

***THE DRUGS RULES, 1945¹**

[21st December, 1945]

In exercise of the powers conferred by ¹[sections 6(2), 12, 33 and 33(N)] of the Drugs ²[and Cosmetics] Act, 1940 (23 of 1940), the Central Government is pleased to make the following Rules:—

PART I PRELIMINARY

1. **Short title, extent and commencement.**—(1) These Rules may be called the Drugs ³[***] Rules, 1945.

(2) They extend to the whole of India ³[***].

2. **Definitions.**—In these Rules, unless there is anything repugnant in the subject or context—

(a) "the Act" means the Drugs and Cosmetics Act, 1940 (23 of 1940), as amended from time to time;

⁶[(aa) "biopharmaceutical classification system" means a system used to classify drugs on the basis of solubility and permeability, classified as category I-high solubility and high permeability, category II-low solubility and high permeability, category III-high solubility and low permeability, and category IV-low solubility and low permeability;] ⁷[(b) "Central Licence Approving Authority" means the Drugs Controller, India, or the Joint Drugs Controller (India) or the Deputy Drugs Controller (India) appointed by the Central Government;]

(c) "Director" means the Director of the Central Drugs Laboratory;

(d) "Form" means a Form set forth in Schedule A;

⁸[(dd) "Homoeopathic medicines" include any drug which is recorded in Homoeopathic provings or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative Homoeopathic literature of India and abroad and which is prepared according to the techniques of Homoeopathic pharmacy and covers combination of ingredients of such

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 therefore, 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 ¹⁹²[***] to which it relates, if in his opinion the approved institution had failed to comply with any of the conditions of the approval or with any provision 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(2) Any approved institution whose approval has been suspended or withdrawn may within three months of the date of the order, appeal to the State Government which shall dispose of the appeal in consultation with a panel of competent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.]

⁶ PART XVI
MANUFACTURE FOR SALE OF AYURVEDIC ⁷[SIDDHA] OR UNANI DRUGS

151. Manufacture on more than one set of premises.—If Ayurvedic ¹⁹³[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.

¹[**153. Application for licence to manufacture Ayurvedic, Siddha or Unani drugs.**—(1) An application for the grant of licence to manufacture for sale of Ayurvedic, Siddha or Unani drug, shall be made—

(a) as defined under clause (a) of section 3 of the Act, in Form 24D to the licensing authority alongwith a fee of rupees two thousand; and

(b) as defined in sub-clause (i) of clause (h) of section 3 of the Act, in Form 24D to the licensing authority alongwith a fee of mpees three thousand for the first ten products and after the said ten products, an additional fee of rupees two thousand per product, through the portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in

the said portal, pertaining to the licence for manufacture for sale of Ayurvedic, Siddha or Unani drugs.

Provided that this rule shall not be applicable to licence obtained under Form 25D prior to the date of commencement of the Drugs (4th Amendment) Rules, 2021 and such licence holder having a Good Manufacturing Practices Certificate on the date of its renewal has to deposit a onetime licence retention fee of rupees one thousand for existing licenced drugs falling under clause (a) of section 3 of the Act; and rupees one thousand for first ten products and a fee at the rate of rupees one thousand per product over and above the said first ten products for existing licenced drugs falling under sub-clause (i) of clause (h) of section 3 of the Act.

Provided further that till the portal e-AUSHADHI (www.e-aushadhi.gov.in) shall come to effect within six months of the commencement of the Drugs (4th Amendment) Rules, 2021 and during this period either of online and offline process of licence application shall be accepted.]

²[**153A. Application for loan licence to manufacture Ayurvedic, Siddha or Unani drugs.**—(1) An application for grant of a loan licence to manufacture for sale of Ayurvedic, Siddha or Unani drug, shall be made—

(a) as defined under clause (a) of section 3 of the Act, in Form 24E to the licensing authority alongwith a fee of rupees two thousand; and

(b) as defined in sub-clause (i) of clause (h) of section 3 of the Act, in Form 24E to the licensing authority alongwith a fee of rupees three thousand for the first ten products and after the said ten products, an additional fee of rupees two thousand per product, through the portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal, pertaining to the loan licence for manufacture for sale of Ayurvedic, Siddha or Unani drugs:

Provided that this rule shall not be applicable to licence obtained under Form 25E prior to the date of commencement of the Drugs (4th Amendment) Rules, 2021 and such licence holder having a Good Manufacturing Practices Certificate of the manufacturing facilitieshe intends to avail on the date of renewal of its licence has to deposit a onetime licenceretention fee of rupees one thousand for existing licenced drags falling under clause (a) of section 3 of the

Act; and rupees one thousand for first ten products and a fee at the rate of rupees one thousand per product over and above the said first ten products for existing licenced drags falling under sub clause (i) of clause (h) of section 3 of the Act.

