7-5/2013/EU/WC-0036
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002
Dated:

To

07 JUN 2022

M/s Neuland Laboratories Ltd., Unit-I,
Sy. No. 347, 473, 474, 490/2,
Bonthapally Village, Veerabhadraswamy
Temple Road, Gummadidala Mandal,
Sangareddy District-502 313, Telangana State, India

Subject:- Written Confirmation of M/s Neuland Laboratories Ltd., Unit-I, Sy. No. 347, 473, 474, 490/2, Bonthapally Village, Veerabhadraswamy Temple Road, Gummadidala Mandal, Sangareddy District-502 313, 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/2021/936 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	26	07 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

CERTIFICATE NO. : WC-0036

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-I,**
Sy. No. 347, 473, 474, 490/2,
Bonthapally Village, Veerabhadraswamy
Temple Road, Gummadidala Mandal,
Sangareddy District-502 313, Telangana State, India

2. Manufacturer's licence number: 184/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 APIs:

As per Enclosed Annexures

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: 29.11.2021 & 30.11.2021

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.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

Stamp of the authority and date

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

07 JUN 2022

7-5/2013/EU/WC-0036
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002
Dated:

28 JUL 2022

To

M/s Neuland Laboratories Ltd., Unit-I,
Sy. No. 347, 473, 474, 490/2,
Bonthapally Village, Veerabhadraswamy
Temple Road, Gummadidala Mandal,
Sangareddy District-502 313, Telangana State, India

Subject:- Written Confirmation of M/s Neuland Laboratories Ltd., Unit-I, Sy. No. 347, 473, 474, 490/2, Bonthapally Village, Veerabhadraswamy Temple Road, Gummadidala Mandal, Sangareddy District-502 313, 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/2021/936 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.

28 JUL 2022

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 Amended	26	28.JUN 2022	16.06.2025
2	04	17.06.2022	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

Amended
Annexure-1

CERTIFICATE NO. : **WC-0036**

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 Neuland Laboratories Ltd., Unit-I, Sy. No. 347, 473, 474, 490/2, Bonthapally Village, Veerabhadraswamy Temple Road, Gummadidala Mandal, Sangareddy District-502 313, Telangana State, India**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Albuterol Sulfate USP	Manufacturing & Packing
2.	Bilastine IH	Manufacturing & Packing
3.	Ciprofloxacin USP/Ph.Eur	Manufacturing & Packing
4.	Donepezil Base IH	Manufacturing & Packing
5.	Donepezil Hydrochloride USP/IH	Manufacturing & Packing
6.	Dorzolamide Hydrochloride USP/Ph.Eur	Manufacturing & Packing
7.	Enalapril Maleate USP/Ph.Eur	Manufacturing & Packing
8.	Escitalopram Oxalate IH/USP	Manufacturing & Packing
9.	Hydralazine Hydrochloride USP	Manufacturing & Packing
10.	Indacaterol Maleate IH	Manufacturing & Packing
11.	Ipratropium Bromide USP/Ph.Eur	Manufacturing & Packing
12.	Levetiracetam USP/Ph.Eur	Manufacturing & Packing
13.	Levofloxacin Hemihydrate USP	Manufacturing & Packing
14.	Mirtazapine USP/Ph.Eur	Manufacturing & Packing
15.	Olanzapine USP/Ph.Eur	Manufacturing & Packing
16.	Paliperidone Palmitate IH	Manufacturing & Packing
17.	Paricalcitol USP	Manufacturing & Packing
18.	Posaconazole IH	Manufacturing & Packing
19.	Ramipril USP/Ph.Eur	Manufacturing & Packing
20.	Ropinirole Base IH	Manufacturing & Packing
21.	Ropinirole Hydrochloride IH/USP	Manufacturing & Packing
22.	Rotigotine IH	Manufacturing & Packing
23.	Salmeterol Xinafoate USP/Ph.Eur	Manufacturing & Packing
24.	Salbutamol Sulphate Ph. Eur	Manufacturing & Packing
25.	Sodium Phenyl Acetate IH	Manufacturing & Packing
26.	Sotalol Hydrochloride USP/Ph.Eur	Manufacturing & Packing

ITEM(S) TWENTY SIX (26) ONLY

The Written Confirmation remains valid until: 16.06.2025

28 JUN 2022

Signature

Stamp of the authority and date

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

7-5/2013/EU/WC-0036
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:

17 JUN 2022

To,

M/s Neuland Laboratories Ltd.,
Unit-1, Sy. No. 347, 473, 474, 490/2,
Bonthapally Village, Veerabhadraswamy,
Temple Road, Gummadidala Mandal,
Sangareddy District – 502313,
Telangana State, India

SUB:- Written Confirmation of M/s Neuland Laboratories Ltd., Unit-1, Sy. No. 347, 473, 474, 490/2, Bonthapally Village, Veerabhadraswamy, Temple Road, Gummadidala Mandal, Sangareddy District – 502313, 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/2022/4168 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
1	26	07.06.2022	16.06.2025
2	04	17 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-2

CERTIFICATE NO. : WC-0036

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-1, Sy. No. 347, 473, 474, 490/2,
Bonthapally Village, Veerabhadraswamy,
Temple Road, Gummadidala Mandal,
Sangareddy District – 502313,
Telangana State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Donepezil Hydrochloride Monohydrate Ph. Eur.	Manufacturing & Packing
2.	Escitalopram Oxalate Ph. Eur.	Manufacturing & Packing
3.	Levofloxacin Hemihydrate Ph. Eur.	Manufacturing & Packing
4.	Ropinirole Hydrochloride Ph. Eur.	Manufacturing & Packing

ITEM(S) FOUR (04) 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 •

17 JUN 2022

7-5/2013/EU/WC-0036

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 19 FEB 2024

To,

M/s. Neuland Laboratories Ltd., Unit-I,
Sy.No. 347, 473, 474, 490/2, Bonthapally Village,
Veerabhadraswamy Temple Road, Gummadidala Mandal,
Sangareddy District – 502 313, Telangana State, India

SUB:- Written Confirmation of M/s. Neuland Laboratories Ltd., Unit-I, Sy.No. 347, 473, 474, 490/2, Bonthapally Village, Veerabhadraswamy Temple Road, Gummadidala Mandal, Sangareddy District – 502 313, 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/2023/6901 dated 05.04.2023 submitted to CDSCO, DDC(I), 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.

9. The manufacturer is required to comply to the provision 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
01 Amended	26	28.07.2022	16.06.2025
02	04	17.06.2022	16.06.2025
03	02	19 FEB 2024	16.06.2025

Yours faithfully,

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

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

Annexure-03

CERTIFICATE NO. : WC-0036

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-I,
Sy.No. 347, 473, 474, 490/2, Bonthapally Village,
Veerabhadraswamy Temple Road, Gummadidala Mandal,
Sangareddy District – 502 313, Telangana State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Sugammadex Sodium IH	Manufacturing & Packing
2.	Vilanterol Trifenatate 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 above 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

Ministry of Health & Family Welfare, Govt. of India

19 FEB 2024