Ayush ministry amends D&C Rules to revise GMP standards for Ayurveda, Siddha, Unani & Homoeopathy drugs

The Union Ministry of Ayush has amended the Good Manufacturing Practices (GMP) rules for manufacturing of Ayurvedic, Siddha and Unani medicines and Homoeopathic drugs with elaborate mandates on manufacturing standards and their documentation, with the revised standards to be implemented within three years from now.

The ministry has issued the final notification of the amendments to the Drugs Rules, 1945 with various significant changes in the rules, including extending the validity of licences and loan licences issued to manufacture Ayurvedic, Siddha, or Unani drugs perpetually.

The amendment to the Schedule T of the Drugs Rules, on the GMP for Ayurveda Siddha and Unani medicines, mandates that the manufacturing plant should have the receiving and storing space for packaging material along with the existing norms on the raw material. It also revises the general requirement for the manufacturing plant, including the location and surroundings, buildings, water supply, disposal of waste and effluent, cleaning of containers, storage area including the requirement for raw material, packaging, and finished goods storage.

It also specifies the quality standards for the working space, health clothing, sanitation and hygiene and medical services for workers, standards on machinery and equipment, with emphasis on documentation of each of the process and record keeping procedures. It elaborates on the standards for batch manufacturing records, distribution records, detailed requirements for quality control, training and internal audits, among others. It also substitutes the existing provisions with revised standards on manufacturing process, and product quality control including product recalls.

"The amendments made to this Schedule by the Drugs (Eleventh Amendment) Rules, 2026 shall be complied ‘within such time, not later than the 31st day of July, 2029," said the Ministry's notification.

Revision has also been made to Schedule M-I of the Drugs Rules, which specifies the GMP for Homoeopathic drugs. Amendment revised various provisions under the general requirement including the building, rooms, water, disposal of waste, medical services, safety measures, among other specifications. Rules related to plant and equipment including quality control division and raw materials, among others has also been revised and updated with the latest specifications.

Amendment to this Schedule shall also be complied within July 31, 2029, it added.

The daft notification on these amendments has been issued on February 14, 2025, and the government has considered the objections and suggestions received from the public, said the Ministry.

In addition to these amendments, the notification also mandates that the list of ingredients in the Ayurvedic, Siddha, and Unani medicines, if larger than what could be accommodated in the label, should be displayed through QR Code or Global Item Number (GTIN) or bar code, enabling tracking and tracing mechanisms into these products.

It also mandates that all the label information may be displayed through QR Code or GTIN or bar code. The specific product code of the drug being preceded by the words “specific product code or S.P.C.”, which shall be printed or written within two years of the commencement of the Drugs (Eleventh Amendment) Rules, 2026, it added.

The Ministry also inserted another sub rule to the rules related to shelf life or date of expiry of medicines in the labelling rules, to add that if the approval of the drug has been granted on the basis of accelerated stability studies, then the licensee shall determine the shelf-life of the respective medicine for one or two years based on the report of three months or six months accelerated stability study respectively and the said report shall be submitted to the licensing authority as referred to in Rule 15. The report of the real-time stability study shall be submitted by the licensee within one year from the expiry of the shelf life granted based on the accelerated stability data.

The Rule 154 and 154A related to attaining license or loan licence for manufacture of Ayurvedic, Siddha or Unani drugs,

has also been revised, making these approval valid perpetually. With this, it has also omitted the provisions which mandated submission of self-declaration within specific timeframe for renewal of the license.

Provisions in the Rule 157 has been amended to allow the industry to name extract based single plant-ingredient of Ayurvedic, Siddha, Sowa-Rigpa or Unani formulations licensed or to be licensed as patent or proprietary medicines, with prefix or suffix with any expression specific to the licencee.

As part of Rule 158B on the guidelines for issue of license with respect to Ayurveda, Siddha or Unani drugs, a uniform pattern of specific product code will be issued with the state or union territory code, along with specification on license (D) or loan license (E), followed by serial number of license/system of medicine, serial number of product and the years of product approval. The existing product code shall be reissued in such patter within a period of two years from the commencement of the amended rules.

"State/Union Territory code/ D or E (License or Loan license)/serial number of license in the product code shall be treated as manufacturing license number," it mandates.

In terms of rules related to approval of institutions for testing Ayurvedic, Siddha and Unani drugs and raw materials, the amendment has now revised the qualification of the experts to be employed with the applicant company, by including experts from Sowa-Rigpa to the existing qualifications.

The qualification of inspectors under the Rule has also been amended to add those with a degree or degree in pharmacy of Sowa-Rigpa conferred by a university recognised by the Central of state government as eligible along with the qualifications in Ayurveda, Siddha and Unani systems of medicines.

The testing of sample of any suspected Ayurveda, Siddha, Unani, Sowa-Rigpa, or Homoeopathy drugs shall be conducted in the authorised drugs testing laboratory of autonomous organisation of Ministry of Ayush, shall act as Central Drugs Laboratory, added the notification.

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