October 27, 2026

CDSCO

# CDSCO asks states to enforce batch testing of drug raw materials

CDSCO's letter of October 27, 2026 asks states to have drug makers test every batch of raw materials and finished formulations and use approved vendors only.

THE CENTRAL DRUGS Standard Control Organization (CDSCO), under the Directorate General of Health Services, wrote to all State/UT Drug Controllers under F. No. DC-DT-15011(11)/144/2025-eoffice, e-file 28466. The letter is stamped October 27, 2026 and signed by Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India). Its subject is "Strict compliance with the Drugs Rules, 1945, for testing of raw materials and finished formulations". CDSCO listed it among its public notices on October 27, 2026. It continues CDSCO's letter of the same number dated October 7, 2025, which it encloses. Copies went to the PS to Joint Secretary (Regulation), MoHFW, CDSCO's Zonal and Sub-zonal offices and the CDSCO website.

KEY FACTS

AUTHORITY

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Letter, F. No. DC-DT-15011(11)/144/2025-eoffice, e-file 28466



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The letter says that, under the Drugs and Cosmetics Act, 1940 and the rules made under it, testing is a statutory requirement. The licensee must test each batch or lot of the raw material used to make the drug product, "including critical excipients like propylene glycol, glycerol, sorbitol etc.", and each batch of the final product. The tests are done in the licensee's own laboratory or in one approved by the licensing authority. The licensee must also keep records or registers of those tests as specified in Schedule U.

State/UT Drug Controllers are asked to direct all manufacturers in their jurisdictions to "Ensure Mandatory Testing of every batch of raw materials and finished formulations as stipulated under the rules". Manufacturers are also to implement vendor qualification and source raw materials and excipients only from reliable approved vendors, "to safeguard the quality, safety, and efficacy of all drug formulations". States are asked to give the matter top priority and ensure strict compliance across all manufacturing units in their jurisdiction.

The enclosed letter of October 7, 2025 gives the background. It says CDSCO has stressed from time to time the testing of raw materials, including excipients, before use. It cites recent reports of child deaths in Chhindwara, Madhya Pradesh, "allegedly linked to contaminated cough syrups". It says inspections of manufacturing sites and investigations of drugs declared Not of Standard Quality found that manufacturers were not testing each batch of excipients and active pharmaceutical ingredients before use, or the finished products. It cites "rule 74 (c) and rule 78 (c) (ii)" of the Drugs Rules for the duty to test each batch or lot of raw material and each batch of the final product, and to keep records as specified in Schedule U. It asked states to ensure testing before manufacture and before a batch is released to the market, through inspections and circulars to manufacturers, and to ensure manufacturers have a vendor qualification system in place and use raw materials, including excipients, from reliable approved vendors only. States were to acknowledge receipt and report the action taken.

Neither letter sets a new rule, a deadline or a penalty. The 2026 letter restates duties it says already apply under the Drugs and Cosmetics Act, 1940 and the rules made under it, and asks states to make manufacturers meet them. It does not name any manufacturer or drug product,

does not say how vendors are to be qualified or which vendors count as approved, and, unlike the 2025 letter, does not ask states to report the action taken.

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| Issued by | Central Drugs Standard Control Organization (Directorate General of Health Services) |
| Document | Letter, F. No. DC-DT-15011(11)/144/2025-eoffice, e-file 28466 |
| Dated | October 27, 2026 (date stamp) |
| Addressed to | All State/UT Drug Controllers |
| Applies to | All drug manufacturers, through the State/UT Drug Controllers |
| Testing | Every batch of raw materials and finished formulations, in the licensee's own laboratory or one approved by the licensing authority |
| Critical excipients listed | "propylene glycol, glycerol, sorbitol etc." |
| Vendors | Vendor qualification; raw materials and excipients only from reliable approved vendors |
| Test records | As specified in Schedule U |
| Rules cited | "rule 74 (c) and rule 78 (c) (ii)" of the Drugs Rules, 1945, in the letter of October 7, 2025 |
| Earlier letter | Same number, dated October 7, 2025, enclosed |
| Takes effect | No date stated; no new rule, deadline or penalty |
| Listed | CDSCO public notices, October 27, 2026 |
| Related | CDSCO letter F. No. IT/ONDLS/MFG/Exp/2025/003, October 27, 2026: Digital Monitoring System on the ONDLS portal for monitoring the supply chain of high-risk solvents |
| Copies to | PS to Joint Secretary (Regulation), MoHFW; Zonal/Sub-zonal offices of CDSCO; CDSCO website |
| Signed by | Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India) |

The letter (PDF, 830 KB)

Source: CDSCO's own copy.

Checked against the official copy on November 1, 2026.

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