Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002

No.: 7-5/2013/EU/WC-0107(Amended)

Dated 08 AUG 2013

To

M/s. Centaur Pharmaceuticals Pvt. Ltd.,
Plot No. 75/76, Chikhloli, MIDC,
Ambernath (W), Dist- Thane Maharashtra.

SUB:- Written Confirmation of M/s. Centaur Pharmaceuticals Pvt. Ltd., Plot No. 75/76, Chikhloli, MIDC, Ambernath (W), Dist- Thane Maharashtra 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 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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.

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

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 Pvt. Ltd.,**
Plot No. 75/76, Chikhloli, MIDC,Ambernath (W),
Dist- Thane, Maharashtra.

2. Manufacturer's licence number: 1149 & KV-06

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

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: 25th May, 2011

The Written Confirmation remains valid until: **02nd July, 2016**

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. G.N. Singh,
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

08 AUG 2011

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

CERTIFICATE. NO. :

Annexure-1
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 Pvt. Ltd.,**
Plot No. 75/76, Chikhloli, MIDC,Ambernath (W),
Dist- Thane, Maharashtra.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Alprazolam (IP/BP/EP/USP/JP)	Manufacturing & Packing
2.	Aripiprazole	Manufacturing & Packing
3.	Benzydamine Hydrochloride (BP)	Manufacturing & Packing
4.	Brimonidine Tartrate	Manufacturing & Packing
5.	Chlordiazepoxide (IP/BP/EP/USP)	Manufacturing & Packing
6.	Chloropyramine Hydrochloride	Manufacturing & Packing
7.	Clobazam (BP/EP/IP)	Manufacturing & Packing
8.	Clonazepam (IP/BP/EP/USP)	Manufacturing & Packing
9.	Diazepam (IP/BP/EP/USP)	Manufacturing & Packing
10.	Es-Zopiclone	Manufacturing & Packing
11.	Flupentixol Di-Hydrochloride (BP/EP)	Manufacturing & Packing
12.	Lorazepam (BP/EP/USP)	Manufacturing & Packing
13.	Melitracen Hydrochloride	Manufacturing & Packing
14.	Methylphenidate HCl (BP/EP/USP)	Manufacturing & Packing
15.	Metolazone (BP/EP/USP)	Manufacturing & Packing
16.	Midazolam (BP/EP/USP)	Manufacturing & Packing
17.	Midazolam HCl	Manufacturing & Packing
18.	Midazolam Maleate	Manufacturing & Packing
19.	Nimorazole	Manufacturing & Packing
20.	Nitrazepam (IP/EP/BP)	Manufacturing & Packing
21.	Nortriptyline HCl (IP/BP/EP/USP)	Manufacturing & Packing
22.	Olopatadine HCl (USP)	Manufacturing & Packing
23.	Oxazepam (IP/BP/EP/USP)	Manufacturing & Packing
24.	Rivastigmine Hydrogen Tartrate	Manufacturing & Packing
25.	Sodium Oxybate (Gamma Hydroxy Butyrate Sodium)	Manufacturing & Packing
26.	Temazepam (BP/EP/USP)	Manufacturing & Packing
27.	Tetrabenazine	Manufacturing & Packing
28	Tetrazepam (BP/EP)	Manufacturing & Packing
29.	Tiemonium Methyl Sulfate	Manufacturing & Packing
30.	Timolol Maleate (IP/BP/EP/USP)	Manufacturing & Packing
31.	Triazolam (USP)	Manufacturing & Packing
32.	Zaleplon (USP)	Manufacturing & Packing
33.	Zolpidem Tartrate (IP/BP/EP/USP)	Manufacturing & Packing
34.	Zopiclone (BP/EP)	Manufacturing & Packing

ITEM(S) Thirty Four (34) ONLY

The Written Confirmation remains valid until: 12th June, 2016

Signature

Stamp of the authority and date

08 AUG 2013

Annexure-2

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 Pvt. Ltd.,
Plot No. 75/76, Chikhloli, MIDC,Ambernath (W),
Dist- Thane, Maharashtra.

AP List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Metopimazine	Manufacturing & Packing
2.	Pitofenone HCl	Manufacturing & Packing
3.	Bromazepam (BP/EP)	Manufacturing & Packing

ITEM(S) Three(03) 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: 02nd July, 2016

Signature

Stamp of the authority and date

08 AUG 2013