RAPID ALERT

DRAP ALERT NO. Nº I/S/03-25-32

CONTAMINATED PROPYLENE GLYCOL (BATCH # YFO1210911) PURPOTEDLY MANUFACTURED BY M/S. DONGYING HI-TECH SPRING CHEMICAL INDUSTRY CO LTD, CHINA.

Date: 15th March, 2025.

Target Audience:

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

Problem Statement:

Directorate Drug Control Punjab (DDCP) has informed Drug Regulatory Authority of Pakistan vide test/analysis report No. 141002343, wherein the sample of Propylene Glycol (Raw Material) has been declared ***'Substandard'***. The falsified excipient was detected in the unregulated supply chain marketed through Facebook page and tested by Drug Testing Laboratory (DTL), Lahore. The contaminated propylene glycol batch (YFO1210911) was purported to be manufactured by Dongying Hi-Tech Spring Chemical Industry China. The results of test have revealed that the level of EG in the batch was 91.4%, far exceeding the accepted criteria of 0.1%. Details of test/analysis report are tabulated as under:

Sr #	Product	Purported manufacturer	Batch No.	Test Results	Permissible values
1.	Propylene Glycol (Raw material)	M/s. Dongying Hi-Tech Spring Chemical Industry Co Ltd, China	YFO1210911	**Ethylene Glycol** 91.4% w/w **Does not comply**	NMT 0.1% w/w

*(**Note:** Earlier in December 2024, DRAP issued a Rapid Alert for the same batch of falsified Propylene Glycol (Raw material) tested by CDL Karachi in compliance to advisory issued by DRAP vide No. 03-41/2023-QC dated 01-12-2023. In this regard, Hi Tech Spring China has confirmed that the said batch is not their product. The firm has provided the original product label, and a comparison between the original and falsified product labels is presented below)*

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

DRAP, Islamabad | 92 51 9107404 | gsms@dra.gov.pk

toxic metabolites that can affect the central nervous system and heart. Moreover, it can also cause kidney damage which may lead to fatal consequences

Comparison of Original and Falsified product labels:

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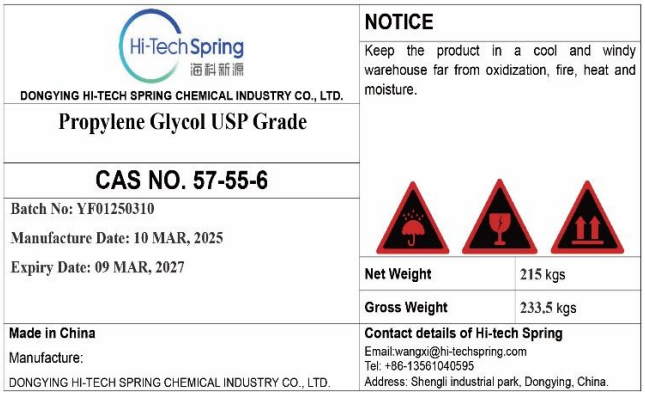

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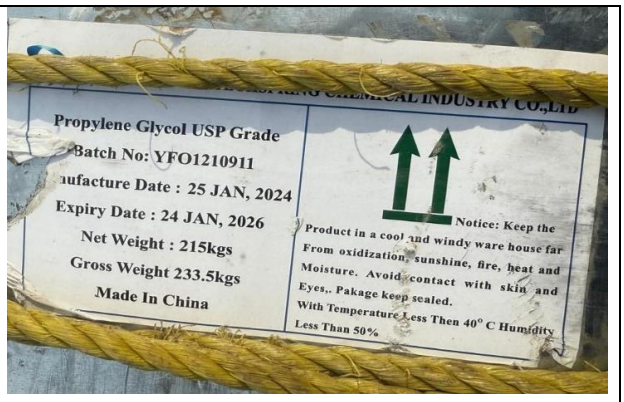

</td>
</tr>
<tr>
<td>Original Product Label</td>
<td>Falsified Product Label</td>
</tr>
</table>

Action Initiated: -

The Regulatory Field Force has been directed to conduct surveillance activities for identification of above mentioned contaminated batch of Propylene glycol in the market. The Regulatory Field Force has also been instructed to seize all oral preparations manufactured 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 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 same lot of Glycerin should be kept on hold. These products should be tested for Propylene glycol 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, DEG and other impurities.
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. 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
محفوظ، موثر اور معیاری اشیائے علاج

DRAP, Islamabad
92 51 9107404
gsms@dra.gov.pk