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:

To 22 JUN 2022

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 online application no. WC/RE/2022/3877 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	42	22 JUN 2022	28.07.2025
02	03	22 JUN 2022	28.07.2025

Yours faithfully,

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

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

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.

2. Manufacturer's license Number:108/MD/AP/97/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 Annexed

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: 29.06.2021 & 30.06.2021

The Written Confirmation remains valid until: 28.07.2025

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

Stamp of the authority and date

Signature

22 JUN 2022

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

Annexure-01
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 Dist. 502 307, Telangana, India.

List of APIs:

Sl.No.	Name of the active substances	Activitie(s)
1.	Aciclovir Ph.Eur	Manufacturing and Packing
2.	Acyclovir USP	Manufacturing and Packing
3.	Almotriptan Malate IH	Manufacturing and Packing
4.	Alprazolam USP/Ph.Eur	Manufacturing and Packing
5.	Amlodipine Besilate Ph.Eur	Manufacturing and Packing
6.	Amlodipine Besylate USP	Manufacturing and Packing
7.	Aripiprazole Ph.Eur	Manufacturing and Packing
8.	Aripiprazole Monohydrate IH	Manufacturing and Packing
9.	Armodafinil IH	Manufacturing and Packing
10.	Blonanserin IH	Manufacturing and Packing
11.	Candesartan Cilexetil Ph.Eur	Manufacturing and Packing
12.	Cetirizine Dihydrochloride Ph.Eur	Manufacturing and Packing
13.	Cetirizine Hydrochloride USP	Manufacturing and Packing
14.	Clarithromycin USP/Ph.Eur	Manufacturing and Packing
15.	Desloratadine Ph.Eur	Manufacturing and Packing
16.	Empagliflozin IH	Manufacturing and Packing
17.	Emtricitabine IH	Manufacturing and Packing
18.	Febuxostat IH	Manufacturing and Packing
19.	Fluconazole USP/Ph.Eur	Manufacturing and Packing
20.	Irbesartan USP/Ph.Eur	Manufacturing and Packing
21.	Itraconazole Ph.Eur	Manufacturing and Packing
22.	Lansoprazole USP/Ph.Eur	Manufacturing and Packing
23.	Loratadine USP/Ph.Eur	Manufacturing and Packing
24.	Nepafenac IH	Manufacturing and Packing
25.	Paliperidone IH	Manufacturing and Packing
26.	Parecoxib Sodium IH	Manufacturing and Packing
27.	Perindopril Erbumine Ph.Eur	Manufacturing and Packing
28.	Perindopril Arginine IH	Manufacturing and Packing
29.	Pioglitazone Hydrochloride USP/Ph.Eur	Manufacturing and Packing
30.	Propafenone Hydrochloride Ph.Eur	Manufacturing and Packing
31.	Risperidone Ph.Eur	Manufacturing and Packing
32.	Rivaroxaban Ph.Eur	Manufacturing and Packing

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Govt. of India

22 JUN 2022

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

CERTIFICATE NO. : WC-0117

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

Sl.No.	Name of the Active Substances	Activitie(s)
33	Rizatriptan Benzoate USP/Ph.Eur	Manufacturing and Packing
34	Rosuvastatin Calcium Ph.Eur	Manufacturing and Packing
35	Telmisartan USP/Ph.Eur	Manufacturing and Packing
36	Tetrabenazine IH	Manufacturing and Packing
37	Ticagrelor IH	Manufacturing and Packing
38	Valacyclovir Hydrochloride USP	Manufacturing and Packing
39	Valacyclovir Hydrochloride Hydrate Ph.Eur	Manufacturing and Packing
40	Verapamil Hydrochloride Ph.Eur	Manufacturing and Packing
41	Vildagliptin IH	Manufacturing and Packing
42	Zolmitriptan Ph.Eur	Manufacturing and Packing

ITEM(S) Forty Two (42) Only

The Written Confirmation remains valid until: 28.07.2025

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization • Ministry of Health & Family Welfare, Govt. of

