



No: WHO-GMP/1807930/ /B 80222
Commissioner
Food & Drugs Control Administration,
Gujarat State, Dr. Jivraj Mehta Bhavan,
Block No.8, 1st floor, Gandhinagar
Date : **16 JUL 2018**

To,
M/s. ALEMBIC PHARMACEUTICALS LIMITED (API DIVISION PANELAV),
AT- PANELAV, TAL- HALOL
PANELAV,
DIST- PANCHMAHAL.

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

Sir,

Ref:- Your letter Dated : 02-05-2018

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/1807930/2018/

/B Gandhinagar Date: - -2018

Copy forwarded to :-

1. Assistant Commissioner, GODHRA
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. : **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

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

Email : **comfdca@gujarat.gov.in**

Phone : **91-79-23253417**, Fax : **91-79-232-5340**

Date : **16/07/2018**



API DIVISION PANELAV,
Tal-Halol, Dist : Panchmahal

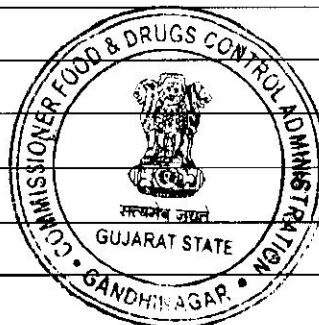
LIST OF PRODUCTS FOR GRANT OF COPP AS PER WHO GUIDELINES

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

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

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

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.,

Bhavesh 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

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

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 15 JUL 2021

ALEMBIC PHARMACEUTICALS LIMITED

REGD. OFFICE : ALEMBIC ROAD, VADODARA - 390 003, INDIA • TEL : +91-0265-2280550 • FAX : +91-0265-2282837
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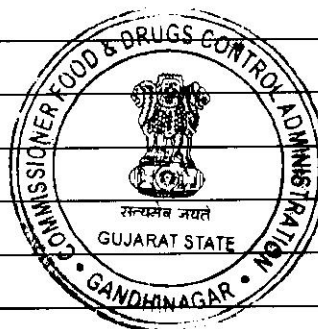
API DIVISION PANELAV,
Tal-Halol, Dist : Panchmahal

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

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



For ALEMBIC PHARMACEUTICALS LTD.,

Bhavesn D. Patel.
Authorized Signatory.


FOR COMMISSIONER
FOOD & DRUGS CONTROL ADMINISTRATION
GUJARAT STATE.

16 JUL 2018 to 5 JUL 2021

ALEMBIC PHARMACEUTICALS LIMITED

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