



## RAPID ALERT

DRAP ALERT NO. N° I/S/02-24-03

### CONTAMINATED GLYCERIN (BATCH # 1A2192K) ALLEGEDLY PRODUCED BY M/S KLK PALM OLEO SDN BHD, MALAYSIA

**Date:** 01<sup>st</sup> February 2024

#### Target Audience:

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

#### Problem Statement:

Ms. Cibex Private Limited Pharmaceuticals, Karachi sent the sample of Glycerin to Central Drugs Laboratory Karachi for test/analysis that was used as a solvent in the manufacturing of oral liquid preparations. The batch was labelled as manufactured by Ms. KLK PALM OLEO SDN BHD, Malaysia. However, on analysis of a sample by the Central Drug Laboratory in Karachi, an unacceptable level of Ethylene Glycol was found. The details of the affected batch are as under:-

Product	Manufacturer (as per label)	Reg. No	Batch No	Mfg Date	Exp. Date	Remarks
Glycerin (Raw Material)	KLK Palm Oleo SDN BHD, Malaysia	Nil	IA2192K	06-10-22	05-10-24	The sample is declared substandard for unacceptable levels (0.1662%) of Ethylene Glycol (EG).

#### Risk Statement:

Glycerin contaminated with Ethylene Glycol (EG) when used in oral liquid preparations can lead to serious health risks due to EG's toxicity. When ingested, EG is metabolized into toxic metabolites that can affect the central nervous system, and heart, and can cause kidney damage, which can be fatal..





### Action Initiated: -

The Regulatory Field Force has directed to take necessary action on above mentioned contaminated batch of Glycerin 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 Glycerin. DRAP has directed the therapeutic industry to ensure the testing of this lot or any other lot of raw material prior to use in manufacturing of finished products.

### 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 (1A2192K) of glycerin 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 glycerin of Ms. KLK PALM OLEO SDN BHD, Malaysia should be held. 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. **Analyze Finished Products:** Before their release into the market, all finished products should be analyzed for EG/DEG contamination.
5. **Compliance:** Ensure compliance with all directives issued by DRAP to safeguard public health from contaminated products.
6. **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 EG toxicity. Close monitoring of patients using the affected products is crucial, and any adverse events should be reported to National or Provincial pharmacovigilance centres.

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](#).





### **Advice for Consumers / General public: -**

Consumers should stay informed about the latest advisories and recalls from DRAP. If they have experienced any problem or unusual symptoms after using oral liquid preparations, seek medical attention immediately and report the incident to the Drug Regulatory Authority of Pakistan / National Pharmacovigilance Centre.

All therapeutic goods must be obtained from licensed pharmacies and other authorized/licensed retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professionals in case of any doubt.



## **Drug Regulatory Authority of Pakistan**

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