



DRUG REGULATORY AUTHORITY OF PAKISTAN

DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° I/S/06-26-34

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL LABORATORIES

Date: 08th June, 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 Laboratory Sindh, Karachi has informed the Drug Regulatory Authority of Pakistan that samples of the below-mentioned medical devices have been declared “Substandard” due to failure of the **Self-Destructive Performance / Auto-Disability Test (re-use prevention feature)**.

S#	Product Name	Manufacturer / Importer & Address	Batch No.	Remarks
1	Clinic Auto Disable Syringe 3ml (MDMR-000115)	M/s Surgi Plast Pvt. Ltd., Plot # 78, Road No. L-4, Industrial Estate Gadoon Amazai, Swabi, Khyber Pakhtunkhwa, Pakistan (ELM # 0030)	3-01B-26	Declared Substandard on the basis of failure of Self- Destructive Performance / Auto-Disability Test (re-use prevention feature).
2.	Medi Aqua Auto Disable Syringe 3ml (MDMR-000145)	M/s Frontier Pharmaceutical (Pvt.) Ltd., (ELM # 0042) W-10, Industrial Estate, Jamrud Road, Peshawar, Pakistan	AD1B25	Declared Substandard on the basis of failure of Self- Destructive Performance / Auto-Disability Test (re-use prevention feature).
3.	Ultra Fine SMD Painless 3ml Syringe (MDMR-000229)	M/s Sehat Medical Devices (Pvt.) Ltd., Plot # 473, Sundar Industrial Estate, Lahore, Pakistan (ELM # 0065)	3088CL & 3090CL & 3013DC	Declared Substandard on the basis of failure of Self- Destructive Performance / Auto-Disability Test (re-use prevention feature).

Risk Statement:

Auto-disable and auto-destruct syringes are designed to become permanently inoperable after a single use. Failure of the self-destructive mechanism may permit reuse of the device, increasing the risk of transmission of blood-borne pathogens including Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV). Reuse of such defective syringes may also result in cross-contamination, healthcare-associated infections and serious public health consequences, particularly during immunization programmes and other invasive medical procedures.

Action initiated: -

The field force of DRAP and Provincial Drug Control Departments has been directed to immediately conduct market surveys for detection of presence and removal of the affected batches from the market. Manufacturers, importers and distributors have been directed to initiate recall of the affected batches in accordance with applicable regulatory requirements.



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Advice for Pharmacies/Medical stores: -

All pharmacists and chemists working at distributions and pharmacies should immediately check their stocks and stop supplying the above-mentioned batches. The remaining stocks should be quarantined and returned to the supplier/company. Regulatory field force of all federating units should also increase surveillance in the market to ensure effective recall of the affected products.

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 and healthcare facilities in possession of the affected batches should immediately stop using these products and contact the supplier, distributor or manufacturer for return or replacement. Any adverse event or quality issue associated with the use of these products should be reported to DRAP/National Pharmacovigilance Centre.



Drug Regulatory Authority of Pakistan

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