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 require for the purpose of ascertaining whether the provisions of the Act and the rules have been observed.

[1][(e) The licensee shall maintain an Inspection Book in form 35 to enable an Inspector to record his impressions and the defects noticed.]

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1. Ins. by G.S.R. 331 (E),dt. 8.5.1984.
2. Ins. by G.S.R. 376 (E), dt. 20.7.1978.
3. Ins. by G.S.R. 512 (E),dt. 9.7.2008.

[1][158(B) Guidelines for issue of license with respect to Ayurveda, Siddha or Unani drugs.-

I. (A). Ayurveda, Siddha Unani Medicines under section 3(a):- Ayurveda, Siddha or Unani drugs 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 system of medicine, as specified in the First Schedule;

(B). Patent or Proprietary medicine under section 3(h);

(i) In relation to Ayurvedic, Siddha and Unani Tibb system of medicine of all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani Tibb system of medicines specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause (a);

(ii) Balya/Poshak/Muqawi/Unavuporutkal/positive health Promoter formulations having ingredients mentioned in books of First Schedule of the Drugs and Cosmetics Act and recommended for promotional and preventive health.

(iii) Saundarya Prasadak (Husane afza)/Azhagh-sadhan formulation having ingredients mentionedin Books of First Schedule of the Drugs and Cosmetics Act and recommended for oral, skin, hair and body care.

(iv) Aushadh Ghana (Medicinal plant extracts - dry/wet) extract obtained from plant mentioned in books of First Schedule of the Act including Aqueous or hydro-alcohol.

II.(A) For issue of licence to the medicine with respect to Ayurvedic, Siddha and Unani, the conditions relating to safety study and the experience or evidence of effectiveness shall be such as specified in columns (5) and (6) of The Table given below:-

Serial number	Category	Ingredient (S)	Indication (s)	Safety study	Experience/Evidence of Effectiveness	
1	2	3	4	5	6	
					Published Literature	Proof of Effectiveness
1	(A) Ayurveda, siddha and Unani drugs, given in 158 B as referred in 3(a)	As per text	As per text	Not Required	Required	Not Required
2	(B) Any change in dosage form of Ayurveda, siddha and Unani drugs, as described in section 3 (a) of the Drugs and Cosmetics	As per text	As per text	Not Required	Required	Not Required

	Act, 1940					
3	(C) Ayurveda, siddha and Unani drugs, referred in 3(a) to be used for new indication	As per text	New	Not Required	If Required	Required

II.B For issue of license with respect to Patent or Proprietary medicine. The condition relating to Safety studies and experience or evidence of effectiveness shall be specified as follows:-

Serial number	Category	Ingredient (S)	Indication (s)	Safety study	Experience/Evidence of Effectiveness	
1	2	3	4	5	6	
					Published Literature	Proof of Effectiveness
1	Patent orProprietary medicine	As per text	Textual Rationale	Not Required	Of Ingredients	Pilot study as per relevant protocol for Ayurveda, siddha and Unani drugs
2	Ayurveda, siddha and Unani drugswith any of the ingredients of Schedule E(1) of the Drugs and Cosmetics Act, 1940	As per text	Existing	Required	Required	Required

III. For issue of license with respect to Balya and Poshak medicines the person who applied for license is required to submit the following:

(i) Photo-copy of the textual reference of ingredients used in the formulation as mentioned in the book of 1st schedule;

(ii) Conduct safety studies in case the product contains of any of the ingredients as specified in the Schedule E (1), as per the guidelines for evaluation of Ayurveda Siddha and Unani Drugs formulations;

(iii) For textual indications the safety and effectiveness study is not required.

IV. For issue of license with respect to Saundarya Prasadak (Husane afza/Azhagu Sodhan) the person who applied for license is required to:-

(i) Submit photo-copy of the textual reference of ingredients used in the formulation as mentioned in the book of 1st schedule;

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1. Ins. by G.S.R. 663 (E),dt. 10.10.2010.

(ii) Conduct safety studies, in case the formulation contains of any of the ingredients as specified in the Schedule E (1), as per the guidelines for evaluation of Ayurveda, Siddha and Unani formulation;

(iii) For textual indications the safety and effectiveness study is not required.

V. For issue of license with respect to medicine Aushadh Ghana extract of medicinal plant (dry or wet).

Serial number	Category	Ingredient (S)	Indication (s)	Safety study	Experience/Evidence of Effectiveness	
1	2	3	4	5	6	
					Published Literature	Proof of Effectiveness
1	(A) Aqueous	As per text	As per text	Not Required	Not Required	Not Required
2	(Al). Aqueous	As per text	New Indication**	Not Required	Not Required	Required
3	(B) Hydro-Alcohol	As per text	As per text	Not Required	If Required	Not Required
4	(B1) Hydro-Alcohol	As specified	New Indication**	Required	If Required	Required
5	Other than Hydro/ HydroAlcohol	As specified	As specified	Required Acute, Chronic, mutagenicity and teratogenicity	If Required	Required

* The standard protocol will also include concept of Anupan, Prakriti & Tridosh etc. published by Central

Research Councils Ayurveda, Siddha, Unani and other Government/Research Bodies.

** New indication means which is other than mentioned in 1st schedule books of Drugs & Cosmetics Act 1940.]

[1][**158C. Form of Free Sale Certificate and Non-Conviction Certificate. –** The State Drug Controller or Licensing Authority shall, on request by the Ayurveda, Siddha and Unani Drugs manufacturer, issue, within 15 days; from the date of application, Free Sale Certificate in Form 26 E2-I for original License holder or in Form 26 E2-II for loan license and Non Conviction Certifacate for both original and loan license holder in Form 26 E3 or in the format as specified by the importing country or tenderer respectively, after fulfilment of all requisite formalities as required in the respective formats.]

1. Ins. by G.S.R. 153 (E),dt. 5.3.2014.

159. ***Cancellation and suspension of licences***— (1) The Licensing Authority may, after giving an opportunity to show cause within a period which shall not be less than fifteen days from the date of receipt of such notice, why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the drugs to which it relates, if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act and the rules made thereunder.

(2) A licensee whose licence has been suspended or cancelled may appeal to the State Government within a period of three months from the date of receipt of the order which shall, after considering the appeal, decide the same.

160. ***Identification of raw materials***.— Raw materials used in the preparation of Ayurvedic (including Siddha) or Unani drugs shall be identified and tested, wherever tests are available for their genuineness, and records of such tests as are carried out for the purpose and the methods thereof shall be maintained.

[1][PART XVI (A)

APPROVAL OF INSTITUTIONS FOR CARRYING OUT TESTS ON AYURVEDIC, SIDDHA AND UNANI DRUGS AND RAW MATERIALS USED IN THEIR MANUFACTURE ON BEHALF OF LICENSEES FOR MANUFACTURE FOR SALE OF AYURVEDIC, SIDDHA AND UNANI DRUGS

160-A. ***Application for grant of approval for testing Ayurvedic, Siddha and Unani drugs***.- Application for grant or renewal of approval for carrying out tests for identity, purity, quality and strength of Ayurvedic, Siddha and Unani drugs or the raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of the said Ayurvedic, Siddha and Unani drugs, shall be made in Form 47 to the Licensing Authority appointed by the State Government for the purposes of Part XVI, XVII or XVIII of these rules, as the case may be, and referred to as the 'approving authority' under this Part and shall be accompanied by an inspection fee of six thousand rupees in respect of the drugs specified in the books prescribed in First Schedule to the Act.

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1. Subs. by G.S.R.73 (E), dt. 31-01-2003 and earlier Ins. by G.S.R. 701(E), dt. 27-9-2001.