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# ગુજરાત આયુર્વેદ ઔષધ મેન્યુફેક્ચરર્સ એસોસીએશન

# Gujarat Ayurved Aushadh Manufacturers Association

(Charitable Trust Reg. No. F / 8123 Dt.24-7-2001 * Society Reg. No.: Guj. 8276 / A Dt.24-7-2003)

**Correspondence Office** : 282, Second Floor, Sukan Mall, Opp. CIMS Hospital, Sola-Science City Road, Ahmedabad-380060, Gujarat

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Vasu Healthcare Pvt. Ltd.
Vadodara.

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Mr. Vijay Hinsu
Mr. Hitesh Chauhan
Mr. Kamal Patel

## COMMENTS ON PROPOSED DRAFT NOTIFICATON G.S.R. 197(E) Dt. 17.03.2021

## PROPOSING THE DRAFT DRUGS AND COSMETICS (AMENDMENT) RULES, 2021 FOR ASU DRUGS

Date: 6th April, 2021

To,
The Secretary,
Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH),
AYUSH Bhawan, B - Block, GPO Complex, INA,
New Delhi – 110023
E-mail: { HYPERLINK "mailto:dcc-ayush@nic.in" }

Dear Sir,
Please refer below mentioned suggestions / comments in content to said draft notification G.S.R. 197(E)

| RULE | DESCRIPTION, as discussed in Draft G.S.R. 197(E) Dt. 17.03.2021 | COMMENTS / SUGGESTIONS |
|---|---|---|
| 151 | for the words "Ayurvedic (including Siddha)", the following words shall be substituted, namely-<br>"Ayurvedic, Siddha" | No comments |
| 153 | **Application for license to manufacture Ayurvedic, Siddha or Unani drugs.**- (1) An application for the grant of a licence to manufacture for sale of Ayurvedic, Siddha or Unani drugs falling under clause (a) of section 3 of the<br>Act shall be made in Form 24D to the licensing authority along with a fee of rupees five thousand. | It should be between 500 to 1000.<br>Rs. 5000 is very high & unjustified as majority of the ASU Classical manufacturers are from MSME sector. |
| | (2) An application for the grant of a licence to manufacture for sale of Ayurvedic, | Fee structure should be common for clause (a) of |

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Mr. Komal Patel

| | | |
|---|---|---|
| | Siddha or Unani drugs falling under clause (h) of section 3 of the Act shall be made in Form 24D to the licensing authority along with a fee of rupees five thousand per product. | section 3 and clause (h) of section 3 and needs to be minimize so affordable to MSME companies also.<br>Rs. 5000 per product is extremely unrealistic which can affect the research-based innovation in ASU Drugs falls under clause (h) of section 3 |
| | (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 license for manufacture for sale of Ayurvedic, Siddha or Unani drugs.<br>Provided that this rule shall not be applicable to licence obtained under Form 25D prior to the date of commencement of this Amendment Rules, 2021. Such licence holders having a valid Good Manufacturing Practices Certificate have to deposit a license retention fee of rupees five thousand for perpetuity of existing licence. | License retention fee of rupees five thousand can be reduced to between two to three thousand perpetuity of existing licence. |
| **153A** | **Application for loan licence to manufacture Ayurvedic, Siddha or Unani drugs.**- 1) An application for the grant of a loan licence to manufacture for sale Ayurvedic, Siddha or Unani drugs falling under clause (a) of section 3 of the Act shall be made in Form 24E to the licensing authority along with a fee of rupees five thousand. | It should be between 500 to 1000.<br>Rs. 5000 is very high & unjustified as majority of the ASU Classical manufacturers are from MSME sector. |
| | (2) An application for the grant of a loan licence to manufacture for sale of Ayurvedic, Siddha or Unani drugs falling under clause (h) of section 3 of the Act shall be made in Form 24E to the licensing | Fee structure should be common for clause (a) of section 3 and clause (h) of section 3 and needs to be |

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| | authority along with a fee of rupees five thousand per product. | minimize so affordable to MSME companies also. Rs. 5000 per product is extremely unrealistic which can affect the research-based innovation in ASU Drugs falls under clause (h) of section 3 |
| | (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 loan license 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 this Amendment Rules, 2021. Such licence holders having a valid Good Manufacturing Practices Certificate of the manufacturing facilities he intends to avail have to deposit a license retention fee of rupees five thousand for perpetuity of existing licence. | License retention fee of rupees five thousand can be reduced to between two to three thousand perpetuity of existing licence. |
| **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 and inspection fee of rupees one thousand. | No comments |
| | (2) Every application in Form 24E-1 shall be made for a unit having premises and other requirements as prescribed under Schedule T. | No comments |

