



MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° I/S/04-25-40

PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES.

Date: 29th April, 2025

Target Audience:

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

Alert Summary:

Directorate of Drug Control (DDC) Punjab has informed Drug Regulatory Authority of Pakistan that the sample of below mentioned product has been reported as '*Substandard*'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	Atopin Injection Each ml contains: Atropine Sulphate.....1mg (50mL) For veterinary use only Reg# 062122	376.ATP	M/s Symans Pharmaceuticals (Pvt) Ltd., 10Km, Sheikhpura Road, Lahore.	'Substandard' on the basis of Bacterial Endotoxin Test.

Risk Statement:

Failure of the Bacterial Endotoxin Test (BET) for an injectable product may result in the release of a product with pyrogenic contamination. This may pose a significant risk of febrile reactions, endotoxic shock, or other serious adverse effects in animals.

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 batch of the product from the market.

Advice for Veterinarian: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by this product. Further information on reporting problems to DRAP is available on this [link](#).



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Advice for farmers / consumer: -

Farmers/consumers should not use this product. They shall contact their veterinarians or healthcare provider(s) if the animal experienced any problem that may be related to using this product.



Drug Regulatory Authority of Pakistan
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