



Food & Drugs Control Administration

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



Certificate No. : **1807930**

On the basis of the inspection carried out on **20/21/06/2018 & 12/07/2018** 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 : **ALEMBIC PHARMACEUTICALS LIMITED (API DIVISION PANELAV)**

AT- PANELAV, TAL- HALOL

City : PANELAV, Dist : PANCHMAHAL, GUJARAT STATE, INDIA

2 Manufacturer's Licence number : **G/25/1411 G/28/1050 G/25-F/50**

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 **15/07/2021**. 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**

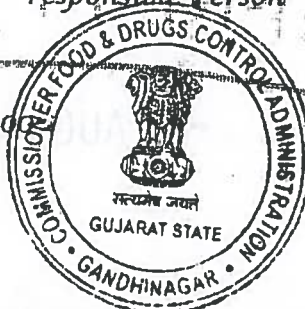
Phone : 91-79-23252017 Fax : 91-79-232-5340

Date : **16/07/2018**

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

My Commission expires on **28-04-2023**

Shilpa B. Zaveri
NOTARY



ATTESTED

SHILPA B. ZAVERI
NOTARY

- 6 AUG 2018



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 ALEMBIC PHARMACEUTICALS LTD

has been signed by S R DIGHE

with the seal / stamp of DY. SECRETARY, FEDERATION OF GUJARAT INDUSTRIES, VADODARA

Certified by
 Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
 on 13-Aug-2018 at NEW DELHI, INDIA

With reference no. GJVD0026537818

Seal / Stamp

Signature

(विद्यमान मुद्रा)
 (DEBARARAT DASH)
 अनुभाग अधिकारी (ओ.आई.)
 Section Officer (O.I.)
 सी.पी.डी. प्रभाग / C.P.V. Division
 विदेशी मामलों, नई दिल्ली
 Ministry of External Affairs
 New Delhi

MINISTRY OF EXTERNAL AFFAIRS
 GOVT OF INDIA NEW DELHI
 50568

Attestation
 The Document / Signature / Paper
 is Attested Ref. No. 06/18-19
 S. R. Dighe
 Deputy Secretary
 Federation of Gujarat Industries

Nitesh Patel
 Secretary General
 Federation of Gujarat Industries

Federation of Gujarat
 Industries, Vadodara is a
 Recognised Chamber of Commerce



- 8 AUG 2018

API DIVISION PANELAV,
Tal-Halol, Dist : Panchmahal

LIST OF PRODUCTS FOR GRANT OF COPP AS PER WHO GUIDELINES

Mfg. Lic. No. G/1411 in Form 25
Mfg. Lic. No. G/1050 in Form 28

Mfg. Lic. No. G/25F/50 in Form 25F

1	Azithromycin Dihydrate JP/USP/Ph.Eur.
2	Azithromycin Monohydrate USP/Ph.Eur.
3	Bupropion Hydrochloride USP
4	Clarithromycin Enteric Coated Granules 28%
5	Clarithromycin Enteric Coated Granules 29%
6	Clarithromycin Enteric Coated Granules 30%
7	Clarithromycin Enteric Coated Granules 31%
8	Clarithromycin Enteric Coated Granules 33%
9	Clarithromycin Enteric Coated Granules 35%
10	Clarithromycin Enteric Coated Granules 36%
11	Clarithromycin Enteric Coated Granules 38%
12	Clarithromycin Enteric Coated Granules 39%
13	Clarithromycin Enteric Coated Granules 40%
14	Clarithromycin Enteric Coated Granules 41%
15	Clarithromycin Enteric Coated Granules 42%
16	Clarithromycin Enteric Coated Granules 43%
17	Clarithromycin Enteric Coated Granules 44%
18	Clarithromycin JP/Ph.Eur./USP
19	Clonidine USP



For ALEMBIC PHARMACEUTICALS LTD.,

Bhavesht D. Patel.
Authorized Signatory.



FOR COMMISSIONER
FOOD & DRUGS CONTROL ADMINISTRATION
GUJARAT STATE.

