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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº II/S/03-26-14

DRUG PRODUCT DECLARED SUBSTANDARD BY DRUG TESTING LABORATORIES, PUNJAB.

Date: 11th March, 2026

Target Audience:

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

Alert Summary:

Drug Testing Laboratories of Punjab Province informed that the samples of below mentioned drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Medizole Suspension 60m1** Each 5 ml contains metronidazole....40 mg Furazolidone....25 mg (Reg # 005721)	SR260004	M/s Medicon Pharmaceutical Industries (Pvt) Ltd. 11 Industrial Estate Hayatabad Peshawar (DML # 000215)	The sample is **"Substandard"** on the basis of pH test performed.
2.	**Sachet PURGO 4mg** Each sachet contains: Montelukast Sodium eq. to Montelukast …….4mg (Reg # 076497)	055	M/s Hiranis Pharmaceuticals (Pvt) Ltd. Plot No. E-145 to E-149 North Western Industrial Zone Port Qasim, Karachi.	The sample is **"Substandard"** on the basis of impurities test.
3.	**Sachet G-Mont** Each sachet contains: Montelukast Sodium eq. to Montelukast …….4mg (Reg # 080691)	GMT108	M/s GT Pharma (Pvt) Ltd. 713 Sundar Industrial Estate Lahore. (DML # 000829)	The sample is **"Substandard"** on the basis of impurities test.

Risk Statement:

The above-mentioned products have been declared **Substandard** based on laboratory testing (pH and impurities failure). Substandard medicines may result in **reduced therapeutic effectiveness, delayed recovery, or unexpected adverse reactions**.

Children suffering from diarrhea and gastrointestinal infections (Medizole Suspension) and **pediatric patients using Montelukast sachets for asthma or allergic conditions** are most likely to be affected. Treatment failure in these populations may lead to worsening of symptoms, increased risk of complications, and unnecessary escalation of therapy.

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

محفوظ، موثر اور معیاری اشیائے علاج