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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/12-25-126

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUGS TESTING LABORATORY.

Date: 30th December, 2025

Target Audience:

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

Alert Summary:

DTL Punjab informed that the samples of below mentioned drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Injection Cara-Doba 5ml** Each 5ml Ampoule contains: Dobutamine HCl eq. to Dobutamine …. 250mg (Reg. # 054987)	24J009 & 25E004	M/s Caraway Pharmaceuticals. Plot No. 12 Street No. N-3 National Industrial Zone (RCCI) Rawat. **(DML # 000629)**	**Batch # 24J009** The sample has been declared **Sub-Standard**, on the basis of Physical Description and Visible Particulates. **Batch # 25E004** The Color has been changed to dark brown with crystallization. *(Physical Description and Visible Particulates).*

Risk Statement:

The administration of sub-standard injectable Dobutamine with visible particulates, discoloration, and crystallization poses a serious and immediate risk to patient safety, particularly for critically ill patients, cardiac patients, and those receiving intensive or emergency care, where Dobutamine is commonly used for acute cardiac support. Such quality defects may lead to embolism, phlebitis, systemic infections, reduced therapeutic efficacy, or unpredictable pharmacological response, potentially resulting in treatment failure, hemodynamic instability, or life-threatening complications, thereby warranting urgent regulatory intervention.

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.

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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