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

# MEDICAL PRODUCT ALERT

**DRAP ALERT NO.** Nº III/S/11-25-106

## DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES

**Date:** 12th November, 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.** | **Tablet Cekamol 500 mg**<br>Each Tablet Contains:<br>Paracetamol ……. 500 mg<br>(Reg. # 004268) | T-5014 | M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd.<br>50/28 Korangi Industrial Area Karachi.<br>(DML # 000144) | The sample is **"Substandard"** with respect to physical characteristics observed. *(White colored, round shaped, flat tablet with bevelled edges, have score line on one side and other side is engraved with "CKD", packed in ALU/PVC blister of 1*10's.*<br><br>*Mmanufacture Sspecification claims that tablet should be round, flat and plain from both sides.)* |

**Risk Statement:**

**The sample of** Tablet Cekamol 500 mg (Batch No. T-5014) **has been declared** "Substandard" **with respect to its** physical characteristics**, as the tablets bear engraving and a score line inconsistent with the approved product specifications. Although this deviation does not affect the** safety, strength, or efficacy **of the medicine, it indicates** non-compliance with Good Manufacturing Practices (GMP) **and approved appearance standards. The defect poses** no direct risk to patient health**; however, recall of the affected batch is recommended to maintain product quality and regulatory compliance.**

**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 Distributors.

DRAP, Islamabad
+92 051 9255969
gsms@dra.gov.pk

**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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