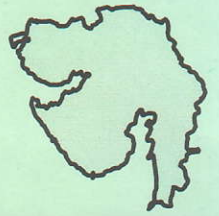




Food & Drugs Control Administration

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



Certificate No. : **S-GMP/1805809**

G.M.P. CERTIFICATE

This is to certify that M/s. **PRUDENCE PHARMA CHEM., PLOT NO:7407,BEHIND LYKA LABS G.I.D.C. IND. ESTATE, ANKLESHWAR, 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 there under. 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 : **03/05/2018** to **02/05/2020**.



(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**

FORM 25

(See Rule 70)

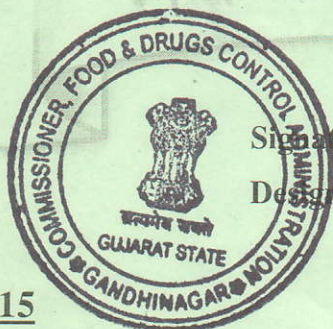
Licence to manufacture for sale (or for distribution) of drugs other than those specified in Schedule C, C(1) and XNumber of licence and date of issue G/25/1656 Date- 08/04/2015

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.



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

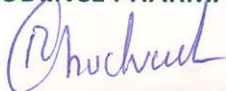
Sr. No	No.	Name of Products	Pharmacopeias/ Specification	For LOCAL/ EXPORT
1	1	GLIBENCLAMIDE	B.P.	FOR EXPORT
	2	GLIBENCLAMIDE	E.P.	FOR EXPORT
	3	GLIBENCLAMIDE [GLYBURIDE]	U.S.P.	FOR EXPORT
	4	GLIBENCLAMIDE	I.P.	FOR LOCAL
2	5	AMLODIPINE BESILATE	B.P.	FOR EXPORT
	6	AMLODIPINE BESILATE	E.P.	FOR EXPORT
	7	AMLODIPINE BESYLATE	U.S.P.	FOR EXPORT
	8	AMLODIPINE BESYLATE	I.P.	FOR LOCAL
3	9	NICLOSAMIDE	B.P.	FOR EXPORT
	10	NICLOSAMIDE	I.P.	FOR LOCAL
4	11	PROGUANIL HCL	B.P.	FOR EXPORT
	12	PROGUANIL HCL	I.P.	FOR LOCAL
5	13	FLUOXETINE HCL	B.P.	FOR EXPORT
	14	FLUOXETINE HCL	E.P.	FOR EXPORT
	15	FLUOXETINE HCL	I.P.	FOR LOCAL
6	16	FLUCONAZOLE	U.S.P.	FOR EXPORT
7	17	METAXALONE	I.N.H.	FOR EXPORT
	18	METAXALONE	I.N.H.	FOR LOCAL
8	19	S-AMLODIPINE BESYLATE	I.P.	FOR EXPORT
	20	S-AMLODIPINE BESYLATE	I.P.	FOR LOCAL

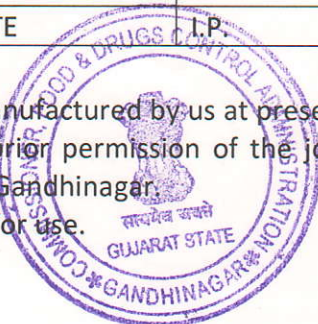
Undertaking:

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 joint Commissioner (Drugs), Food & Drugs Control Administration, Gujarat State, Gandhinagar.

We declare that the products are safe for use.

FOR, PRUDENCE PHARMA CHEM


AUTHORIZE SIGNATORY /PARTNER




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

- 8 APR 2015 to 7 APR 2020