RAPID ALERT

DRAP ALERT NO. Nº I/S/04-24-19

CONTAMINATED SORBITOL SAMPLE (BATCH # 09-LM-023) MANUFACTURED BY M/S. M/S. MASTER SWEETENER, KARACHI.

Date: 15th May, 2024.

Target Audience:

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

Problem Statement:

The Federal Government Analyst, Central Drugs Laboratory Karachi vide test/analysis report No. RM-2-24-000136 dated 22-03-2024 declared the sample of Sorbitol (Raw material) sent to CDL Karachi by M/s. Herbiotics Healthcare Rawalpindi in compliance to letter vide No. 03-41/2023-QC dated 01-12-2023. Details of CDL test/analysis report are as under:

S#	Product	Manufacturer as per label	Batch No.	Test Results	Limits
01	Sorbitol	M/s. Master Sweetener, Karachi	09-LM-023	**Ethylene Glycol:** 0.6431% **Does not comply**	**Ethylene Glycol:** NMT 0.1%

Risk Statement:

Ethylene Glycol (EG) contaminated raw materials when used in oral liquid preparations can lead to serious health risks. When ingested, EG is 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 therapeutic goods manufacturer has been instructed to recall any finished products that were manufactured using the same lot of Sorbitol. The Regulatory Field Force has also been instructed to seize all preparations manufactured using the same batch of Sorbitol if found in the market.

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

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 Sorbitol 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 sorbitol 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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