October 28, 2026

CDSCO

Draft would suspend drug licences on NSQ reports until CAPA

Draft G.S.R. 956(E) would make licensing authorities suspend a drug's manufacturing licence at once on a Government Analyst's not of standard quality report.

G.S.R. 956(E) IS A NOTIFICATION of the Ministry of Health and Family Welfare (Department of Health and Family Welfare), dated October 28, 2026, publishing draft rules further to amend the Drugs Rules, 1945. It appears in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 855, dated October 29, 2026. 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.

KEY FACTS

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

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G.S.R. 956(E), draft rules: the Drugs (..... Amendment) Rules, 2026



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The draft inserts sub-rules (2A) and (2AA) in rule 85, the rule on cancellation and suspension of licences. Under (2A), whatever sub-rules (1) and (2) say, the Central Licensing Approving Authority or the State Licensing Authority, on receiving a Government Analyst's certificate of test or analysis giving the opinion that a drug is not of standard quality "with respect to Assay/Dissolution/Related Substance/Impurity/Sterility", "shall immediately suspend the manufacturing licence granted to manufacture the said drug". The licence stays suspended until the licensee carries out an effective root cause analysis and implements Corrective Action and Preventive Action (CAPA) to the licensing authority's satisfaction. Under (2AA), the licensing authority may revoke the suspension only after the CAPA is implemented and it has verified it. A proviso lets the Central Licensing Approving Authority seek the root cause analysis, the CAPA, the "investigational report" and the State Licensing Authority's final action. Sub-rule (3) of rule 85, on appeals against a suspension or cancellation, would also refer to sub-rule (2A).

The draft makes the same change in rule 122O, which covers licences under Part X-B of the rules, on blood banks and blood products, by new sub-rules (1A) and (1AA) and a reference to (1A) in sub-rule (2). There, (1A) applies to any drug found not of standard quality, with no list of tests, and (1AA), as printed, refers to the suspension "referred in sub-rule (2A)". The draft also adds a "Copy to" line to Form 13, the Government Analyst's certificate, naming the Drugs Controller General of India, the State or UT drugs controlling authority where the manufacturing site is, and the manufacturer and marketer on the label.

Rule 85, in CDSCO's compiled copy of the Drugs Rules, lets the authority cancel or suspend a licence only after giving the licensee an opportunity to show cause. The draft does not mention a show cause notice for the new suspension, and it does not say whether the suspension covers other drugs made under the same licence. The rules are to be called the Drugs (..... Amendment) Rules, 2026, with the number left blank, and would 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, U-6, Work Hall- C Wing, First Floor, Kartavya Bhawan-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-04112026-277656, and its digital signature date the copy November 4, 2026; thirty days counted from then end on December 4, 2026. It is signed by Pushpendra Rajput, Joint Secretary, under F. No. X11014/25/2026-DR. No final rules had appeared by November 7, 2026.

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	G.S.R. 956(E), draft rules: the Drugs (..... Amendment) Rules, 2026
Dated	October 28, 2026
Gazette	Extraordinary, Part II, Section 3, Sub-section (i), No. 855, October 29, 2026
Gazette ID	CG-DL-E-04112026-277656; the e-Gazette copy is dated November 4, 2026
Amends	Drugs Rules, 1945: rule 85, new sub-rules (2A) and (2AA) and sub-rule (3); rule 122O, new sub-rules (1A) and (1AA) and sub-rule (2); Form 13
Applies to	Holders of drug manufacturing licences
Trigger under rule 85	A Government Analyst's opinion that the drug is not of standard quality on assay, dissolution, related substance, impurity or sterility
Trigger under rule 122O	A Government Analyst's opinion that the drug is not of standard quality
Action	Immediate suspension of the manufacturing licence for the drug by the Central Licensing Approving Authority or the State Licensing Authority
Suspension lifted	Only after CAPA is implemented and verified by the licensing authority
Form 13 copies	Drugs Controller General of India; State/UT drugs controlling authority for the manufacturing site; manufacturer and marketer on the label
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 4, 2026, the date of the e-Gazette copy, thirty days end on December 4, 2026
Send comments to	Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, U-6, Work Hall- C Wing, First Floor, Kartavya

	Bhawan-1, New Delhi, 110001, or drugsdiv-mohfw@gov.in
Final rules	None by November 7, 2026
Signed by	Pushpendra Rajput, Jt. Secy.
File number	F. No. X11014/25/2026-DR

The notification (draft rules) (PDF, 653 KB)

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Checked against the official copy on November 7, 2026.

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