



Food & Drugs Control Administration

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



Certificate No. : **S-GMP/20051984**

G.M.P. CERTIFICATE

This is to certify that M/s. PRUDENCE PHARMA CHEM, PLOT NO:7407, B/H. LYKA LAB., G.I.D.C. IND. ESTATE, ANKLESHWAR- 393 002, Dist.- BHARUCH is holding valid drug manufacturing licenses in Form No. 25 bearing No. G/1656 issued by this administration under the provisions of Drugs & Cosmetics Act 1940 & Rules thereunder. Under the said licenses the firm is permitted to manufacture & sell drugs covered under the following categories.

Dosage Form (s)	Category (ies)
Bulk Drugs (APIs)	General

The firm has employed competent technical staff to undertake manufacturing & testing of the permitted drugs. They are following GOOD MANUFACTURING PRACTICES in manufacturing and testing as laid down under the REVISED SCHEDULE - M of Drugs & Cosmetics Act 1940 & Rules There under.

The manufacturing plant is subjected to inspection at suitable intervals by competent authority.

This certificate is valid from Dt : 19/05/2020 to 18/05/2022.

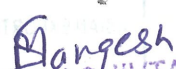



(Dr. H. G. KOSHIA)
Commissioner

Food & Drugs Control Administration
Gandhinagar, Gujarat State

Email : comfdca@gujarat.gov.in

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


MANGESH SHIVTARKAR
Accounts Assistant



ATTESTED

15 JUL 2020



ATTESTED

H. CHOWDHARY
PUBLIC NOTARY
(GOVT OF INDIA)

18 SEP 2020

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 ASIAN EXPORTERS CHAMBER OF
COMMERCE & INDUSTRY, MUMBAI

Certified
at NEW DELHI, INDIA the 21-Sep-2020
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. MHMC0003960720

Seal / Stamp is issued to PRUDENCE PHARMA CHEM

Signature



(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ आई)
Section Officer (OI)
सी. पी. वी. प्रभाग / C.P.V. Div.
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs New



ATTESTED

Swarn Lata

SWARN LATA
EXECUTIVE DIRECTOR
ASIAN EXPORTERS CHAMBER OF COMMERCE AND INDUSTRY
NAVI MUMBAI, INDIA

Ref No. 23782/20

FORM 25

(See Rule 70)

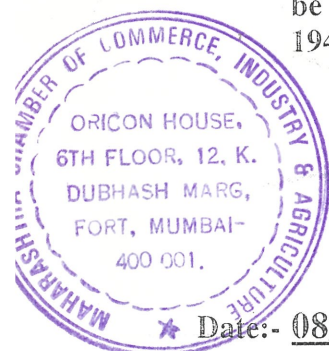
Licence to manufacture for sale (or for distribution) of drugs other than those specified in Schedule C, C(1) and XNumber of licence and date of issue G/25/1656 Date- 08/04/2015

1. 1. MR. R.D. CHODVADIYA, 2. MR. V. G. CHODVADIYA, 3. MR. N. P. CHODVADIYA, 4. MR. G. D. CHODVADIYA, 5. MR. V. N. CHODVADIYA, PARTNERS of M/s. PRUDENCE PHARMA CHEM is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in Scheduled C, C(1), and X to the Drugs & Cosmetics Rules, 1945, on the premises situated at PLOT No. - 7407, B / h. LYKA LAB., G.I.D.C. IND. ESTATE, ANKLESHWAR, DIST. - BHARUCH - 393 002.

under the direction and supervision of the following (competent technical staff):-

- (a) Competent technical staff (Names) As Per List Approved & Annexed
 (b) Names of Drugs As Per List Approved & Annexed
 (each item to be separately specified)

2. The licence authorizes the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale.
3. The licence shall be in force From: 08/04/2015 To 07/04/2020
4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940.



Signature :

Designation :

Commissioner

Food & Drugs Control Administration
Gujarat State.★ Date:- 08/05/2015**Conditions of Licence**

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the (competent technical staff) named in the licence shall be forthwith reported to the Licensing Authority.
3. If the licensee wants to manufacture for sale additional items of drugs not included above he should apply to the Licensing Authority for the necessary endorsement as provided in Rule 69(5). This licence will be deemed to extend to the categories so endorsed.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

FDCA/GUJARAT/25/899

ATTESTED

Mangesh
 MANGESH SHIVTARKAR
 Accounts Assistant

15 JUL 2020



ATTESTED

M. H. CROWDHARY
PUBLIC NOTARY
(GOVT OF INDIA)
18 SEP 2020

भारत सरकार GOVERNMENT OF INDIA
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Certified
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No. MHMC0003960620

