7-5/2013/EU/WC-0016
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 26 JUN 2019

To,

M/s. Mylan Laboratories Ltd (Unit-IX),
Plot No. 5, Road No. 12,
Jawaharlal Nehru Pharma City,Tadi (V),
Visakhapatnam District, Andhra Pradesh, India

SUB:- Written Confirmation of M/s. Mylan Laboratories Ltd (Unit-IX), Plot No. 5, Road No. 12, Jawaharlal Nehru Pharma City, Tadi (V), Visakhapatnam District, 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 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
1	16	26 JUN 2019	Three years from the date of issue

Yours faithfully,

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

18-6-19

19/06/19

Annexure-1

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

WC-0016

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 Ltd (Unit-IX),
Plot No. 5, Road No. 12,
Jawaharlal Nehru Pharma City,Tadi (V),
Visakhapatnam District, Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Celecoxib USP/Ph.Eur	Manufacturing & Packing
2.	Dipyridamole USP/Ph.Eur	Manufacturing & Packing
3.	Emtricitabine IH	Manufacturing & Packing
4.	Etoricoxib IH	Manufacturing & Packing
5.	Etravirine IH	Manufacturing & Packing
6.	Levofloxacin USP	Manufacturing & Packing
7.	Levofloxacin Hemihydrates IH	Manufacturing & Packing
8.	Lumefantrine USP	Manufacturing & Packing
9.	Milnacipran Hydrochloride IH	Manufacturing & Packing
10.	Pantoprazole Sodium USP	Manufacturing & Packing
11.	Pantoprazole Sodium Sesquihydrate Ph.Eur	Manufacturing & Packing
12.	Piperaquine Tetra Phosphate IH	Manufacturing & Packing
13.	Sevelamer Carbonate IH	Manufacturing & Packing
14.	Sertraline Hydrochloride USP/Ph.Eur	Manufacturing & Packing
15.	Sildenafil Citrate USP/Ph.Eur	Manufacturing & Packing
16.	Zidovudine USP/Ph.Eur	Manufacturing & Packing

ITEM(S) Sixteen (16) ONLY

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

Signature

18-6-19

Stamp of the authority and date

Central Drugs Standard Control Organization
सत्यमेव जयते
Ministry of Health & Family Welfare, Government of India

26 JUN 2019