RAPID ALERT

DRAP ALERT NO. Nº I/S/03-24-14

CONTAMINATED PROPYLENE GLYCOL IDENIFIED AND CONFISCATED

Date: **08th March, 2024**

Target Audience:

- Therapeutic Goods industry
- Manufactures of Oral liquid preparations

Problem Statement:

Federal Government Analyst, Central Drugs Laboratory Karachi vide test/analysis vide No. RM-2-24-000179 and No. RM-2-24-000180 dated 01-03-2024 declared the sample of Propylene Glycol (Raw material) sent to CDL Karachi by Federal Inspector of Drugs Islamabad-I as of substandard quality.

Two samples were collected from separate containers which were labelled as Propylene Glycol, Batch# C815L44R41 and Batch# C815L44R52, purportedly manufactured by Dow Chemical Pacific (Singapore) Private Limited. However, upon further investigation, it seems that none of the samples were actually manufactured by Dow Chemicals and the labels were false. The analysis reveals that these samples were highly contaminated as shown below:

Sample 1	Sample 2
Ethylene Glycol: 20.0978% **Di-Ethylene Glycol:** 7.3086%	**Ethylene Glycol:** 34.6887%

It is important to note that on January 11, 2024, a rapid alert was also issued for contaminated Propylene Glycol with batch number C815N30R41, which was labelled as being manufactured by Dow Chemicals, Thailand. However, Dow Chemicals, Thailand has clarified to DRAP that it was not their original product and was falsified by some miscreants. The company also analyzed the retained samples of the original product and shared an analysis report, which showed that it was in compliance with the required specifications.

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Risk Statement:

Diethylene glycol (DEG) and Ethylene Glycol (EG) contamination in Propylene Glycol (PG) can lead to serious health risks when used in oral liquid preparations. Upon ingestion, these chemicals (EG and DEG) are converted into toxic metabolites which 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 taken possession of contaminated raw materials and commenced an investigation to trace the supply chain of these containers. Manufacturers of therapeutic goods have been prohibited from using propylene glycol without testing for the presence of EG/DEG levels. These materials should only be obtained from authorized suppliers of original manufacturers with thorough verification of the integrity of the supply chain and originality of the product. The Regulatory Field Force has also been directed to ensure compliance and seize any such raw materials or products found to be contaminated in the market.

Advice for Therapeutic Goods Manufacturers: -

Manufacturers of therapeutic goods are required to follow these instructions:

1. **Recall Products:** If any batches were produced using the same lots of Propylene Glycol that have been identified as contaminated, it is crucial to test both the raw materials and finished products for contamination immediately. If any contamination is found, the affected products should be recalled promptly from the local and export markets.
2. **Hold Other Batches:** All finished products manufactured from propylene glycol 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 of 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.

DRAP's 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.

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