



DRUG REGULATORY AUTHORITY OF PAKISTAN

Division of Quality Assurance and Laboratory Testing

RAPID ALERT

DRAP ALERT No: N° I/S/06-26-32

SPURIOUS / FALSIFIED DANZEN DS TABLETS

Date: 02nd June, 2026

Target Audience:

- Regulatory Field Force of DRAP and Provincial Drug Control departments.
- Healthcare Professionals
- Consumers

Problem Statement:

Drug Testing Laboratory (DTL), Government of Punjab has reported that the sample of the following drug product has been declared SPURIOUS under Section 3(z-b)(i) & (ii) of the Drugs Act, 1976, based on the laboratory findings and confirmation received from the manufacturer.

S#	Product Name	Batch	Manufacturer	Remarks
1	DANZEN® DS Tablets (Serratiopeptidase 10 mg) Reg. No. 028173	4476	<i>Purportedly manufactured under license of</i> Helix Pharma (Pvt.) Ltd., Karachi.	Declared Spurious by DTL; Serratiopeptidase not identified; Assay 0%; Manufacturer has confirmed the sample was not manufactured by Helix Pharma and has disowned the batch.

Helix Pharma (Pvt.) Ltd. has formally communicated to the regulatory authorities that the submitted sample was not manufactured by the company. Following a comparative investigation against its reference sample.

S.#	Parameters	Reference Sample (Danzen DS 10mg Batch No. 4476)	Manufacturer Portion / spurious (Danzen DS 10mg Batch No. 4476)
01	Color of Tablet	Color of tablet observed dark pink with smooth coating as compare to Warrantor sample.	Color of tablet observed different.
02	Color of Blister Strip	Color of blister observed Blue.	Color of blister observed different as dark blue.
03	Font size and Style of Embossed Batch number and Expiry	Font size and style of embossed batch number and expiry observed as per standard font size.	Font size and style of embossed batch number and expiry observed different as compare to reference standard sample.





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Risk Statement:

Laboratory analysis conducted by Drug Testing Laboratory, Punjab revealed that Serratiopeptidase, the declared active pharmaceutical ingredient, could not be identified in the tested sample. Assay testing demonstrated complete absence of the declared active ingredient, with results showing 0.0 mg/tablet against the labeled claim of 10 mg/tablet.

Use of this counterfeit/spurious product may result in:

- Complete therapeutic failure.
- Failure to achieve the intended anti-inflammatory effect.
- Delay in appropriate treatment and recovery.
- Exposure to unknown or undeclared ingredients of uncertain quality, safety and efficacy.
- Potential adverse health consequences arising from the use of falsified medicines.

Action Initiated: -

The Regulatory Field Force of DRAP and Provincial Drug Control Departments has been directed to conduct surveillance activities throughout the supply chain to confiscate the falsified products.

Advice for Healthcare Professionals: -

DRAP requests healthcare professionals to have increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by above mentioned product. Any adverse events or quality problems experienced with the use of these products should be reported to National or Provincial pharmacovigilance centers using [Adverse Event Reporting Form](#) or online through this [link](#). Further information on reporting problems to DRAP is available on this [link](#).

Advice for Consumers:

Consumers should not use these products and should contact their physician or healthcare provider(s) if they have experienced any problem related to taking or using the above mentioned products and should report the incident to the Drug Regulatory Authority of Pakistan / National Pharmacovigilance Centre. All therapeutic goods must be obtained from licensed pharmacies and other authorized/licensed retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professionals in case of any doubt.



Drug Regulatory Authority of Pakistan

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