



DRUG REGULATORY AUTHORITY OF PAKISTAN

DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° I/S/05-26-26

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL LABORATORIES

Date: 04th May, 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 (DTL) Punjab informed that the samples of below mentioned drug products have been declared as '**Substandard**'.

S#	Product Name	Batch	Manufacturers	Remarks
1.	ZYOCAIN Gel Lignocaine Hydrochloride B.P 2% w/v (Reg # 012523)	G026	M/s PharmaWise Laba. (Pvt.) Ltd. Formerty Fakma Pharma 25-41 QA Industrial Estate, Lahore-Pakistan (DML # 000182)	The Sample is declared as " sub-standard " on the basis of Sterility Test.
2.	Neocobal Injection 0.5/mg Each ml contains: Mecobalamin.....0.5mg (Reg # 071447)	S-3050	M/s Pulse Pharmaceuticals (Pvt) Ltd. Mozay Badoke Raiwind Road (Sua Asil Road) Lahore. (DML # 000564)	The sample is declared as " sub-standard " on the basis of Assay Test & " adulterated " as per section 3 (a) (iv) of The Drugs Act 1976 (Cyanocobalamin is Identified).
3.	Injection Neutroline 10 ml Water for injection 10ml (Reg # 096698)	L387	M/s Neutro Pharma (Pvt) Ltd. 9.5-Km Sheikhpura Road Lahore. (DML # 000576)	The Sample is declared as " sub-standard " on the basis of Endotoxin Test.
4.	CARA-DOBA Injection Each 5mL ampoule contains Dobutamine HCL USP Eq to Dobutamine 250mg (Reg # 054987)	25E004	M/s Caraway Pharmaceuticals. Plot No. 12 Street No. N-3 National Industrial Zone (RCCI) Rawat. (DML # 000629)	The sample is sub-standard , on the basis " Physical description " and " Visible particulate matter " tests.
5.	PAINSTOP Injection Each 3ml contains Diclofenac Sodium B.P.....75mg (Reg # 023730)	PS-090, PS-091	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8- Km Thokar Raiwind Road Lahore. (DML # 000342)	The above sample is sub-standard on the basis " Physical Description-Visible Particulate matter ".



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6.	SENSOCAIN Injection Each ml contains: Bupivacaine Hydrochloride 5 mg (Reg # 047396)	172K25	M/s Brookes Pharma Private Limited 58-59 Sector 15 Korangi Industrial Area Karachi. (DML # 000275)	The sample is sub-standard on the basis of Sterility test.
7.	Tablet Kadin 2 mg Each Tablet Contains Tizanidine (as Hydrochloride) ... 2mg (Reg # 033347)	570	M/s FYNK Pharmaceuticals. 19-Km Ferozepur Road G.T. Road Kala shah Kaku Lahore. (DML # 000494)	The sample is declared as " adulterated " as per section 3 (a) (iv) of The Drugs Act 1976 (Paracetamol identified).
8.	Infusion. GEE-SOL NS 1000ML Sodium Chloride 0.9% w/v (Reg # 080418)	26A025	M/s Gallop Water Sciences, 404-Sundar Industrial Estate, Lahore. (DML # 000817)	The sample is sub-standard , on the basis of Bacterial Endotoxins Test.
9.	Infusion. GEE-SOL RL 500ml (Compound Sodium Lactate) (Reg # 080910)	25MM264	M/s Gallop Water Sciences, 404-Sundar Industrial Estate, Lahore. (DML # 000817)	The sample is sub-standard , on the basis of Bacterial Endotoxins Test.

Risk Statement:

The identified products present **moderate to high public health risk**, particularly because several are **parenteral (injectable/infusion) preparations**, which bypass natural body defenses. Failures in **sterility and endotoxin tests** (e.g., ZYOCAIN Gel, SENSOCAIN, Neutroline, GEE-SOL infusions) can lead to **sepsis, pyrogenic reactions, or life-threatening infections**, especially in **hospitalized, immunocompromised, pediatric, and ICU patients**, who are the most vulnerable. Products with **visible particulate matter** (CARA-DOBA, PAINSTOP) pose risks of **embolism, inflammation, and organ damage**. **Adulterated medicines** (Neocobal, Kadin) indicate **serious quality breaches**, potentially causing **therapeutic failure, unexpected pharmacological effects, or toxicity**, undermining clinician trust and treatment outcomes. The most likely affected population includes **inpatients in public/private hospitals, emergency care recipients, and patients receiving IV therapy**, where such products are commonly used. Overall, these defects reflect **critical lapses in manufacturing quality systems**, with the highest risk concentrated in **injectables and infusions used in acute care settings**.

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 batches of drug products. The remaining stocks should be quarantined and returned to the supplier/company.



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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 batches of the drug 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



DRAP, Islamabad



+92 051 9255969



gsms@dra.gov.pk