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No: WHO-GMP/20082164/ /B
Commissioner
Food & Drugs Control Administration,
Gujarat State, Dr. Jivraj Mehta Bhavan,
Block No.8, 1st floor, Gandhinagar
Date :

11 8 AUG 2020

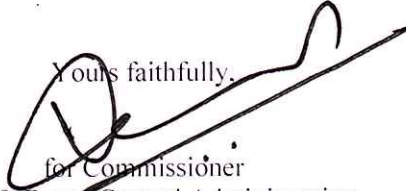
To,
✓ M/s. CADILA HEALTHCARE LTD.,
PLOT SURVEY NO. 23, 25P, 37, 40/P, 42 to 47,
SARKHEJ - BAVLA N. H. No. - 8 A, OPP RAMDEV MASALA,
VILLAGE:- CHANGODAR, TAL -SANAND,
DIST.- AHMEDABAD

Sub :- Drugs & Cosmetics Act, 1940 & Rules thereunder.
Issue of WHO-GMP Certificate

Sir,

Ref:- Your letter Dated : 17/08/2020

I send herewith World Health Organisation – Good Manufacturing Practices Certificate (WHO-GMP) in ONE copy as desired by you.

Yours faithfully,

for Commissioner
Food & Drugs Control Administration

No: WHO-GMP/20082164/2020/

/B Gandhinagar Date: - -2020

Copy forwarded to :-

1. Assistant Commissioner, AHMEDABAD
2. Copy to Dy. Drugs Controller, CDSCO, Air Cargo Complex, Ahmedabad
3. G-Branch.

for Commissioner
Food & Drugs Control Administration



Food & Drugs Control Administration

BLOCK NO. 8, 1ST FLOOR, Dr. JIVRAJ MEHTA BHAVAN,
GANDHINAGAR, GUJARAT STATE, INDIA. PIN : 382010



Certificate No. : **20082164**

On the basis of the inspection carried out on **11/07/2020** we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

¹ Name & Address of site : **CADILA HEALTHCARE LTD.**
PLOT SURVEY NO. 23, 25P, 37, 40/P, 42 to 47 , SARKHEJ -
BAVLA N. H. No. - 8 A, OPP RAMDEV MASALA, VILLAGE:-
CHANGODAR , TAL -SANAND
City : CHANGODAR - 382 213, DIST.- AHMEDABAD
GUJARAT STATE, INDIA

² Manufacturer's Licence number : **G/28/1544**

³ Table : 1

Dosage Form (s)	Category (ies)	Activity (ies)
SVP (LIQUID, LYOPHILIZED)	General	Manufacturer

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until **12/09/2020**. It becomes invalid if the activities and /or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP

Format of this certificate is as per WHO TRS No. 908 of 2003.

Address of certifying authority

Food & Drugs Control Administration, Block
No. 8, 1ST floor, Dr. Jivraj Mehta Bhavan,
Gandhinagar, Gujarat State, India. - Pin :
382010

Email : comfdca@gujarat.gov.in

Phone : 91-79-23253417, Fax : 91-79-232-53400

Date : 18/08/2020

Name & function of : **(Dr. H.G. KOSHIA)**
responsible Person **Commissioner**



Page 1 of 1

List of products for grant of COPP as per WHO guidelines

License in Form No.: 28

License No.G/28/1544 Valid From 21/10/2015

1.	Remdesivir for Injection 100mg/vial (Lyophilized powder) Each Lyophilized vial contains: Remdesivir 100mg Excipients q.s.	FOR EXPORT
2.	Remdesivir for Injection 100mg/vial (Lyophilized powder) REMDAC Each Lyophilized vial contains: Remdesivir 100mg Excipients q.s.	FOR EXPORT
3.	Bacteriostatic Water for Injection B.P. (Use only for Trastuzumab150 mg - Lyophilized powder for intravenous infusion) Each 7.2 mL solution contains: Benzyl alcohol 1.1% Water for Injection B.P. q.s.	FOR EXPORT
4.	Bacteriostatic Water for Injection Ph. Eur (Use only for Trastuzumab150 mg - Lyophilized powder for intravenous infusion) Each 7.2 mL solution contains: Benzyl alcohol 1.1% Water for Injection Ph. Eur q.s.	FOR EXPORT
5.	Bacteriostatic Water for Injection U.S.P. (Use only for Trastuzumab150 mg - Lyophilized powder for intravenous infusion) Each 7.2 mL solution contains: Benzyl alcohol 1.1% Water for Injection U.S.P. q.s.	FOR EXPORT
6.	Bacteriostatic Water for Injection (Use for Trastuzumab only) Each 20 mL solution contains: Benzyl alcohol 1.1% Water for Injection (IP / Ph. Eur. / USP) q.s.	FOR EXPORT

For Cadila Healthcare Ltd.

AUTHORIZED SIGNATORY



FOR COMMISSIONER
FOOD & DRUGS CONTROL ADMINISTRATION
GUJARAT STATE

8 AUG 2020 + 2 SEP 2020

Site Address : Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, Sarkhej-Bavla N. H. No.-8A, Opp. Ramdev Masala,
Village : Changodar, Tal : Sanand, Dist : Ahmedabad - 382213, Gujarat, India.

Regd. Office : 'Zydus Tower', Satellite Cross Roads, Ahmedabad 380 015, India.
Phone : +91-79-2686 8100 (20 lines) www.zyduscadila.com CIN : L24230GJ1995PLC025878