F. No: 7-5/2016/EU/WC-0359
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi- 110 002.
Dated: 21 MAY 2019

To

M/s Mylan Laboratories Limited.,
Unit-10, Plot No: 86, Ramky Pharma City (I) Ltd.
SEZ, Jawaharlal Nehru Pharma City
Parawada (M), Visakhapatnam Dist-531019.
Andhra Pradesh, India.

Sub:-Written Confirmation of M/s Mylan Laboratories Limited., Unit-10, Plot No: 86,Ramky Pharma City (I) Ltd., SEZ, Jawaharlal Nehru Pharma City, Parwada (M),Visakhapatnam Dist-531019, 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 The Written Confirmation will be withdrawn in the event of non-compliance of Standards.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.	04	21 MAY 2019	Three years from the date of issue
02	02	21 MAY 2019	Three years from the date of issue

Yours faithfully,

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

s/c

14.5.19

15-5-19

17.05.19

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

CERTIFICATE NO. :

Annexure – 02
WC-359

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-10, Plot No: 86, Ramky Pharma City (I) Ltd.,
SEZ, Jawaharlal Nehru Pharma City,
Parawada (M),Visakhapatnam, Dist-531019.
Andhra Pradesh, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1	Tenofovir Disoproxil Orotate IH	Manufacturing & Packing
2	Tenofovir Disoproxil Maleate IH	Manufacturing &Packing

ITEM(S) Two (02) 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

21 MAY 2019

14.5.19.

15-5-19

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

CERTIFICATE NO. : WC-359

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-10, Plot No: 86, Ramky Pharma City (I) Ltd.,
SEZ, Jawaharlal Nehru Pharma City,
Parawada (M), Visakhapatnam Dist-531019.
Andhra Pradesh, India.

2. **Manufacturer's license number**: 34/VP/AP/2012/B/G

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: 16th &17th 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

21 MAY 2019

o/c 14.5.19

15-5-19

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

CERTIFICATE NO. :

Annexure – 01
WC-0359

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-10, Plot No: 86,Ramky Pharma City (I) Ltd.,
SEZ, Jawaharlal Nehru Pharma City
Parawada (M), Visakhapatnam Dist-531019.
Andhra Pradesh, INDIA.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1	Citalopram Hydrobromide USP/Ph.Eur	Manufacturing & Packing
2	Abacavir Sulfate USP	Manufacturing & Packing
3	Carvedilol USP/Ph.Eur	Manufacturing &Packing
4	Carvedilol Phosphate IH	Manufacturing &Packing

ITEM(s) Four (04) Only

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

Signature

Stamp of the authority and date

21 MAY 2019

14.5.19.

15-5-19

17/05/19