

**MINISTRY OF HEALTH AND FAMILY WELFARE****(Department of Health and Family Welfare)****Notification**

New Delhi, 16 February, 2026.

**G.S.R. 135(E).**— Whereas a draft of certain rules further to amend the Drugs Rules, 1945 was 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. 345 (E), dated the 28<sup>th</sup> May 2025, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), 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 Gazette containing the said notification were made available to the public;

And whereas, copies of the said Gazette were made available to the public on the 28<sup>th</sup> May 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 section 12 and section 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: —

- (i) These rules may be called the Drugs (Amendment) Rules, 2026.
- (ii) These rules shall come into force on the date of their publication in the Official Gazette.

1. In the Drugs Rules, 1945 (hereinafter to as the said rules), —

(a) for rule 121A, the following rule shall be substituted, namely: —

“121A. **Test for Bacterial endotoxins-Pyrogens.** — Solution of substances intended for parenteral administration (as well as water or any other aqueous solvent supplied along with such substance) shall comply with a test for bacterial endotoxins or, where justified and authorised, with the test for pyrogens and the test for Bacterial endotoxins-Pyrogens shall be carried out as per current edition of Indian Pharmacopoeia (I.P).”;

(b) in the said rules, in Schedule A, —

(i) in Form 20B, —

(A) after paragraph 2, the following paragraph shall be inserted, namely: —

“3. The sale shall be under the personal supervision of a competent person.

(Name of the competent person) .....”;

(B) under the sub-heading “Conditions of License”, after condition 2, the following condition shall be inserted, namely: —

“2A. The licensee shall report to the licensing authority any change in competent person within one month of such change.”;

(ii). in Form 20G, —

(A) after paragraph 3, the following paragraph shall be inserted, namely: —

“3A. The sale shall be under the personal supervision of a competent person.

(Name of the competent person) .....

(B) under the sub-heading “Conditions of Licence”, after condition 2, the following condition shall be inserted, namely: —

“2A. The licensee shall report to the licensing authority any change in competent person within one month of such change.”;

(iii). in Form 21B, under the sub-heading “Conditions of Licence”, after condition 1, the following condition shall be inserted, namely: —

“1A. The licensee shall report to the licensing authority any change in competent person within one month of such change.”;

(c) in the said rule, in Schedule H, in the foot note, after entry number 5, the following entry shall be inserted, namely: —

“6. Class of drugs mentioned at serial number 15 of Schedule K shall not be covered under this Schedule.”.

[F. No. X.11014/01/2025-DR]

HARSH MANGLA, Jt. Secy.

**Note:** The Drugs Rules, 1945 were published in the Official Gazette *vide* notification No. F. 28-10/45-H(1) dated the 21<sup>st</sup> December, 1945 and last amended *vide* notification number G.S.R. 554(E), dated 18th August, 2025