November 4, 2026

CDSCO

Draft would make drug licensees comply with GSDP guidelines

Draft rules of November 4, 2026 would add a licence condition to nine rules of the Drugs Rules, 1945: comply with the Good Distribution Practices Guidelines.

HOLDERS OF DRUG licences under nine rules of the Drugs Rules, 1945 would have to comply with the Good Distribution Practices Guidelines, under draft rules the Ministry of Health and Family Welfare has published for comment. The draft is notification G.S.R. 984(E), dated November 4, 2026, of the Department of Health and Family Welfare, and adds the same condition to each of those nine rules: "The licensee shall ensure compliance with the Good Distribution Practices Guidelines." It appears in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 878, dated November 12, 2026.

KEY FACTS

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

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G.S.R. 984(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 e-Gazette lists it as a "Draft notification for guidelines on goods storage and distribution Practices (GSDP) for Pharmaceutical Products."

The draft first adds a definition to rule 2 in Part I. "Guidelines on Good Storage and Distribution Practices (GSDP) for Pharmaceutical Products" would mean "the Good Distribution Practices Guidelines for ensuring the quality and identity of pharmaceutical products throughout all aspects of the distribution process in India, formulated by the Central Drugs Standard Control Organisation and adopted by the Drugs Technical Advisory Board." The draft says to insert it after sub-rule (i); the English text letters it (k) and the Hindi text (j).

It then inserts the compliance condition as a new sub-rule in rules 26, 33A, 65, 74, 74A, 74B, 78, 78A and 122P, as the table below shows. The draft names the rules by number only. It does not set out the guidelines themselves or say where they are published.

The rules are to be called the Drugs (..... Amendment) Rules, 2026, and would come into force from the date the Government specifies at the time 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, C Wing, First Floor, Kartavya Bhavan 1, New Delhi - 110001, or emailed to drugsdiv-mohfw@gov.in.

The draft gives no end date for comments. Its e-Gazette ID, CG-DL-E-18112026-278021, 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.11014/17/2026-DR.

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Document	G.S.R. 984(E), draft rules: the Drugs (..... Amendment) Rules, 2026
Dated	November 4, 2026
Gazette	Extraordinary, Part II, Section 3, Sub-section (i), No. 878, November 12, 2026
Gazette ID	CG-DL-E-18112026-278021; the e-Gazette copy is dated November 18, 2026
Amends	Drugs Rules, 1945: rule 2 (a new definition) and rules 26, 33A, 65, 74, 74A, 74B, 78, 78A and 122P (a new sub-rule each)
New condition	"The licensee shall ensure compliance with the Good Distribution Practices Guidelines."
Guidelines	Formulated by the Central Drugs Standard Control Organisation and adopted by the Drugs Technical Advisory Board
Takes effect	From the date the Government specifies at the time 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-18112026-278021), thirty days end on December 18, 2026
Send comments to	Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, C Wing, First Floor, Kartavya Bhavan 1, New Delhi - 110001, or drugsdiv-mohfw@gov.in
Signed by	Pushpendra Rajput, Jt. Secy.
File number	F. No. X.11014/17/2026-DR

Where the draft inserts the compliance condition in the Drugs Rules, 1945

Rule	Inserted after	New sub-rule
Rule 26	Sub-rule (vii)	Sub-rule (viii)
Rule 33A	Sub-rule (g)	Sub-rule (h)
Rule 65	Sub-rule (21)	Sub-rule (22)
Rule 74	Sub-rule (i)	Sub-rule (r)
Rule 74A	Sub-rule (i)	Sub-rule (j)
Rule 74B	Sub-rule (8)	Sub-rule (9)
Rule 78	Sub-rule (r)	Sub-rule (s)

Rule 78A	Sub-rule (9)	Sub-rule (10)
Rule 122P	Sub-rule (xv)	Sub-rule (xvi)

The notification (draft rules) (PDF, 471 KB)

Source: Gazette of India, CG-DL-E-18112026-278021.

Checked against the official copy on November 21, 2026.

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