Government of Telangana
Drugs Control Administration

Circular Memo. No. 28/DG-Peshi/2025 **Date: 13-10-2025**

CIRCULAR

Sub: Drugs Control Administration – Virtual Meeting held with Liquid Oral Manufacturers in Telangana on 10.10.2025 – **Minutes Communicated** – Mandatory Compliance Measures regarding Diethylene Glycol (DEG) and Ethylene Glycol (EG) Testing in Liquid Oral Formulations – Reg.

Ref: Virtual Meeting convened by the Drugs Control Administration with all Liquid Oral Manufacturers in Telangana on 10.10.2025.

*****

In view of the recent reports of deaths among children in Madhya Pradesh, particularly in Chhindwara District, following suspected kidney failure linked to adulterated cough syrups containing Diethylene Glycol (DEG), the Drugs Control Administration, Telangana, convened a virtual meeting on 10.10.2025 with all Liquid Oral Manufacturers in the State to emphasize the critical importance of ensuring the safety and quality of all liquid oral formulations, including cough syrups, cold syrups, and other liquid dosage forms.

Accordingly, all Liquid Oral Manufacturers in Telangana are hereby instructed to mandatorily comply with the minutes of the meeting convened, encapsulated as follows:

1. Pharmaceutical aids or excipients such as Glycerin, Propylene Glycol, Sorbitol Solution, etc., shall mandatorily be procured **directly from the manufacturers**.

2. All raw materials shall comply with pharmacopoeial standards, and **only pharmacopoeial grade excipients** shall be used in production.

3. **Raw materials** such as Glycerin, Propylene Glycol, Sorbitol Solution, etc., must be tested for Diethylene Glycol (DEG) and Ethylene Glycol (EG) prior to their use in manufacturing. The limit shall not exceed 0.10% as per the respective pharmacopoeial monographs.

4. As an abundant precaution, manufacturers shall sample and test **all the individual containers or packs** of Glycerin, Propylene Glycol, Sorbitol Solution, and other excipients upon receipt of raw materials.

5. All **liquid oral finished products** must be tested for Diethylene Glycol (DEG) and Ethylene Glycol (EG) as per the amendment to the Indian Pharmacopoeia 2022 dated 10.10.2025, without fail, with the permissible limit not exceeding 0.10%.

6. Manufacturers shall mandatorily **ensure authentic testing** for the absence of DEG and EG in raw materials and finished oral liquids, especially when such testing is outsourced to any approved laboratory.

7. Firms must ensure and be able to demonstrate that actual testing has been carried out and that data integrity is maintained for all test reports relating to DEG and EG content.

8. The test reports for DEG and EG shall be periodically submitted to the Directorate of Drugs Control Administration, with a copy marked to the concerned Drugs Inspector, without fail.

9. The Drugs Control Administration, Telangana, strongly recommends that manufacturers **conduct in-house testing** for DEG and EG by arranging Gas Chromatographs in their own Quality Control sections.

10. The Drugs Control Administration will carry out surprise inspections of manufacturing facilities to verify compliance with these requirements.

11. Any non-conformity or lapse in ensuring product quality leading to adverse events will attract stringent action, including the arrest and prosecution of the manufacturers and the responsible technical staff under Section 27(a) of the Drugs and Cosmetics Act, 1940, which is punishable with imprisonment for a term of not less than ten years, extendable to life imprisonment, and a fine of not less than ten lakh rupees. Additionally, action may be initiated under Section 105 (Culpable Homicide Not Amounting to Murder) and Section 276 (Adulteration of Drugs) of the Bharatiya Nyaya Sanhita, 2023, in the event of any adverse incidents.

Liquid Oral Manufacturers are reminded that any non-conformity in ensuring the absence of Diethylene Glycol (DEG) and Ethylene Glycol (EG) can have severe consequences on pediatric health. Any negligence in this regard will be viewed with utmost seriousness and will attract strict regulatory and penal action against the manufacturing firms and the responsible personnel.

