MEDICAL PRODUCT ALERT

DRAP ALERT NO. F.No.03-09/2021-QC

DRUG RECALL of Adulterated & Sub-Standard Conus Injection, Reg. No. 055956, Batch No. 091, Mfg. Date 06-2020, Exp. Date 12-2021, Manufactured by M/s. Epoch Pharmaceuticals (Pvt.) Ltd., Karachi.

Date:- 31st May 2021

Target Audience:-

I. Healthcare Professionals- Physicians, Pharmacists & Nurses.
II. General Public.

Problem or Issue:-

The sample of Conus Injection has been declared as Adulterated & Substandard quality by Central Drug Laboratory, Karachi report vide No.KQ.34/2021 dated 12-03-2021 on the basis of presence of black particles visible to the naked eye in Conus Injection B#091.

Details of Product:-

S.No.	Name of product	Manufactured by	Reg No.	Batch No.	Mfg. date	Exp. Date	Result of CDL
01	Conus Injection	M/s. Epoch Pharmaceuticals (Pvt.) Ltd., Karachi	055956	091	06-2020	12-2021	Adulterated & Sub-Standard

Action to be taken/ Advice for Healthcare Professionals:-

I. The drug product should be visually inspected for any foreign particulate matter and/or variation for physical aspect prior to administration.
II. The vials should be returned to the distributor/manufacturer if any foreign particulate matter and/or variation appeared. For more information/ queries please contact QA&LT Division at +92 51 926 21 42.
III. If the patient has suffered an adverse event or an unexpected event, he/she should immediately seek the advice from a qualified healthcare professional, and ensure that events shall be reported to **Pakistan National Pharmacovigilance Centre,** Drug Regulatory Authority of Pakistan through **DRAP Med Vigilance e-reporting system** http//: https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PK or at npc@dra.gov.pk.

DRAP, Islamabad

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