7-5/2013/EU/WC-0049
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. Lupin Limited,
Block-21, Dabhasa, Tal-Padra,
Dist.- Vadodara-391440, Gujarat, India

Subject:- Written Confirmation of M/s. Lupin Limited, Block-21, Dabhasa, Tal-Padra, Dist-Vadodara-391440, Gujarat, 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/2021/1109 submitted to CDSCO, Ahmedabad zone office and the recommendation received from DDC(I), Ahmedabad 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
-----	33	07 JUN 2022	16th, June, 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-0049**

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. Lupin Limited,**
Block-21, Dabhasa, Tal-Padra,
Dist.- Vadodara-391440, Gujarat, India

2. **Manufacturer's licence number**: G/25/1815 and G/28/1305

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 of API annexed (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: 24-25.02.2020 & 19.09.2020

The Written Confirmation remains valid until: 16th, June, 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

07 JUN 2022

Stamp of the authority and date

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

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

Annexure-01

CERTIFICATE NO. : WC-0049

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 Lupin Limited,
Block-21, Dabhasa, Tal- Padra,
Dist- Vadodara-391440 Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Acotiamide Hydrochloride Hydrate IH	Manufacturing & Packing
2.	Atazanavir Sulphate IH	Manufacturing & Packing
3.	Atorvastatin Calcium EP	Manufacturing & Packing
4.	Azithromycin Monohydrate USP	Manufacturing & Packing
5.	Cinacalcet Hydrochloride IH	Manufacturing & Packing
6.	Dabigatran Etexilate Mesylate IH	Manufacturing & Packing
7.	Desvenlafexine Succinate IH	Manufacturing & Packing
8.	Dronedarone Hydrochloride IH	Manufacturing & Packing
9.	Eslicarbazepine Acetate IH	Manufacturing & Packing
10.	Esomeprazole Magnesium Dihydrate Ph.Eur.	Manufacturing & Packing
11.	Febuxostat IH	Manufacturing & Packing
12.	Lacosamide Ph.Eur	Manufacturing & Packing
13.	Levetiracetam EP	Manufacturing & Packing
14.	Levetiracetam USP	Manufacturing & Packing
15.	Mesalamine USP	Manufacturing & Packing
16.	Pirfenidone Ph.Eur	Manufacturing & Packing
17.	Prasugrel Hydrochloride IH	Manufacturing & Packing
18.	Pregabalin Ph.Eur	Manufacturing & Packing
19.	Rifabutin USP	Manufacturing & Packing
20.	Rifaximin EP	Manufacturing & Packing
21.	Ritonavir USP	Manufacturing & Packing
22.	Rivaroxaban IH	Manufacturing & Packing
23.	Sevelamer Carbonate IH	Manufacturing & Packing
24.	Teneligliptine Hydrobromide Hydrate IH	Manufacturing & Packing
25.	Venlafaxine Hydrochloride USP	Manufacturing & Packing

ITEM(S) Twenty Five (25) ONLY

The Written Confirmation remains valid until: 16th June, 2025

Signature

Stamp of the authority and date

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

07 JUN 2022

Annexure-02

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

WC-0049

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 Lupin Limited,
Block-21, Dabhasa, Tal- Padra,
Dist- Vadodara-391440 Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Apremilast IH	Manufacturing & Packing
2.	Brivaracetam IH	Manufacturing & Packing
3.	Desvenlafexine Benzoate IH	Manufacturing & Packing
4.	Dexlansoprazole IH	Manufacturing & Packing
5.	Droxidopa IH	Manufacturing & Packing
6.	Ferric Citrate IH	Manufacturing & Packing
7.	Mirabegron IH	Manufacturing & Packing
8.	Sucroferric Oxyhydroxide IH	Manufacturing & Packing

ITEM(S) Eight (08) ONLY

This certificate is being issued subject to condition that the firm shall obtained NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substance 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: 16th June, 2025.

Signature

Stamp of the authority and date

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

07 JUN 2022