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: 19 AUG 2025

To,

M/s. Centaur Pharmaceuticals Pvt. Ltd. (Private Limited)
Plot No. 75/76, 76/1 & 74, Chikhloli MIDC, Ambernath -421501,
Taluka: Ambarnath City, District: Thane-Zone 6,
Maharashtra, India

SUB:- Written Confirmation of **M/s. Centaur Pharmaceuticals Pvt. Ltd. (Private Limited), Plot No. 75/76, 76/1 & 74, Chikhloli MIDC, Ambernath -421501, Taluka: Ambarnath City, District: Thane-Zone 6, 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 no. **WC/RE/2025/10047** submitted to CDSCO, West – Zone Mumbai office, and the recommendation received from DDC (I), CDSCO, 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.

9. The manufacturer is required to comply to the provision of GSR 20(E) dated 18.01.2022.

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
--	--	19 AUG 2025	25.06.2028
01	32	19 AUG 2025	25.06.2028
02	32	19 AUG 2025	25.06.2028
03	14	19 AUG 2025	25.06.2028
04	21	19 AUG 2025	25.06.2028

Yours faithfully,

Chandrashekar
19/08/25

Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

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

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 & 74, Chikhloli MIDC,
Ambernath -421501, Taluka: Ambarnath City,
District: Thane-Zone 6, Maharashtra, India

2. Manufacturer's licence number: **25-KD/1149 & 25F-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(s) enclosed

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: 23.04.2025 & 24.04.2025

The Written Confirmation remains valid until: **25.06.2028**

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: Ranga Chandrashekar,
Joint Drugs Controller (India)

E-mail: ***ranga.cs@cdsco.nic.in;***
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Chandrashekar

Signature चंद्रशेखर रंगा/Chandrashekar Ranga 19/08/25
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

19 AUG 2025

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 & 74, Chikhloli MIDC,
Ambernath -421501, Taluka: Ambarnath City,
District: Thane-Zone 6, Maharashtra, India

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Chlordiazepoxide BP	Manufacturing & Packing
2.	Chlordiazepoxide EP	Manufacturing & Packing
3.	Chlordiazepoxide USP	Manufacturing & Packing
4.	Chloropyramine Hydrochloride IH	Manufacturing & Packing
5.	Clobazam IP	Manufacturing & Packing
6.	Clobazam BP	Manufacturing & Packing
7.	Clobazam EP	Manufacturing & Packing
8.	Clonazepam IP	Manufacturing & Packing
9.	Clonazepam BP	Manufacturing & Packing
10.	Clonazepam EP	Manufacturing & Packing
11.	Clonazepam USP	Manufacturing & Packing
12.	Diazepam IP	Manufacturing & Packing
13.	Diazepam USP	Manufacturing & Packing
14.	Diazepam BP	Manufacturing & Packing
15.	Diazepam EP	Manufacturing & Packing
16.	Es-Zopiclone USP	Manufacturing & Packing
17.	Etizolam JP	Manufacturing & Packing
18.	Flupentixol Dihydrochloride BP	Manufacturing & Packing
19.	Flupentixol Dihydrochloride EP	Manufacturing & Packing
20.	Fluphenazine Hydrochloride IP	Manufacturing & Packing
21.	Fluphenazine Hydrochloride BP	Manufacturing & Packing
22.	Fluphenazine Hydrochloride EP	Manufacturing & Packing
23.	Fluphenazine Hydrochloride USP	Manufacturing & Packing
24.	Flurazepam Monohydrochloride EP	Manufacturing & Packing
25.	Flurazepam Monohydrochloride BP	Manufacturing & Packing
26.	Lorazepam BP	Manufacturing & Packing
27.	Lorazepam EP	Manufacturing & Packing
28.	Lorazepam USP	Manufacturing & Packing
29.	Loxapine succinate USP	Manufacturing & Packing
30.	Melitracen Hydrochloride IH	Manufacturing & Packing
31.	Metolazone BP	Manufacturing & Packing
32.	Metolazone EP	Manufacturing & Packing

