7-5/2013/EU/WC-0118
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 05 AUG 2019

To,

M/s. Mylan Laboratories Limited.,
Unit-1, Survey No. 10, Gaddapotharam (V),
Kazipally Industrial Area, Jinnaram (M),
Sangareddy Dist.-502319, Telangana State, India

SUB:- Written Confirmation of M/s. Mylan Laboratories Limited., Unit-1, Survey No. 10, Gaddapotharam (V), Kazipally Industrial Area, Jinnaram (M),Sangareddy Dist.-502319, Telangana State, 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 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	32	05 AUG 2019	Three years from the date of issue
02	02	05 AUG 2019	Three years from the date of issue

Yours faithfully,

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

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

CERTIFICATE NO. : WC-0118

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-1, Survey No. 10, Gaddapotharam (V),
Kazipally Industrial Area, Jinnaram (M),
Sangareddy Dist.-502319, Telangana State, India

2. Manufacturer's licence number 18/MD/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 and Annexure- 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: 17-18/09/2018

The Written Confirmation remains valid until: 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: dcg@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

Stamp of the authority and date

05 AUG 2019

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

Annexure-01

CERTIFICATE NO. : WC-0118

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-1, Survey No. 10, Gaddapotharam (V),
Kazipally Industrial Area, Jinnaram (M),
Sangareddy Dist.-502319, Telangana State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Atomoxetine Hydrochloride Ph.Eur/USP	Manufacturing & Packing
2.	Bosentan Monohydrate IH	Manufacturing & Packing
3.	Clindamycin Palmitate Hydrochloride USP	Manufacturing & Packing
4.	Clopidogrel Hydrogen Sulfate Ph.Eur	Manufacturing & Packing
5.	Darunavir IH	Manufacturing & Packing
6.	Duloxetine Hydrochloride Ph.Eur/USP	Manufacturing & Packing
7.	Efavirenz USP/IH	Manufacturing & Packing
8.	Eletriptan Hydrobromide IH	Manufacturing & Packing
9.	Ezetimibe IH/USP	Manufacturing & Packing
10.	Gatifloxacin IH	Manufacturing & Packing
11.	Lamivudine USP/Ph.Eur	Manufacturing & Packing
12.	Lopinavir USP	Manufacturing & Packing
13.	Montelukast Sodium Ph.Eur	Manufacturing & Packing
14.	Moxifloxacin hydrochloride Ph.Eur	Manufacturing & Packing
15.	Nadolol USP/Ph.Eur	Manufacturing & Packing
16.	Nevirapine anhydrous Ph.Eur	Manufacturing & Packing
17.	Olmesartan Medoxomil Ph.Eur/USP/JP	Manufacturing & Packing
18.	Paroxetine Hydrochloride anhydrous USP/Ph.Eur	Manufacturing & Packing
19.	Paroxetine Hydrochloride Hemihydrate Ph.Eur	Manufacturing & Packing
20.	Pregabalin IH	Manufacturing & Packing
21.	Quetiapine Fumarate Ph.Eur/IH	Manufacturing & Packing
22.	Quinapril Hydrochloride USP	Manufacturing & Packing
23.	Raltegravir Potassium IH	Manufacturing & Packing
24.	Sitagliptin Phosphate IH	Manufacturing & Packing
25.	Sumatriptan Succinate USP/Ph.Eur	Manufacturing & Packing
26.	Tenofovir Disoproxil Fumarate IH	Manufacturing & Packing
27.	Valganciclovir Hydrochloride USP	Manufacturing & Packing
28.	Voriconazole Ph.Eur	Manufacturing & Packing
29.	Zidovudine USP/Ph.Eur	Manufacturing & Packing
30.	Zolpidem Tartrate USP/Ph.Eur	Manufacturing & Packing
31.	Desmopressin Ph.Eur	Manufacturing & Packing
32.	Tolmetin Sodium Dihydrate USP	Manufacturing & Packing

ITEM(S) Thirty Two (32) ONLY

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

Signature

Stamp of the authority and date

05 AUG 2019

Annexure-02

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

CERTIFICATE NO. : WC-0118

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-1, Survey No. 10, Gaddapotharam (V),
Kazipally Industrial Area, Jinnaram (M),
Sangareddy Dist.-502319, Telangana State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Fosamprenavir Calcium IH	Manufacturing & Packing
2.	Atovaquone USP/Ph.Eur	Manufacturing & Packing

ITEM(S) Two (02) ONLY

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

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

Signature

Stamp of the authority and date

05 AUG 2019