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: 17 JUN 2019

To

M/s. Neuland Laboratories Ltd., Unit-II,
Plot No. 92-94, 257-259, IDA, Pashamylaram,
Isnapur 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, Isnapur 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 application 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	25	17 JUN 2019	Three (03) years from date of issue
2	2	17 JUN 2019	Three (03) years from date of issue

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

14/06/19

14/06/19

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

2. Manufacturer's licence number: 25/185/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

As per List enclosed as Annexure-1 & 2

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: 27.07.2018 & 28.07.2019

The Written Confirmation remains valid until: **Three (03) years from date of issue.**

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. S. Eswara Reddy,
Drugs Controller General (India)

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

14/06/19

14/06/19

Stamp of the authority and date

17 JUN 2019

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

CERTIFICATE NO. : **WC-0037**

Annexure-1

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-II, Plot No. 92-94, 257-259, IDA, Pashamylaram, Isnapur 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.	Enalapril Maleate USP/Ph. Eur	Manufacturing & Packing
10.	Entacapone USP/Ph. Eur	Manufacturing & Packing
11.	Ezetimibe IH	Manufacturing & Packing
12.	Labetalol Hydrochloride USP/Ph.Eur	Manufacturing & Packing
13.	Levetiracetam USP/Ph. Eur	Manufacturing & Packing
14.	Levofloxacin Hemihydrate IH	Manufacturing & Packing
15.	Linezolid IH	Manufacturing & Packing
16.	Mirtazapine USP/Ph.Eur	Manufacturing & Packing
17.	Moxonidine Ph. Eur	Manufacturing & Packing
18.	Ofloxacin USP/Ph. Eur.	Manufacturing & Packing
19.	Propofol USP/Ph. Eur	Manufacturing & Packing
20.	Rivaroxaban IH	Manufacturing & Packing
21.	Sevelamer Carbonate IH	Manufacturing & Packing
22.	Sotalol Hydrochloride USP/Ph.Eur	Manufacturing & Packing
23.	Voriconazole Ph. Eur./USP	Manufacturing & Packing
24.	Escitalopram Oxalate USP/Ph.Eur	Manufacturing & Packing
25.	Ticagrelor IH	Manufacturing & Packing

ITEM(S) Twenty Five (25) ONLY

The Written Confirmation remains valid until: Three (03) years from date of issue.

Signature

14/06/19

14/06/19

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Government of India
सत्यमेव जयते

17 JUN 2019

Annexure-2

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

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-502 319, Telangana State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	D6-Tetrabenazine–SD-809 IH	Manufacturing & Packing
2.	Ethacrynic Acid USP	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: Three (03) years from date of issue.

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
सत्यमेव जयते
Ministry of Health Family Welfare, Government of India

17 JUN 2019