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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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)

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

Annexure-3

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 • सत्यमेव जयते

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

14 JUN 2022

Stamp of the authority and date

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