

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

RAPID ALERT

DRAP ALERT No: N° I/S/10-25-96

CRACKDOWN AGAINST FALSIFIED / SPURIOUS - CIALIS®

Date: 20th October, 2025

Target Audience:

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

Problem Statement:

Central Drugs Laboratory certified that <u>Cialis® 20 mg</u> Tablet bearing <u>Batch # 24576</u> purported to be manufactured by M/s Eli Lilly and Company Limited, & <u>Cialis® 20 mg Gold (Batch # MAL</u>

1990546AG) purported to be manufactured by M/s Lilly ICOS, USA are "Falsified & spurious" identified in the Pakistani market. The reported Brands & batch numbers are not imported, manufactured, or supplied by the manufacturers mentioned on the label. The packaging falsely uses the name and branding, but it does not come from any authorized supply chain.

Risk Statement:

These falsified and spurious products pose a significant health risk to the public. Since the brands & batches have not been imported or supplied through any authorized or traceable source, its actual composition, safety, and efficacy remain unknown. Individuals who may have purchased this product from unauthorized medical stores, online platforms, or informal supply chains are at particular risk of exposure to unverified and potentially harmful ingredients. Use of such falsified medicine can lead to serious adverse health effects, therapeutic failure, or toxic reactions, especially among patients with cardiovascular or metabolic conditions.

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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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 <u>Adverse Event Reporting Form</u> or online through this <u>link</u>. Further information on reporting problems to DRAP is available on this <u>link</u>.

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.







