October 27, 2026

CDSCO

High-risk solvent batches need an ONDLS NOC before distribution

CDSCO asks states to have makers and suppliers of pharmaceutical-grade high-risk solvents register on ONDLS and get a system NOC before a batch is distributed.

THE CENTRAL DRUGS Standard Control Organization (CDSCO), Directorate General of Health Services, wrote to all State/UT Drug Controllers under F. No. IT/ONDLS/MFG/Exp/2025/003 on the Digital Monitoring System on the ONDLS portal for monitoring the supply chain of high-risk solvents. The letter is stamped October 27, 2026 and signed by Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India). It continues CDSCO's letter of the same number dated October 22, 2025, which it encloses with that letter's Annexure-1, the list of high-risk solvents. CDSCO listed it among its public notices on October 27, 2026. Copies went to the PS to the Joint Secretary (Regulation) in the Ministry of Health and Family Welfare, CDSCO's zonal and sub-zonal offices, the Director of CDAC, Noida, and the CDSCO website.

KEY FACTS

AUTHORITY

CDSCO

PUBLISHED

October 27, 2026

ISSUED BY

Central Drugs Standard Control Organization, Directorate General of Health Services

DOCUMENT

Letter, F. No. IT/ONDLS/MFG/Exp/2025/003, enclosing the letter of October 22, 2025 and its Annexure-1

High-risk solvent batches need an ONDLS NOC before distribution

CDSCO · October 27, 2026

The Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, wrote to all State/UT Drug Controllers under F. No. IT/ONDLS/MFG/Exp/2025/003 on the Digital Monitoring System on the ONDLS portal for monitoring the supply chain of high-risk solvents. The letter is stamped October 27, 2026 and signed by Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India). It continues CDSCO's letter of the same number dated October 22, 2025, which it encloses with that letter's Annexure-1, the list of high-risk solvents. CDSCO listed it among its public notices on October 27, 2026. Copies went to the PS to the Joint Secretary (Regulation) in the Ministry of Health and Family Welfare, CDSCO's zonal and sub-zonal offices, the Director of CDAC, Noida, and the CDSCO website.

The letter says CDSCO has set up a Digital Monitoring System (DMS) on the Online National Drug Licensing System (ONDLS) portal to oversee the supply chain integrity and quality parameters of high-risk pharmaceutical solvents and excipients "such as propylene glycol, glycerine, sorbitol, etc." States are to direct all manufacturers and vendors/suppliers of pharmaceutical-grade high-risk solvents in their jurisdictions to complete mandatory registration on the ONDLS portal immediately. They are also to upload batch-wise data as the portal asks for it, including total quantities manufactured, Certificates of Analysis (CoA), quantities supplied, vendor credentials and complete onward distribution trails. States are to ensure that no batch of pharmaceutical grade of these solvents is distributed without uploading the details sought on the DMS and obtaining a system-generated NOC. Technical or system questions go to ithelpdesk.statedrugs@cdsco.nic.in and it-cell@cdsco.nic.in, and a user guidance document is on the ONDLS website. States are asked to give the matter high priority and ensure strict compliance across all manufacturing and supply units.

The enclosed letter of October 22, 2025 cited recent reports of contamination of cough syrups with DEG. It also cited a high-level meeting chaired by the Union Health Secretary with all States and Union Territories on October 5, 2025, and CDSCO's letter of October 7, 2025 asking states to take measures to ensure testing before the manufacture and release of a batch to the market. It said a Digital Monitoring System on ONDLS was needed for the supply chain and quality of the high-risk solvents in Annexure-1, including propylene glycol, and that the portal had been upgraded and made live. States were to direct all manufacturers of pharma grade solvents to obtain a manufacturing licence through ONDLS or, if they already held one, to register on ONDLS and submit the data through "Old Licence Management". Solvent manufacturers were to upload details of each batch manufactured, with quantity, CoA and the vendors to whom the solvents are sold, and states were to ensure that "no batch is available in the market without complying to above direction".

