



## RAPID ALERT

DRAP ALERT NO. N° I/S/02-24-06

### CONTAMINATED PROPYLENE GLYCOL (BATCH # 1P03-202308194) ALLEGEDLY PRODUCED BY M/S. SHINGHWA AMPEREX TECHNOLOGY (DONGYING) CO. LTD., CHINA.

**Date:**

13<sup>th</sup> February 2024

**Target Audience:**

- Regulatory Field Force.
- Therapeutic Goods industry
- Manufactures of Oral liquid preparations

**Problem Statement:**

Federal Government Analyst, Central Drugs Laboratory Karachi vide test/analysis No. RM-1-24-000027 dated 31-01-2024 declared the sample of Propylene Glycol (Raw material) sent to CDL Karachi by M/s. Biolabs (Pvt.) Ltd., Islamabad in compliance to letter vide No. 03-41/2023-QC dated 01-12-2023. Details of test/analysis report are given as under:

S#	Product	Mfg. by	Batch No.	Test Results	Permissible Values
01	Propylene Glycol	M/s. Shinghwa Amperex Technology (Dongying) Co. Ltd., China.	1P03- 202308194	<b>Ethylene Glycol:</b> 44.4727% <b>Diethylene Glycol:</b> 0.3211%	<b>Ethylene Glycol:</b> NMT 0.1% <b>Diethylene Glycol:</b> 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 directed to take necessary action on above mentioned contaminated batch of Propylene Glycol and is investigating the entire supply chain of this batch. The therapeutic goods manufacturer has been instructed to recall any finished products that were manufactured using the same lot of propylene glycol. The Regulatory Field Force has also been instructed to seize all oral preparations





that were made using the same batch of propylene glycol if found in the market.

### **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 (1P03-202308194) 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 any other lot of propylene glycol of M/s. Shingwa Ampere Technology (Dongying) Co. Ltd., China 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.

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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