# RAPID ALERT

**DRAP ALERT NO.** Nº I/S/02-25-23

## CONTAMINATED PROPYLENE GLYCOL (BATCH # A803S96G46) PURPOTEDLY MANUFACTURED BY M/S. DOW CHEMICAL PACIFIC (SINGAPORE) PRIVATE LIMITED.

**Date:** 25th February, 2025.

## Target Audience:

- Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Therapeutic Goods industry
- Manufacturers of Oral liquid preparations

## Problem Statement:

Federal Government Analyst, Central Drugs Laboratory Karachi vide test/analysis No. RM-1-25-000007 dated 20-02-2025, has declared the sample of Propylene glycol (Raw material) as '***Substandard'*** sent to CDL Karachi by the licensed pharmaceutical manufacturer in compliance to advisory issued by DRAP vide No. 03-41/2023-QC dated 01-12-2023. Details of test/analysis report are given as under:

| Sr # | Product | Purported manufacturer | Batch No. | Test Results | Permissible values |
|---|---|---|---|---|---|
| 1. | Propylene Glycol (Raw material) | M/s. Dow Chemical Pacific (Singapore) Private Limited. | A803S96G46 | **Ethylene Glycol** 0.1906% **Does not comply** | NMT 0.1% |

## Risk Statement:

Di-Ethylene glycol (DEG) and Ethylene Glycol (EG) contaminated Propylene Glycol (PG) when used in oral liquid preparations can lead to serious health risks. When ingested, EG and DEG are converted into toxic metabolites that can affect the central nervous system and heart. Moreover, it can also cause kidney damage which may lead to fatal consequences.

## Action Initiated: -

The Regulatory Field Force has been directed to conduct surveillance activities for identification of above mentioned contaminated batch of Propylene glycol in the market and is investigating the entire supply chain of this batch. The Regulatory Field Force has also been instructed to seize all oral preparations manufactured using the same batch of propylene glycol if found in the market.

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## Advice for Therapeutic Goods Manufacturers: -

Manufacturers of therapeutic goods are required to follow these instructions:

1. **Recall Products:** If any batch was manufactured using the same lot of Propylene glycol that has been identified as contaminated, all finished products from local and export markets should be recalled.
2. **Hold Other Batches:** All finished products manufactured from same lot of Glycerin should be kept on hold. These products should be tested for Propylene glycol contamination before releasing them into the supply chain.
3. **Screen Raw Materials:** Before using them in the manufacturing of oral liquid preparations, all raw materials should be screened for contamination with EG, DEG and other impurities.
4. **Compliance:** Ensure compliance with all directives issued by DRAP to safeguard public health from contaminated products.
5. **Follow Guidelines:** Adhere to the pharmacopoeia monograph and WHO guidelines for testing EG/DEG in oral liquid preparations during the analysis of both raw materials and finished products.

Our utmost priority is public safety. DRAP is committed to supporting the industry in maintaining rigorous quality control and testing procedures to prevent any potential harm caused by contaminated products.

## Advice for Healthcare Professionals: -

DRAP requests healthcare professionals to stay updated with advisories and recalls. Close monitoring of patients using the affected products is crucial, and any adverse events should be reported to National or Provincial pharmacovigilance centers.

Adverse reactions or quality problems experienced with the use of these products shall be reported to the National Pharmacovigilance Centre(NPC), DRAP using Adverse Event Reporting Form or online through this link. Further information on reporting problems to DRAP is available on this link.

**Drug Regulatory Authority of Pakistan**
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