



# DRUG REGULATORY AUTHORITY OF PAKISTAN

## DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

### MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° I/S/10-25-84

## VETERINARY DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES.

**Date:** 09<sup>th</sup> October, 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	<b>Injection Micrise-2% 50ml</b> Ivermectin: 20 mg/ml	MR-075	M/s Biorise Pharmaceuticals. 19-Km, Lahore Road, Multan. (DML # 000934)	The sample is declared as " <b>Sub-Standard</b> " on the basis of Assay Test and Chromatographic Purity Test.
2.	<b>Injection Ivozon 2% 10 ml</b> Ivermectin: 20 mg/ml	AP/INJ-G/25-83	M/s. Amazon Pharmaceutical (Pvt) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK (DML # 000975)	The sample is declared as " <b>Sub-Standard</b> " on the basis of Assay Test and Test for Related Substances.
3.	<b>Injection IVERMEC 1% 50ml</b> Ivermectin: 10 mg/ml	GI - 25E 140	M/s Grand Pharma (Pvt) Ltd. Plot No. 5-A Street No. N-5 National Industrial Zone Rawat (DML # 000680)	The sample is declared as " <b>Sub-Standard</b> " on the basis of Chromatographic Purity Test.
4.	<b>Injection Selmec 50 ml</b> Ivermectin: 20 mg/ml	SN-116	M/s Selmore Pharmaceuticals (Pvt) Ltd. 36 Km Off. Multan Road Lahore. (DML # 000507)	The sample is declared as " <b>Sub-Standard</b> " on the basis of Assay Test and Test for Related Substances.



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5.	<b>Injection Ivomek 2% 10 ml</b> Ivermectin: 20 mg/ml	NI-807	M/s Nawal Pharmaceuticals. Plot No. 11-A Punjab Small Industrial Estate Taxila. (DML # 000735)	The sample is declared as <b>'Misbranded'</b> as per section 3(s)(vi) of the Drugs Act 1976 & 3(g)(i) of the Drugs (Labelling and Packing) Rules 1986, and <b>"Substandard"</b> on the basis of Assay Test and Chromatographic Purity Test.
6.	<b>Injection Ivergen 50ml</b> Ivermectin: 10 mg/ml	594.IV	M/s Symans Pharmaceuticals (Pvt) Ltd. 10-Km Sheikhpura Road Lahore. (DML # 000323)	The sample is declared as <b>"Sub-Standard"</b> on the basis of Assay Test and Test for Related Substances
7.	<b>Injection Fosphovetz</b> Each ml contains: Butaphosphan (MS).....100mg Cyanocobalamine (B.P)...50mcg Taurine (USP).....37.3mg Nicotinamide (B.P) .....23mg DL-Methionine (B.P) ....18.7mg	24119013	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot No. Q-1 SITE Kotri Sindh (DML # 000813)	The Sample is declared as <b>"Sub-Standard"</b> on the basis of Assay of Cyanocobalamine and Bacterial Endotoxin Test (BET).
8.	<b>Oxyvetz 5% 100ml Injection</b> Each ml contains: Oxytetracycline HCl BP....50mg	25157083	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot No. Q-1 SITE Kotri Sindh (DML # 000813)	Sample is <b>'Sub-standard'</b> with regards to Bacterial Endotoxins Test and Misbranded with regards to Labelling (as per Section 3 (s) (iv) of The Drugs Act 1976).

#### Risk Statement:

Laboratory testing identified serious quality defects including assay failure, excessive impurities/related substances, misbranding of label information, and failure of bacterial endotoxin and sterility-related tests.

These medicines are widely used for **livestock and food-producing animals** (e.g., cattle, sheep, goats) for parasitic control, metabolic support, and infection treatment. Their use can lead to ineffective therapy, toxic reactions, contamination risk, and unsafe drug residues in milk and meat, posing both animal health and public health hazards.

#### 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.





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### 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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