7-5/2013/EU/WC-0107
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:

08 JUN 2022

To,

M/s Centaur Pharmaceuticals Private Limited,
Plot No. 75, 76 & 76/1 Chikhloli MIDC,
Ambernath (West), Thane-421501,
Maharashtra State, India

SUB:- Written Confirmation of M/s. Centaur Pharmaceuticals Private Limited, Plot No. 75, 76 & 76/1 Chikhloli MIDC, Ambernath (West), Thane-421501, Maharashtra State, 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/2022/2312 submitted to CDSCO, West Zonal office and the recommendation received from DDC(I), West Zonal office 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
01	33	08 JUN 2022	25.06.2025
02	15	08 JUN 2022	25.06.2025

Yours faithfully,

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

WC-0107

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

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. Centaur Pharmaceuticals Private Limited, Plot No. 75, 76 & 76/1 Chikhloli MIDC, Ambernath (West), Thane-421501, Maharashtra State, India**

2. **Manufacturer's licence number**: KD/1149 & KV/6

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 Annexure I & Annexure 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: 12.04.2022 & 13.04.2022

The Written Confirmation remains valid until: 25.06.2025

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

Signature

Stamp of the authority and date

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

08 JUN 2022

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

Annexure-01

CERTIFICATE NO. :

WC-0107

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. Centaur Pharmaceuticals Private Limited,
Plot No. 75, 76 & 76/1 Chikhloli MIDC,
Ambernath (West), Thane-421501,
Maharashtra State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Alprazolam IP/BP/EP/USP/JP	Manufacturing & Packing
2.	Aripiprazole IP/BP/EP/USP	Manufacturing & Packing
3.	Benzydamine Hydrochloride BP	Manufacturing & Packing
4.	Brimonidine Tartrate IP/BP/EP	Manufacturing & Packing
5.	Chlordiazepoxide IP/BP/EP/USP	Manufacturing & Packing
6.	Chloropyramine Hydrochloride IH	Manufacturing & Packing
7.	Clobazam IP/BP/EP	Manufacturing & Packing
8.	Clonazepam IP/BP/EP/USP	Manufacturing & Packing
9.	Diazepam IP/BP/EP/USP	Manufacturing & Packing
10.	Es-Zopiclone USP	Manufacturing & Packing
11.	Etizolam JP	Manufacturing & Packing
12.	Flupentixol Dihydrochloride BP/EP	Manufacturing & Packing
13.	Fluphenazine Hydrochloride IP/BP/EP/USP	Manufacturing & Packing
14.	Flurazepam Monohydrochloride EP/BP	Manufacturing & Packing
15.	Lorazepam BP/EP/USP	Manufacturing & Packing
16.	Loxapine Succinate USP	Manufacturing & Packing
17.	Melitracen Hydrochloride IH	Manufacturing & Packing
18.	Methyl Phenidate Hydrochloride BP/EP/USP	Manufacturing & Packing
19.	Metolazone BP/EP/USP	Manufacturing & Packing
20.	Midazolam BP/EP/USP	Manufacturing & Packing
21.	Midazolam Hydrochloride IH	Manufacturing & Packing
22.	Midazolam Maleate IH	Manufacturing & Packing
23.	Milnacipran HCL IH	Manufacturing & Packing
24.	Nitrazepam IP/BP	Manufacturing & Packing
25.	Oxazepam EP/USP/IP/BP	Manufacturing & Packing
26.	Rivastigmine Hydrogen Tartrate IH	Manufacturing & Packing
27.	Nitrazepam EP	Manufacturing & Packing
28.	Timolol Maleate IP/USP/EP/BP	Manufacturing & Packing

08 JUN 2022

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

CERTIFICATE NO. :

Annexure-01

WC-0107

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. Centaur Pharmaceuticals Private Limited,
Plot No. 75, 76 & 76/1 Chikhloli MIDC,
Ambernath (West), Thane-421501,
Maharashtra State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
29.	Tranyl Cypromine Sulphate BP	Manufacturing & Packing
30.	Zaleplon USP	Manufacturing & Packing
31.	Zolpidem Tartrate IP/BP/EP/USP	Manufacturing & Packing
32.	Zopiclone BP/EP	Manufacturing & Packing
33.	Tetrabenazine IH	Manufacturing & Packing

ITEM(S) Thirty Three (33) ONLY

The Written Confirmation remains valid until: 25/06/2025

Signature

Stamp of the authority and date

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

08 JUN 2022

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

CERTIFICATE NO. :

Annexure-02

WC-0107

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. Centaur Pharmaceuticals Private Limited,
Plot No. 75, 76 & 76/1 Chikhloli MIDC,
Ambernath (West), Thane-421501,
Maharashtra State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Bromazepam BP/EP	Manufacturing & Packing
2.	Brotizolam EP	Manufacturing & Packing
3.	Clotiazepam JP	Manufacturing & Packing
4.	Estazolam IH	Manufacturing & Packing
5.	Lormetazepam BP	Manufacturing & Packing
6.	Metopimazine IH	Manufacturing & Packing
7.	Nortriptyline Hydrochloride IP/BP/EP/USP	Manufacturing & Packing
8.	Pitofenone Hydrochloride IH	Manufacturing & Packing
9.	Prazepam EP	Manufacturing & Packing
10.	Propiverine Hydrochloride IH	Manufacturing & Packing
11.	Sodium Oxybate (Gamma Hydroxy Butyrate Sodium) IH	Manufacturing & Packing
12.	Temazepam BP/EP/USP	Manufacturing & Packing
13.	Tiemonium Methyl Sulfate IH	Manufacturing & Packing
14.	Triazolam USP	Manufacturing & Packing
15.	Fludiazepam IH	Manufacturing & Packing

ITEM(S) Fifteen (15) 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: 25/06/2025

Signature

08 JUN 2022

Stamp of the authority and date

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