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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/10-25-105

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES

Date: 30th October, 2025

Target Audience:

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

Alert Summary:

Drug Testing Laboratory from Province informed that the sample of below mentioned drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Injection Nidagyl 100ml** Metronidazole...500mg/100ml (Reg # 020601)	HM 139	M/s Star Laboratories (Pvt) Ltd. (Human Healthcare Division), 23 Km Multan Road Lahore. (DML # 000130)	The sample is declared as **"Adulterated"**
2.	**Myteka Sachet** Each Sachet contains: Montelukast (as sodium) ... 4mg (Reg. # 039427)	155321	M/s Hilton Pharma (Pvt) Ltd. Plot No. 13 & 14 Sector 15 Korangi Industrial Area Karachi. (DML # 000136)	The sample is **Sub-Standard** on the basis of Impurities Test.
3.	**Sterile Water for Injection** Water for injection 5ml	WI-132	M/s FYNK Pharmaceuticals. 19-Km Ferozepur Road G.T. Road Kala shah Kaku Lahore. (DML # 000494)	The Sample is **Sub-Standard** on the basis "Visible particulate matter" as per USP.

Risk Statement:

The use of these defective human drug products poses potential health risks to patients. *Injection Nidagyl (Batch HM 139)*, declared adulterated, may cause treatment failure or toxic reactions in patients receiving parenteral therapy for infections. *Myteka Sachet (Batch 155321)*, found sub-standard due to impurities, may lead to reduced efficacy or adverse effects in pediatric and asthmatic patients commonly using Montelukast. *Sterile Water for Injection (Batch WI-132)*, declared sub-standard due to visible particulate matter, poses a serious risk of embolism or infection in patients where sterility is critical, particularly neonates, elderly, and hospitalized patients.

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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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