DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No.**346732/TS/2020** **Dated:** 21/06/2020

To,
HETERO LABS LIMITED,

Sy.No.321, Biotech Park, Phase-III C/o M/s. Aspiro Pharma Limited,Karkapatla (V),Markook (M),SIDDIPET (D), Telangana State,India.

Sir,

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Approval of Additional Products in Form 28A – Regarding.

Ref: Your application dated, 21/06/2020

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With reference to your application cited, you are hereby permitted to manufacture the products mentioned below as additional items under your Drug Licence in Form 28A bearing No.21/MD/TS/2014/F/G(L)

List Enclosed

The additional product/s mentioned below is/are granted subject to the following conditions:

1. You are informed that on failure to manufacture any of the Drugs approved herewith without a reasonable cause during the licensing period the matter will be reviewed and such drugs are liable for deletion.

2.The provision of Drugs Price Control Order, 2013 shall be complied with.

3. You should ensure that the drugs approved herewith shall not make any false/misleading/objectionable claims and should not be an imitation or resemble any other drug in respect of design, colour combination etc., and shall comply with all the provisions relating to the labeling of Drugs.

4. You should note that the brand names approved herewith are without prejudice to the existing brand names and are liable for review in future.

5. Specific permission for each export order need not be obtained. However, the details of exports by the exporter shall be furnished immediately after completion of each export in the format mentioned below.

Sl.	Date of export.	Names of the drugs exported	Batch No. of the drug.	Quantity of the drug.	Name of importing country.
1.	2.	3.	4.	5.	6.

6. Detailed particulars of rejects/ returned goods if any shall be furnished to this office at once for the purpose of issuing necessary orders in such cases. Till such time, the goods shall not be altered/ disposed of in any other manner.

7. The specification/standards asked for by the Importing Country/firm shall be complied with while exporting the drugs.

8. The federal regulations of the importing country shall be fulfilled while exporting/supplying the drugs.

In case of Narcotics/Psychotropic Drugs, you are also directed to approach The Narcotic Commissioner of India, 19, The Mall, Morar, Gwalior – 474 006, Madhya Pradesh, India so far as the provisions of the NDPS Act and the Rules are concerned in the matter.

Further, you are informed that non-compliance of any of the conditions mentioned above the matter will be reviewed and the licenses/permissions issued herewith are liable for suspension/cancellation for which you may take this as a notice under Rule 85(2) of the Drugs and Cosmetics Rules. You are therefore requested to plan your production accordingly.

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List of Product/s (Under –Form 28A)

S.No	Generic Name	Brand Name	Composition	Pack Size	Market
1	Remdesivir Injection 100 mg / 20 mL		Each mL contains, Remdesivir 5 mg, Liquid Injection for IV Infusion		Domestic & Export
2	Remdesivir for Injection 100 mg / vial		Each Lyophilized vial contains, Remdesivir 100 mg, Lyophilized powder for Injection for IV Infusion		Domestic & Export
3	Remdesivir Injection 100 mg / 20 mL	COVIFOR	Each mL contains, Remdesivir 5 mg, Liquid Injection for IV Infusion		Export
4	Remdesivir for Injection 100 mg / vial	COVIFOR	Each Lyophilized vial contains, Remdesivir 100 mg, Lyophilized powder for Injection for IV Infusion		Export

Digitally Signed By
DR Y NAVEEN KUMAR
Joint Director,Licensing & Controlling Authority
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:21-06-2020 14:59:47 PM

This Document is Digitally Signed. Signature is not required