

Drugs and Cosmetics Act 1945

[Rule-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[(1A) For getting a certificate of 'Good Manufacturing Practices' of Ayurveda -Siddha-Unani drugs, the applicant shall make application on a plain paper, providing the information on existing infrastructure of the manufacturing unit, and the licensing authority shall after verification of the requirements as per Schedule 'T', issue the certificate within a period of 3 months in Form 26-E-I].
- 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.