

F. No. IT/ONDLS/MFG/Exp/2025/003
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

Dated: 22/10/2025

To,

All State/ UT Drug Controllers

Subject: Digital Monitoring System on the ONDLS portal for monitoring the supply chain of high risk solvents - regarding

Sir/ Madam,

As you are aware that there have been recent reports of contamination of cough syrups with DEG, raising serious safety concerns.

In this regard, a high-level meeting under the chairmanship of the Union Health Secretary was also held with all States and Union Territories on 5.10.2025 to review compliance with drug quality norms and promote the rational use of cough syrups, especially in paediatric populations

Further, this Directorate vide letter dated 07.10.2025 has requested all the States/ UTs to take measures to ensure testing before the manufacture and release of the batch to the market by way of monitoring during inspections, sensitising the manufacturers through circulars, etc.

It has been decided that a Digital Monitoring System on the ONDLS portal needs to be established for monitoring the supply chain as well as quality of the high risk solvents (**Annexure-1**) including the Propylene Glycol. Accordingly, ONDLS portal has been upgraded and made **Live** by this Directorate for addressing this issue.

You are requested to direct all the manufacturers of pharma grade solvents to obtain manufacturing licence through ONDLS portal. In case the manufacturer already holds the manufacturing licence, he must register on the ONDLS portal and submit the data through "Old Licence Management" under ONDLS.

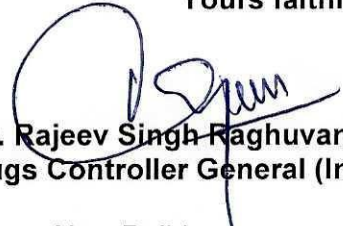
Further, the solvent manufacturers shall also upload details on the ONDLS portal regarding each batch manufactured with quantity, CoA, etc. and details of the vendors to whom the solvents are sold from time to time.

You are also requested to ensure that no batch is available in the market without complying to above direction.

In case of any difficulties, CDAC may be contacted at uttamkumar@cdac.in or ondlssupport-noida@cdac.in for any assistance.

This is for your information and necessary compliance.

Yours faithfully,


(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy to: 1. PS to Joint Secretary (Regulation), MoHFW, Nirman Bhawan, New Delhi
2. Zonal/ Sub-zonal offices of CDSCO for necessary coordination with respective States/ UTs
3. Director, CDAC Noida
4. Website of CDSCO

Annexure- 1

List of high risk solvents

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