

Drugs and Cosmetics (1st Amendment) Rules, 2010
MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Ayurveda, Yoga and Naturopathy, Unani,
Siddha and Homoeopathy)

NOTIFICATION

New Delhi, the 7th January, 2010

***G.S.R. 17(E).**— The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by Section 33-N of the Drugs and Cosmetics Act, 1940 (23 of 1940), is hereby published as required by the said section for the information of all persons likely to be affected thereby, and notice is hereby given that the said draft rules will be taken into consideration after the expiry of a period of forty five days from the date on which copies of the Official Gazette in which this notification is published, are made available to the public;

Objection or suggestion, if any, may be addressed to the Secretary, Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy, Ministry of Health and Family Welfare, Indian Red Cross Society Building, New Delhi – 110001;

DRAFT RULES

(1) **Short title and Commencement.**—These rules may be called the **Drugs and Cosmetics (1st Amendment) Rules, 2010**.

(2) They shall come into force on the date of their final publication in the Official Gazette.

(3) **Amendment of Rule 155 B.**—The Rule 155B of the said rules, shall be numbered as sub-rule (1) thereof, and after sub-rule (1) as so numbered, the following sub-rule shall be inserted, after the word “issued”, the words “for a period of five years” shall be inserted.

Further, after the word Schedule T, the following shall be inserted;

“(2) The certificate referred to in sub-rule (1) shall be issued for a period of five years from the date of issuance of T licence.”

(4) **Amendment of Rule 156.**—In Rule 156, for the words “three years” the words “five years” shall be substituted.

(5) **Amendment of Rule 156A.**—In Rule 156A of the said rules, for the words, “three years” “five years” shall be substituted.

(6) **Amendment of Rule 157.**—In Rule 157 of the said rules, the existing clause :—

“[(1A) For getting a certificate of Good Manufacturing Practices of Ayurveda Siddha-Unani drugs, the applicant shall make an 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 three months in Form 26 E-I]”

shall be substituted with the following :—

“[(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 26 E-I, simultaneously along with grant or renewal of Licence in Form 25-D.]”

(7) **Amendment of Form 13A.**—In the Form 13A of the said rules, after serial number 7 and entries relating thereto, the following shall be inserted, namely,—

In the opinion of the undersigned the sample referred to above is of standard/is not standard quality as defined in the Drugs and Cosmetics Act, 1940 and rules made thereunder for the reasons given below :—

(8) **Amendment of Form 26E-1.**—In Form 26E-1 of the said rules, for the words “period of two years”, the words “period of five years and the Good Manufacturing Practices (GMP) is valid for the various dosage forms or Rasaushadhis, as follows :— ” shall be substituted.

[F.No.K.11020/04/2009-DCC (AYUSH)]

B. ANAND, Jt. Secy.

Foot Note: The Principal rules were published in the Official Gazette *vide* Notification No. F.28-10/45-H(I), dated 21-12-1945 and the last amended *vide* No. G.S.R. 917(E), dated 22-12-2009.