MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/3-25-28

SUBSTANDARD PRODUCTS DECLARED BY PROVINCIAL DRUG TESTING LABORATORIES.

Date: 12th March, 2025

Target Audience:

- National Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Healthcare Professionals (Physicians, Pharmacists & Nurses).
- General Public.

Alert Summary:

Directorate of Drug Control (DDC) Punjab has informed Drug Regulatory Authority of Pakistan that the samples of below mentioned products have been reported as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Syrup Divanza 120ml** Each 5ml contains: Sodium Valproate eq. to Valproic acid …..250mg Reg. No. 096103	021	**M/s. Hiranis Pharmaceuticals (Pvt.) Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi.	**'Substandard'** as it contains Diethylene Glycol above the permissible limit.
2.	**Tablet Mebrosil Antacid** Each tablet contains: Magnesium Trisilicate...500mg, Aluminium Hydroxide…250mg Reg. No. 007733	8576	**M/s. Jawa Pharmaceuticals (Pvt) Ltd,** 112/10 Quaid-e-Azam Industrial Area, Kot-Lakhpat, Lahore.	**'Misbranded'** under clause (iv) of sub-section (s) of section 3 of Drugs Act 1976, and **'Substandard'** with respect to Assay test performed.
3.	**Capsule Lanroz 30mg** Each capsule contains: Lansoprazole….30mg Reg. No. 047803	C-032	**M/s. Hisun Pharmaceuticals Indsutries,** 37-A, R-2, Industrial Estate, Gadoon-Pakistan.	**'Substandard'** with regards to Assay test and '**Adulterated'** as it contains Omeprazole as an ingredient.

4.	**Sterile Disposable Fresline** (Tubing Sets for Hemodialysis) Reg. No. MDIR-0001626	2401151264	**Manufactured by: M/s Vital Healthcare SDN. BHD.,** Lot 3, Jalan sultan Mohamed 3, Bandar Sultan Sulaiman, 42000 Pelabuhan klang, Selangor Darul Ehsan, Malaysia. **Imported by**: **Fresenius Medical Care Pakistan (Pvt.) Ltd.,** TAMC, First Floor, 27-C III, M.M Alam Road, Gulberg III, Lahore.	**'Substandard'** with respect to Sterility test performed.
5.	**Tablet AMLOShine 5mg** Each tablet contains: Amlodipine as besylate…5mg Reg. No. 062420	6752	**M/s Sunshine Pharmaceuticals**, Khan payara, near Saim Nala, Emanabad Road, Emanabad, Gujranwala	**'Substandard'** on the basis of impurities test.
6.	**AME-CLOP Injection** Each 2ml contains: Metoclopramide HCL....10mg Reg. No. 048388	MC-120	**M/s Ameer Pharma (Pvt) Ltd.,** 23-Km, Sheikhupura Road, Lahore.	**'Substandard'** on the basis of visible white fibers and particles.
7.	**Injection Anacobin 500µg** (Mecobalamin 500 µg/ml, 1ml) Reg. No. 047494	AF133	**M/s Epharm Laboratories,** A-40, Road No. 1, S.I.T.E., Super Highway, Industrial Area, North Karachi.	**'Substandard'** on the basis of Assay Test & **'Adulterated'** as per Drugs Act, 1976.
8.	**Tablet Normax 5mg** Each tablet contains: Amlodipine as besylate…..5mg Reg. No. 062644	327	**M/s Murfy Pharmaceuticals (Pvt) Ltd.,** 8-Km Raiwind Road, Lahore.	**'Adulterated'** under clause (iv) of sub-section (a) of Section 3 of The Drugs Act, 1976.

Risk Statement:

The use of substandard products can result in therapy failure, increasing the risk of complications, particularly in vulnerable groups such as immunocompromised individuals, as well as pediatric and geriatric population.

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
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