7-5/2013/EU/WC-0113
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 26 AUG 2025

To

M/s. Cipla Limited
Old Madras Road, Virgo Nagar Post,
Bengaluru - 560049, Karnataka, India

SUB:- Written Confirmation of **M/s Cipla Limited, Old Madras Road, Virgo Nagar Post, Bengaluru - 560049, Karnataka, 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/2025/9877** submitted to CDSCO, Bangalore Zone office, and the recommendation received from DDC (I), Bangalore 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.

9. The manufacturer is required to comply with the provisions of GSR 20(E), dated 18.01.2022.

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
--	--	26 AUG 2025	08.08.2028
01	27	26 AUG 2025	08.08.2028
02	03	26 AUG 2025	08.08.2028

Yours faithfully,

Chandrashekar
26/08/25

Ranga Chandrashekar
Joint Drugs Controller (India)
चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O.(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

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

CERTIFICATE NO. : **WC-0113**

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. Cipla Limited**
Old Madras Road, Virgo Nagar Post,
Bengaluru - 560049, Karnataka, India

2. Manufacturer's licence number: **NB-110/78**

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

List of API(s):

And as per the annexure(s) enclosed.

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: 02.07.2025 and 03.07.2025

The Written Confirmation remains valid until: **08.08.2028**
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: Ranga Chandrashekar,
Joint Drugs Controller (India)

E-mail: ***ranga.cs@cdsco.nic.in;***
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Chandrashekar 26/08/25

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केन्द्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Signature

Stamp of the authority and date

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

26 AUG 2025

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

CERTIFICATE NO. :

Annexure-01
WC-0113

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. Cipla Limited
Old Madras Road, Virgo Nagar Post,
Bengaluru - 560049, Karnataka, India

List of APIs:

S. No.	Active substance (s)	Activity(ies)
1.	Amlodipine Besylate BP	Manufacturing & Packing
2.	Amlodipine Besylate Ph.Eur.	Manufacturing & Packing
3.	Apremilast IH	Manufacturing & Packing
4.	Donepezil Hydrochloride Monohydrate Ph. Eur.	Manufacturing & Packing
5.	Esomeprazole Magnesium Dihydrate Ph.Eur.	Manufacturing & Packing
6.	Esomeprazole Magnesium Dihydrate BP	Manufacturing & Packing
7.	Esomeprazole Magnesium Dihydrate IH	Manufacturing & Packing
8.	Esomeprazole Magnesium Trihydrate Ph.Eur.	Manufacturing & Packing
9.	Etoposide BP	Manufacturing & Packing
10.	Etoposide Ph.Eur.	Manufacturing & Packing
11.	Felodipine BP	Manufacturing & Packing
12.	Felodipine Ph.Eur.	Manufacturing & Packing
13.	Granisetron Hydrochloride Ph.Eur.	Manufacturing & Packing
14.	Leflunomide BP	Manufacturing & Packing
15.	Leflunomide Ph.Eur.	Manufacturing & Packing
16.	Levofloxacin Hemihydrate USP	Manufacturing & Packing
17.	Linagliptin IH	Manufacturing & Packing
18.	Omeprazole Ph. Eur.	Manufacturing & Packing
19.	Omeprazole BP	Manufacturing & Packing
20.	Omeprazole Sodium Ph. Eur.	Manufacturing & Packing
21.	Omeprazole Sodium BP	Manufacturing & Packing
22.	Pantoprazole Sodium Sesquihydrate Ph. Eur.	Manufacturing & Packing
23.	Pantoprazole Sodium Sesquihydrate BP	Manufacturing & Packing
24.	Risperidone BP	Manufacturing & Packing
25.	Risperidone Ph. Eur.	Manufacturing & Packing
26.	Ritonavir USP	Manufacturing & Packing
27.	Topiramate USP	Manufacturing & Packing

ITEM(S) Twenty-Seven (27) ONLY

The Written Confirmation remains valid until: 08.08.2028

Signature

Dr. Chandrashekar Ranga
केंद्रीय औषधि मानक नियंत्रक (भारत) / Joint Drugs Controller (India)
C.D.S.C.O.(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

26/08/2025

Stamp of the authority and date

Ministry of Health & Family Welfare, Govt. of India

26 AUG 2025

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

Annexure-02
WC-0113

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. Cipla Limited**
Old Madras Road, Virgo Nagar Post,
Bengaluru - 560049, Karnataka, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Amlodipine Mesylate Monohydrate IH	Manufacturing & Packing
2.	Granisetron Base IH	Manufacturing & Packing
3.	Nintedanib Esylate IH	Manufacturing & Packing

ITEM(S) Three (03) 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 substance(s) for the purpose of export only, as the above-mentioned active substance(s) are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 08.08.2028

Chandrashekar Ranga
चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केन्द्रीय मानक औषध नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O.(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, GOI

26 AUG 2025

7-5/2013/EU/WC-0113

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 30 SEP 2025

To

M/s. Cipla Limited
Old Madras Road, Virgo Nagar Post,
Bengaluru - 560049, Karnataka, India

SUB:- Written Confirmation of **M/s Cipla Limited, Old Madras Road, Virgo Nagar Post, Bengaluru - 560049, Karnataka, 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/2025/7196** submitted to CDSCO, Bangalore Zone office, and the recommendation received from DDC (I), Bangalore 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.

9. The manufacturer is required to comply with the provisions of GSR 20(E), dated 18.01.2022.

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
--	--	26.08.2025	**08.08.2028**
01	27	26.08.2025	**08.08.2028**
02	03	26.08.2025	**08.08.2028**
03	01	30 SEP 2025	**08.08.2028**

Yours faithfully,

30/09/25

Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत)/Joint Drugs Controller (India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O.(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

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

CERTIFICATE NO. :

Annexure-03
WC-0113

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. Cipla Limited**
Old Madras Road, Virgo Nagar Post,
Bengaluru - 560049, Karnataka, India

List of APIs:

S. No.	Active substance (s)	Activity(ies)
1.	Topiramate Ph.Eur.	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 08.08.2028

Signature

Dr. Chandrashekar B.C.
30/09/25
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

30 SEP 2025