

L. Dis. No.: 1655/E(R)/TS/2018

Dated: 28-06-2018

To

M/s. MYLAN LABORATORIES LTD (Unit 7),
Plot No. 14, 99 & 100, IDA, Pashamylaram,
Phase-II, Patancheru, Sangareddy District – 502307,
Telangana, India.

Sirs,

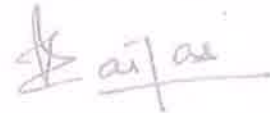
Sub:- Drugs and Cosmetics Act, 1940 and Rules made thereunder-
Issue of **World Health Organization Good Manufacturing Practice**
Certificate- Regarding.

Ref:- 1. Your application dt. 19-02-2018
2. CDSCO Ref.No.5-6(100 A2)/HZ/2017-18/2415-16 dated 12-06-2018
3. Joint Inspection dt. 26/2/2018 & 27/2/2018

With reference to your application cited, I forward herewith the **WORLD HEALTH ORGANISATION GOOD MANUFACTURING PRACTICE** Certificate for the products mentioned in the Joint Inspection Report of the Officers of Drug Control Administration, Hyderabad, Telangana and CDSCO, Zonal Office vide reference 3rd cited.

This certificate is valid for a period of **Three years** from the date of issue.

Yours faithfully,



T. KAILASAM
Joint Director & Licensing Authority

Date: 29-6-18



026792

ATTESTED

Gur Singh Dharwal
Executive Assistant

PHD Chamber of Commerce and Industry
New Delhi (INDIA)



TRUE COPY ATTESTED

YOGENDRA SINGH
NOTARY NOIDA
G.B. NAGAR (U.P.) INDIA

Page 1 of 3



17 JUL 2018



भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
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accepts no responsibility for the
contents of the above documents.

This public document of the type
COMMERCIAL DOCUMENT

is issued to MYLAN LABORATORIES LTD.

has been signed by GUR SINGH DHARWAL

with the seal / stamp of EXEC. ASSTT. PHD CHAMBER OF
COMMERCE AND INDUSTRY, NEW DELHI

Certified by

Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS

on 18-Jul-2018 at NEW DELHI, INDIA

with reference no. DLND0023573818

Seal / Stamp

Signature



(देबाब्रत पाल)
(DEBABRATA PAUL)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (O.I.)
श्री पी. वी. प्रसाद/C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi

प्रमाणित किया जाता है कि
यह दस्तावेज़ (Document)
सही है।

L. Dis. No.:1655/E(R)/TS/2018

Dated: -06-2018

LIST OF PRODUCTS APPROVED UNDER WHO GMP
CERTIFICATION SCHEME FOR EXPORT PURPOSE

S.No.	Name of the Product	Specification
1.	Acyclovir / Aciclovir	USP/BP/Ph.Eur/JP
2.	Alprazolam	USP/Ph.Eur
3.	Amlodipine Besilate / Amlodipine Besylate	USP/Ph.Eur
4.	Asenapine Maleate	IH
5.	Armodafinil	IH
6.	Azelnidipine	IH
7.	Cetirizine Hydrochloride / Cetirizine Dihydrochloride	USP/Ph.Eur
8.	Clarithromycin	USP/Ph.Eur
9.	Cyclobenzaprine Hydrochloride	USP
10.	Desloratadine	IH/Ph.Eur
11.	Dexlansoprazole Amorphous	IH
12.	Dronedarone Hydrochloride	IH
13.	Fluconazole	USP/Ph.Eur
14.	Irbesartan	USP/Ph.Eur
15.	Itraconazole	USP/Ph.Eur
16.	Labetalol Hydrochloride	USP/Ph.Eur
17.	Lamotrigine	USP/Ph.Eur
18.	Lansoprazole	USP/Ph.Eur
19.	Loratadine	USP/Ph.Eur
20.	Losartan Potassium	USP/Ph.Eur
21.	O-Desmethyl Venlafaxine Succinate	IH
22.	O-Desmethyl Venlafaxine Fumarate	IH
23.	Omeprazole Magnesium	USP/Ph.Eur
24.	Oxybutynin Chloride / Oxybutynin Hydrochloride	USP/Ph.Eur
25.	Paliperidone	IH
26.	Perindopril Arginine	IH
27.	Perindopril Tert-Butylamine	Ph.Eur
28.	Pitavastatin Calcium	IH
29.	Prothionamide	IH
30.	Rabeprazole Sodium	IH
31.	Risperidone	USP/Ph.Eur
32.	Rizatriptan Benzoate	IH/USP/Ph.Eur
33.	Rosuvastatin Calcium	IH
34.	Telmisartan	USP/Ph.Eur
35.	Temazepam	USP
36.	Tetrabenazine	IH
37.	Valacyclovir Hydrochloride	USP/Ph.Eur
38.	Zolmitriptan	IH