16 JUL 2018 To 15 JUL 2021

ALEMBIC PHARMACEUTICALS LIMITED

REGD. OFFICE : ALEMBIC ROAD, VADODARA - 390 003, INDIA • TEL : +91-0265-2280550 • FAX : +91-0265-2282837
Website : www.alembicpharmaceuticals.com • E-mail : alembic@alembic.co.in • CIN: L24230GJ2010PLC061123

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

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Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 21-Aug-2018 at NEW DELHI, INDIA

with reference no. GJVD0027519618

Seal / Stamp

Signature

(देवब्रत पाण्डे)
(DEVABRATH PAUL)
अध्यापक अधिकारी (ओ.आई.)
Section Officer (O.I.)
वि.प्र.सं. प्रभाग, C.P.V. Division
जिनांग बसस्टेशन, नई दिल्ली
Ministry of External Affairs
New Delhi

The Ministry of External Affairs
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S. R. Dighe
Deputy Secretary
Federation of Gujarat Industries

Nitesh Patel
Secretary General
Federation of Gujarat Industries

Federation of Gujarat
Industries, Vadodara is a
Recognised Chamber of Commerce

- 8 AUG 2018



API DIVISION PANELAV,
Tal-Halol, Dist : Panchmahal

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Mfg. Lic. No. G/1411 in Form 25
Mfg. Lic. No. G/1050 in Form 28

Mfg. Lic. No. G/25F/50 in Form 25F

20	Clonidine Hydrochloride USP/Ph.Eur
21	Celecoxib USP/Ph.Eur.
22	Deferasirox
23	Erythromycin BP/USP/Ph.Eur.
24	Etoricoxib
25	Fenofibrate Ph.Eur./BP/USP
26	Fenofibric acid
27	Fenofibric Acid Choline salt
28	Fluoxetine Hydrochloride Ph.Eur./USP
29	Hydrochlorothiazide Ph.Eur./JP/USP
30	Irbesartan USP/Ph. Eur
31	Ivabradine Adipate
32	Ivabradine Hydrochloride
33	Lacosamide
34	Lamotrigine Ph.Eur./USP
35	Leflunomide Ph.Eur./USP
36	Lercanidipine Hydrochloride
37	Linezolid
38	Memantine Hydrochloride / Memantine Hydrochloride USP
39	Meprobamate USP



For ALEMBIC PHARMACEUTICALS LTD.,

Bhaves D. Patel.
Authorized Signatory.

FOR COMMISSIONER
FOOD & DRUGS CONTROL ADMINISTRATION
GUJARAT STATE.



6 JUL 2018 To 5 JUL 2021

ALEMBIC PHARMACEUTICALS LIMITED

REGD. OFFICE : ALEMBIC ROAD, VADODARA - 390 003, INDIA • TEL : +91-0265-2280650 • FAX : +91-0265-2282837
Website : www.alembicpharmaceuticals.com • E-mail : alembic@alembic.co.in • CIN: L24230GJ2010PLC061123

**API DIVISION PANELAV,
Tal-Halol, Dist : Panchmahal**

LIST OF PRODUCTS FOR GRANT OF COPP AS PER WHO GUIDELINES

Mfg. Lic. No. G/1411 in Form 25

Mfg. Lic. No. G/25F/50 in Form 25F

Mfg. Lic. No. G/1050 in Form 28

40	Metoprolol Succinate Ph.Eur./USP
41	Metoprolol Tartrate USP/EP
42	Mexiletine Hydrochloride Ph.Eur./USP
43	Modafinil Ph.Eur./USP
44	O-Desmethyl Venlafaxine Succinate Monohydrate
45	O-Desmethyl Venlafaxine
46	Olmesartan Medoxomil Ph.Eur./ USP
47	Pregabalin Ph. Eur
48	Pramipexole Dihydrochloride Monohydrate Ph. Eur
49	Quetiapine Fumarate USP / Ph. Eur
50	Rivastigmine Base / Rivastigmine Base Ph. Eur
51	Rivastigmine Hydrogen Tartrate Ph. Eur
52	Rivastigmine USP
53	Rivastigmine Tartrate USP
54	Ropinirole hydrochloride USP
55	Roxythromycin JP/CP/Ph.Eur.
56	Telmisartan USP/Ph.Eur./JP
57	Teriflunomide
58	Valsartan USP/Ph.Eur.
59	Venlafaxine Hydrochloride Ph.Eur./USP
60	Vildagliptin



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Deputy Secretary / Secretary General
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8 AUG 2018

