

**7-5/2013/EU/WC-0157**  
**Government of India**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organisation**  
**(International Cell)**

FDA Bhawan, Kotla Road,  
New Delhi-110002

Dated: **11 OCT 2019**

To

**M/s. Mylan Laboratories Ltd.,  
1A/2, M.I.D.C. Industrial Estate,  
Panvel, Taloja, Dist. Raigad- 410 208,  
Maharashtra State, India**

**Subject:- Written Confirmation of M/s. Mylan Laboratories Ltd., 1A/2, M.I.D.C. Industrial Estate, Panvel, Taloja, Dist. Raigad- 410 208, Maharashtra 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, West Zone office Mumbai and the recommendation received from DDC(I), West Zone Mumbai 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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.

o/c

Annexure No.	No. of Products	Date of Issue	Valid Upto
1	21	11 OCT 2019	02.07.2022
2	07	11 OCT 2019	02.07.2022

Yours faithfully,

*V.G.*  
(Dr. V.G. Somani)  
Drugs Controller General (India)

*Admission*  
02/10/19

*P*  
09-10-19  
*N*



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

CERTIFICATE NO. : WC-0157

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 Ltd.,  
1A/2, M.I.D.C. Industrial Estate,  
Panvel, Talaja, Dist. Raigad- 410 208,  
Maharashtra State, India**

2. Manufacturer's license number: 25-KD/415

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-1 & 2**

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: 10.08.2018**

**The Written Confirmation remains valid until: 02<sup>nd</sup> July, 2022**

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. V.G. Somani  
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



11 OCT 2019



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

CERTIFICATE NO. :

Annexure-1  
WC-0157

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

Name and address of site: **M/s. Mylan Laboratories Ltd.,  
1A/2, M.I.D.C. Industrial Estate,  
Panvel, Talaja, Dist. Raigad- 410 208,  
Maharashtra State, India**

**List of APIs:**

S. No.	Active substance(s)	Activity(ies)
1.	Adefovir Dipivoxil IH	Manufacturing & Packing
2.	Bosentan IH	Manufacturing & Packing
3.	Formoterol Fumarate Dihydrate Ph. Eur/USP	Manufacturing & Packing
4.	Lenalidomide IH	Manufacturing & Packing
5.	Letrozole USP/Ph.Eur	Manufacturing & Packing
6.	Pramipexole Dihydrochloride Monohydrate Ph.Eur	Manufacturing & Packing
7.	Proguanil Hydrochloride USP/Ph.Eur	Manufacturing & Packing
8.	(S)-Pregabalin IH	Manufacturing & Packing
9.	Rasagiline Mesylate IH	Manufacturing & Packing
10.	Rivastigmine IH/Ph.Eur/USP	Manufacturing & Packing
11.	Salmeterol Xinafoate USP/Ph.Eur	Manufacturing & Packing
12.	Sunitinib Malate IH	Manufacturing & Packing
13.	Febuxostat IH	Manufacturing & Packing
14.	Fluticasone Propionate USP	Manufacturing & Packing
15.	Dimethyl Fumarate IH	Manufacturing & Packing
16.	Prasugrel Hydrochloride IH	Manufacturing & Packing
17.	Thiotepa USP	Manufacturing & Packing
18.	Roflumilast IH	Manufacturing & Packing
19.	Rivastigmine Hydrogen Tartrate Ph.Eur	Manufacturing & Packing
20.	Saxagliptin Hydrochloride Dihydrate IH	Manufacturing & Packing
21.	Tolvaptan IH	Manufacturing & Packing

**ITEM(S) Twenty One (21) ONLY**

The Written Confirmation remains valid until: **02<sup>nd</sup> July, 2022**

Signature

*[Handwritten Signature]*

Stamp of the authority and date



11 OCT 2019

*[Handwritten Signature]*  
07/10/19

*[Handwritten Signature]*  
04-10-19

*[Handwritten Signature]*



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

CERTIFICATE NO. : Annexure-2  
WC-0157

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

Name and address of site: M/s. Mylan Laboratories Ltd.,  
1A/2, M.I.D.C. Industrial Estate,  
Panvel, Talaja, Dist. Raigad- 410 208,  
Maharashtra State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Palbocicib IH	Manufacturing & Packing
2.	Fingolimod Hydrochloride IH	Manufacturing & Packing
3.	Rotigotine IH	Manufacturing & Packing
4.	Zofenopril Calcium IH	Manufacturing & Packing
5.	Macitentan IH	Manufacturing & Packing
6.	Prasugrel Besylate IH	Manufacturing & Packing
7.	Epinephrine Bitartrate USP	Manufacturing & Packing

ITEM(S) Seven (07) 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 for sale in India.

The Written Confirmation remains valid until: 02<sup>nd</sup> July, 2022

Signature

*[Handwritten Signature]*  
07/10/19

*[Handwritten Signature]*  
09-10-19

Stamp of the authority and date



11 OCT 2019