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| | | |
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| | (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. | No comments |
| **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 drugs shall be issued in Form 25-D. The licence shall be issued within a period of two months from the date of receipt of the application or from the date of fulfilment by the applicant of any shortcomings highlighted by the licensing authority as the case maybe. | Licence issuing time can be reduced up to 45 days in case of all compliance. |
| | (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. | No comments |
| | (3) The application shall be processed through portal e-AUSHADHI (www.e-aushadhi.gov.in) and license in Form 25D issued online as per the format provided in the said portal. | No comments |
| **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. The licence shall be issued within a period of two months from the date of receipt of the application or from the date of fulfilment of | Licence issuing time can be reduced up to 45 days in case of all compliance. |

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| | shortcomings if any highlighted by the licensing authority as the case maybe. | |
| | (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. | No comments |
| | (3) The Licensing Authority shall, before the grant of a loan licence, satisfy himself that the manufacturing unit licensed under Form 25 D 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. | No comments |
| | (4) The application shall be processed through portal e-AUSHADHI (www.e-aushadhi.gov.in) and license in Form 25E issued online as per the format provided in the said portal.॥<br>9. The rule 155, shall be omitted.<br>10.The rule 155A, shall be omitted.<br>11.(i). In sub clause (1) of rule 155B for the words —for a period of five yearsl the words —in form 26 E-1 shall be substituted. (ii). The sub clause (2) shall be omitted. | No comments |
| 156 | **Duration of licence** - (1) A licence issued in Form 25D shall remain valid perpetually. Provided that the licencee shall submits a self declaration of adherence to the conditions of license and the provisions of the Drugs and Cosmetics Act and the Rules, every three years from the date of issue of license in form 25 D or from the date of submission of last self declaration as the case may be . | Duration for licence should be five years instead of three years and needs to revise self-declaration period from one month to three months. |

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| | Further, provided that such self declaration should be made within one month of completion of three years from the date of issue of license in form 25 D or from the date of submission of last self declaration as the case may, and in the event of non submission of such self declaration, license shall be deemed to have been cancelled.l.<br>13. The rule 156A, shall be substituted with the following rule, namely, — | |
| **156A** | **Duration of loan licence** - (1) A loan licence issued in Form 25E shall remain valid perpetually.<br>Provided that the licencee, submits a self declaration of adherence to the conditions of license and the provisions of the Drugs and Cosmetics Act and the Rules, every three years from the date of issue of license in form 25 E or from the date of submission of last self declaration as the case may be. Further, provided that such self declaration should be made within one month of completion of three years from the date of issue of license in form 25 E or from the date of submission of last self declaration as the case may, and in the event of non submission of such self declaration license shall be deemed to have been cancelled.l.<br>14. After rule 156A, the following rules shall be inserted, namely, — | Duration for licence should be five years instead of three years and needs to revise self-declaration period from one month to three months. |
| **156AA** | 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 if the licencee deposits a certificate retention fee referred to in sub-rule (2) before the expiry of a period of every succeeding five years from the date | No comments |

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| | of its issue, unless, it is cancelled by the licensing authority. | |
| | (2) The certificate retention fee referred to in sub-rule(1) shall be rupees two thousand. | No comments |
| | (3) If the licensee fail 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 along with 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. | No comments |
| **156AB** | Inspection for grant of license 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. The inspector or inspectors shall examine the establishment intended to be used or being used for the manufacture of drugs. | No comments |
| | (2) The establishment licensed under sub-rule (1) shall be inspected by the drug inspectors appointed by the State Government under this Act to verify the self declaration of adherence to the conditions of license and the provisions of the Drugs and Cosmetics Act and the Drugs and Cosmetics Rules not less than once in three years or as needed as per risk based approach. | No comments |

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Sunrise Remedies Pvt. Ltd.
Ahmedabad.

**VICE PRESIDENT**
**Hardikbhai Ukani**
Vasu Healthcare Pvt. Ltd
Vadodara.

**SECRETARY**
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Vivaan Herbals & Healthcare
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Mr. Kaushal Dhuleshia, Rajkot.
Mr. Yash Mankad, Junagadh.
Mr. Purshottam Mistry, Surat.
Mr. Dinesh Vadhadiya, Vadodara.
Mr. Jigar Shah, Vadodara.

