



# DRUG REGULATORY AUTHORITY OF PAKISTAN

## DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

### MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° I/S/10-25-86

**DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES.**

**Date:** 08<sup>th</sup> October, 2025

#### Target Audience:

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

#### Alert Summary:

Provincial Health Departments informed the Drug Regulatory Authority of Pakistan that the samples of below mentioned drug products have been declared as '*Substandard*'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	<b>Tablet Rolekast 10mg</b> Each film coated tablet contains: Montelukast (as Sodium)...10 mg	1397	M/s Roryan Pharmaceutical industries (Pvt) Ltd. 85-B Hayatabad Industrial Estate Peshawar. (DML # 000566)	The sample is declared as " <b>Sub-Standard</b> " on the basis of Dissolution Test and impurities test.
2.	<b>AME-CLOP Injection</b> Each 2mL contains: Metoclopramide HCL....10mg	MC-126	M/s Ameer Pharma (Pvt) Ltd. 23-Km Sheikhpura Road, Lahore. (DML # 000604)	sample is ' <b>Sub-Standard</b> ' on the basis "Particulate contamination: visible particles" as per BP.
3.	<b>Infusion DORCIP</b> Each ml contains: Ciprofloxacin (as Lactate)....2mg	DC-120	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8- Km Thokar Raiwind Road Lahore. (DML # 000342)	The Sample is declared as " <b>Sub-Standard</b> " on the basis of Visible Particulates, pH Test, Sterility Test and Bacterial Endotoxin Test (BET).

#### Risk Statement:

Tablet Rolekast 10 mg (Batch 1397), used for asthma and allergic rhinitis in children and adults, has failed dissolution and impurity tests. AME-CLOP Injection (Batch MC-126), used for severe nausea, vomiting and gastrointestinal disorders in patients including pregnant women, surgical and chemotherapy cases, contains visible particles posing risk of embolism and infection and DORCIP Infusion (Batch DC-120), used in serious infections among adults and critically ill patients, failed sterility, endotoxin and pH tests, risking sepsis and life-threatening reactions. Use of these



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defective medicines can cause ineffective treatment, adverse reactions, and serious safety hazards. Healthcare providers and distributors must immediately stop use and sale, quarantine affected stock, and return it to the supplier, while patients should discontinue these batches and seek medical advice if exposed.

#### 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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