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:
07 JUN 2022

To

M/s. Neuland Laboratories Ltd., Unit-II,
Plot No. 92-94, 257-259, IDA, Pashamylaram,
Isnapur Village, Patancheru Mandal,
Sangareddy District-502319, Telangana State, India

Subject:- Written Confirmation of M/s. Neuland Laboratories Ltd., Unit-II, Plot No. 92-94, 257-259, IDA, Pashamylaram, Isnapur Village, Patancheru Mandal, Sangareddy District-502319, 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 online application No. WC/RE/2022/2875 submitted to CDSCO, Hyderabad Zone office and the recommendation received from DDC(I), Hyderabad Zonal 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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.

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.

Yours faithfully,

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

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

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, Isnapur Village, Patancheru Mandal, Sangareddy District-502319, 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):

S. No.	Active substance(s)	Activity(ies)
1.	Bempedoic Acid IH	Manufacturing & Packing

TEM(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 substance is not approved for manufacture for sale in India.

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: 23.02.2022 to 25.02.2022

The Written Confirmation remains valid until: 16.06.2025

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.: +91-11-23236963
Fax no.: +91-11-23236975

Signature

Stamp of the authority and date

07 JUN 2022

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:

08 JUN 2022

To

M/s. Neuland Laboratories Ltd., Unit-II,
Plot No. 92-94, 257-259, IDA
Pashamylaram Village, Patancheru Mandal,
Sangareddy District-502 319, Telangana State, India

Subject:- Written Confirmation of M/s. Neuland Laboratories Ltd., Unit-II, Plot No. 92-94, 257-259, IDA Pashamylaram Village, Patancheru Mandal, Sangareddy District-502 319, 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 online application No. WC/RE/2021/932 submitted to CDSCO, Hyderabad Zone office and the recommendation received from DDC(I), Hyderabad Zonal 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.

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	07.06.2022	16.06.2025
01	27	08 JUN 2022	16.06.2025
02	01	08 JUN 2022	16.06.2025

Yours faithfully,

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

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

Annexure-01
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 Village, Patancheru Mandal,
Sangareddy District-502 319, Telangana State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Apixaban IH	Manufacturing & Packing
2.	Aripiprazole USP/Ph. Eur./IH	Manufacturing & Packing
3.	Bosentan Monohydrate IH	Manufacturing & Packing
4.	Brinzolamide USP	Manufacturing & Packing
5.	Ciprofloxacin USP/Ph. Eur	Manufacturing & Packing
6.	Ciprofloxacin Hydrochloride USP/Ph. Eur	Manufacturing & Packing
7.	Dabigatran Etexilate Mesylate IH	Manufacturing & Packing
8.	Deferasirox IH	Manufacturing & Packing
9.	Deutetrabenazine (SD-809) IH	Manufacturing & Packing
10.	Enalapril Maleate USP/Ph. Eur	Manufacturing & Packing
11.	Entacapone USP/Ph. Eur	Manufacturing & Packing
12.	Escitalopram Oxalate USP/Ph. Eur	Manufacturing & Packing
13.	Ethacrynic Acid USP	Manufacturing & Packing
14.	Ezetimibe IH	Manufacturing & Packing
15.	Labetalol Hydrochloride USP/Ph. Eur	Manufacturing & Packing
16.	Levetiracetam USP/Ph. Eur	Manufacturing & Packing
17.	Levofloxacin Hemihydrate IH	Manufacturing & Packing
18.	Linezolid IH	Manufacturing & Packing
19.	Mirtazapine USP/Ph. Eur	Manufacturing & Packing
20.	Moxonidine Ph. Eur	Manufacturing & Packing
21.	Nitrofurantoin USP/Ph. Eur	Manufacturing & Packing
22.	Ofloxacin USP/Ph. Eur	Manufacturing & Packing
23.	Propofol USP/Ph. Eur	Manufacturing & Packing
24.	Rivaroxaban IH	Manufacturing & Packing
25.	Sotalol Hydrochloride USP/Ph. Eur	Manufacturing & Packing
26.	Ticagrelor IH	Manufacturing & Packing
27.	Voriconazole USP/Ph. Eur	Manufacturing & Packing

