



21456

No: WHO-GMP/1802635/ /B
Commissioner
Food & Drugs Control Administration,
Gujarat State, Dr. Jivraj Mehta Bhavan,
Block No.8, 1st floor, Gandhinagar
Date : 23 FEB 2018

Regd. No.: 1305
Page : 04
Date : 01/03/2018

To,
M/s. CADILA HEALTHCARE LIMITED,
PLOT NO.26 TO 29 & 31,,DABHASA, TAL- PADRA
DABHASA- 391 440,
DIST- VADODARA.

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

Sir,

Ref:- Your letter Dated : 17-07-2017

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

Yours faithfully,

for Commissioner
Food & Drugs Control Administration

No: WHO-GMP/1802635/2018/

/B Gandhinagar Date: - -2018

Copy forwarded to :-

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

for Commissioner
Food & Drugs Control Administration



TUSHAR PANDYA
ASST. SECRETARY, SERVICE CENTER
GUJARAT CHAMBER OF COMMERCE & INDUSTRY
AHMEDABAD



भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
INDIA

**This public document of the type
COMMERCIAL DOCUMENT**

is issued to **CADILA HEALTHCARE LTD.**

has been signed by **TUSHAR PANDYA**

with the seal / stamp of **ASSTT. SECRETARY, GUJARAT
CHAMBER OF COMMERCE & INDUSTRY, AHMEDABAD**

Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on **04-Sep-2018** at **NEW DELHI, INDIA**

with reference no. **GJAH0028488618**

Seal / Stamp

Signature
(देबप्रताप पाण्डे)
(DEBAPRATA PAUL)
सहायक सचिव (ओ.आई.)
Section Officer (O.I.)
बी.पी.ओ. प्रशा/C.S.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi

महाराष्ट्र
GOVT. OF INDIA, NEW DELHI



Food & Drugs Control Administration

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



Certificate No. : **1802635**

On the basis of the inspection carried out on 14-15/09/2017 & 11/01/2018 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 LIMITED**

PLOT NO.26 TO 29 & 31,, DABHASA, TAL- PADRA

City : DABHASA- 391 440, Dist : VADODARA, GUJARAT STATE, INDIA

2 Manufacturer's Licence number : **G/25/1409 G/28/1292**

3 Table : 1

Dosage Form (s)	Category (ies)	Activity (ies)
Bulk Drugs (APIs)	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 **23/01/2020**. 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 : **24/01/2018**

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



TUSHAR PANDYA
ASST. SECRETARY, SERVICE CENTER
GUJARAT CHAMBER OF COMMERCE & INDUSTRY
AHMEDABAD



 भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
INDIA

This public document of the type
COMMERCIAL DOCUMENT

is issued to CADILA HEALTHCARE LTD.

has been signed by TUSHAR PANDYA

with the seal / stamp of ASSTT. SECRETARY, GUJARAT
CHAMBER OF COMMERCE & INDUSTRY, AHMEDABAD

Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 04-Sep-2018 at NEW DELHI, INDIA

with reference no. GJAH0028488818

Seal / Stamp

The Ministry of External Affairs
does not accept any responsibility for the
contents of the above documents.



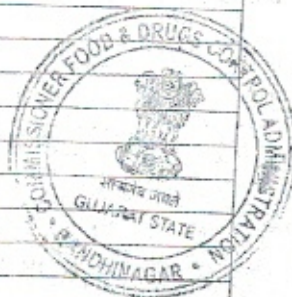
(देवव्रता पाण्डे)
(DEVABRATA PAUL)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (O.I.)
सी.पी.डी. प्रभाग, C.P.V. Division
मिनिस्टर ऑफ़ एक्सटर्नल अफ़ेयर्स,
Ministry of External Affairs
New Delhi



OF PRODUCTS COVERED UNDER WHO-GMP CERTIFICATE
MANUFACTURING LICENCE NO. G/1409 IN FORM 25
& LICENCE NO G/28/1292 IN FORM 28

BULK DRUGS (APIs)

Sr. No	NAME OF PRODUCT
1	Acipimox
2	Alfuzosin Hydrochloride
3	Anagrelide Hydrochloride
4	Aripiprazole
5	Atenolol BP/USP/EP
6	Atomoxetine Hydrochloride
7	Azelastine Hydrochloride EP
8	Balofloxacin Dihydrate
9	Bosentan Monohydrate
10	Bupropion Hydrochloride
11	Carvedilol BP/EP/USP/JP
12	Clindamycin Hydrochloride USP/EP
13	Clindamycin Phosphate USP/EP/BP
14	Clonidine EP/USP
15	Clopidogrel Besylate
16	Clopidogrel Bisulfate USP
17	Deferiprone
18	Desvenlafaxine Succinate
19	Diclofenac Diethylamine BP
20	Donepezil Hydrochloride
21	Duloxetine HCl EP/USP
22	Entecavir
23	Esomeprazole Magnesium USP
24	Ethacrynic Acid USP/EP
25	Famotidine BP/USP/EP
26	Febuxostat
27	Fluconazole
28	Fosphenytoin Sodium USP
29	Hexoprenaline Sulfate
30	Hydrochlorothiazide USP/EP
31	Hydroxychloroquine Sulfate BP/USP
32	Irbesartan
33	Ivabradine HCl
34	Lamotrigine EP/USP
35	Linezolid
36	Losartan Potassium EP /USP
37	Mesalamine EP/USP



For Commissioner
Food & Drugs Control Administration
Gujarat State Gandhinagar

For Cadila Healthcare Ltd.,

(Authorised Signatory)

Factory : Plot No. 26 to 29 & 31, Dabhasa-Umaraya Road, Vill. Dabhasa, 391440, Tal. Padra, Dist. Vadodara, Gujarat, India.

