RAPID ALERT

DRAP ALERT NO. Nº I/S/03-24-12

SUBSTANDARD PROPYLENE GLYCOL (BATCH # G01821UG) ALLEGEDLY PRODUCED BY SK PICOGLOBAL CO. LTD., KOREA

Date: **8th March 2024**

Target Audience:

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

Problem Statement:

Ms. MKB Pharmaceuticals (Pvt) Ltd., Peshawar sent the sample of Propylene Glycol (PG) 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 SK picoglobal Co. Ltd. Korea. Analysis of the sample by the Central Drug Laboratory, Karachi detected unacceptable level of Ethylene Glycol. The details of the affected product is as under:-.

Name of Product	Manufactured by (as per label)	Batch no.	Mfg. Date	Exp. Date	Remarks
Propylene Glycol (Raw Material)	Ms. SK Picoglobal Co. Ltd. Korea.	G01821UG	12-08-2023	11-08-2025	The sample is declared substandard for unacceptable levels of Ethylene Glycol (0.4671%).

Risk Statement:

Propylene Glycol (PG) 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.

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Action Initiated: -

The manufacturer company has been instructed to recall finished products that were manufactured using the contaminated 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. DRAP has directed the therapeutic industry to hold finished products manufactured from any other lot of propylene glycol of Ms. SK picoglobal Co. Ltd. Korea and ensure testing of finished products for EG/DEG contamination before releasing them into the supply chain.

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 (YF01200730) 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 SK picoglobal Co. Ltd. Korea 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. 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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