ITEM(S) TWENTY SEVEN (27) ONLY

The Written Confirmation remains valid until: 16.06.2025

08 JUN 2022

Signature

Stamp of the authority and date

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

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

Annexure-02
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 Village, Patancheru Mandal,
Sangareddy District-502 319, Telangana State, India**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Apremilast 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 substance is not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 16.06.2025

Signature

Stamp of the authority and date

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

0 8 JUN 2022

7-5/2013/EU/WC-0037

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

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002
Dated

14 JUN 2022

To

M/s Neuland Laboratories Ltd., Unit-II
Plot No 92-94, 257-259, IDA
Pashamylaram Village, Patancheru Mandal,
Sangareddy District-502319, Telangana State, India

SUB:- Written Confirmation of M/s Neuland Laboratories Ltd., Unit-II, Plot No 92-94, 257-259, IDA, Pashamylaram Village, Patancheru Mandal,Sangareddy District-502319, 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 online application no. WC/ED/2022/3748 dated 07.05.2022 submitted to CDSCO, Hyderabad Zonal office and the recommendation received from DDC(I), Hyderabad Zonal 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.

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	07.06.2022	16.06.2025
01	27	08.06.2022	16.06.2025
02	01	08.06.2022	16.06.2025
03	07	14 JUN 2022	16.06.2025
04	02	14 JUN 2022	16.06.2025

Yours faithfully,

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

Annexure-3

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 Village, Patancheru Mandal,
Sangareddy District-502319, Telangana State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Aripiprazole Monohydrate IH	Manufacturing & Packing
2.	Deferasirox Ph.Eur	Manufacturing & Packing
3.	Edaravone IH	Manufacturing & Packing
4.	Levofloxacin Hemihydrate USP	Manufacturing & Packing
5.	Ezetimibe USP	Manufacturing & Packing
6.	Linezolid USP	Manufacturing & Packing
7.	Rivaroxaban Ph.Eur	Manufacturing & Packing

ITEM(S) SEVEN (07) ONLY

The Written Confirmation remains valid until: 16.06.2025

Signature

Stamp of the authority and date

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

14 JUN 2022

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

CERTIFICATE NO. : WC-0037

Annexure-4

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 Village, Patancheru Mandal,
Sangareddy District-502319, Telangana State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Ibrexafungerp Citrate 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 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: 16.06.2025

Signature

Stamp of the authority and date

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

14 JUN 2022

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 2022

To,

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

Subject:- Application for amendment of the Written Confirmation of M/s. Neuland Laboratories Ltd., Unit-II, Plot No. 92-94, 257-259, I.D.A., Pashamylaram, Pashamylaram Village, Patancheru Mandal, Sangareddy District-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 submitted vide letter No. NU/U-II/address correction/076/2022 dated 22.06.2022 for the necessary correction in the Written Confirmation Certificate issued by this office.

In this regard, kindly find the enclosed amended certificate. The condition of the 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 will remain same.

Please acknowledge the receipt.

Yours faithfully,

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

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

Amended

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 of site:** M/s. Neuland Laboratories Ltd.
2. **Manufacturer's License Number:** 185/MD/AP/96/B/R

The address of the manufacturer mentioned in the Written Confirmation Certificate (WC-0037) issued on date 07.06.2022 and 08.06.2022 is hereby amended as follows:

In place of:
M/s. Neuland Laboratories Ltd., Unit-II, Plot No. 92-94, 257-259, IDA Pashamylaram Village, Patancheru Mandal, Sangareddy District-502 319, Telangana State, India.

Read as:
M/s. Neuland Laboratories Ltd., Unit-II, Plot No. 92-94, 257-259, I.D.A., Pashamylaram, Pashamylaram Village, Patancheru Mandal, Sangareddy District-502 307, Telangana State, India.

All other conditions of Written Confirmation Certificate will remain same.

Signature

27 JUN 2022

Stamp of the authority and date

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