6-2/2025(DDQAVII)
Government of Pakistan
Drug Regulatory Authority of Pakistan (DRAP)
Prime Minister's National Health Complex, Park Road, Islamabad
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Islamabad, the 14th October, 2025

ADVISORY

SUBJECT: ADVISORY TO THERAPEUTIC GOODS MANUFACTURERS: MEASURES TO PREVENT DEG/EG CONTAMINATION IN ORAL LIQUID PREPARATIONS

This advisory is issued in furtherance of the Drugs Regulatory Authority of Pakistan (DRAP) Advisory No. 13-30/2024-DD(QA-VIII), dated 16-04-2025, concerning the mitigation of Diethylene Glycol (DEG) and Ethylene Glycol (EG) contamination in Therapeutic Goods. Given the anticipated increase in demand and production of cough syrups and oral liquid preparations especially with the onset of the winter season, it is vital to re-emphasize the critical need for quality assurance measures to safeguard public health and ensure compliance with Good Manufacturing Practices (GMP).

2. In addition to the above-mentioned instructions and the applicable regulatory requirements concerning the quality and purity of Glycerin, Sorbitol and Propylene Glycol. All the Therapeutic Goods manufacturers are hereby directed to ensure strict compliance to the below mentioned directions:-

i. Procurement of these critical raw materials shall only be from qualified vendors/manufacturers. The vendor qualification process shall be in accordance with the current Good Manufacturing Practices (cGMP) guidelines and applicable rules.
ii. Manufacturers shall ensure pre-use testing of Glycerin, Sorbitol and Propylene Glycol for the presence of DEG/EG impurities in all procured batches, prior to their use in the manufacturing processes. Moreover, manufacturers that do not possess in-house testing capabilities are once again directed to utilize the services of the Central Drug Laboratory (CDL) Karachi and any Provincial Drug Testing Laboratories (DTLs) having requisite facilities.
iii. The results of all mandatory purity testing (through in-house facility, CDL Karachi or any Provincial DTL having requisite facility) and Certificate of Analysis (CoA) obtained from the manufacturer must be thoroughly verified and documented as part of the Batch Manufacturing Record (BMR) to ensure traceability, patient safety and consistent quality of the final product.

3. All relevant manufacturers are advised to ensure strict compliance to above-mentioned directives to ensure the product quality and patient safety. Non-compliance with these directives shall attract stringent regulatory action in accordance with the Drugs Act, 1976 / DRAP Act 2012 and rules framed thereunder.

14-X-2025

Ishtiaq Shafiq
Deputy Director QA&LT

Copy for necessary action: -

1. Additional Director, DRAP, Lahore, Karachi, Islamabad, Peshawar and Office in-charge DRAP Quetta, with request to ensure the compliance through Deputy Director (import & export) / area FID.
2. Central Drug Testing Laboratory (CDL) Karachi with the request to process the testing/analysis of these samples on priority.
3. All provincial Drug Testing Laboratories with the request to process the testing/analysis of these samples on priority.
4. Director MIS, DRAP with the request to upload on official website of DRAP.

Copy for information and compliance: -

1. The Pakistan Pharmaceutical Manufacturing Association (PPMA).
2. The Pharma Bureau Pakistan.
3. Pakistan Chemists & Druggists Association.
4. Pakistan Tibbi Pharmaceutical Manufacturers Association (PTPMA), Near Chowk Noranian, Opposite Jamia Masjid Ghausia, New Shalimar, Multan Road, Lahore.
5. Homeopathic Pharmaceutical & Chemist Association Pakistan,29-A, Anum Road, Industrial Estate (Glaxo Town), 20 Km, Ferozpur Road, Lahore.
6. Pakistan Alternative Medicine Manufacturers Association, Suite No. 503, 5th Floor, Al-Amin Tower, NIPA Chowrangi, Block 10, Gulshan e Iqbal, Karachi.