22 JUN 2022

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

Annexure-02

CERTIFICATE NO. : WC-0117

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.	Dexalansoprazole Sesquihydrate IH	Manufacturing and Packing
2.	Dexlansoprazole (Amorphous) IH	Manufacturing and Packing
3.	Paliperidone Palmitate IH	Manufacturing and Packing

ITEM(S) Three (03) 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: 28.07.2025

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Govt. of India

22 JUN 2022

7-5/2016/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:
31 JAN 2023

To,

M/s. Mylan Laboratories Limited,
Unit-7, Plot No. 14, 99 & 100, IDA, Pashamylaram,
Phase-II, Patancheru, Sangareddy District - 502307
Telangana, India.

Subject :- Written Confirmation of M/s. Mylan Laboratories Limited, 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 – Regarding.

Sir,

Please refer to your online application submitted vide WC/ED/2022/5858 to the CDSCO, Zone, Hyderabad office and the recommendation received from DDC(I), 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	42	22.06.2022	28.07.2025
02	03	22.06.2022	28.07.2025
03	01	31 JAN 2023	28.07.2025

Yours faithfully,

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

Annexure-03

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

CERTIFICATE NO. : WC-0117

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 - 502307
Telangana, India.

List of APIs:

Sr. No.	Active substance(s)	Activity(ies)
1.	Zofenopril Calcium IH	Manufacturing & Packing

ITEM(S) ONE (01) 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: 28.07.2025.

Signature

Stamp of the authority and date

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

31 JAN 2023 JAN 2023

7-5/2013/EU/WC-0117
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

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

To,

M/s. Mylan Laboratories Limited,
Plot No. 14, 99 & 100, IDA, Pashamylaram Phase-II,
Hyderabad , Sangareddy-502307, Telangana India.

10 MAY 2023

Subject :- Written Confirmation M/s. Mylan Laboratories Limited, Plot No. 14, 99 & 100, IDA, Pashamylaram Phase-II Hyderabad , Sangareddy-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-Regarding.

Sir,

Please refer to your online application no. WC/ED/2023/6563 submitted to CDSCO, Hyderabad zone office and the recommendation received from DDC (I), 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	42	22.06.2022	28.07.2025
02	03	22.06.2022	28.07.2025
03	01	31.01.2023	28.07.2025
04	01	10 MAY 2023	28.07.2025

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

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

Annexure-04

CERTIFICATE NO. : WC-0117

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,
Plot No. 14, 99 & 100, IDA, Pashamylaram Phase-II,
Hyderabad , Sangareddy-502307, Telangana India.

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Telbivudine IH	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 28.07.2025.

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Govt. of India
Sample Copy

10 MAY 2023

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:

22 MAY 2023

To

M/s. Mylan Laboratories Limited (Unit-7),
Plot No. 14, 99 & 100, IDA,
Pashamylaram, Phase-II, Patancheru,
Sangareddy District-502 307 Telangana, India

Subject:- Written Confirmation of M/s. Mylan Laboratories Limited (Unit-7), Plot No. 14, 99 & 100, IDA, Pashamylaram, Phase-II, Patancheru, Sangareddy District-502 307 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 online application no WC/ED/2023/6838 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	42	22.06.2022	**28.07.2025**
2	03	22.06.2022	**28.07.2025**
3	01	30.01.2023	**28.07.2025**
4	01	10.05.2023	**28.07.2025**
5	01	22 MAY 2023	**28.07.2025**

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

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

CERTIFICATE NO. : **Annexure-5**
WC-0117

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 Limited, Unit-7, Plot No. 14, 99 & 100, IDA, Pashamylaram, Phase-II, Patancheru, Sangareddy District-502 307 Telangana, India**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Edoxaban Tosylate IH	Manufacturing & Packing

ITEM(S) One (01) 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: 28th Jul, 2025

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Govt. of India

22 MAY 2023