7-5/2013/EU/WC/0037

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

FDA, Bhawan Kotla Road,
New Delhi-110002
Dated: 27 JUN 2025

To

M/s. Neuland Laboratories Ltd., Unit-II,
Plot No. 92-94, 257-259, IDA Pashamylaram,
Pashamylaram Village, Patancheru Mandal,
Sangareddy District, Pin code- 502 307,
Telangana State, India.

Subject:- Written Confirmation of **M/s. Neuland Laboratories Ltd., Unit-II, Plot No. 92-94, 257-259, IDA Pashamylaram, Pashamylaram Village, Patancheru Mandal, Sangareddy District, Pin code-502 307, Telangana State, 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 no. **WC/RE/2024/9378** dated 03-DEC-2024 submitted to CDSCO, DDC(I), Hyderabad zone office, and the recommendation received from DDC(I), Hyderabad Zone office, 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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 to the provision of GSR 20(E) dated 18.01.2022.

10. The manufacturer shall obtain NOC from the respective CDSCO office on case to case basis for manufacture of active substance for export purpose, if active substance is falling under Unapproved/Banned/ New drug in India.

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
--	--	27 JUN 2025	**16.06.2028**
01	22	27 JUN 2025	**16.06.2028**
02	02	27 JUN 2025	**16.06.2028**

Yours faithfully,

Chandrashekar
27/06/25

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-0037**

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. Neuland Laboratories Ltd., Unit-II, Plot No. 92-94, 257-259, IDA Pashamylaram, Pashamylaram Village, Patancheru Mandal, Sangareddy District, Pin code-502 307, Telangana State, India.**

2. Manufacturer's licence number: **185/MD/AP/96/B/R**

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):

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: 10.06.2025 & 11.06.2025

The Written Confirmation remains valid until: **16.06.2028**
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
27/06/25

Signature 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

Stamp of the authority and date

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

27 JUN 2025

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

CERTIFICATE NO. : **Annexure-01**
WC-0037

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. Neuland Laboratories Ltd., Unit-II, Plot No. 92-94, 257-259, IDA Pashamylaram, Pashamylaram Village, Patancheru Mandal, Sangareddy District, Pincode 502 307, Telangana State, India.**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Apixaban IH	Manufacturing & Packing
2.	Apremilast IH	Manufacturing & Packing
3.	Aripiprazole USP/Ph. Eur.	Manufacturing & Packing
4.	Aripiprazole Monohydrate IH	Manufacturing & Packing
5.	Bempedoic Acid IH	Manufacturing & Packing
6.	Brinzolamide USP	Manufacturing & Packing
7.	Ciprofloxacin USP/ Ph. Eur	Manufacturing & Packing
8.	Ciprofloxacin Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
9.	Dabigatran Etexilate Mesylate IH	Manufacturing & Packing
10.	Deferasirox IH/Ph.Eur.	Manufacturing & Packing
11.	Edaravone IH	Manufacturing & Packing
12.	Entacapone USP/Ph. Eur	Manufacturing & Packing
13.	Ezetimibe IH/USP	Manufacturing & Packing
14.	Labetalol Hydrochloride USP/Ph. Eur	Manufacturing & Packing
15.	Linezolid IH/USP	Manufacturing & Packing
16.	Mirtazapine USP/Ph. Eur	Manufacturing & Packing
17.	Moxonidine Ph. Eur	Manufacturing & Packing
18.	Nitrofurantoin USP/Ph. Eur	Manufacturing & Packing
19.	Propofol USP/Ph. Eur	Manufacturing & Packing
20.	Rivaroxaban IH/Ph.Eur.	Manufacturing & Packing
21.	Ticagrelor IH	Manufacturing & Packing
22.	Voriconazole USP/Ph.Eur.	Manufacturing & Packing

ITEM(S) TWENTY-TWO (22) ONLY

The Written Confirmation remains valid until: 16.06.2028

Stamp of the authority and date

Signature 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

27 JUN 2025

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

CERTIFICATE NO. :

Annexure-02
WC-0037

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. Neuland Laboratories Ltd., Unit-II, Plot No. 92-94, 257-259, IDA Pashamylaram, Pashamylaram Village, Patancheru Mandal, Sangareddy District, Pincode 502 307, Telangana State, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Deutetrabenazine IH	Manufacturing & Packing
2.	Tafamidis Meglumine 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 substance(s) for the purpose of export only, as the above-mentioned active substance(s) is not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 16.06.2028

Signature 27/06/25

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

Stamp of the authority and date

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

27 JUN 2025

7-5/2013/EU/WC/0037

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

FDA, Bhawan Kotla Road,
New Delhi-110002
Dated: 01 AUG 2025

To

M/s. Neuland Laboratories Ltd., Unit-II,
Plot No. 92-94, 257-259, IDA Pashamylaram,
Pashamylaram Village, Patancheru Mandal,
Sangareddy District, Pin code- 502 307,
Telangana State, India.

Subject:- Written Confirmation of **M/s. Neuland Laboratories Ltd., Unit-II, Plot No. 92-94, 257-259, IDA Pashamylaram, Pashamylaram Village, Patancheru Mandal, Sangareddy District, Pin code-502 307, Telangana State, 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 no. **WC/ED/2024/8059** dated 03-DEC-2024 submitted to CDSCO, DDC(I), Hyderabad zone office, and the recommendation received from DDC(I), Hyderabad Zone office, 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.

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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 to the provision of GSR 20(E) dated 18.01.2022.

10. The manufacturer shall obtain NOC from the respective CDSCO office on case to case basis for manufacture of active substance for export purpose, if active substance is falling under Unapproved/Banned/ New drug in India.

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
--	--	27.06.2025	**16.06.2028**
01	22	27.06.2025	**16.06.2028**
02	02	27.06.2025	**16.06.2028**
03	01	01 AUG 2025	**16.06.2028**

Yours faithfully,

Chandrashekar
01/08/25

Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशेखर रंग / 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

Annexure-03
WC-0037

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. Neuland Laboratories Ltd., Unit-II, Plot No. 92-94, 257-259, IDA Pashamylaram, Pashamylaram Village, Patancheru Mandal, Sangareddy District, Pincode 502 307, Telangana State, India.**

List of APIs:

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

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 16.06.2028

Chandrashekar
01/08/25

Signature

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

Stamp of the authority and date

Ministry of Health & Family Welfare, Govt. of India

01 AUG 2025