



No: WHO-GMP/1705075/ /B
Commissioner 50300
Food & Drugs Control Administration,
Gujarat State, Dr. Jivraj Mehta Bhavan,
Block No.8, 1st floor, Gandhinagar
Date :

06 MAY 2017

To,
M/s. DY-MACH PHARMA,
C-1 / 2343-46 IIIRD PHASE,,GIDC,
VAPI,
DIST- VALSAD.

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

Sir,

Ref:- Your letter Dated : 28-12-2016

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/1705075/2017/ /B Gandhinagar Date: - -2017

Copy forwarded to :-

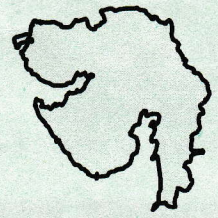
1. Assistant Commissioner, VALSAD
2. Copy to Dy. Drugs Controller , CDSCO, Air Cargo Complex, Ahmedabad
3. G-Branch.

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. : **1705075**

On the basis of the inspection carried out on **22-23/02/2017 & 03/05/2017** 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 : **DY-MACH PHARMA.**

C-1 / 2343-46 IIIRD PHASE,, GIDC, AT & POST- VAPI

City : VAPI, Dist : VALSAD,

GUJARAT STATE, INDIA

2 Manufacturer's Licence number :

G/445

G/201

3 Table : 1

Dosage Form (s)	Category (ies)	Activity (ies)
Bulk Drugs (APIs)	General	Manufacturer
Bulk Drugs (APIs)	Sex Hormones	

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 **05/05/2019**. 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

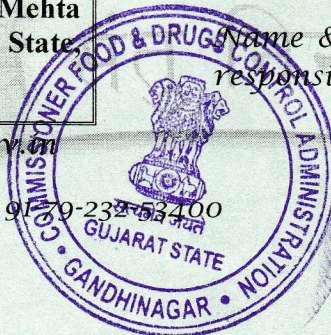
Food & Drugs Control Administration,
Block No. 8, 1ST floor, Dr. Jivraj Mehta
Bhavan, Gandhinagar, Gujarat State,
India. – Pin : 382010

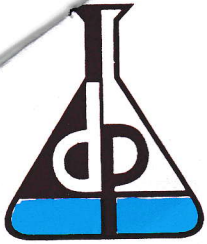
Name & function of : **(Dr.H.G.KOSHIA)**
responsible Person **Commissioner**

Email : comfdca@gujarat.gov.in

Phone : 91-79-23253417, Fax : 91-79-23253400

Date : **06/05/2017**





ISO 9001-2008
Quality Management System
CERT. NO. QMS-K12074

Phone : 0091-22-2683 3227
0091-22-6570 2850
Fax : 0091-22-2682 4225
E-mail : dymach@vsnl.com

dy-mach pharma

(Govt. Recognize Export House)

Manufacturers of Bulk Drugs and Drug Intermediate


Office : B-12, Anand Sagar, Old Nagardas Road, Andheri (East), Mumbai - 400 069. INDIA
Factory : C-1 / 2343 - 46, Illrd Phase, G.I.D.C., VAPI-396195 (GUJARAT). INDIA

List of product for Grant of COPP s per WHO GMP Guideline

Licence in form 25 Lic. No. – G/445
Licence in form 28 Lic. No. – G/201

#	NAME OF PRODUCT
1	DANAZOLE I.P. / U.S.P.
2	NIFEDIPINE I.P. / B.P. / U.S.P.
3	CLOMIPHENE CITRATE I.P. / B.P. / U.S.P.
4	SULPHAMETHIZOL B.P. / U.S.P.
5	AMISULPRIDE I.P. / B.P.

For DY-MACH PHARMA


General Manager
(Prashant M. Parikh)




For, Commissioner
Food & Drugs Control Administration
Gujarat State,

6 MAY 2017

5 MAY 2019