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: 0 5 AUG 2025

To

M/s. Lupin Manufacturing Solutions Limited,
Block -21, At & Post. -Dabhasa, Tal. -Padra,
Dist. -Vadodara -391 440, Gujarat, India

Subject: -Written Confirmation of **M/s. Lupin Manufacturing Solutions Limited, Block -21, At & Post. -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/2024/9517** 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.

9. The manufacturer is required to comply with the provisions 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
--	--	05 AUG 2025	**16.06.2028**
01	25	05 AUG 2025	**16.06.2028**
02	04	05 AUG 2025	**16.06.2028**

Yours faithfully,

Chandrashekar
05/08/25

Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशे... ...kar Ranga
संयुक्त औषधि नि... ...gs Controller(India)
केंद्रीय औषधि मानक ... ...स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(H... ...al of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय ... ...ry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

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 Manufacturing Solutions Limited, Block -21, At & Post. -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

List of API(s):

And as per the annexure(s) enclosed.

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: **29.05.2023 & 30.05.2023**

The Written Confirmation remains valid until: **16.06.2028**

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: Ranga Chandrashekar,
Joint Drugs Controller (India)

E-mail: ***ranga.cs@cdsco.nic.in;***
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Chandrashekar 05/08/25

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन / Central Drugs Standard Control Organization, स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफडीए भवन, कोटला रोड, नई दिल्ली-110002 FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

0 5 AUG 2025

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

Annexure-01
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 Manufacturing Solutions Limited, Block -21, At & Post. -Dabhasa, Tal. -Padra, Dist. -Vadodara -391440, Gujarat, India**

List of API(s):

S. No.	Active Substance(s)	Activity(ies)
1.	Acotiamide Hydrochloride Hydrate IH	Manufacturing & Packing
2.	Apremilast IH	Manufacturing & Packing
3.	Atazanavir Sulphate IH	Manufacturing & Packing
4.	Atorvastatin Calcium Ph.Eur.	Manufacturing & Packing
5.	Cinacalcet Hydrochloride IH	Manufacturing & Packing
6.	Levetiracetam Ph.Eur.	Manufacturing & Packing
7.	Mesalamine USP	Manufacturing & Packing
8.	Desvenlafaxine Benzoate IH	Manufacturing & Packing
9.	Desvenlafaxine Succinate USP	Manufacturing & Packing
10.	Eslicarbazepine Acetate IH	Manufacturing & Packing
11.	Lacosamide Ph.Eur.	Manufacturing & Packing
12.	Levetiracetam USP	Manufacturing & Packing
13.	Mirabegron IH	Manufacturing & Packing
14.	Pirfenidone Ph.Eur.	Manufacturing & Packing
15.	Esomeprazole Magnesium Dihydrate Ph.Eur.	Manufacturing & Packing
16.	Febuxostat IH	Manufacturing & Packing
17.	Pregabalin Ph.Eur.	Manufacturing & Packing
18.	Rifabutin USP	Manufacturing & Packing
19.	Rifaximin Ph.Eur.	Manufacturing & Packing
20.	Ritonavir USP	Manufacturing & Packing
21.	Rivaroxaban IH	Manufacturing & Packing
22.	Sevelamer Carbonate IH	Manufacturing & Packing
23.	Sevelamer Hydrochloride IH	Manufacturing & Packing
24.	Sucrofferric Oxyhydroxide IH	Manufacturing & Packing
25.	Venlafaxine Hydrochloride Ph.Eur.	Manufacturing & Packing

ITEM(s) Twenty-Five (25) Only

The Written Confirmation remains valid until: 16.06.2028

Chandrashekar
05/08/25

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत)/Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन/C.D.S.C.O(HQ), Directorate General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय/Ministry of Health and Family Welfare
एफडीए भवन, कोटला रोड, नई दिल्ली-110002/FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

0 5 AUG 2025

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

CERTIFICATE NO. :

Annexure-02
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 Manufacturing Solutions Limited, Block -21, At & Post. -Dabhasa, Tal. -Padra, Dist. -Vadodara -391440, Gujarat, India**

List of API(s):

S. No.	Active Substance(s)	Activity(ies)
1.	Deutetrabenazine IH	Manufacturing & Packing
2.	Ferric Citrate IH	Manufacturing & Packing
3.	Migalastat Hydrochloride IH	Manufacturing & Packing
4.	Sodium Zirconium Cyclosilicate IH	Manufacturing & Packing

ITEM(s) Four (04) 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 substance(s) for the purpose of export only, as the above-mentioned active substance(s) are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 16.06.2028

Chandrashekar
05/08/25

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केन्द्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O.(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

05 AUG 2025