



No: WHO-GMP/21072791/ /B 58259
Commissioner
Food & Drugs Control Administration,
Gujarat State, Dr. Jivraj Mehta Bhavan,
Block No.8, 1st floor, Gandhinagar
Date :

14 JUL 2021

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

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

Sir,

Ref:- Your letter Dated : 04/06/2021

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

Yours faithfully,

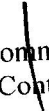

for Commissioner
Food & Drugs Control Administration

/B Gandhinagar Date: - -2021

No: WHO-GMP/21072791/2021/

Copy forwarded to :-

1. Assistant Commissioner, PANCHMAHAL
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. : **21072791**

On the basis of the inspection carried out on **17-18/06/2021 & 09/07/2021** 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/1411** **G/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 **13/07/2024**. 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. KOSHIA)**
responsible Person **Commissioner**

(Signature)

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

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

Date : **14/07/2021**

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	Clarithromycin Enteric Coated Granules 28%
4	Clarithromycin Enteric Coated Granules 29%
5	Clarithromycin Enteric Coated Granules 30%
6	Clarithromycin Enteric Coated Granules 31%
7	Clarithromycin Enteric Coated Granules 32%
8	Clarithromycin Enteric Coated Granules 33%
9	Clarithromycin Enteric Coated Granules 34%
10	Clarithromycin Enteric Coated Granules 35%
11	Clarithromycin Enteric Coated Granules 36%
12	Clarithromycin Enteric Coated Granules 37%
13	Clarithromycin Enteric Coated Granules 38%
14	Clarithromycin Enteric Coated Granules 39%
15	Clarithromycin Enteric Coated Granules 40%
16	Clarithromycin Enteric Coated Granules 41%
17	Clarithromycin Enteric Coated Granules 42%
18	Clarithromycin Enteric Coated Granules 43%
19	Clarithromycin Enteric Coated Granules 44%
20	Clarithromycin JP/Ph.Eur./USP
21	Clonidine USP



For ALEMBIC PHARMACEUTICALS LTD.,

Bhaves D. Patel.
Authorized Signatory.

For Commissioner
Food & Drugs Control Administration
Gujarat State, Gandhinagar.

14 JUL 2021 To 13 JUL 2024

ALEMBIC PHARMACEUTICALS LIMITED

REGD. OFFICE : ALEMBIC ROAD, VADODARA - 390 003, INDIA • TEL : +91-265-2280550 • FAX : +91-265-2282837
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

22	Clonidine Hydrochloride USP/Ph.Eur
23	Celecoxib USP/Ph.Eur.
24	Deferasirox
25	Deferasirox Ph.Eur.
26	Erythromycin BP/USP/Ph.Eur.
27	Erythromycin Ethyl succinate USP
28	Etoricoxib
29	Famotidine Ph.Eur. /USP
30	Fenofibrate Ph.Eur./BP/USP
31	Fenofibric acid
32	Choline Fenofibrate (Fenofibric Acid Choline salt)
33	Fluoxetine Hydrochloride Ph.Eur./USP
34	Hydrochlorothiazide Ph.Eur./JP/USP
35	Irbesartan USP/Ph. Eur
36	Ivabradine Adipate
37	Ivabradine Hydrochloride
38	Lacosamide
39	Lacosamide Ph. Eur
40	Lamotrigine Ph.Eur./USP
41	Leflunomide Ph.Eur./USP
42	Lercanidipine Hydrochloride
43	Linezolid



For ALEMBIC PHARMACEUTICALS LTD.,

Bhavesh D. Patel.
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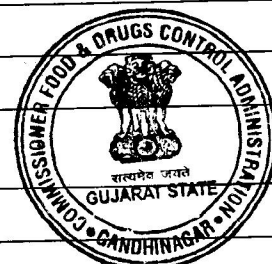
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Tal-Halol, Dist : Panchmahal

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

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

44	Linezolid USP
45	Memantine Hydrochloride
46	Memantine Hydrochloride USP
47	Meprobamate USP
48	Metoprolol Succinate Ph.Eur./USP
49	Metoprolol Tartrate USP/EP
50	Mexiletine Hydrochloride Ph.Eur./USP
51	Modafinil Ph.Eur./USP
52	O-Desmethyl Venlafaxine Succinate Monohydrate
53	Desmethyl Venlafaxine Succinate USP
54	O-Desmethyl Venlafaxine
55	Desmethyl Venlafaxine USP
56	Olmesartan Medoxomil Ph.Eur./ USP
57	Pramipexole Dihydrochloride Monohydrate Ph. Eur/ Pramipexole Dihydrochloride USP (As Monohydrate)
58	Quetiapine Fumarate USP/Ph.Eur.
59	Rivastigmine Base Ph.Eur./Rivastigmine USP
60	Rivastigmine Hydrogen Tartrate Ph. Eur
61	Rivastigmine Tartrate USP
62	Ropinirole hydrochloride USP
63	Roxithromycin JP/CP/Ph.Eur.



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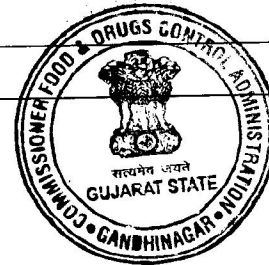
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Mfg. Lic. No. G/1050 in Form 28

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

64	Telmisartan USP/Ph.Eur/JP
65	Teriflunomide
66	Teriflunomide Ph.Eur
67	Valsartan USP/Ph.Eur.
68	Venlafaxine Hydrochloride Ph.Eur./USP
69	Vildagliptin

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