F. No.03-34/2020-QC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services,
Regulation & Coordination
****

MOST IMMEDIATE
THROUGH COURRIER

Islamabad, the 25th September, 2020.

[Medical Product Alert]

"Redzi 100mg Solution for Injection"

(Remdesivir 5mg/ml)

M/s Wnsfeild Pharmaceuticals,
Plot No. 122, Block-A, Phase-V
Hattar Industrial Estate,
Haripur.

Subject: **DRUG RECALL OF SUBSTANDARD REDZI 100MG SOLUTION FOR INFUSION, REG. NO. 103179, BATCH NO. LV-004, MFG. DATE 07-2020, EXP. DATE 07-2021 MANUFACTURED BY M/S WNSFEILD PHARMACEUTICALS, HATTAR.**

I am directed to refer to the subject cited above and CDL, Karachi report vide No.KQ.189/2020 dated 28th July, 2020 wherein your product "Redzi 100mg Solution for Infusion (Remdesivir 5mg/ml)", Reg. No.103179, Batch No.LV-004, Mfg. Date 07-2020, Exp. Date 07-2021 has been declared of Substandard quality. Details of CDL reports are as under;

S.No.	test	Specifications	Result	Reference
1	Description	Clear colorless solution in clear glass vial.	Complies	Innovator Specs.
2	Identification	Remdesivir identified	Complies	Innovator Specs.
3	pH determined	3.0 -4.0	Complies	Innovator Specs.
4	***Bacterial Sterility test***	***Non-sterile***	**Does not comply**	**USP 42**
5	Endotoxin test	Not more than 1.0 EU per mg	Complies	USP 42
6	**Assay** Remdesivir (label claim 5mg/ml)	90.0% - 110.0%	95.1%	Innovator Specs

02. You are therefore directed to recall all the stock of above-mentioned batch of product "Redzi 100mg Solution for Infusion" 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.