

**7-5/2013/EU/WC-0101**  
**Government of India**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organisation**  
**(International Cell)**

FDA Bhawan, Kotla Road  
New Delhi-110002

Dated: **07 OCT 2019**

To  
M/s Lake Chemicals Pvt Ltd.,  
No.21M, Attibele Industrial Area,  
Anekal Taluk, Bangalore-562107.

**SUB: Written Confirmation of M/s Lake Chemicals Pvt Ltd., No.21M, Attibele Industrial Area, Anekal Taluk, Bangalore-562107, 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, Sub-Zone Bangalore and the recommendation received from DDC (I), Sub Zone Bangalore 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	Validity
01	15	07 OCT 2019	02.07.2022
02	06	07 OCT 2019	02.07.2022

Yours faithfully,

*V.G.S.*

(Dr. V.G. Somani)

Drugs Controller General (India)

*n/c*  
*[Signature]*  
4.10.19

*[Signature]*  
4-10-19



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 Lake Chemicals Pvt Ltd.,  
No.21M, Attibele Industrial Area,  
Anekal Taluk, Bangalore-562107.
2. Manufacturer's license Number: KTK/25/295/92

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 Annexed

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<sup>th</sup> & 26<sup>th</sup> Feb 2019

The Written Confirmation remains valid until: 02<sup>nd</sup> JULY 2022

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

Vh

4-10-19



07 OCT 2019



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. 1. Name and address of site: M/s Lake Chemicals Pvt Ltd.,  
No.21M, Attibele Industrial Area,  
Anekal Taluk, Bangalore-562107.

List of APIs:

Sl.No.	Active substance(s)	Activity(ies)
1.	Bromazepam Ph.Eur/BP	Manufacturing & Packing.
2.	Flunitrazepam IH	Manufacturing & Packing
3.	Nordazepam IH	Manufacturing & Packing
4.	Pinazepam IH	Manufacturing & Packing
5.	Triazolam USP	Manufacturing & Packing
6.	Nimetazepam IH	Manufacturing & Packing

No. of Item(S) Six (06) 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 or sale in India.

The Written Confirmation remains valid until: 02.07.2022

Signature

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% 4.10.19

4-10-19

Stamp of the authority and date



07 OCT 2019



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

Annexure- 01  
CERTIFICATE NO. : WC 0101

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 Lake Chemicals Pvt Ltd.,  
No.21M, Attibele Industrial Area,  
Anekal Taluk, Bangalore-562107

List of APIs:

Sl.No.	Active Substance(s)	Activitie(s)
1.	Alprazolam Ph. Eur	Manufacturing & Packing
2.	Chlordiazepoxide Ph.Eur	Manufacturing & Packing
3.	Clobazam Ph.Eur	Manufacturing & Packing
4.	Clonazepam Ph. Eur	Manufacturing & Packing
5.	Diazepam Ph.Eur	Manufacturing & Packing
6.	Dorzolamide Hydrochloride USP	Manufacturing & Packing
7.	Flurazepam Dihydrochloride IH	Manufacturing & Packing
8.	Fluvoxamine Maleate EP	Manufacturing & Packing
9.	Loperamide Hydrochloride Ph.Eur	Manufacturing & Packing
10.	Lorazepam EP	Manufacturing & Packing
11.	Midazolam Hydrochloride IH	Manufacturing & Packing
12.	Midazolam Maleate IH	Manufacturing & Packing
13.	Midazolam Ph.Eur	Manufacturing & Packing
14.	Olanzapine IH	Manufacturing & Packing
15.	Zolpidem Tartarate Ph.Eur	Manufacturing & Packing

**ITEM(S) Fifteen (15) Only**

The Written Confirmation remains valid until: **02.07.2022**

Signature

*[Handwritten Signature]*

o/c

*[Handwritten Signature]* 4-10-19

*[Handwritten Signature]* 4-10-19



07 OCT 2019