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

RAPID ALERT

DRAP ALERT No: Nº I/S/09-25-81

CRACKDOWN AGAINST FALSIFIED / SPURIOUS PRODUCTS

Date: 26th September , 2025

Target Audience:

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

Problem Statement:

Directorate of Drugs Control Punjab (DDCP) have informed the Drug Regulatory Authority of Pakistan that the samples of below mentioned products have been declared ***'Spurious'*** as its packaging falsely claims that it was manufactured by a licensed pharmaceutical company whereas it was not. The details of reports are as under:

S#	Product Name	Batch No.	Purported Manufacturer	Remarks
1.	**Capsule Eskem 40 MG** Each Capsule Contains: Enetric Coated Pellets of Esomeprazole Magnesium Tri-hydrate Equivalent to Esomeprazole ……. 40 Mg (Reg.# 044310)	Not mentioned	Purported to be manufactured by M/s High-Q Pharmaceuticals, Plot No. 224 & 225/1, Sector 23, Korangi Industrial Area, Karachi.	**'Substandard'** with respect to physical characteristics and **"Misbranded"** as defined under clause (i) of sub-section (s) of section 3 of The Drugs Act, 1976 and **"Spurious"** as defined under clause (i) & iii of subsection (zb) of section 3 of The Drugs Act, 1976. **Details:** *Product label on outer carton does not bear batch number and immediate blister have illegible embossed marking. Moreover, as per the manufacturer's method, the product is described as amethyst-colored capsules with the cap imprinted 'High Q' in black and the body imprinted Eskem 40, However, no such printing was observed on the actual capsules. Esomeprazole is not identified. Omeprazole is identified.*

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Risk Statement:

Critical non-compliances include absence of batch number on the outer carton, illegible embossed markings on immediate blister packs, and deviation from the manufacturer's approved description of capsule appearance (color and printing). Analytical testing confirmed that **Esomeprazole was not identified** and instead **Omeprazole was detected**, representing potential therapeutic failure and risk of inappropriate treatment. The presence of a spurious and misbranded product in the supply chain poses a **serious threat to patient safety** due to lack of assured identity, quality, and efficacy and requires immediate regulatory and field action to prevent its distribution and use.

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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