



Islamabad, the 15<sup>th</sup> October, 2020.

## [Medical Product Alert]

### “Fenaclocl Injection.”

M/s Epoch Pharmaceuticals,  
Plot No. 83-85, Sector No. 15,  
Korangi Industrial Area;  
**Karachi.**

Subject: **DRUG RECALL OF ADULTERATED & SUBSTANDARD FENACLOD INJECTION, REG. NO. 050475, BATCH NO.039, MFG. DATE 10-2019, EXP. DATE 10-2021 MANUFACTURED BY M/S EPOCH PHARMACEUTICALS, KARACHI.**

I am directed to refer to the subject cited above and CDL, Karachi report vide No.KQ.234/2020 dated 28<sup>th</sup> September, 2020 wherein your product “FENACLOD INJECTION, REG. NO. 050475, BATCH NO.039, MFG. DATE 10-2019, EXP. DATE 10-2021 has been declared as of Adulterated & Substandard quality. Details of CDL reports are as under;

S.No.	Test	Specification	Result	Reference
1	Appearance	Clear and colorless liquid	Pink colored liquid containing visible glass particles. <b>Does not Comply.</b>	Mfg. Specs.
2	Identification	Diclofenac Sodium must be identified	Complies	Mfg. Specs.
3	pH	8.0 – 9.0	9.69 <b>Does not Comply.</b>	Mfg. Specs.
4	Bacterial Sterility test	Must be sterile	Complies	USP 43
6	Assay Diclofenac Sodium (Label claim 75mg/3ml)	90.0% to 110.0%	104.9%	Mfg. Specs.

02. You are therefore directed to recall all the stock of above-mentioned batch of product “Fenaclocl Injection, Batch No. 039” 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-  
(Shahid Nawaz)  
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 Director, QA&LT, DRAP, Islamabad.
- ✓ ii. The Additional Director MIS **with request to upload it on official website in the larger interest of public.**
- iii. FID-V, DRAP, Karachi for information record and necessary action, if any, please.
- iv. PS to CEO, DRAP, Islamabad.
- v. Assistant Director QC-I, DRAP, Islamabad.
- vi. Office copy.

  
15-10-2020  
(Assistant Director QC-II)