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: 13 AUG 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	29.07.2019	28.07.2022
02	10	13 AUG 2019	28.07.2022
03	05	13 AUG 2019	28.07.2022

Yours faithfully,

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

o/c 7.8.2019

13/08/19

Annexure-02
WC-0117

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-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	Blonanserin IH	Manufacturing and Packing
2	Cetirizine Dihydrochloride Ph. Eur	Manufacturing and Packing
3	Cetirizine Hydrochloride USP	Manufacturing and Packing
4	Cyclobenzaprine Hydrochloride USP	Manufacturing and Packing
5	Desloratadine Ph.Eur	Manufacturing and Packing
6	Fluconazole Ph. Eur/ USP	Manufacturing and Packing
7	Irbesartan Ph.Eur/ USP	Manufacturing and Packing
8	Itraconazole Ph. Eur	Manufacturing and Packing
9	Lamotrigine USP/Ph. Eur	Manufacturing and Packing
10	Lansoprazole USP/Ph.Eur	Manufacturing and Packing

ITEM(S) Ten (10) Only

The Written Confirmation remains valid until: 28.07.2022

Signature

Stamp of the authority and date

13 AUG 2019

o/c 7.8.2019

07/08/19

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

Annexure-03
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.

List of APIs:

S. No.	Name of the Active substance(s)	Activitie(s)
1	Azelnidipine IH	Manufacturing & Packing
2	O-Desmethyl Venlafaxine Fumarate IH	Manufacturing & Packing
3	O-Desmethyl Venlafaxine Succinate IH	Manufacturing & Packing
4	Dexlansoprazole Sesquihydrate IH	Manufacturing & Packing
5	Dexlansoprazole (Amporphous) IH	Manufacturing & Packing

ITEM(S) Five (05) 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: 28.07.2022

Signature

Stamp of the authority and date

13 AUG 2019

o/c 7.08.2019