Provided further that till the portal e-AUSHADHI (www.e-aushadhi.gov.in) shall come to effect within six months of the commencement of the Drugs (4th Amendment) Rules, 2021 and during this period either of online and offline process of licence application shall be accepted.

Explanation—For the purposes of this rule, a "loan licence" means a licence issued by the Licensing Authority to an applicant who does not have his own arrangements for manufacture but intends to avail himself of the manufacturing facilities owned by a licensee in Form 25D.

153B. Application for Certificate of Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing unit.—(1) An application for the grant of a Certificate of Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing unit shall be made in Form 24E-1 to the licensing authority along with a fee of rupees five thousand.

(2) Every application in Form 24E-1 shall be made for a unit having premises and other requirements as prescribed under Schedule T.

(3) The application shall be made through portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal, pertaining to the Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing units.]

¹**[154. Form of licence to manufacture Ayurvedic, Siddha or Unani drugs.**—(1) Subject to the conditions of rule 157 being fulfilled, a licence to manufacture for sale of any Ayurvedic, Siddha or Unani drags shall be issued in Form 25D within a period of two months from the date of receipt of the application or from the date of compliance by the applicant of shortcomings, if any, highlighted by the licensing authority, as the case may be.

(2) A licence under this rule shall be granted by the licensing authority after consulting such expert in Ayurvedic, Siddha or Unani Systems of

medicine, as the case may be, which the State Government may approve in this behalf.

(3) The application shall be processed through portal e-AUSHADHI (www.e-ajshadhi.gov.in) and the licence in Form 25D shall be issued online as per the format provided in the said portal.]

¹[**154A. Form of loan licence to manufacture for sale of Ayurvedic, Siddha or Unani drugs.**—(1) A loan licence to manufacture for sale of any Ayurvedic, Siddha or Unani drugs shall be issued in Form 25E within a period of two months from the date of receipt of the application or from the date of compliance of shortcomings, if any, highlighted by the licensing authority, as the case may be.

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

(3) The Licensing Authority after being satisfied that the manufacturing unit licenced under Form 25D has adequate equipment, staff and capacity for manufacture and facilities for testing, to undertake the manufacture on behalf of the applicant for a loan licence shall grant a loan licence.

(4) The application shall be processed through portal e-AUSHADHI (www.e-aushadhi.gov.in) and licence in Form 25E shall be issued online as per the format provided in the said portal.]

155. ¹⁹⁴[***]

155A. ¹⁹⁵[***]

⁴[**155B. Certificate of award of Good Manufacturing Practices Ayurveda, Siddha and Unani Drugs.**—¹⁹⁶[(1)] The certificate of Good Manufacturing Practices (GMP) to manufacturers of Ayurved-Siddha or Unani drugs shall be issued ¹⁹⁷[in Form 26E-1] to licensee who comply with the requirements of Good Manufacturing Practice (GMP) of Ayurveda, Siddha and Unani drugs as laid down Schedule T.]

(2) ¹⁹⁸[***]

⁸**[156. Duration of licence.—(1) A licence issued in Form 25D shall remain valid perpetually:**

Provided that the licensee shall submit a self-declaration of adherence to the conditions of licence and the provisions of the Drugs and Cosmetics Act and the rules made thereunder, every year from the date of issue of licence in Form 25 D or from the date of submission of last self-declaration, as the case may be:

Provided further that such self-declaration shall be made within three months, of completion of one year from the date of issue of licence in form 25 D or from the date of submission of last self-declaration, as the case may be, and in the event of non-submission of such self-declaration, within the time mentioned in the licence of the said product shall be suspended temporarily and if the licensee fails to submit the self-declaration within a further period of three months, the licence of the said product shall be deemed to have been cancelled.]

