DRUG REGULATORY AUTHORITY OF PAKISTAN
DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/12-25-123

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUGS TESTING LABORATORY.

Date: 18th December, 2025

Target Audience:

- National Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Healthcare Professionals (Physicians, Pharmacists & Nurses).
- General Public.

Alert Summary:

Drugs, Water & Food Testing Laboratory, Government of Gilgit Baltistan informed that the samples of below mentioned drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Remarks	Manufacturers
1.	**Glitric Tablets** Each prolonged release tablet contains: Glyceryl Trinitrate …….. 2.6 mg (Reg. # 119607)	25H261 & 25H262	**Batch # 25H261** The sample has been declared **"Substandard"** on the basis of Assay & Dissolution Test. **Batch # 25H262** The sample has been declared **"Substandard"** on the basis of Assay Test.	M/s Linta Pharmaceuticals. Plot # 03, Street S-5, National Industrial Zone, Rawat, Islamabad. **(DML # 000810)**
2.	**Betahist Tablet** Each Tablet contains: Betahistine DiHydrochloride … 16 mg **(Reg. 091595)**	25H249	The sample has been declared **"Substandard"** on the basis of Physical description. *(Tablets found with softening, cracking, rough orange peel texture, easily break, and become powder when pressed with fingers).*	

Risk Statement:

The identified quality defects in Glyceryl Trinitrate prolonged-release tablets (Glitric 2.6 mg), including failure of assay and dissolution, and the severe physical instability observed in Betahistine tablets (Betahist 16 mg) may result in therapeutic failure and unpredictable dosing. Glyceryl Trinitrate is a critical cardiovascular medicine with a sensitive therapeutic window, and inadequate dosing may precipitate angina or serious ischemic events, particularly in elderly patients and those with ischemic heart disease. Betahistine defects may lead to loss of efficacy in patients suffering from vertigo and balance disorders. The public most likely to be affected includes chronic cardiovascular and vestibular disorder patients, especially the elderly and comorbid populations.

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Action initiated: -

The field force of DRAP and Provincial Drug Control departments have been directed to immediately conduct market surveys for detection of presence and removal of mentioned batches from the market.

Advice for Pharmacies/Medical stores: -

All pharmacists and chemist working at distributions and pharmacies should **immediately check** their stocks and stop supplying mentioned products. The remaining stocks should be quarantined and returned to the supplier/company. Regulatory field force of all federating units (DRAP and Provincial Health Departments) should also increase surveillance in the market to ensure the effective recall of defective products(s).

Advice for Healthcare Professionals: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by batches of mentioned products. Adverse reactions or quality problems experienced with the use of above mentioned product are to be reported to the National Pharmacovigilance Centre (NPC), DRAP using Adverse Event Reporting Form or online through this link. Further information of reporting problems to DRAP is available on this link.

Advice for Consumers/general public: -

Consumers should stop using products bearing the affected batch number(s) and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product, and report the incident to Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

Drug Regulatory Authority of Pakistan

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