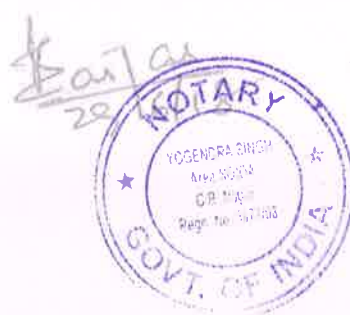


ATTESTED

Gur Singh Dharwal
Executive Assistant

PHD Chamber of Commerce and Industry
New Delhi (INDIA)

026782



TRUE COPY ATTESTED

YOGENDRA SINGH
NOTARY Noida
G.B. NAGAR (U.P.) INDIA

17 JUL 2018



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COMMERCE AND INDUSTRY, NEW DELHI

Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 18-Jul-2018 at NEW DELHI, INDIA

with reference no. DLND0023574018

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(देबाबरात पॉल)
(DEBABRATA PAUL)
अधुनाग अधिकारी (ओ.आई.)
Section Officer (O.I.)
सी.पी.वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi



DRUGS CONTROL ADMINISTRATION
Government of Telangana



L. Dis. No.: 1655/E(R)/TS/2018

Dated: 29-06-2018

Manufacturer : Mylan Laboratories Limited (Unit 7)
Plot No. 14, 99 & 100, IDA, Pashamylaram,
Phase-II, Patancheru, Sangareddy District-502307,
Telangana, India.

When applicable : Placing the products on the market
as above:

It is certified that the above products had been authorized to be placed on the market for use
in the country and exporting countries.

Drug License No. : 108/MD/AP/97/B/R dated 30-09-1997
Under Form- 25 Valid till 19-05-2023

It is also Certified that (a) the manufacturing plant in which the products are produced is
subject to inspection at suitable intervals.

The Unit M/s.Mylan Laboratories Limited (Unit 7), Plot No. 14, 99 & 100, IDA,
Pashamylaram, Phase-II, Patancheru, Sangareddy District - 502307, Telangana, India. was
Jointly inspected by Mr. Bikramaditya Chowdhury, Drugs Inspector, CDSCO, Hyderabad and
Sri. Ch.Karthik Siva Chaitanya, Drugs Inspector, R.C.Puram(Mfg.), Drugs Control
Administration, Hyderabad on 26-02-2018 & 27-02-2018.

The manufacturer conforms to requirements for Good Manufacturing Practices in the
manufacture and Quality control (As recommended by the World Health Organization) in
respect of products mentioned above 38 Products (Thirty eight Products) to be sold or
distributed with in the country of origin (or to be exported).



This certificate is valid for a period of **Three years** from the date of issue.



Yours faithfully,

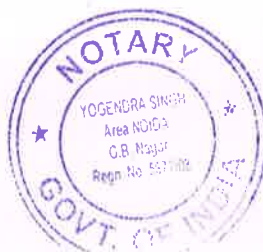
T. Kailasam
29/6/18
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Joint Director & Licensing Authority

Date: 29-06-2018
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ATTESTED
Gur Singh Dharwal
Executive Assistant
PWD Chamber of Commerce and Industry
New Delhi (INDIA)



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Yogendra Singh
YOGENDRA SINGH
NOTARY NOIDA
G.B. NAGAR (U.P.) INDIA

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17 JUL 2018

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 (DEBABRATA PAUL)
 अनुभाग अधिकारी (ओ.आई.)
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