**TECHNICAL COMMITTEE**
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Mr. Hitesh Chauhan
Mr. Hemal Patel

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| | (3) Provided the drug inspectors are allotted the inspection duty in a randomized manner ensuring same drug inspector is not assigned inspection of a particular establishment consecutively for two terms of not less than three years duration. | No comments |
| **156AC** | 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. 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 the Requirements of Plant and Equipments as laid down in Schedule T. | No comments |
| | (2) The Inspector shall forward a detailed descriptive report giving his findings on each aspect of inspection along with his recommendations after completion of his inspection in accordance with the sub- rule (1), to the Licensing Authority. | No comments |
| **156AD** | Procedure of Licensing Authority - (1) If the Licensing Authority after such further enquiry, if any, as he may consider necessary, is satisfied that the requirements of the Rules under the Act have been complied with and that the conditions of the | No comments |

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# ગુજરાત આયુર્વેદ ઔષધ મેન્યુફેક્ચરર્સ એસોસીએશન

# Gujarat Ayurved Aushadh Manufacturers Association

(Charitable Trust Reg. No. F / 8123 Dt.24-7-2001 * Society Reg. No.: Guj. 8276 / A Dt.24-7-2003)

**Correspondence Office** : 282, Second Floor, Sukan Mall, Opp. CIMS Hospital, Sola-Science City Road, Ahmedabad-380060, Gujarat

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| | licence and the Rules under the Act shall be observed, he shall issue a licence under this Part. | |
| | (2) If the Licensing Authority is not satisfied, he shall issue a memorandum of shortcoming, and the conditions which must be satisfied before a licence can be granted and shall supply the applicant with a copy of the inspection report. | No comments |
| | (3) Such memorandum of shortcomings as under sub-rule (2) is to be replied back by the applicant within two months of issue of such memorandum. | No comments |
| | (4) On non-submission of requirements in sub-rule (2), the Licensing Authority shall reject the application and shall inform the applicant, the reasons for such rejection. | No comments |
| | (5) For this purpose, the licensing authority shall intimate the applicant and process the application through portal e- AUSHADHI (www.e-aushadhi.gov.in). | No comments |
| **156AE** | **Further application after rejection** - If 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, the applicant informs the Licensing Authority that the conditions laid down have been satisfied and deposits an inspection fee of rupees one thousand the Licensing Authority may after causing a further inspection to be made, he is satisfied that the conditions for the grant of a licence or certificate have been complied with, issue a licence or certificate under this Part. | No comments |
| | 15. In rule 157, (i) the words —or renewed in Form 26-D shall be omitted. | No comments |

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| | (ii) In sub clause (1) for the words —Ayurvedic (including Siddha) the words - Ayurvedic, Siddhal shall be substituted.<br>(iii) In sub clause (1A), the words —or renewal shall be omitted.<br>(iv) In sub clause (1D) for the words —period for renewal the words - perpetuity; for the words —renewal the words-perpetuity; and for the words —Drugs and Cosmetics (4th Amendment) Rules, 2015 the words —Drugs and Cosmetics Rules, 2021 shall be substituted.<br>(v) The proviso under sub clause (1D) shall be omitted. | |
| | 16. In rule 157A, the following proviso —For this purpose 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. shall be inserted. | No comments |
| | 17. In rule 158, the sub-clause (c) shall be substituted, namely, —(c) For this purpose the applicant and inspector shall submit the record online through portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal. | No comments |
| | 18. In rule 158A, the sub-clause (e) shall be substituted, namely, —(e) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed. The following sub-clause —For this purpose the applicant and inspector shall submit the record online through portal e-AUSHADHI (www.eaushadhi.gov.in) as per the format provided in the said portal. | No comments |
| | 19.In rule 158C, the following proviso shall be inserted, namely,- For this purpose the | No comments |

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| | applicant or licensing authority shall apply or issue certificate online respectively through portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal. | |
| | 20. In sub-rule (1) of rule 160B after the words shall be granted in Form 48 the following words shall be inserted, namely,- The licence shall be issued within a period of two months from the date of receipt of the application or from the date of fulfillment of shortcomings if any highlighted by the licensing authority as the case maybe. | No comments |
| **160K** | Information to be uploaded by the licensee on online portal. - (1) The applicant or licensee under this part shall register with portal, e-AUSHADHI (www.e-aushadhi.gov.in) and upload information, as per the format provided in the said portal, pertaining to license application, renewal, tests carried out and other such information as required and shall be updated from time to time.<br>(2) The information uploaded by the licensee in the portal under sub-rule (1) shall be verified by the concerned licensing authority. | No comments |

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