7-5/2013/EU/WC/0201
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan,Kotla Road,
New Delhi-110002
Dated:
30 SEP 2022

To

M/s Lupin Ltd.
T-142, MIDC, Tarapur, Boisar, Palghar – 401506,
Maharashtra, India

Subject: Written Confirmation of Renewal of Written Confirmation to M/s Lupin Ltd., T-142, MIDC, Tarapur, Boisar, Palghar – 401506, Maharashtra, 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/2022/4631 submitted to CDSCO, West Zone, Mumbai office and the recommendation received from DDC(I), West Zone, Mumbai 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	32	19 SEP 2022	10.09.2025
2	02	19 SEP 2022	10.09.2025

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-0201

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 Ltd.
T-142, MIDC, Tarapur, Boisar, Palghar – 401506,
Maharashtra, India

2. Manufacturer's license number: 25-KD/466 & 28-KD/96

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):

As per List enclosed as Annexure-1 and 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: 25.07.2022 & 26.07.2022

The Written Confirmation remains valid until: 10.09.2025

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

30 SEP 2022

Signature

Stamp of the authority and date

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

Annexure-1

CERTIFICATE NO.: WC-0201

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 Lupin Ltd.**
T-142, MIDC, Tarapur, Boisar, Palghar – 401506,
Maharashtra, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Abacavir Sulphate USP/Ph. Eur.	Manufacturing & Packing
2.	Amlodipine Besilate USP/Ph. Eur.	Manufacturing & Packing
3.	Celecoxib USP/Ph.Eur.	Manufacturing & Packing
4.	Choline Fenofibrate IH	Manufacturing & Packing
5.	Desloratadine USP/Ph. Eur.	Manufacturing & Packing
6.	Duloxetine Hydrochloride USP/Ph. Eur.	Manufacturing & Packing
7.	Emtricitabine IH	Manufacturing & Packing
8.	Escitalopram Oxalate USP	Manufacturing & Packing
9.	Eszopiclone USP	Manufacturing & Packing
10.	Ethambutol Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
11.	Ezetimibe IH/USP	Manufacturing & Packing
12.	Fenofibrate USP	Manufacturing & Packing
13.	Gatifloxacin IH	Manufacturing & Packing
14.	Imipramine Pamoate USP	Manufacturing & Packing
15.	Lansoprazole Ph.Eur.	Manufacturing & Packing
16.	Levetiracetam USP/Ph.Eur.	Manufacturing & Packing
17.	Losartan Potassium Amorphous USP	Manufacturing & Packing
18.	Lovastatin USP	Manufacturing & Packing
19.	Memantine Hydrochloride IH/USP	Manufacturing & Packing
20.	Pyrazinamide USP	Manufacturing & Packing
21.	Quetiapine Fumarate IH/ USP/Ph. Eur	Manufacturing & Packing
22.	Rabeprazole sodium IH	Manufacturing & Packing
23.	Ranolazine IH	Manufacturing & Packing
24.	Rifabutin USP	Manufacturing & Packing
25.	Rifampicin EP/BP/USP	Manufacturing & Packing
26.	Rifaximin Ph.Eur./IH	Manufacturing & Packing
27.	Risperiodine Ph.Eur.	Manufacturing & Packing
28.	Sertraline Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
29.	Simvastatin Ph.Eur./USP	Manufacturing & Packing
30.	Tenofovir Disoproxil Fumarate IH	Manufacturing & Packing
31.	Ziprasidone Hydrochloride USP	Manufacturing & Packing
32.	Zolpidem Tartrate USP/Ph.Eur.	Manufacturing & Packing

ITEM(S) THIRTY TWO (32) ONLY

The Written Confirmation remains valid until: 10.09.2025

Signature 30 SEP 2022

Stamp of the authority and date

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

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

CERTIFICATE NO. : **Annexure-2**
WC-0201

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 Lupin Ltd.
T-142, MIDC, Tarapur, Boisar, Palghar – 401506,
Maharashtra, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1	Abacavir Hydrochloride IH	Manufacturing & Packing
2	Tenofovir Disoproxil Phosphate 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: 10.09.2025

Signature

Stamp of the authority and date

30 SEP 2022