Against the 2025 letter, the 2026 letter brings in vendors and suppliers, not only manufacturers, to register and upload data. It lists quantities supplied, vendor credentials and complete onward

distribution trails among the batch data, where the 2025 letter asked for quantity, CoA and details of the vendors to whom the solvents are sold. It also makes a system-generated NOC on the DMS a condition for distributing any batch. Both letters are addressed to the State/UT Drug Controllers, who are asked to direct the firms; neither mentions imports, importers, or foreign manufacturers or suppliers. Neither cites a provision of the Drugs and Cosmetics Act, 1940 or the Drugs Rules, 1945, or states a consequence of not complying. The 2026 letter does not say what the NOC certifies or how long the system takes to issue it, and sets no date other than "immediately" for registration. Annexure-1 has ten numbered entries, and entries 3, 4 and 9 each name more than one substance or form.

On the same day CDSCO also wrote to all State/UT Drug Controllers under F. No. DC-DT-15011(11)/144/2025-eoffice, e-file 28466, on "Strict compliance with the Drugs Rules, 1945, for testing of raw materials and finished formulations", continuing its letter of October 7, 2025. It restates the requirement to test each batch or lot of raw material, including critical excipients like propylene glycol, glycerol and sorbitol, and each batch of the final product, keeping records as Schedule U specifies, and asks states to direct all manufacturers to test every batch and to source raw materials and excipients only from reliable approved vendors.

Issued by	Central Drugs Standard Control Organization, Directorate General of Health Services
Document	Letter, F. No. IT/ONDLS/MFG/Exp/2025/003, enclosing the letter of October 22, 2025 and its Annexure-1
Dated	October 27, 2026 (date stamp)
Addressed to	All State/UT Drug Controllers
Applies to	Manufacturers and vendors/suppliers of pharmaceutical-grade high-risk solvents, through the State/UT Drug Controllers
Registration	Mandatory, on the Online National Drug Licensing System (ONDLS) portal, immediately
Batch-wise data	Total quantities manufactured, Certificates of Analysis, quantities supplied, vendor credentials and complete onward distribution trails, as the portal asks
Before distribution	Details uploaded on the Digital Monitoring System and a system-generated NOC obtained, for every batch of pharmaceutical grade
Solvents covered	The ten entries of Annexure-1, from glycerin and propylene glycol to ethyl alcohol
Takes effect	No date stated; registration "immediately"

Earlier letter	October 22, 2025, same file number: a manufacturing licence through ONDLS, or registration under "Old Licence Management" for existing licence holders, and batch uploads with quantity, CoA and the vendors to whom the solvents are sold
Imports	Neither letter mentions imports, importers or foreign suppliers
Help	ithelpdesk.statedrugs@cdsco.nic.in and it-cell@cdsco.nic.in; a user guidance document on the ONDLS website
Listed	CDSCO public notices, October 27, 2026
Related	CDSCO's letter of October 27, 2026, F. No. DC-DT-15011(11)/144/2025-eoffice, e-file 28466, "Strict compliance with the Drugs Rules, 1945, for testing of raw materials and finished formulations", continuing its letter of October 7, 2025: every batch of raw materials, including critical excipients like propylene glycol, glycerol and sorbitol, and of finished formulations to be tested, and raw materials and excipients sourced only from reliable approved vendors
Copies to	PS to Joint Secretary (Regulation), MoHFW, Kartavya Bhawan, New Delhi; CDSCO zonal and sub-zonal offices; Director, CDAC, Noida; CDSCO website
Signed by	Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India)

Annexure-1: List of high risk solvents

No.	Solvent
1	Glycerin
2	Propylene Glycol
3	Maltitol and Maltitol Solution
4	Sorbitol and Sorbitol Solution
5	Hydrogenated Starch Hydrolysate
6	Polyethylene Glycol (MW <1000)
7	Diethylene Glycol Stearates
8	Polyethylene Glycol Monomethyl Ether (certain low MWs)
9	Polysorbate 20/40/60/80, Polyoxyl 15 Hydroxystearate, Polyoxyl 20 Cetostearyl Ether, Polyoxyl 8 Stearate, Octoxynol 9, and Nonoxynol 9
10	Ethyl alcohol

The letter (PDF, 1011 KB)

Source: CDSCO's own copy.

Checked against the official copy on November 1, 2026.

IndusDesk

hello@indusdesk.com · +91 11 4141 3939

9th Floor, Hemkunt House, Rajendra Place, New Delhi, Delhi 110008, India

Read online: indusdesk.com/cdsco/insights/high-risk-solvent-batches-need-an-ondls-noc-before-distribution/