DRUG REGULATORY AUTHORITY OF PAKISTAN
Division of Quality Assurance and Laboratory Testing

RAPID ALERT

DRAP ALERT No: Nº I/S/03-26-09

SPURIOUS CEFIXIME 400 mg CAPSULE (BATCH NO. LLM034)

Date: 11th March, 2026

Target Audience:

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

Problem Statement:

Drug Testing Laboratory (DTL), Punjab has declared following sample of product as **'Spurious'** purported to be manufactured/marketed by the stated manufacturer, however, upon laboratory analysis and comparison with the genuine QC retention sample, it has been determined that the product is not the authentic product of the registered manufacturer and is therefore classified as spurious under the Drugs Act, 1976.

S#	Product Name	Batch	Manufacturer	Test Result
1	**Capsule CARICEF** Cefixime Trihydrate equivalent to Cefixime ……...400 mg (Reg # 022416)	LLM034	***Purported to be manufactured by:*** M/s Healthtek (Pvt.) Ltd., Plot No. 14, Sector 19, Korangi Industrial Area, Karachi **Marketer** SAMI Pharmaceuticals (Pvt.) Ltd., F-95, S.I.T.E., Karachi	Declared **Spurious**

Risk Statement:

The subject product has been declared **Spurious**, as laboratory analysis confirmed absence of the stated active ingredient (Cefixime), resulting in complete therapeutic failure. Packaging comparison with the genuine manufacturer's QC retention sample revealed significant discrepancies in printing, hologram security features, blister demarcation, and labeling details, confirming it is not an authentic product. Use of this falsified antibiotic may lead to disease progression, complications, and increased antimicrobial resistance. The risk to public health is assessed as **high**, particularly for patients requiring effective antibacterial therapy.

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.

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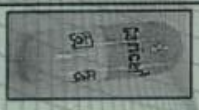
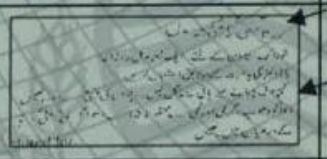
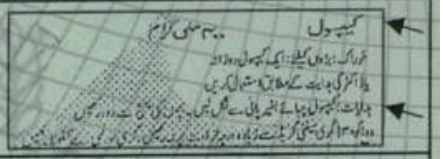
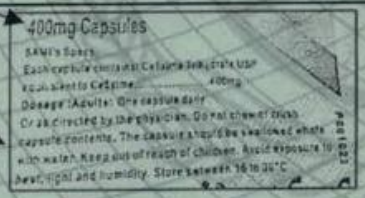
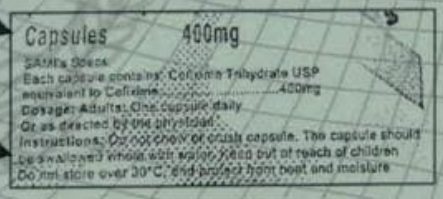
Sample Received from Drug Inspector (Batch No. LLM034)	QC retention sample received from M/S Healthtek (Batch No. LLM034)
Capsule shell is **without any printing** and are packed in blister with **loosens powder.** 	Capsule shell is **printed** with **Caricef® 400mg on cap** & **Company's logo is present 3 times on body**. Capsules have no shredded powder in the blister. 
Unit carton has **hologram** with **printing** of word **"SAMI PHARMA"** & hologram **doesn't change color** on rotating the unit carton at different angles. 	Unit carton has **hologram** with **debossing** of word **"SAMI PHARMA"** & hologram changes color on rotating the unit carton at different angles. 
Printing on the **blister** is **not symmetrical** & **does not** have **demarcation** for **6th bubble** as compared to QC retention sample received from manufacturer. 	**Printing** on the **blister** is **symmetrical** & have **demarcation for empty 6th bubble.** 
Dosage & **Instructions on blister** in **Urdu** is different as compared to QC retention sample received from manufacturer. 	**Dosage** & **Instructions on blister** in **Urdu** is written as: 
Dosage & **Instructions on blister** in **English** is different as compared to QC retention sample received from manufacturer. 	**Dosage** & **Instructions on blister** in **English** is written as: 
Font (Size & style) **& Technique** used for printing of B.No, Mfg, Exp, MRP is not in congruence as compared to QC retention sample received from the manufacturer.	

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.

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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

محفوظ، موثر اور معیاری اشیائے علاج

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