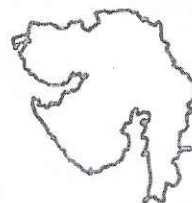




Food & Drugs Control Administration

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



Certificate No. : **1808977**

On the basis of the inspection carried out on 30-31/05/2018 & 02/08/2018 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 : **ZCL CHEMICALS LIMITED**

3102/ B, GIDC, INDUSTRIAL ESTATE, ANKLESHWAR

City : ANKLESHWAR -393 002, Dist : BHARUCH, GUJARAT STATE, INDIA

2 Manufacturer's Licence number : **G/25/1777** **G/25-F/52**

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 **12/08/2021**. 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 : 91-79-23253417, Fax : 91-79-232-53400

Date : **13/08/2018**



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

MS. SADHANA RAJESH DESAI
MANAGER



A copy of this document / CERTIFICATE
has been recorded with the Chamber

Authorized Signatory

Bombay Chamber of Commerce and Industry

Regn. No. **41964** Date **29 JUN 2019**



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

Country **REPUBLIC OF INDIA**

This public document
COMMERCIAL DOCUMENT
has been signed by **H G KOSHIA**
acting in the capacity of **COMMISSIONER**
bears the seal/stamp of **BOMBAY CHAMBER OF COMMERCE AND INDUSTRY**

Certified
at **NEW DELHI, INDIA** the **01-Jul-2019**
by **SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS**
No. **MHMC0003542819**

Seal / Stamp
is issued to **ZCL CHEMICALS LTD.**


Signature
(सुनील चनाप)
(SUKIL CHANAP)
अनुभाग अधिकारी (ओ. आर.)
Section Officer (O.A.)
सी.पी.ओ. प्रभाग - विभाग
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

Ministry of External Affairs
responsibility for the
documents.



ATTESTED BY ME

S. R. LOKHANDE
NOTARY
MUMBAI MAHARASHTRA

29 JUN 2019



Date: 05.05.2018

List of products for grant of COPP as per WHO -GMP Guidelines (For Export only)
Manufacturing License in Form 25, License No - G/25/1777 & Form 25-F, License No -G/25F/52

Sr no	Name of Product	Market
1.	Trifluoperazine Hydrochloride EP	(For Export)
2.	Trifluoperazine Hydrochloride USP	(For Export)
3.	Fluvoxamine Maleate EP	(For Export)
4.	Fluvoxamine Maleate USP	(For Export)
5.	Fluvoxamine Maleate BP	(For Export)
6.	Memantine Hydrochloride	(For Export)
7.	Memantine Hydrochloride USP	(For Export)
8.	Betahistine Hydrochloride EP	(For Export)
9.	Betahistine Hydrochloride BP	(For Export)
10.	Betahistine Hydrochloride USP	(For Export)
11.	Zaltoprofen JP	(For Export)
12.	Atomoxetine Hydrochloride	(For Export)
13.	Atomoxetine Hydrochloride EP	(For Export)
14.	Atomoxetine Hydrochloride USP	(For Export)
15.	Felbinac EP	(For Export)
16.	Felbinac BP	(For Export)
17.	Methylphenidate Hydrochloride EP	(For Export)
18.	Methylphenidate Hydrochloride USP	(For Export)
19.	Aripiprazole EP	(For Export)
20.	Aripiprazole USP	(For Export)
21.	Clozapine EP	(For Export)
22.	Clozapine BP	(For Export)
23.	Clozapine USP	(For Export)
24.	Zonisamide USP	(For Export)
25.	Quetiapine Fumarate BP	(For Export)
26.	Quetiapine Fumarate EP	(For Export)
27.	Quetiapine Fumarate USP	(For Export)
28.	Pirfenidone EP	(For Export)
29.	Pirfenidone BP	(For Export)
30.	Rivaroxaban	(For Export)
31.	Lurasidone Hydrochloride	(For Export)
32.	Eslicarbazepine acetate	(For Export)
33.	Levomepromazine Maleate EP	(For Export)
34.	Levomepromazine Maleate BP	(For Export)

For, ZCL Chemicals Limited,

Authorized Signatory.

S.B.Shah.

(Vice President- Quality)

For Commissioner
Food & Drugs Control Administration
Gujarat State

13 AUG 2018 To 12 AUG 2021

Registered office

ZCL Chemicals Ltd.

215 Atrium, "C" Wing, 8th Floor, 819-821,
Andheri Kurla Road, Chakala, Andheri (E),
Mumbai - 400 093, Maharashtra, India.

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Email: enquiries@zclchemicals.com
Web: www.zclchemicals.com

CIN : U24100MH1991PLC060748

Manufacturing

ZCL Chemicals Ltd.

Plot No. 3102/B, G.I.D.C.
Ankleshwar - 393 002.
Gujarat, India.