[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:

<table>
<thead>
<tr>
<th>S.No.</th>
<th>test</th>
<th>Specifications</th>
<th>Result</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Description</td>
<td></td>
<td>Complies</td>
<td>Innovator Specs.</td>
</tr>
<tr>
<td>2</td>
<td>Identification</td>
<td></td>
<td>Complies</td>
<td>Innovator Specs.</td>
</tr>
<tr>
<td>3</td>
<td>pH determined</td>
<td></td>
<td>Complies</td>
<td>Innovator Specs.</td>
</tr>
<tr>
<td>4</td>
<td><strong>Bacterial Sterility test</strong></td>
<td><strong>Non-sterile</strong></td>
<td>Does not comply</td>
<td>Innovator Specs.</td>
</tr>
<tr>
<td>5</td>
<td>Endotoxin test</td>
<td></td>
<td>Complies</td>
<td>USP 42</td>
</tr>
<tr>
<td>6</td>
<td>Assay</td>
<td>Remdesivir identified</td>
<td>95.1%</td>
<td>Innovator Specs</td>
</tr>
<tr>
<td></td>
<td>(label claim 5mg/ml)</td>
<td>90.0% - 110.0%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.
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 NHSR&C, Islamabad.
8. The Director General Health, Government of Punjab.
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.

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. Office copy.

(Additional Director QC-II)