



DRUG REGULATORY AUTHORITY OF PAKISTAN

DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° I/S/07-26-36

MEDICAL DEVICES DECLARED SUBSTANDARD BY CENTRAL DRUG LABORATORY KARACHI

Date: 14th July, 2026

Target Audience:

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

Alert Summary:

Central Drugs Laboratory (CDL), Karachi has informed that samples of the below-mentioned Medical Devices have been declared “**Substandard**”.

S#	Product Name	Batch No.	Manufacturer / Importer details	Remarks
1	BD 10ML Syringe (MDMR-0000035)	5349764	Manufacturer: Becton Dickinson Medical (S) Pte. Ltd. 30 Tuas Avenue 2, Singapore. Importer: M/s Asto Life Sciences (Pvt.) Ltd. Plaza #1, Block Orchard-1, Gate #2, Paragon City, Barki Road, Lahore. (ELI-00103)	Substandard on the basis of Absorbance test.
2.	Accuject Auto-Disable Syringe 5ml (MDMR-000507)	S502E26	Manufacturer: M/s Faiz Surgical and Medical Industries (Pvt.) Ltd. Plot No. 540-B, Sundar Industrial Estate, Lahore. (ELM-0093)	Substandard on the basis of Sterility test.

Risk Statement:

The affected batches have been declared substandard due to failure of critical quality tests. The BD 10 mL Syringe (Batch No. 5349764) failed the Absorbance test, indicating excessive extractable substances that may compromise product safety and quality for parenteral use. The Accuject Auto-Disable Syringe 5 mL (Batch No. S502E26) failed the Sterility test, indicating possible microbial contamination that may increase the risk of infection, including serious systemic infections, upon use.

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



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distributors have been directed to initiate recall of the affected batches in accordance with applicable regulatory requirements.

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

محفوظ، موثر اور معیاری اشیائے علاج



DRAP, Islamabad



+92 051 9255969



gsms@dra.gov.pk