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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/09-25-73

VETERINARY DRUG PRODUCTS DECLARED SUBSTANDARD
BY PROVINCIAL DRUG TESTING LABORATORIES.

Date: 18th September, 2025

Target Audience:

- National Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Healthcare Professionals-Veterinarians
- Farmers/consumers

Alert Summary:

Drug Testing Laboratories from Provinces informed the Drug Regulatory Authority of Pakistan that the samples of below mentioned **Veterinary products** have been declared as '***Substandard***'.

S#	Product Details	Batch #	Manufacturer details	Remarks
1	**Inj. Rasomycin-5 50ml** Oxytetracycline HCl - 50 mg /ml	VM800	M/s Star Laboratories (Pvt) Ltd. 23 Km Multan Road Lahore. (DML # 000130)	The Drug Testing Laboratory, Bahawalpur has declared the product '***misbranded'*** under Section 3(s)(iv) of the Drugs Act, 1976, and '***substandard'*** due to failure in the **Bacterial Endotoxin Test**.
2.	**Inj. Duralin -50** Oxytetracycline (as HCl) -50mg/ml	5807	M/s Mylabs (Pvt) Ltd. Khanka Sharif Tehsil and District Bahawalpur. (DML # 000747)	The Drug Testing Laboratory, Multan has declared the product '***misbranded'*** under Section 3(s)(iv) of the Drugs Act, 1976, and '***substandard'*** due to failure in the **Sterility Test**.

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Risk Statement:

These quality defects directly compromise animal safety, therapeutic effectiveness, and indirectly pose risks to public health through the livestock production chain. Therefore, the products are classified as high-risk veterinary medicines requiring immediate regulatory attention**.**

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 Veterinarian: -

This alert applies strictly to the specific batches listed above and does not apply to other batches of the **same** products. Veterinarians are therefore advised not to prescribe, administer, or stock these identified batches under any circumstances. In case any of the above-mentioned batches have already been administered, treated animals should be closely monitored for possible signs of infection, treatment failure, or adverse reactions, and appropriate supportive care must be provided. Any suspected adverse events or quality-related problems linked to these batches should be reported immediately to **DRAP's Pharmacovigilance Centre** and to the Provincial Livestock & Dairy Development Departments**.** Practitioners are further advised to ensure that only alternative registered and quality-assured batches are used in veterinary practice.

Advice for Farmers and Livestock Owners:

Farmers, dairy owners, and animal keepers are strictly advised not to use these identified batches for their cattle or other livestock, as they may cause serious illness, infection, treatment failure, or even death in animals. If any of these batches have already been given, animals should be observed carefully for unusual symptoms such as fever, weakness, swelling at the injection site, or lack of recovery, and immediate veterinary assistance should be sought. Farmers are further advised to return such products to their supplier and use only safe, registered, and quality-assured veterinary medicines and vaccines to protect the health of their animals and avoid financial losses.

Drug Regulatory Authority of Pakistan
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