

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 9th June, 2026

G.S.R. 477(E).— Whereas a draft of certain rules further to amend the Drugs Rules, 1945 were published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 927 (E), dated the 29th December, 2025 published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), dated the 30th December, 2025 inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 30th December, 2025;

And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely: —

1. (1) These rules may be called the Drugs (Fifth Amendment) Rules, 2026.
(2) They shall come into force on the date of their publication in the Official Gazette.
2. In the Drugs Rules, 1945, in Schedule K, in the column, under the heading Class of Drugs, against serial number 13, in item number (7), the word “Syrups,” shall be omitted.

[F. No. X.11014/11/2025-DR]

HARSH MANGLA, Jt. Secy.

Note: The Drugs Rules, 1945 were published in the Official Gazette *vide* notification No. F. 28-10/45H(1), dated the 21st the December, 1945 and last amended *vide* notification number G.S.R. 444(E), dated.1st June, 2026.