

7-5/2013/EU/WC-0117
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 29 JUL 2019

To
M/s. Mylan Laboratories Ltd.,
Unit-7, Plot No. 14, 99, &100, IDA
Pashamylaram, Phase-II, Patancheru,
Sangareddy 502 307, Telangana, India.

SUB: Written Confirmation of M/s. Mylan Laboratories Ltd., Unit-7, Plot No. 14, 99, &100 IDA Pashamylaram, Phase-II, Patancheru, Sangareddy District 502307, Telangana, India as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India-reg.

Sir,

Please refer to your application submitted to CDSCO, Hyderabad Zone and the recommendation received from DDC (I), Hyderabad zone on the above noted subject.

Written Confirmation as required for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India is herewith granted subject to the following conditions:-

1. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).
2. The manufacturer is subject to regular, strict and transparent controls and to the effective enforcement of Good Manufacturing Practice, including repeated and unannounced inspections, so as to ensure a protection of public health equivalent to that in the EU.
3. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.
4. Written Confirmation shall be produced by the Authorized Exporter as and when required, by the Drug Regulatory Authority.
5. The Written Confirmation will be withdrawn in the events of non-compliance of Standards.
6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.

7. In the event of any Non-Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt of report.

8. In the event of any drug found not of standard quality, the same shall be reported to this office within 7 days of receipt of report.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid upto
01	29	29 JUL 2019	Three years from the date of issue

Yours faithfully,



(Dr. S. Eswara Reddy)
Drugs Controller General (India)



GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

WC-0117

CERTIFICATE NO. :

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s. Mylan Laboratories Limited,
Unit-7, Plot No. 14, 99, &100, IDA,
Pashamylaram, Phase-II, Patancheru,
Sangareddy District 502 307, Telangana, India.

2. Manufacturer's license Number: 108/MD/AP/97/B/R

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

As per list Annexed

The issuing Regulatory Authority hereby confirms that:

The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7):

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of Inspection of the plant: 06th & 07th June 2019

The Written Confirmation remains valid until: (03) Three years from the date of issue.

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority: Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road,
New Delhi- 110 002, India.

Name and function of responsible person: Dr.S.Eswara Reddy.
Drugs Controller General (India).

E-mail:

Telephone no.:

Fax no.:

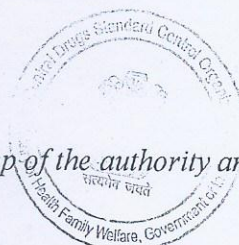
dcic@nic.in,

+91-11-23236965

+91-11-23236973


Signature

Stamp of the authority and date



20 JUN 2019



CERTIFICATE NO. :

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s. Mylan Laboratories Limited.,
Unit-7, Plot No. 14, 99, &100, IDA
Pashamylaram, Phase-II, Patancheru,
Sangareddy Dist. 502 307,
Telangana, India.

List of APIs:

Sl.No.	Name of the active substances	Activitie(s)
1.	Aciclovir Ph.Eur	Manufacturing and Packing
2.	Acyclovir USP	Manufacturing and Packing
3.	Alprazolam USP/ Ph. Eur	Manufacturing and Packing
4.	Almotriptan Malate IH	
5.	Amlodipine Besilate Ph. Eur	Manufacturing and Packing
6.	Amlodipine Besylate USP	Manufacturing and Packing
7.	Armodafinil IH	Manufacturing and Packing
8.	Asenapine Maleate IH	Manufacturing and Packing
9.	Clarithromycin Ph. Eur/ USP	Manufacturing and Packing
10.	Loratadine USP/Ph. Eur	Manufacturing and Packing
11.	Losartan Potassium Ph.Eur/USP	Manufacturing and Packing
12.	Nepafenac IH	Manufacturing and Packing
13.	Oxybutynin Hydrochloride Ph. Eur	Manufacturing and Packing
14.	Paliperidone IH	Manufacturing and Packing
15.	Parecoxib Sodium IH	Manufacturing and Packing
16.	Perindopril Arginine IH	Manufacturing and Packing
17.	Perindopril Erbumine Ph.Eur	Manufacturing and Packing
18.	Pioglitazone Hydrochloride USP/EP.	Manufacturing and Packing
19.	Pitavastatin Calcium IH	Manufacturing and Packing
20.	Rabeprazole Sodium IH	Manufacturing and Packing
21.	Risperidone USP/Ph.Eur	Manufacturing and Packing
22.	Rizatriptan Benzoate USP/Ph.Eur	Manufacturing and Packing
23.	Rosuvastatin Calcium IH	Manufacturing and Packing



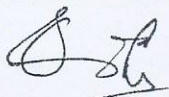
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Sl.No.	Name of the Active Substances	Activitie(s)
24	Telmisartan USP/Ph.Eur	Manufacturing and Packing
25	Tetrabenazine IH	Manufacturing and Packing
26	Valacyclovir Hydrochloride USP	Manufacturing and Packing
27	Valacyclovir Hydrochloride Hydrated Ph. Eur	Manufacturing and Packing
28	Zoledronic Acid IH	Manufacturing and Packing
29	Zolmitriptan IH	Manufacturing and Packing

ITEM(S) Twenty Nine (29) Only

The Written Confirmation remains valid until: (03)Three Years from the date of Issue


Signature


Stamp of the authority and date

29 JUL 2019