Strict compliance is mandatory.

DIRECTOR GENERAL

To
All Liquid Oral Manufacturers in Telangana

Copy to:

- The Joint Director, Drugs Control Administration, Telangana – for information and monitoring compliance.
- All Deputy Directors, Drugs Control Administration, Telangana – for information and monitoring compliance.
- All Assistant Directors, Drugs Control Administration, Telangana – for information and monitoring compliance.
- All Drugs Inspectors concerned – for follow-up action and compliance verification.

Government of Telangana
Drugs Control Administration

Circular Memo. No. 28/DG-Peshi/2025-1 **Date: 12-11-2025**

CIRCULAR

Sub: Drugs Control Administration – Circular Issued regarding Mandatory Compliance Measures regarding Diethylene Glycol (DEG) and Ethylene Glycol (EG) Testing in Liquid Oral Formulations – Certain **Further Compliance Measures** – Reg.

Ref: 1) Virtual Meeting convened by the Drugs Control Administration with all Liquid Oral Manufacturers in Telangana on 10.10.2025.
2) Circular Memo. No. 28/DG-Peshi/2025, dated: 13-10-2025 of the Drugs Control Administration, Telangana.

*****

In continuation of Circular Memo No. 28/DG-Peshi/2025, dated 13-10-2025, of the Drugs Control Administration, Telangana, indicating certain mandatory compliance measures regarding Diethylene Glycol (DEG) and Ethylene Glycol (EG) testing in liquid oral formulations, this office hereby issues further instructions pertaining to the compliance measures to be adhered to by the liquid oral manufacturers in the State.

1) The raw materials, including pharmaceutical aids or excipients such as Glycerin, Propylene Glycol, Sorbitol Solution, etc., shall be purchased only from the approved suppliers and, where possible, directly from the producer, as required under Para 14.8 of Part I of Schedule M (Revised) of the Drugs Rules, 1945.

2) Further, the liquid oral manufacturers shall ensure that the manufacturers of high-risk solvents such as Glycerin, Propylene Glycol, Sorbitol Solution, etc., which are sourced by the liquid oral manufacturers, are mandatorily registered under the Digital Monitoring System on the ONDLS portal of CDSCO for monitoring the supply chain of high-risk solvents. It shall be strictly ensured that every batch of such high-risk solvents utilized in production pertains only to manufacturers registered under the Digital Monitoring System.

3) It is also reiterated that the liquid oral manufacturers shall ensure strict adherence to the provisions pertaining to suppliers' audits and approval, as specified under Para 10.8 of Part I of Schedule M of the Drugs Rules, 1945. It shall be ensured that the person responsible

for Quality Control shall have the responsibility, together with other relevant departments, for approving suppliers who can reliably supply starting materials, including pharmaceutical aids or excipients such as Glycerin, Propylene Glycol, Sorbitol Solution, etc., that meet established specifications. Further, it shall be ensured that before suppliers are approved and included in the approved suppliers' list or specifications, they are duly evaluated. The evaluation shall take into account the supplier's history and the nature of the materials to be supplied. If an audit is required, it shall determine the supplier's ability to conform to Good Manufacturing Practices (GMP) standards.

Any negligence in this regard, or with respect to the contents of the Circular dated: 13th October, 2025 (reference 2nd cited), shall be viewed with utmost seriousness and shall attract strict regulatory and penal action against the manufacturing firms and the responsible personnel.

Strict compliance is mandatory.

DIRECTOR GENERAL

To
All Liquid Oral Manufacturers in Telangana

Copy to:

- The Joint Director, Drugs Control Administration, Telangana – for information and monitoring compliance.
- All Deputy Directors, Drugs Control Administration, Telangana – for information and monitoring compliance.
- All Assistant Directors, Drugs Control Administration, Telangana – for information and monitoring compliance.
- All Drugs Inspectors concerned – for follow-up action and compliance verification.