CDSCO

Oral formulations over 12% alcohol to join Schedule H1

G.S.R. 607(E) adds oral formulations with more than 12% alcohol v/v, in packs over 30 ml, to Schedule H1 and excepts them from Schedule K serial no. 10.

THE MINISTRY OF HEALTH and Family Welfare (Department of Health and Family Welfare) issued notification G.S.R. 607(E), dated July 8, 2026, making the Drugs (Tenth Amendment) Rules, 2026. It was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 549, dated July 9, 2026. The Central Government made the rules under sections 12 and 33 of the Drugs and Cosmetics Act, 1940, after consultation with the Drugs Technical Advisory Board. They follow draft rules published as G.S.R. 760(E), dated October 16, 2025, and made available to the public on October 18, 2025; the notification records that no objections or suggestions were received from the public. CDSCO lists the same file as a "Notification regarding restriction of sale of drug products containing alcohol content under Drugs Rules 1945".

KEY FACTS

AUTHORITY
CDSCO

PUBLISHED
July 8, 2026

ISSUED BY
Ministry of Health and Family Welfare (Department of Health and Family Welfare)

DOCUMENT
Notification G.S.R. 607(E), the Drugs (Tenth Amendment) Rules, 2026

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The rules make two changes to the Drugs Rules, 1945. In Schedule K, under the heading Extent and Conditions of Exemptions, against serial no. 10, they insert after the words "Act and rules thereunder" the words "except for all oral formulations containing more than 12% alcohol v/v (Ethyl Alcohol) packed and sold in packings or bottles of more than 30 milliliters." In Schedule H1, after the entry "51. Pregabalin", they insert a new entry: "52. All oral formulations containing more than 12% alcohol v/v (Ethyl Alcohol) packed and sold in packings or bottles of more than 30 milliliters." Both changes describe the same products.

The notification does not say what serial no. 10 of Schedule K covers. In CDSCO's compiled copy of the Drugs Rules, 1945, as amended up to July 1, 2024, serial no. 10 lists substances "used both as articles of food as well as drugs": condensed or powdered milk, cereal preparations such as Farex and oats, predigested foods such as Virol, Bovril and chicken essence, and spices and condiments unless specially labeled as conforming to pharmacopoeial standards, and it exempts them from all provisions of Chapter IV of the Act and the rules. In the same copy, rule 65 provides that a Schedule H1 drug may not be sold by retail except on the prescription of a Registered Medical Practitioner, and that each supply is recorded in a separate register, kept for three years, giving the prescriber, the patient, the drug and the quantity.

The rules "shall come into force after the 6 months of publication of these rules in the Official Gazette". The Gazette issue is dated July 9, 2026; the rules give no calendar date. The draft would have taken effect on final publication and numbered the new Schedule H1 entry 51. The rules do not define "oral formulations", do not name any product, and make no provision for stock made, labeled or sold before they take effect. The new entry does not cover packs of 30 milliliters or less, or formulations with 12% alcohol v/v or less. The notification is signed by Harsh Mangla, Joint Secretary, under F. No. X.11014/07/2025-DR-Part(3).

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	Notification G.S.R. 607(E), the Drugs (Tenth Amendment) Rules, 2026
Dated	July 8, 2026
Published	Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 549, July 9, 2026
Gazette ID	CG-DL-E-09072026-274311
Amends	Drugs Rules, 1945: Schedule K, serial no. 10; Schedule H1, new entry 52 after "51. Pregabalin"
Applies to	All oral formulations containing more than 12% alcohol v/v (Ethyl Alcohol) packed and sold in packings or bottles of more than 30 milliliters
Alcohol content	More than 12% v/v (Ethyl Alcohol)
Pack size	Packings or bottles of more than 30 milliliters
Takes effect	"after the 6 months of publication of these rules in the Official Gazette"; the Gazette issue is dated July 9, 2026
Draft	G.S.R. 760(E), October 16, 2025, made available to the public on October 18, 2025; no objections or suggestions received
Legal basis	Sections 12 and 33, Drugs and Cosmetics Act, 1940
Related	Draft G.S.R. 745(E), August 19, 2026, would add four drugs to Schedule H1 after serial number 52
Signed by	Harsh Mangla, Joint Secretary
File number	F. No. X.11014/07/2025-DR-Part(3)

The notification (PDF, 1.1 MB)

Source: Gazette of India, CG-DL-E-09072026-274311.

Checked against the official copy on October 28, 2026.

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