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(SUNIL CHANAP)
अनुभाग अधिकारी (ओ आई)
Section Officer (OI)
सी. पी. वी. प्रभाग / C.P.V. DIV
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs NEW



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EXECUTIVE DIRECTOR
ASIAN EXPORTERS CHAMBER OF COMMERCE AND INDUSTRY
NAVI MUMBAI, INDIA

Ref No. 23783/20

RETENTION OF LICENCE

Retention of Licence to manufacture for sale (or for distribution) of drugs other than those specified in Schedule C, C (1) and X

Certified that Licence in Form 25, No: G/25/1656, Granted on the Date: 08/04/2015

To M/s. PRUDENCE PHARMA CHEM

for the manufacture of the following categories of drugs being drugs other than those specified in Schedule C and C (1) and "X" to the Drugs and Cosmetics Rules, 1945 at the premises situated at PLOT No. - 7407, B / h. LYKA LAB., G.I.D.C. IND. ESTATE, ANKLESHWAR - 393 002, DIST. - BHARUCH.

has been retained from: 08/04/2020 To 07/04/2025

Name(s) of drugs as retained (each item to be separately specified) : **As per list Approved & Annexed**
Names of approved competent technical staff as retained : **As per list Approved & Annexed**



Signature :

Designation :

(Dr. H. G. KOSHIA)
Commissioner,

Food & Drugs Control Administration,
Gujarat State

Date: 22/04/2020

Note: You are requested to apply for the Retention of the above licence in 3 months before its Validity Expires.



Mangesh
MANDESH SHIVTARKAR
Accounts Assistant

15 JUL 2020



ATTESTED

M. H. CHOWDHARY
PUBLIC NOTARY
(GOVT. OF INDIA)
18 SEP 2020

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Section Officer (OI)
सी. पी. डी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs New



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NAVI MUMBAI, INDIA

Ref No. 23784/20



PRUDENCE PHARMA CHEM

MFG. & EXP. : Bulk Drugs & Drugs Intermediates

List of products specified in other than C, C1, & X to be manufactured under license in Form No. 25, G/1656
Renewal for period: **08.04.2020 to 07.04.2025.**

Sr. No	No.	Name of Products	Pharmacopeias/ Specification	For DOMESTIC /EXPORT
1	A	GLIBENCLAMIDE	BP	EXPORT
	B	GLIBENCLAMIDE	EP	EXPORT
	C	GLIBENCLAMIDE [GLYBURIDE]	USP	EXPORT
	D	GLIBENCLAMIDE	IP	DOMESTIC
2	A	AMLODIPINE BESILATE	BP	EXPORT
	B	AMLODIPINE BESILATE	EP	EXPORT
	C	AMLODIPINE BESYLATE	USP	EXPORT
	D	AMLODIPINE BESYLATE	IP	DOMESTIC
3	A	GLIMEPIRIDE	BP	EXPORT
	B	GLIMEPIRIDE	EP	EXPORT
	C	GLIMEPIRIDE	USP	EXPORT
	D	GLIMEPIRIDE	IP	DOMESTIC
4	A	S-AMLODIPINE BESYLATE [=LEVAMLODIPINE BESYLATE]	-	EXPORT
	B	S-AMLODIPINE BESYLATE [=LEVAMLODIPINE BESYLATE]	IP	DOMESTIC
5	A	CELECOXIB	BP	EXPORT / DOMESTIC
	B	CELECOXIB	EP	EXPORT
	C	CELECOXIB	USP	EXPORT
6	A	ETORICOXIB	-	EXPORT
	B	ETORICOXIB	IP	DOMESTIC
7	A	SILODOSIN	JP	EXPORT
	B	SILODOSIN	-	DOMESTIC

Undertaking:

The above is the only product to be manufactured by us at present, any addition there to or deletion there from shall not be done without the prior permission of the Commissioner, Food & Drugs Control Administration, Gujarat State, Gandhinagar-India
We further declare that this products are safe for use.

ATTESTED

MANGESH SHIVTARKAR
Accounts Assistant

For, PRUDENCE PHARMA CHEM

Chuchauk

PARTNER 15 JUL 2020

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

8 APR 2020 to 7 APR 2025

Apostile

(5)

N/A
10

(5)



ATTESTED

M. H. CHAUDHARY
PUBLIC NOTARY
(GOVT OF INDIA)

18 SEP 2020

भारत सरकार GOVERNMENT OF INDIA
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विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs New



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NAVI MUMBAI, INDIA

Ref No.

23785/20