Item(s) Thirty-Two (32) Only

The Written Confirmation remains valid until: 25.06.2028

Chandrashekar 19/08/25

Signature चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

19 AUG 2025

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 & 74, Chikhloli MIDC,
Ambernath -421501, Taluka: Ambarnath City,
District: Thane-Zone 6, Maharashtra, India

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Metolazone USP	Manufacturing & Packing
2.	Midazolam BP	Manufacturing & Packing
3.	Midazolam EP	Manufacturing & Packing
4.	Midazolam USP	Manufacturing & Packing
5.	Midazolam Hydrochloride IH	Manufacturing & Packing
6.	Midazolam Maleate IH	Manufacturing & Packing
7.	Milnacipran HCL IH	Manufacturing & Packing
8.	Nitrazepam IP	Manufacturing & Packing
9.	Nitrazepam BP	Manufacturing & Packing
10.	Nitrazepam EP	Manufacturing & Packing
11.	Oxazepam EP	Manufacturing & Packing
12.	Oxazepam IP	Manufacturing & Packing
13.	Oxazepam BP	Manufacturing & Packing
14.	Oxazepam USP	Manufacturing & Packing
15.	Rivastigmine Hydrogen Tartrate IH	Manufacturing & Packing
16.	Timolol Maleate IP	Manufacturing & Packing
17.	Timolol Maleate BP	Manufacturing & Packing
18.	Timolol Maleate EP	Manufacturing & Packing
19.	Timolol Maleate USP	Manufacturing & Packing
20.	Tranyl Cypromine Sulphate BP	Manufacturing & Packing
21.	Zaleplon USP	Manufacturing & Packing
22.	Zolpidem Tartrate IP	Manufacturing & Packing
23.	Zolpidem Tartrate BP	Manufacturing & Packing
24.	Zolpidem Tartrate EP	Manufacturing & Packing
25.	Zolpidem Tartrate USP	Manufacturing & Packing
26.	Zopiclone BP	Manufacturing & Packing
27.	Zopiclone EP	Manufacturing & Packing
28.	Tetrabenazine IH	Manufacturing & Packing
29.	Linagliptin IH	Manufacturing & Packing
30.	Methyl Phenidate Hydrochloride BP	Manufacturing & Packing
31.	Methyl Phenidate Hydrochloride EP	Manufacturing & Packing
32.	Methyl Phenidate Hydrochloride USP	Manufacturing & Packing

Item(s) Thirty-Two (32) Only

The Written Confirmation remains valid until: 25.06.2028

Signature

Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

19 AUG 2025

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

CERTIFICATE NO. :

Annexure-03
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 & 74, Chikhloli MIDC,
   Ambernath -421501, Taluka: Ambarnath City,
   District: Thane-Zone 6, Maharashtra, India

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Alprazolam IP	Manufacturing & Packing
2.	Alprazolam BP	Manufacturing & Packing
3.	Alprazolam EP	Manufacturing & Packing
4.	Alprazolam USP	Manufacturing & Packing
5.	Alprazolam JP	Manufacturing & Packing
6.	Aripiprazole IP	Manufacturing & Packing
7.	Aripiprazole BP	Manufacturing & Packing
8.	Aripiprazole EP	Manufacturing & Packing
9.	Aripiprazole USP	Manufacturing & Packing
10.	Benzydamine Hydrochloride BP	Manufacturing & Packing
11.	Brimonidine Tartrate IP	Manufacturing & Packing
12.	Brimonidine Tartrate BP	Manufacturing & Packing
13.	Brimonidine Tartrate EP	Manufacturing & Packing
14.	Chlordiazepoxide IP	Manufacturing & Packing

Item(s) Fourteen (14) Only

The Written Confirmation remains valid until: 25.06.2028

Signature चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare, Govt. of India
सत्यमेव जयते

19 AUG 2025

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

Annexure-04
WC-0107

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 & 74, Chikhloli MIDC,
Ambernath -421501, Taluka: Ambarnath City,
District: Thane-Zone 6, Maharashtra, India

List of API(s):

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

Item(s) Twenty-One (21) 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 substance(s) for the purpose of export only, as the above-mentioned active substance(s) are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 25.06.2028

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

19 AUG 2025