



F. No.03-13/2021-QC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services,
Regulation & Coordination

MOST IMMEDIATE
THROUGH UMS

Islamabad, the 07th June 2021.

[Medical Product Alert]

“Protonix 40mg Tablet”

M/s Wilshire Laboratories (Pvt.) Limited,
124/1 Industrial Estate Kot Lakhpat
Lahore.

Subject: **DRUG RECALL of Substandard Protonix 40mg Tablet, Reg. No. 030041, Batch No. 069, Mfg. Date Jan. 2020, Exp. Date Jan.2023, Manufactured by M/s. Wilshire Laboratories (Pvt.) Limited, Lahore.**

I am directed to refer to the subject cited above and CDL, Karachi report vide No.LHR.18/2021 dated 21-05-2021 wherein your following product has been declared as Adulterated & Substandard quality. Details of CDL reports are as under;

S.No.	Name of product	Manufactured by	Reg No.	Batch No.	Mfg. date	Exp. Date	Test Report No. & Date	Result of CDL
01	Protonix 40mg Tablet	M/s. Wilshire Laboratories (Pvt.) Limited, Lahore.	030041	069	Jan. 2020	Jan. 2023	No.LHR.18/2021 dated 21-05-2021	Sub-Standard

02. You are therefore directed to recall all the stock of above-mentioned batches of product “Protonix 40mg Tablet” from market & alert your sales officers/suppliers/ distributors to issue instructions to the pharmacies/hospitals, point of sales/purchase/use for the return of suspected stocks of product in question. Furthermore, you are directed to submit a compliance report of recall to this division within seven (07) days positively.

-/sd-
(Mehwish Tanveer)
Assistant Director (QC-II)

Copy for information and necessary action – with request to issue necessary directions to points of use/sale (Hospitals Pharmacies, Medical stores, Distributors, Whole sellers, etc) under administrative control/ fall under area of jurisdiction, please.

1. The Secretary (SHC&ME) Health Department (Government of Punjab).
2. The Secretary Primary and Secondary Health Department (Government of Punjab).
3. The Secretary Health Department (Government of Sindh).
4. The Secretary (SHC&ME) Health Department (Government of KPK).
5. The Secretary (SHC&ME) Health Department (Government of Baluchistan).
6. The Secretary (SHC&ME) Health Department (Government of AJ&K).
7. The Director General Health, M/o NHR&C, Islamabad.
8. The Director General Health, Government of Punjab.
9. The Director General Health, Government of Sindh.
10. The Director General Health, Government of KPK.
11. The Director General Health, Government of Baluchistan.
12. The Director General Health, Government of AJ&K.
13. The Additional Director / Office In-charge, DRAP, Lahore, Karachi, Islamabad, Peshawar, and Quetta.
14. The Chief Drug Controller / Inspector Punjab, Sindh, KPK, Baluchistan, AJ&K, GB and ICT.

Copy to:-

- i. The Additional Director, QA<, DRAP, Islamabad.
- ii. Additional Director MIS with request to upload it on official website in the larger interest of public.
- iii. Area FID, DRAP, Karachi for information record and necessary action, if any, please.
- iv. PS to CEO, DRAP, Islamabad.
- v. Office copy.


Assistant Director (QC-II)