



Islamabad, the 31st May 2021.

[Medical Product Alert]

“Hilixophin 500mg injection”

M/s Mediate Pharmaceutical (Pvt.) Ltd.,
Plot No. 150-151 Sector 24 Korangi Industrial Area,
Karachi.

Subject: **Manufacture & Sale of Sub-Standard Hilixophin 500mg Injection (vial) Reg. No. 044105, Batch No. V-20085, Mfg. Date 12-2020, Exp. Date 12-2022 and Sterile Water for Injection Reg. No. 053244, Batch No. W-20024, Mfg. Date 12-2020, Exp. Date 12-2023 Manufactured by M/s. Mediate Pharmaceutical (Pvt.) Ltd., Karachi.**

I am directed to refer to the subject cited above and CDL, Karachi report vide No.KQ.92/2021 dated 19-05-2021 wherein your following product has been declared as of 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	Hilixophin 500mg Injection (vial)	Mediate Pharmaceutical (Pvt.) Ltd., Karachi	044105	V-20085	12-2020	12-2022	No.KQ.91/2021 dated 19-05-2021	Sub-Standard quality
02	Sterile water for injection (ampoule)	Mediate Pharmaceutical (Pvt.) Ltd., Karachi	053244	W-20024	12-2020	12-2023	No.KQ.91/2021 dated 19-05-2021	

02. You are therefore directed to recall all the stock of above-mentioned batch of product “Hilixophin 500mg Injection” 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.

15. The Secretary (SHC&ME) Health Department (Government of Punjab).
16. The Secretary Primary and Secondary Health Department (Government of Punjab).
17. The Secretary Health Department (Government of Sindh).
18. The Secretary (SHC&ME) Health Department (Government of KPK).
19. The Secretary (SHC&ME) Health Department (Government of Baluchistan).
20. The Secretary (SHC&ME) Health Department (Government of AJ&K).
21. The Director General Health, M/o NHR&C, Islamabad.
22. The Director General Health, Government of Punjab.
23. The Director General Health, Government of Sindh.
24. The Director General Health, Government of KPK.
25. The Director General Health, Government of Baluchistan.
26. The Director General Health, Government of AJ&K.
27. The Additional Director / Office In-charge, DRAP, Lahore, Karachi, Islamabad, Peshawar, and Quetta.
28. The Chief Drug Controller / Inspector Punjab, Sindh, KPK, Baluchistan, AJ&K, GB and ICT.

Copy to:-

- vii. The Additional Director, QA<, DRAP, Islamabad.
- viii. Additional Director MIS with request to upload it on official website in the larger interest of public.
- ix. Area FID, DRAP, Karachi for information record and necessary action, if any, please.
- x. PS to CEO, DRAP, Islamabad.
- xi. Assistant Director QC-I, DRAP, Islamabad.
- xii. Office copy.


Assistant Director (QC-II)