



# DRUG REGULATORY AUTHORITY OF PAKISTAN

## DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

### MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° I/S/09-25-57

**ANAROB INFUSION DECLARED SUBSTANDARD BY CENTRAL DRUGS LABORATORY, KARACHI**

**Date:** 09<sup>th</sup> September, 2025

#### 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 Karachi informed the Drug Regulatory Authority of Pakistan that the samples of below mentioned drug product has been declared as '**Substandard**'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	<b>Anarob Infusion</b> Each 100 ml of infusion contains: Metronidazole ...500 mg	H24219	M/s Vision Pharmaceuticals (Pvt.) Ltd, (DML # 000517) Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad	Central Drugs Laboratory declared the <b>Anarob Infusion</b> (Batch # H24219) as ' <b>Substandard</b> ' on the basis of out of specification results for the test Bacterial Endotoxins.

#### Risk Statement:

The affected batch of **Anarob Infusion (Batch # H24219)** has been declared out of specification for bacterial endotoxins. **Use of this contaminated infusion may cause severe adverse reactions such as fever, chills, septic shock, and life-threatening complications.** Hospitalized and immunocompromised patients are at the greatest risk.

#### 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 products. The remaining stocks should be quarantined and returned to the supplier/company. Regulatory field force of all federating units (DRAP and Provincial Health



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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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