7h680

**No.: AP/CHL/FDA/2020/** **/B**
Office of the COMMISSIONER
Food & Drugs Control Administration
1st Floor, Block No.8
Dr. Jivraj Mehta Bhavan
Gandhinagar, Gujarat State

Date: 7 AUG 2020

**To**
**M/s. CADILA HEALTHCARE LIMITED,**
**Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47,**
**Opp. Ramdev Masala, Sarkhej- Bavla N.H.No.-8A,**
**Village - Changodar,Tal: Sanand, Dist.-Ahmedabad – 382213**

SUB: Drugs & Cosmetics Act, 1940 & Rules thereunder
Permission to Manufacture Additional Products.

Dear Sir,

**Ref: Your letter No.: ZCP/FDA/AP/2020159** **Date: 07/08/2020**

I have to state that, you are permitted to manufacture and market the following products as per the supplementary list submitted by you vide letter under reference.

1. **Remdesivir for Injection 100mg/vial**
2. **Remdesivir for Injection 100mg/vial** **FOR EXPORT**
3. **REMDAC** **FOR EXPORT**

The above product permission is granted subject to following conditions.

1. The product should be safe and efficacious.
2. You should see that you comply with the labeling provisions made under the Drugs and Cosmetics Rules 1945 (as amended) for this product before marketing and furnish printed labels of the product in question Rules 96 of Drugs & Cosmetics Rules as amended require that the proper name of the drugs shall be given in a more conspicuous manner and the trade name, if any, which shall be shown immediately after or under the proper name.
3. In case of new Drugs as given 69-B of Drugs and Cosmetics Rules, permission to import raw materials be obtained under Rule 30 (A) from the Drugs Controller General, (India) New Delhi.
4. The permission is granted only subject to the provisions of Drugs & Cosmetics Act, 1940 and does not relieve you of your responsibilities to clear the items covered under the list from any enactment of status or order issued either by the State Government or Central Government and enforced by any authorities. You must therefore, obtain clearance before marketing this product.
5. Before introducing this product in the market you should comply with the provisions of Drugs (Price Control) order, 2013.
6. You are hereby requested to continue the data entry of freshly granted product permission and submit the printout of the same to your circle for verification & authentication till further instruction.
7. The original product list attested by this office are returned herewith. Kindly acknowledge the receipt of this letter.

**Yours Faithfully,**

**For Commissioner**
**Food & Drugs Control Administration**
**Gandhinagar, Gujarat State.**

**No. AP/CHL/FDA/2020/** **/B.GANDHINAGAR, DATE,**
Copy with a copy of attested list of product forwarded to:-
1) The Assistant Commissioner (Ahmedabad Rural) Gandhinagar for Information.
2) PA to commissioner

**For Commissioner**
**Food & Drugs Control Administration.**
**Gandhinagar, Gujarat State.**

Zydus dedicated to life

Cadila Healthcare Limited

**Factory Address: Cadila Healthcare Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, Opp. Ramdev Masala, Sarkhej- Bavla N.H.No.-8A, Village - Changodar, Tal: Sanand, Dist.-Ahmedabad – 382213**



## LIST OF ADDITIONAL PRODUCTS

MFG. LICENCE IN FORM No.: **28**
MFG. LICENCE NO.: **G/28/1544**

| | | |
|---|---|---|
| 1. | **Remdesivir for Injection 100mg/vial (Lyophilized powder)**<br><br>Each Lyophilized vial contains:<br>Remdesivir .....100mg<br>Excipients.....q.s. | **(Single-Dose Vial)**<br><br>**Permission No.: MF/FF/SND/164/2020**<br>**Date: 06/08/2020** |
| 2. | **Remdesivir for Injection 100mg/vial (Lyophilized powder)**<br><br>Each Lyophilized vial contains:<br>Remdesivir .....100mg<br>Excipients.....q.s. | **FOR EXPORT**<br>**(Single-Dose Vial)**<br><br>**Permission No.: MF/FF/SND/164/2020**<br>**Date: 06/08/2020** |
| 3. | **Remdesivir for Injection 100mg/vial (Lyophilized powder)**<br><br>**REMDAC**<br><br>Each Lyophilized vial contains:<br>Remdesivir .....100mg<br>Excipients.....q.s. | **FOR EXPORT**<br>**(Single-Dose Vial)**<br><br>**Permission No.: MF/FF/SND/164/2020**<br>**Date: 06/08/2020** |

COMMISSIONER FOOD & DRUGS CONTROL ADMINISTRATION GUJARAT STATE GANDHINAGAR

The above are the only additional products to be manufactured by us, any addition thereto or deletion therefrom will not be carried out without the prior permission of the Commissioner, Food & Drugs Control Admn., Gujarat State, Gandhinagar.

We declare that the products are safe for use in respect of context of active ingredients, vehicle, excipients, additives and Pharmaceutical aids used in the formulation.

For **CADILA HEALTHCARE LIMITED**

**AUTHORIZED SIGNATORY**

For, Commissioner
Food & Drugs Control Administration
Gujarat State, Gandhinagar.

- 7 AUG 2020