DRUG REGULATORY AUTHORITY OF PAKISTAN
DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº II/S/08-25-55

DRUG PRODUCTS DECLARED SUBSTANDARD BY CENTRAL DRUGS LABORATORY, KARACHI

Date: 18th August, 2025

Target Audience:

National Regulatory Field Force of DRAP and Provincial Drug Control Departments.

Healthcare Professionals (Physicians, Pharmacists & Nurses).

General Public.

Alert Summary:

Central Drugs Laboratory Karachi informed the Drug Regulatory Authority of Pakistan that the samples of below mentioned drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Famila 28F Tablets** Each Tablet contains: Levonorgestrel...0.15mg Ethinyl Estradiol...0.03mg Ferrous Iron….24.37mg (Reg. No. 023941)	K185	**M/s. ZAFA Pharmaceutical Laboratories (Pvt.) Ltd.** A-46 SITE North Karachi **(DML#000490)**	**'Substandard'** on the basis of tests of **content uniformity** (Levonorgestrel, Ethinyl Estradiol) and **Assay**(Levonorgestrel).
2.	**Famila 28F Tablets** Each Tablet contains: Levonorgestrel…..0.15mg Ethinyl Estradiol...0.03mg Ferrous Iron….24.37mg (Reg. No. 023941)	K189	**M/s. ZAFA Pharmaceutical Laboratories (Pvt.) Ltd.** A-46 SITE North Karachi **(DML#000490)**	**'Substandard'** on the basis of tests of **content uniformity** (Levonorgestrel, Ethinyl Estradiol) and **Assay** (Levonorgestrel).

3.	**Famila 28F Tablets** Each Tablet contains: Levonorgestrel…...0.15mg Ethinyl Estradiol...0.03mg Ferrous Iron….24.37mg (Reg. No. 023941)	K187	**M/s. ZAFA Pharmaceutical Laboratories (Pvt.) Ltd.** A-46 SITE North Karachi **(DML#000490)**	**'Substandard'** on the basis of tests of **content uniformity** (Levonorgestrel, Ethinyl Estradiol), **Weight variation** of Ferrous Iron and **Assay** (Levonorgestrel & Ethinyl Estradiol).
4.	**Famila 28F Tablets** Each Tablet contains: Levonorgestrel…...0.15mg Ethinyl Estradiol...0.03mg Ferrous Iron….24.37mg (Reg. No. 023941)	K192	**M/s. ZAFA Pharmaceutical Laboratories (Pvt.) Ltd.** A-46 SITE North Karachi **(DML#000490)**	**'Substandard'** on the basis of tests of **content uniformity** (Levonorgestrel, Ethinyl Estradiol), and **Assay** (Levonorgestrel & Ethinyl Estradiol).
5.	**Famila 28F Tablets** Each Tablet contains: Levonorgestrel…...0.15mg Ethinyl Estradiol...0.03mg Ferrous Iron….24.37mg (Reg. No. 023941)	K194	**M/s. ZAFA Pharmaceutical Laboratories (Pvt.) Ltd.** A-46 SITE North Karachi **(DML#000490)**	**'Substandard'** on the basis of tests of **content uniformity** (Levonorgestrel, Ethinyl Estradiol), and **Assay** (Levonorgestrel).
6.	**Famila 28F Tablets** Each Tablet contains: Levonorgestrel…...0.15mg Ethinyl Estradiol...0.03mg Ferrous Iron….24.37mg (Reg. No. 023941)	K195	**M/s. ZAFA Pharmaceutical Laboratories (Pvt.) Ltd.** A-46 SITE North Karachi **(DML#000490)**	**'Substandard'** on the basis of tests of **content uniformity** (Levonorgestrel, Ethinyl Estradiol), and **Assay** (Levonorgestrel).

7.	**Imcomox 125mg/5ml Suspension** Each 5ml of reconstituted suspension contains: Amoxicillin (as Trihydrate) …….125mg (Reg. No. 013756)	029	**M/s. Imco Pharmaceutical Lab.** 73/A Industrial Estate Jamrud Road, Peshawar **(DML#000317)**	**'Substandard'** on the basis of Assay (Amoxicillin trihydrate).
8.	**Imcodal Oral Suspension** Each 5ml of Suspension contains: Metronidazole Benzoate.. 64mg Ethinyl Furazolidone….25mg (Reg. No. 013363)	013	**M/s. Imco Pharmaceutical Lab.** 73/A Industrial Estate Jamrud Road, Peshawar **(DML#000317)**	**'Substandard'** on the basis of Assay (Furazolidone).

Risk Statement:

***Famila 28F*:** The affected batches of *Famila 28F Tablets* due to content uniformity, assay failures of hormonal ingredients, and weight variation in the iron component, may lead to reduced contraceptive efficacy, hormonal imbalance, and inconsistent iron supplementation, increasing the risk of complications, particularly in vulnerable groups such as Young Women, Perimenopausal Women, Women with history of Anemia, Patients with Comorbidities.

***Imcomox*:** Laboratory testing has confirmed that the amoxicillin content in this drug product is below the approved specification range**,** making it **subpotent.** Such reduced strength may cause treatment failure, particularly in infants and young children, the primary users of this medicine. The recall is being undertaken to prevent potential health risks and safeguard public safety.

Imcodal: Laboratory testing has confirmed that the furazolidone content in this suspension is below the approved specification range**,** indicating subpotency. Inadequate active ingredient may lead to ineffective treatment of gastrointestinal infections, particularly in children**,** who are the primary recipients of this medicine. This recall is being carried out to prevent treatment failure and protect public health.

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 batches from the market.

Advice for Pharmacies/Medical stores: -

All pharmacists and chemist working at distributions and pharmacies should **immediately check** their stocks and stop supplying mentioned products. The remaining stocks should be quarantined and returned to the supplier/company. Regulatory field force of all federating units (DRAP and Provincial Health Departments) should also increase surveillance in the market to ensure the effective recall of defective products(s).

Advice for Healthcare Professionals: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by batches of mentioned products. Adverse reactions or quality problems experienced with the use of above mentioned product are to be reported to the National Pharmacovigilance Centre (NPC), DRAP using Adverse Event Reporting Form or online through this link. Further information of reporting problems to DRAP is available on this link.

Advice for Consumers/general public: -

Consumers should stop using products bearing the affected batch number(s) and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product, and report the incident to Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

Drug Regulatory Authority of Pakistan
محفوظ، موثر اور معیاری اشیائے علاج