



F. No.13- 13/2020-QC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services,
Regulation & Coordination

MOST IMMEDIATE
THROUGH COURRIER

Islamabad, the 28th April, 2020.

[Medical Product Alert]
“Nexalite Injection (Tranexamic Acid 250mg/5ml)”

M/s Elite Pharma (Pvt.) Ltd.,
9.5 KM Sheikhpura road,
PDH Street,
Lahore.

Subject: **VOLUNTARY PRODUCT RECALL OF PRODUCT NEXALITE INJ. BATCH NO. 028.**

I am directed to refer to the subject cited above and your letter vide No. NIL dated 12-03-2020 wherein you have informed about the voluntary product recall of product Nexalite Inj., details of which are as under;

Product Name: Nexalite Inj.
Generic Name: Tranexamic Acid.....250mg/5ml
Manufacturer: M/s. Elite Pharma (Pvt.) Ltd., 9.5 KM Sheikhpura road, PDH Street, Lahore.
Pack Size: 5ml x 10amp
Batch Number: 028
MFG: 01-2019
EXP: 01-2021

02. You are therefore advised to recall all the stocks of suspected batches of product Nexalite (Tranexamic Acid...250mg/5ml), 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. It shall be ensured that compliance report to this effect should reach to this division within seven (07) days positively.

-/sd-
(Hafiz Sanaullah Babar)
Assistant Director QC-III

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 DRAP, Lahore.
14. The Additional Director DRAP, Karachi.
15. The Additional Director DRAP, Islamabad.
16. The Additional Director DRAP, Peshawar.
17. The Additional Director DRAP, Quetta.
18. The Chief Drug Inspector Baluchistan.
19. The Chief Drug Controller Punjab.
20. The Chief Drug Inspector Sindh.
21. The Chief Drug Inspector KPK.
22. The Chief Drug Inspector G.B.
23. The Chief Drug Inspector AJ&K.
24. Senior Drug Inspector, ICT, Islamabad.

Copy to: -

- i. The Director, QA<, DRAP, Islamabad.
- ii. The Additional Director MIS **with request to upload it on official website in the larger interest of public.**
- iii. The FID Karachi for information record and necessary action please.
- iv. M/s. Elite Pharma (Pvt.) Ltd., 9.5 KM Shekhupura road, PDH Street, Lahore with request to alert your sales officers/suppliers/distributors and issue necessary instructions for stoppage of use of suspected batches of Nexalite Inj. (Tranexamic Acid 250mg/5ml) throughout the hospitals in Pakistan for larger public interest.
- v. PA to Minister M/s NHS&RC Islamabad.
- vi. PS to CEO, DRAP, Islamabad.
- vii. Office copy.

S. Saad
24-4-2020

(Assistant Director QC-III)