¹**[156A. Duration of loan licence.—**A loan licence issued in Form 25E shall remain valid perpetually:

Provided that the licensee shall submit a self-declaration of adherence to the conditions of licence and the provisions of the Drugs and Cosmetics Act and the rules made thereunder, every year from the date of issue of licence in form 25 E or from the date of submission of last self-declaration, as the case may be.

Provided further that such self-declaration shall be made within three months, of completion of one year from the date of issue of licence in form 25 E or from the date of submission of last self-declaration, as the case may be, and in the event of non-submission of such self-declaration, within the time mentioned in the Licence of the said product shall be suspended temporarily and if the licensee fails to submit the self-declaration within a further period of three months, the licence of the said product shall be deemed to have been cancelled.

156B. Duration of Certificate of Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing units—(1) A certificate issued in form 26E-1 shall remain valid unless it is cancelled by the Licensing Authority subject to deposit of a certificate retention fee of rupees one thousand before the expiry of a period of every succeeding five years from the date of its issue.

(2) If the licensee fails to pay certificate retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay certificate retention fee alongwith a late fee calculated at the rate of two per cent of the certificate retention fee for every month or part thereof up to six months, and in the event of non-payment of such fee, the certificate shall be deemed to have been cancelled.

156C. Inspection for grant of licence and verification of compliance.—

(1) Before a certificate in Form 26E-1 is granted, the licensing authority shall cause the establishment in which the manufacture of drugs is proposed to be conducted or being conducted to be inspected by one or more inspectors appointed by the State Government under this Act, with or without an expert in the field concerned and the inspector or inspectors shall examine the establishment intended to be used or being used for the manufacture of drugs.

(2) The inspectors shall verify the self-declaration of adherence to the conditions of licence and the provisions of the Drugs and Cosmetics Act and the Drugs Rules once in five years or as needed as per risk based approach.

Provided that the inspectors are allotted the inspection duty in a randomized manner ensuring that the same inspector is not assigned inspection of a particular establishment consecutively for two terms of not less than five years' duration.

Provided further that if the premises is not inspected within the period of the validity of the GMP certificate or even after submission of retention fee, the GMP certificate shall be deemed to be continued for further term of five years.

156D. Report by Inspector.—(1) The Inspector or Inspectors shall examine all areas of the premises, plant and appliances and also inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for standardizing and testing the drugs to be manufactured or being manufactured and enquire into the professional qualifications of the technical staff to be employed and he shall also examine and verify the statements made in the application in regard to their correctness, and the capability of the applicant to comply with the requirements of competent technical staff, manufacturing plants, testing equipments and the Requirements of Good Manufacturing Practices and Plant and Equipments as laid down in Schedule T.

(2) The Inspector after completion of his inspection shall forward a detailed report giving his findings on each aspect of inspection alongwith his recommendations, to the Licensing Authority.

156E. Procedure of Licensing Authority.—(1) If the Licensing Authority after such further enquiry, if any, as he may consider necessary, and after being satisfied that the requirements of the provisions referred to in the rules under the Act have been complied with and that the conditions of the licence shall be observed, shall issue a licence under this Part.

(2) If the Licensing Authority is not satisfied of the requirements under sub-rule (1), shall issue a memorandum of shortcoming, and the conditions which shall be satisfied before a licence is granted and shall supply the applicant a copy of the inspection report.

(3) The applicant within two months of issue of such memorandum under sub-rule (2) shall reply the same.

(4) On non-submission of requirements under sub-rule (2), the Licensing Authority shall reject the application and shall inform the applicant, the reasons for such rejection.

(5) For this purpose, the licensing authority shall intimate the applicant and process the application through portal e-AUSHADHI (www.e-aushadhi.gov.in).

156F. Further application after rejection.—If the applicant, within a period of six months from the rejection of an application for a licence or Certificate of Good Manufacturing Practices, as the case may be, informs the Licensing Authority that the conditions laid down have been complied with and deposit an inspection fee of rupees one thousand, the Licensing Authority may, after a further inspection, if any, is satisfied that the conditions for the grant of a licence or certificate have been complied with, issue a licence or certificate under thus Part.]