Phone : +91 - 2662 - 244411 / 244412 / 244396 / 244397 Fax : +91 - 2662 - 244243 www.zyduscadila.com

Regd. Office : 'Zydus Tower', Satellite Cross Road, Ahmedabad-380015, India. Phone : +91-79-2686 61 00 (25 Lines) Fax : +91-79-2686 23 65 / 66

CIN : L24230GJ1995PLC025078

24 JAN 2018 To 23 JAN 2020



TUSHAR PANDYA
ASST. SECRETARY, SERVICE CENTER
GUJARAT CHAMBER OF COMMERCE & INDUSTRY
AHMEDABAD



भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
INDIA

**This public document of the type
COMMERCIAL DOCUMENT**

is issued to CADILA HEALTHCARE LTD.

has been signed by TUSHAR PANDYA

with the seal / stamp of ASSTT. SECRETARY, GUJARAT
CHAMBER OF COMMERCE & INDUSTRY, AHMEDABAD

Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 04-Sep-2018 at NEW DELHI, INDIA

with reference no. GJAH0028488918

Seal / Stamp

Signature

(DEBABRATA PAUL)
(DEBABRATA PAUL)
अनुपाय अधिकारी (ओ.आई.)
Section Officer (O.I.)
सी.पी.बी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi

मुं० 568
MINISTRY OF EXTERNAL AFFAIRS
GOVT. OF INDIA, NEW DELHI



Cadila
Healthcare Limited
Dabhaha-Vadodara

LIST OF PRODUCTS COVERED UNDER WHO-GMP CERTIFICATE
MANUFACTURING LICENCE NO. G/1409 IN FORM 25
& LICENCE NO G/28/1292 IN FORM 28

BULK DRUGS (APIs)

Sr. No	NAME OF PRODUCT
38	Metoprolol Succinate USP/EP
39	Midodrine Hydrochloride
40	Naftopidil
41	Olanzapine
42	Olmesartan Medoxomil
43	Paliperidone
44	Pantoprazole Sodium Sesquihydrate EP
45	Paroxetine Hydrochloride
46	Paroxetine Hydrochloride Hemihydrate
47	Pioglitazone HCl USP/JP
48	Pitavastatin Calcium
49	Pramipexole Dihydrochloride
50	Promethazine Hydrochloride USP/EP
51	Propafenone HCl EP/USP
52	Rabeprazole Sodium IP
53	Risperidone EP/BP/USP
54	Rivastigmine
55	Salmeterol Xinafoate
56	Saroglitazar
57	Silodosin
58	Simvastatin USP/EP
59	Sitagliptin Phosphate
60	Tamsulosin Hydrochloride
61	Terazosin Hydrochloride BP
62	Tirofiban HCl
63	Topiramate
64	Venlafaxine Hydrochloride BP/EP
65	Warfarin Sodium BP/USP/EP
66	Ziprasidone Hydrochloride Anhydrous
67	Ziprasidone Hydrochloride Monohydrate
68	Zolpidem Tartrate EP
69	Zonisamide
70	Cinacalcet hydrochloride
71	Hyoscyamine Sulfate IP/EP/BP/USP
72	Linagliptin (Amorphous)
73	Lurasidone Hydrochloride
74	Rasagiline Besylate
75	Roflumilast

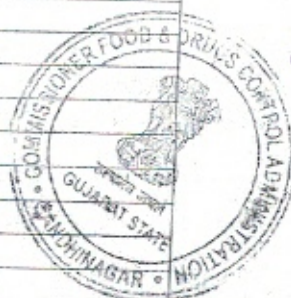
My Commission Expires
On 19th September 2021

J. H. THAKOR
NOTARY

J. H. THAKOR
ADVOCATE & NOTARY
1, PARAMKRUPA SOCIETY,
NR. ARUNACHAL SOCIETY,
SUBHANPURA, VADODARA-23
GUJARAT, INDIA.
MOBILE : 97232 89463

TRUE COPY

J. H. Thakor
1-3-2018
J. H. THAKOR
NOTARY



[Signature]
For Commissioner
Food & Drugs Control Administration
Gujarat State Gandhinagar

For Cadila Healthcare Ltd.,

24 JAN 2018 TO 23 JAN 2020

(Authorised Signatory)

Factory : Plot No. 20 to 29/31, Dabhaha-Umaraya Road, Vill. Dabhaha - 391440, Tal. Padra, Dist. Vadodara, Gujarat, India.
Phone : +91 - 2662 - 244411 / 244412 / 244396 / 244397 Fax : +91 - 2662 - 244243 www.zyduscadila.com
Regd. Office : 'Zydus Tower', Satellite Cross Road, Ahmedabad - 380015, India. Phone : +91-79-2686 81 00 (20 Lines) Fax : +91-79-2686 23 65 / 86



TUSHAR PANDYA
ASST. SECRETARY, SERVICE CENTER
GUJARAT CHAMBER OF COMMERCE & INDUSTRY
AHMEDABAD

भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
INDIA

*This public document of the type
COMMERCIAL DOCUMENT*

is issued to CADILA HEALTHCARE LTD.

has been signed by TUSHAR PANDYA

with the seal / stamp of ASSTT. SECRETARY, GUJARAT
CHAMBER OF COMMERCE & INDUSTRY, AHMEDABAD

Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 04-Sep-2018 at NEW DELHI, INDIA
with reference no. GJAH0028489118

Seal/Stamp

Signature

My Ministry of External Affairs
accepts no responsibility for the
contents of the above documents.



(देबाप्रता पॉल)
(DEBARATA PAUL)
असिस्टेंट सेक्टर ऑफिसर (अ.अ.ई.)
Section Officer (O.I.)
सी.पी.डी. प्रभाग/C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi