F. No.03-40/2020-QC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services,
Regulation & Coordination
****

MOST IMMEDIATE
THROUGH COURRIER

Islamabad, the 15th September, 2020.

[Medical Product Alert]

"Colicraft Lyophilized Powder for Injection & Infusion."

M/s Biolabs (Pvt) Ltd.,
Plot No.145 Kahuta Triangle Industrial
Estate Islamabad.,

Subject: **DRUG RECALL OF SUBSTANDARD COLICRAFT LYOPHILIZED POWDER FOR INJECTION & INFUSION., REG. NO. 082407, BATCH NO. L-279, MFG. DATE 02-2020, EXP. DATE 01-2022 MANUFACTURED BY M/S BIOLABS (PVT.) LTD., ISLAMABAD.**

I am directed to refer to the subject cited above and CDL, Karachi report vide No.R.KQ.209/2020 dated 26th August, 2020 wherein your product "COLICRAFT LYOPHILIZED POWDER FOR INJECTION & INFUSION., REG. NO. 082407, BATCH NO. L-279, MFG. DATE 02-2020, EXP. DATE 01-2022 has been declared of Substandard quality. Details of CDL reports are as under;

S. No.	test	Specifications	Result	Reference
1	Description	Off white lyophilized powder in clear glass vial.	Complies.	Mfg. Specs.
2	Identification	Colistimethate Sodium identified.	Complies.	USP 43
3	***Bacterial Sterility***	Must be sterile.	**Does not comply.**	USP 43
4	Endotoxin test	Not more than 2.0 EU per mg	Complies.	USP 43
5	**Assay** Colistin	90.0% - 110.0%	109.4%	USP 43

02. You are therefore directed to recall all the stock of above-mentioned batch of product "COLICRAFT LYOPHILIZED POWDER FOR INJECTION & INFUSION., REG. NO. 082407" 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.