F. No: 7-5/2013/EU/WC-0015
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi- 110 002.
Dated: 03 JUN 2019

To
M/s Mylan Laboratories Limited.,
Unit-8, G.Chodavaram (V),
Pusapatirega (M),
Vizianagaram-535204,
Andhra Pradesh, India.

Sub: Written Confirmation of M/s Mylan Laboratories Limited.,Unit-8, G.Chodavaram Village, Pusapatirega(M),Vizianagaram-535204, Andhra Pradesh, 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 Zonal office 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 The Written Confirmation will be withdrawn in the event of non-compliance of Standards.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 up to
01.	33	03 JUN 2019	Three years from the date of issue
02	04	03 JUN 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-015

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-8, G.Chodavaram Village,
Pusapatirega Mandal,
Vizianagaram-535204,
Andhra Pradesh, India.

2. Manufacturer's license number: 177/VN/AP/96/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 enclosed as Annexure- 01 & 02

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: 25th & 26th July 2018.

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: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

Stamp of the authority and date

03 JUN 2019

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

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-8, G.Chodavaram Village,
Pusapatirega (M),Vizianagaram-535204,
Andhra Pradesh, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Abacavir Sulfate USP/Ph.Eur	Manufacturing & Packing
2.	Alendronate Sodium USP/Ph.Eur	Manufacturing & Packing
3.	Allopurinol USP/Ph.Eur	Manufacturing &Packing
4.	Ambrisentan IH	Manufacturing &Packing
5.	Atazanavir Sulfate IH	Manufacturing &Packing
6.	Atorvasatatin Calcium Trihydrate Ph.Eur	Manufacturing & Packing
7.	Baclofen USP/Ph.Eur	Manufacturing & Packing
8.	Canagliflozin IH	Manufacturing & Packing
9.	Clozapine USP/Ph.Eur	Manufacturing &Packing
10.	Cetirizine Hydrochloride USP/Ph.Eur	Manufacturing & Packing
11.	Deferasirox IH	Manufacturing &Packing
12.	Efavirenz IH/USP	Manufacturing &Packing
13.	Gabapentin USP/Ph.Eur	Manufacturing &Packing
14.	Lamivudine USP/Ph.Eur	Manufacturing &Packing
15.	Lanthanum Carbonate IH	Manufacturing &Packing
16.	Linagliptin IH	Manufacturing &Packing
17.	Memantine Hydrochloride IH	Manufacturing &Packing
18.	Nabumetone Ph.Eur	Manufacturing &Packing
19.	Naproxen Sodium USP/Ph.Eur	Manufacturing &Packing
20.	Pantoprazole Sodium USP	Manufacturing &Packing
21.	Pantoprazole Sodium Sesquihydrate Ph.Eur	Manufacturing &Packing
22.	Propafenone Hydrochloride USP/Ph.Eur	Manufacturing &Packing
23.	Risedronate Sodium USP	Manufacturing &Packing
24.	Risedronate Sodium 2.5 Hydrate Ph.Eur	Manufacturing &Packing
25.	Ritonavir USP/Ph.Eur	Manufacturing &Packing
26.	Slidenafil Citrate USP/Ph.Eur	Manufacturing &Packing

GOVERNMENT OF INDIA
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S. No.	Active substance(s)	Activity(ies)
27	Sildenafil IH	Manufacturing & Packing
28	Sofosbuvir IH	Manufacturing & Packing
29	Tenofovir Disoproxil Fumarate IH	Manufacturing & Packing
30	Tiaprofenic Acid Ph.Eur	Manufacturing &Packing
31	Trazadone Hydrochloride USP/BP	Manufacturing &Packing
32	Varenicline Tartrate IH	Manufacturing &Packing
33	Quetiapine Fumarate USP/Ph.Eur	Manufacturing &Packing

Item (s) (033)Thirty Three Only

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

Signature

Stamp of the authority and date

03 JUN 2019

Annexure – 02
WC-015

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

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-8, G.Chodavaram Village,
Pusapatirega (M), Vizianagaram-535204,
Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1	Cobicistat on Silicondioxide IH	Manufacturing & Packing
2	Daclatasvir Dihydrochloride IH	Manufacturing & Packing
3	Ledipasvir IH	Manufacturing &Packing
4	Velpatasvir IH	Manufacturing &Packing

ITEM(S) Four (04) Only

This certificate is being issued subject to condition that the firm shall obtain NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substances for the purpose of export only, as the above mentioned active substances are not approved for manufacture or sale in India.

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

Signature

Stamp of the authority and date

03 JUN 2019