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: 11 SEP 2019

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 application 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	53	11 SEP 2019	Three years from the date of issue.
2	02	11 SEP 2019	Three years from the date of issue

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

Nagendra (TDA) Kumar 29/08/19 Y/C

30/08/19

3/9/19

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

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: 26.06.2019 & 27.06.2019

The Written Confirmation remains valid until three years from the 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. V. G. Somani,
Drugs Controller General (India)

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

Signature

Narendra Kumar 29/08/19 c/c EPCA 30/08/19

Stamp of the authority and date

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

11 SEP 2019

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

CERTIFICATE NO. : **Annexure-1**

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

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Abacavir Sulphate USP	Manufacturing & Packing
2.	Amlodipine Besylate USP	Manufacturing & Packing
3.	Amlodipine Besylate Micronised USP	Manufacturing & Packing
4.	Carvedilol (Micronised) Ph.Eur.	Manufacturing & Packing
5.	Celecoxib USP/Ph.Eur.	Manufacturing & Packing
6.	Choline fenofibrate IH	Manufacturing & Packing
7.	Darunavir (Amorphous) IH	Manufacturing & Packing
8.	Darunavir n-Propanolate IH	Manufacturing & Packing
9.	Desloratadine IH	Manufacturing & Packing
10.	Duloxetine Hydrochloride IH/Ph.Eur.	Manufacturing & Packing
11.	Duloxetine Hydrochloride (Micronised) Ph.Eur.	Manufacturing & Packing
12.	Efavirenz (Micronised) USP	Manufacturing & Packing
13.	Emtricitabine IH	Manufacturing & Packing
14.	Escitalopram Oxalate IH	Manufacturing & Packing
15.	Escitalopram Oxalate (Micronised) USP	Manufacturing & Packing
16.	Eszopiclone IH	Manufacturing & Packing
17.	Ethambutol Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
18.	Ezetimibe IH/USP	Manufacturing & Packing
19.	Fenofibrate (Micronised) USP	Manufacturing & Packing
20.	Gatifloxacin IH	Manufacturing & Packing
21.	Imipramine Hydrochloride USP	Manufacturing & Packing
22.	Imipramine Pamoate IH	Manufacturing & Packing
23.	Irbesartan USP/Ph.Eur.	Manufacturing & Packing
24.	Lansoprazole Micronised Ph.Eur.	Manufacturing & Packing
25.	Levetiracetam USP/Ph.Eur.	Manufacturing & Packing
26.	Levetiracetam (Micronised) Ph.Eur.	Manufacturing & Packing
27.	Losartan Potassium Amorphous USP	Manufacturing & Packing
28.	Lovastatin USP	Manufacturing & Packing
29.	Memantine Hydrochloride IH	Manufacturing & Packing
30.	Mesalamine USP	Manufacturing & Packing
31.	Omeprazole USP	Manufacturing & Packing
32.	Pregabalin IH	Manufacturing & Packing

o/c ESCI 30/08/19 Narendra kumar 29/08/19

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

1. Name and address of site: M/s Lupin Ltd.
T-142, MIDC, Tarapur, Boisar, Palghar – 401506,
Maharashtra, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
33.	Pyrazinamide Ph.Eur./BP/USP	Manufacturing & Packing
34.	Pyrazinamide (Micronised) USP	Manufacturing & Packing
35.	Quetiapine Fumarate IH	Manufacturing & Packing
36.	Rabeprazole sodium (Micronised) IH	Manufacturing & Packing
37.	Raltegravir Potassium IH	Manufacturing & Packing
38.	Ranolazine IH	Manufacturing & Packing
39.	Rifabutin USP	Manufacturing & Packing
40.	Rifampicin Ph.Eur./BP/USP	Manufacturing & Packing
41.	Rifaximin Ph.Eur./IH	Manufacturing & Packing
42.	Risperiodine Ph.Eur.	Manufacturing & Packing
43.	Sertraline Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
44.	Sevelamer Carbonate IH	Manufacturing & Packing
45.	Simvastatin Ph.Eur./BP/USP	Manufacturing & Packing
46.	Simvastatin Micronised USP	Manufacturing & Packing
47.	Telmisartan USP	Manufacturing & Packing
48.	Tenofovir Disoproxil Fumarate IH	Manufacturing & Packing
49.	Tolterodine Tartrate IH	Manufacturing & Packing
50.	Valsartan USP/Ph.Eur.	Manufacturing & Packing
51.	Venlafaxine Hydrochloride IH	Manufacturing & Packing
52.	Ziprasidone Hydrochloride USP	Manufacturing & Packing
53.	Zolpidem Tartrate USP/Ph.Eur.	Manufacturing & Packing

ITEM(S) fifty three (53) ONLY

The Written Confirmation remains valid until: Three years from date of issue

Signature

e/c ERC 30/08/19 Narendra Kumar 29/08/19

Stamp of the authority and date

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

11 SEP 2019

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

Annexure-2

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

List of APIs:

Sr. 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: Three 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

11 SEP 2019