RAPID ALERT

DRAP ALERT NO. Nº I/S/10-24-38

CONTAMINATED PROPYLENE GLYCOL (BATCH # YF01230522)

Date: 25th October 2024.

Target Audience:

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

Problem Statement:

The Federal Government Analyst at Central Drugs Laboratory (CDL) Karachi has identified a contaminated batch of Propylene Glycol which has been declared substandard vide Report No. RM-8-24-000486 dated 19-09-2024. Samples of this Propylene Glycol (Raw material) were sent to CDL Karachi by a licensed pharmaceutical manufacturer in compliance with DRAP advisory on solvent testing. The manufacturer has been stopped from using the contaminated material and its supply chain is under investigation.

Details of the test/analysis report are given as under:

Material Name	Batch Details	Test Results	Limits	Name of Manufacturer *(as per label)*
Mono Propylene Glycol (Raw material)	Batch # YF01230522 Mfg.Date: 22-May-2023 Exp.Date: 21-May-2025	Ethylene Glycol 2.3727% **Does not comply**	NMT 0.1%	M/s. Dongying Hi-Tech Spring Chemical Industry Co. Ltd., China. *[The material found in the packaging with the label of this manufacturer, however product authenticity and supply chain integrity are under investigation and yet not confirmed.]*

Note: On February 13, 2024, DRAP issued a Rapid Alert regarding contaminated Propylene Glycol (Batch #1P03-202308194). The investigation revealed that a falsified product had been packaged and labelled as being manufactured by Dongying Hi-Tech Spring Chemical Industry Co., Ltd. in China. The manufacturer also provided Certificate of Analysis (CoAs) to DRAP showing that the original product was not contaminated and analysis of retained samples met all required specifications.

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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 manufacturer has been instructed to halt the consumption of the contaminated material, and an investigation into the supply chain is underway. The Regulatory Field Force has increased surveillance to identify the contaminated batch of Propylene Glycol in the market. DRAP has strictly prohibited manufacturers of therapeutic goods from using Propylene Glycol without testing for Ethylene Glycol (EG) and Diethylene Glycol (DEG) levels.

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 the same lot of propylene glycol should be kept on hold. These products should be tested for EG/DEG 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 and DEG.
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. Patients should be educated about the risks and symptoms of DEG/EG toxicity. Close monitoring of patients using the affected products is crucial, and any adverse events should be reported to National or Provincial pharmacovigilance centers.

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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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