157. Conditions for the grant ¹[*] of a licence in Form 25D.**—Before a licence in Form 25D is granted ¹⁹⁹[***], the following conditions shall be complied with by the applicant, namely:—

(1) The manufacture of Ayurvedic ²⁰⁰[Siddha] or Unani drugs shall be carried out in such premises and under such hygienic conditions as are specified in Schedule T.

¹[(1A) 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 26E-I, simultaneously along with grant ²⁰¹[***] of Licence in Form 25D.]

³[(1B) No manufacturer shall use any prefix or suffix with the name of any Ayurvedic, Siddha or Unani Tibb 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 that formulation.]

(1C) The name of any Ayurvedic, Siddha or Unani Tibb 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 Unani Tibb 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 Unani Tibb formulation Licensed or to be Licensed as patent or proprietary medicine under sub-clause (i) of clause (h) of section 3 of the Act.

⁴[(1D) Whoever contravenes the provisions of sub-rules (1B) and (1C) shall be punishable in accordance with the provisions of the Act.]

(IE) ²⁰²[***]

(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 qualification, 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 Medicine recognised 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 or an Institution recognised by the Central Government for this purpose, or

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

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

(e) a qualification as Pharmacist in Ayurvedic (including Siddha) or Unani systems of medicine, possessing experience of not less than eight years in the manufacture of Ayurvedic or Siddha or Unani drugs as may be recognised 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 qualifications in Siddha or Unani, as the case may be.

¹[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 performa 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:]

²[Provided that the applicant shall submit the record online through portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal and such records shall be retained by the manufacturer for a period of one year after the submission.]

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 materials as well as the finished products, and to inspect the records maintained under these rules.

¹[(c) The applicant and inspector shall submit the record online through e-AUSITADHI (www.e-aushadhi.gov.in) portal as per the format provided in the said portal.]

²[158A. Conditions of loan licence.—A licence in Form 25E shall be subject to the following further 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 IVA 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, 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.]

³[(e) The applicant and inspector shall submit the record online through e-AUSHADHI (www.e-aushadhi.gov.in) portal as per the format provided in the said portal.]

⁴[**158B. Guidelines for issue of license with respect to Ayurveda, Siddha or Unani drugs.**—I. (A) Ayurveda, Siddha or 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/posilive 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 mentioned in 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) (3)	Indication (s) (4)	Safety study (5)	Experience / Evidence of Effectiveness (6)	
(1)	(2)	(3)	(4)	(5)	Published Literature	Proof of Effectiveness
1.	(A) Ayurveda, Siddha and Unani drugs, given in 158B 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 Act, 1940	As per text	As per text	Not Required	Required	Not Required
3.	(C) Ayurveda, Siddha and	As per text	New	Not	If	Required

Serial number	Category	Ingredient (S)	Indication (s)	Safety study	Experience / Evidence of Effectiveness	
	Unani drugs referred in 3(a) to be used for new indication			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 or Proprietary medicine	As per text	Textual rationale	Not Required	Of Ingredients	*Pilot study as per relevant protocol for Ayurveda, Sidha and Unani drugs.
2.	Ayurveda, Siddha, Unani drug with 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;

(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.	(Bl) Hydro-	As	New	Required	If	Required

	Alcohol	specified	Indication**		Required	
5.	Other than Hydro/Hydro-Alcohol	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 and 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 fifteen 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 licensee and Non-Conviction Certificate 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 fulfillment of all requisite formalities as required in the respective formats.]

² [Explanation.—For the purposes of this rule, the applicant shall apply online and licensing authority shall issue such certificate online through portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal.]

159. Cancellation and suspension of licences.—(1) The licensing authority may, after giving the licensee an opportunity to show cause, within a period which shall not be less than fifteen days form 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 or 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.]

^a[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

160A. 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 First Schedule to the Act:

Provided that the applicant shall furnish to the approving authority such additional information as may be required by it in connection with the application in Form 47:

Provided further that if the applicant applies for renewal of approval after its expiry but within six months of such expiry, the inspection fee payable shall be six thousand rupees plus an additional inspection fee at the rate of one thousand