

No.: MFG/Certi/CHC/2020/HC/78373 /B  
Commissioner of  
Food & Drug Control Administration,  
Block No.8, 1st Floor, Dr. Jivraj Mehta Bhavan,  
Old Sachivalaya, Gandhinagar.

Date :  
18 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, Gujarat, India.

Sub : Drugs & Cosmetics Act 1940 & Rules thereunder  
Issue of Free Sale Certificate

Ref : Your letter no. CHL/FDA/FSC/2020087, dated: 10/08/2020

Dear Sir,

I send herewith the necessary **Free Sale Certificate** in five Copies, as requested by you for the enclosed product.

Sr. No.	Name of Product	No. of Copies	Country
1.	Remdac (Remdesivir for Injection 100mg/vial)	5	All countries except India
2.	Remdesivir for Injection 100mg/vial	5	All countries except India

Yours faithfully,

  
For Commissioner  
Food and Drug Control Administration  
Gujarat state

No. Mfg/Certi/ 28374  
OFFICE OF THE COMMISSIONER,  
FOOD & DRUGS CONTROL ADMINISTRATION,  
DR. JIVRAJ MEHTA BHAVAN, GUJARAT STATE,  
BLOCK NO.8, 1<sup>ST</sup> FLOOR, GANDHINAGAR.  
DATE:

18 AUG 2020

**FREE SALE CERTIFICATE**

This is to certify that 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, Gujarat, India is holding valid Drugs manufacturing license in form no. 28 bearing license No. G/28/1544 issued on date 21/10/2015 and valid up to 20/10/2020 by administration under the provisions of Drug and Cosmetic act 1940, and rules thereunder.

Under the above license the firm is permitted to manufacture and market the product listed below to be exported freely. Such types of similar products are available in country of origin subject to laws of land in question.

The detailed qualitative and quantitative composition is attached as per annexure.

Sr. No.	Product Name	Composition
1	Remdac (Remdesivir for Injection 100mg/vial)	Each lyophilised vial contains: Remdesivir.....100mg Excipients.....q.s

This is also certified that manufacturing plant in which the product is manufactured is subjected to regular inspection at suitable intervals.

This certificate is valid for two years from date of issue.



  
For Commissioner  
Food and Drug Control Administration  
Gandhinagar, Gujarat state, India

**CADILA HEALTHCARE LIMITED.**

Factory Address: 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, Gujarat, India.

**Annexure**

**QUALITATIVE & QUANTITATIVE COMPOSITION FOR**

**Remdac (Remdesivir for Injection 100mg/vial)**

Sr. No.	Name of Ingredient	Pharmac. Reference	Quantity/ m L
1.	Remdesivir	IH	6.5 mg
2.	Betadex sulfobutyl ether sodium	NF	195 mg
3.	Sodium Hydroxide	IH	q.s to pH Adjustment
4.	Hydrochloric acid	NF	q.s to pH Adjustment
5.	Water for Injection	USP/Ph.Eur./BP	q.s to 1 mL

IH: In house

**For, CADILA HEALTHCARE LIMITED**



**AUTHORIZED SIGNATORY**



No. Mfg/Certi/ 78375  
OFFICE OF THE COMMISSIONER,  
FOOD & DRUGS CONTROL ADMINISTRATION,  
DR. JIVRAJ MEHTA BHAVAN, GUJARAT STATE,  
BLOCK NO.8, 1<sup>st</sup> FLOOR, GANDHINAGAR.

DATE: 18 AUG 2020

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IH: In house

**For, CADILA HEALTHCARE LIMITED**



**AUTHORIZED SIGNATORY**

