F. No: 7-5/2013/EU/WC-049
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi- 110 002.
Dated: 17 DEC 2018

To,

M/s Lupin Limited.,
Block -21, Dabhasa,Tal.-Padra,
Dist.-Vadodara-391440,
Gujarat,India.

Sub: - 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 application submitted to CDSCO, Ahmedabad Zonal 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 The Written Confirmation will be withdrawn in the event of non-compliance of Standards.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 up to
01.	12	10.09.2018	05.06.2019
02.	03	07.12.2017	05.06.2019
03	01	19.03.2018	05.06.2019
04	03	25.06.2018	05.06.2019
05	02	29.10.2018	05.06.2019
06	01	17 DEC 2018	05.06.2019

Yours faithfully,

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

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

Annexure – 06
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 API:

S. No.	Active substance(s)	Activity(ies)
1	Esomeprazole Magnesium Dihydrate Ph.Eur	Manufacturing & Packing

ITEM One (01) ONLY

The Written Confirmation remains valid until: 05th June 2019.

Signature

Stamp of the authority and date

17 DEC 2018

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

CERTIFICATE NO. :

Amended
Annexure -05
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.

The Name of the drug mentioned in the Written Confirmation Certificate (WC-049) granted on date 29.10.2018 is hereby amended as follows:

S. No	*In place of:*	*Read as:*
1.	**"Levetriacetam USP"**	**"Levetiracetam USP"**

All the other conditions of Written Confirmation Certificate will remain same.

Signature

Stamp of the authority and date

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

17 DEC 2018