November 6, 2026

CDSCO

Draft would let authorities relax Schedule M for medicinal gases

Draft rules of November 6, 2026 add a note to Part XIII of Schedule M on drugs such as empty gelatin capsules and disinfectant fluids. Comments: 30 days.

LICENSING AUTHORITIES could modify the Schedule M requirements for some categories of drugs, such as medicinal gases, empty gelatin capsules and disinfectant fluids, under draft rules the Ministry of Health and Family Welfare has published for comment. The draft is notification G.S.R. 985(E), dated November 6, 2026, of the Department of Health and Family Welfare, and would add a note at the end of Part XIII of Schedule M of the Drugs Rules, 1945, giving the Licensing Authority or Central Licence Approving Authority "the discretion to modify the requirements of this Schedule" for "certain categories of drugs such as medicinal gases, empty gelatin capsules, and disinfectant fluids". It appears in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 879, dated November 12, 2026.

KEY FACTS

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G.S.R. 985(E), draft rules: the Drugs (..... Amendment) Rules, 2026

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The Central Government proposes to make the rules under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940, after consultation with the Drugs Technical Advisory Board.

The note says these are categories of drugs for which Schedule M "does not prescribe specific requirements of space and equipments". The authority may use the discretion "if he is of the opinion that having regard to the nature of the products and extent of manufacturing operations and for reasons to be recorded in writing, it is necessary to relax or alter them in the circumstances of a particular case". It may then "direct the manufacturer to carry out necessary modifications in them and the modifications having been made, approve the manufacture of such categories of the drugs".

The rules are to be called the Drugs (..... Amendment) Rules, 2026, and "shall come into force on the date of their final publication in the Official Gazette". The draft will be taken into consideration on or after the expiry of thirty days from the date copies of the Gazette containing it are made available to the public. Objections and suggestions may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Kartavya Bhawan-1, New Delhi - 110011, or emailed to drugsdiv-mohfw@gov.in.

The draft gives no end date for comments. Its e-Gazette ID, CG-DL-E-18112026-278031, and its digital signature date the copy November 18, 2026; thirty days counted from then end on December 18, 2026. It is signed by Pushpendra Rajput, Joint Secretary, under F. No. X.11014/10/2026-DR.

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	G.S.R. 985(E), draft rules: the Drugs (..... Amendment) Rules, 2026
Dated	November 6, 2026

Gazette	Extraordinary, Part II, Section 3, Sub-section (i), No. 879, November 12, 2026
Gazette ID	CG-DL-E-18112026-278031; the e-Gazette copy is dated November 18, 2026
Amends	Drugs Rules, 1945: Schedule M, a note inserted at the end of Part XIII
Examples named	Certain categories of drugs "such as medicinal gases, empty gelatin capsules, and disinfectant fluids"; the note does not give a full list
Who decides	The Licensing Authority or Central Licence Approving Authority, as the case may be
Conditions	Having regard to the nature of the products and extent of manufacturing operations, for reasons recorded in writing, in the circumstances of a particular case
Takes effect	On the date of final publication in the Official Gazette
Comment period	Thirty days from the date copies of the Gazette are made available to the public; no end date is given. Counted from November 18, 2026, the date of the e-Gazette copy (CG-DL-E-18112026-278031), thirty days end on December 18, 2026
Send comments to	Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Kartavya Bhawan-1, New Delhi - 110011, or drugsdiv-mohfw@gov.in
Signed by	Pushpendra Rajput, Jt. Secy.
File number	F. No. X.11014/10/2026-DR

The notification (draft rules) (PDF, 477 KB)

Source: Gazette of India, CG-DL-E-18112026-278031.

Checked against the official copy on November 21, 2026.

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