

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy)

NOTIFICATION

New Delhi, the 23rd October, 2008

G.S.R. 755(E).— Whereas the draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required by section 33-N of the Drugs and Cosmetics Act, 1940 (23 of 1940), in the Gazette of India, Extraordinary, dated the 9th July, 2008 vide Number GSR 513 (E) inviting objections and suggestions from persons likely to be affected thereby and notice was given that the said draft 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 containing the said notification were made available to the public;

And whereas, the said Gazette was made available to the public on the 9th July, 2008;

And whereas, objections and suggestions received from the public on the said draft rules Drugs & Cosmetics Act, 1940 (23 of 1940) have been considered by the Central Government in consultation with Chairperson of the Ayurvedic Pharmacopoeia Committee and other experts;

Now, therefore, in exercise of the powers conferred by Section 33-N of the Drugs & Cosmetics Act, 1940 (23 of 1940) the Central Government, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (Second Amendment) Rules, 2008.
 - (2) They shall come into force from the date of their publication in the Official Gazette.
2. In the Drugs and Cosmetics Rules, 1945, for rule 169, the following rule shall be substituted, namely: -

"169. Permitted Excipients: Permitted Excipients along with their standards i.e. additives, preservatives, antioxidants, flavouring agents, chelating agents etc permitted in the Indian Pharmacopoeia (IP), Prevention of Food Adulteration Act, 1954 and Bureau of Indian Standard Act, 1986 are

permitted for use in Ayurveda, Siddha and Unani drugs with the following conditions, namely:-

1. The above excipients shall be used in the permissible limits as prescribed in the Indian Pharmacopoeia/Prevention of Food Adulteration Act, 1954/Food Product Order/Bureau of Indian Standard Act, 1986 and they shall comply with the respective quality specifications, not exceeding any specified limits of usage therein, and except Hydrogenated vegetable oil.
2. Only Natural coloring agents as permitted under rule 26 of Prevention of Food Adulteration Rules 1955 will be used for Ayurveda, Siddha and Unani drugs and additionally, colors permitted under rule 127 of Drugs and Cosmetic Rules 1945 shall be used for Proprietary Ayurveda, Siddha and Unani drugs as defined in subclause (i) of clause (h) of section 3 of Drugs and Cosmetics Act 1940, not exceeding any specified limits of usage therein.
3. Preservatives and Colouring agents shall be mentioned on the label for the information of the consumer as required under rule 161 of the Drugs and Cosmetics rule, 1945.
4. Additives used in various processes and in formulating dosage forms shall be mentioned clearly with quantities used, in the application for licenses and the record for the same shall be maintained by the manufacturers.
5. Manufacturers shall be responsible to ensure rationality, safety and quantity used of various excipients in the formulation.
6. If any excipients or additive or preservative etc referred in Indian Pharmacopoeia/Prevention of Food Adulteration Act, 1954/Food Product Order/Bureau of Indian Standard Act, 1986 is deleted at a particular point of time, this will also be deleted simultaneously for the use in Ayurveda, Siddha and Unani drugs.
7. Following artificial sweeteners as per maximum limit indicated below may be used in various dosage forms of Ayurveda, Siddha, Unani Proprietary Medicines:-

Artificial sweeteners may be used only in proprietary ASU products and the label of such products should carry a statutory warning stating the name and quantity of the artificial sweetener used.

The recommended Acceptable Daily Intake (ADI) of these sweeteners as laid down by US FDA is as follows:

S. No.	Sucralose	Aspartame	Saccharin	Acesulfame K
1.	5 mg/kg body weight	40mg/kg body weight	5 mg/kg body weight	15 mg/kg body weight

One third of the above ADI would be permissible for use in Ayurveda, Siddha, Unani Patent & Proprietary drugs.

8. Any previous notification issued by the Department of AYUSH regarding use of excipients/additives or preservatives in Ayurveda, Siddha and Unani medicines stands superseded.

[No. K. 11022/47/2006-DCC (AYUSH)]

VERGHESE SAMUEL, Jt. Secy.

Footnote : The Principal rules were published in the Gazette of India vide Notification Number F. 28-10/45-H(I), dated the 21st December, 1945 and last amended vide notification numbers: - GSR 678(E), dated 31st October, 2006.