

**F.No:7-5/2013/EU/WC-0147**  
**Government of India**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organisation**  
**(International Cell)**

FDA Bhawan, Kotla Road  
New Delhi-110002

Dated: 05 JUL 2019

To  
M/s Shilpa Medicare Limited,  
100% EOU, Raichur Industrial Growth Centre,  
Plot No. 33, 33A, 40-47, Block C,D,E,H,I,AM,  
Chicksugur-584134, District-Raichur,  
Karnataka, INDIA.

**SUB:Written Confirmation of M/s Shilpa Medicare Limited, 100% EOU, Raichur Industrial Growth Centre,Plot No. 33, 33A, 40-47, Block C, D, E, H, I, AM, Chicksugur-584134, District-Raichur, Karnataka, INDIA 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, Bangalore Sub Zone and the recommendation received from DDC (I), Bangalore Sub 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.

*o/c*

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	17	05 JUL 2019	02.07.2022
02	01	05 JUL 2019	02.07.2022

Yours faithfully,

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

o/c  
28.06.2019

28-6-19

01/07/19



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 Shilpa Medicare Limited,  
100% EOU, Raichur Industrial Growth Centre,  
Plot No. 33, 33A, 40-47, Block C, D, E, H, I, AM,  
Chicksugur-584134, District-Raichur,  
Karnataka, INDIA.

2. Manufacturer's license Number: KTK/25/564/2009

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: 07<sup>th</sup> & 08<sup>th</sup> MAY 2019

The Written Confirmation remains valid until: 02.07.2022.

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

E-mail:

Telephone no.:

Fax no.:

dci@nic.in,

+91-11-23236965

+91-11-23236973

Signature

Stamp of the authority and date



05 JUL 2019

o/c [Signature] 28-06-2019 [Signature] 28-6-19 [Signature] 01/07/19



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

Annexure - 02  
WC-0147

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Karnataka, INDIA.

List of APIs:

S. No.	Name of the Active substance(s)	Activity(ies)
1	Fingolimod Hydrochloride IH	Manufacturing & Packing.

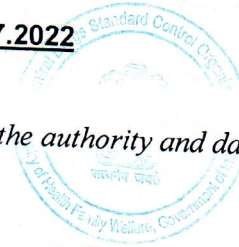
ITEM(S) ONE (01) Only

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

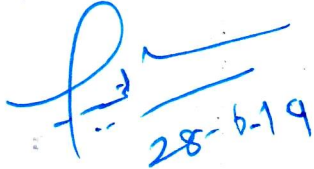
  
Signature

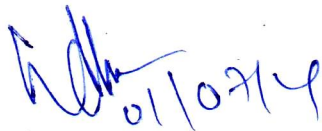
Stamp of the authority and date



05 JUL 2019

*o/c*  28-06-2019

  
28-6-19

  
01/07/19



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Karnataka, INDIA.

List of APIs:

Sl.No.	Name of the Active Substances	Activitie(s)
1.	Anastrozole USP/Ph.Eur	Manufacturing and Packing
2.	Azacitidine IH	Manufacturing and Packing
3.	Bendamustine Hydrochloride IH	Manufacturing and Packing
4.	Bicalutamide IH	Manufacturing and Packing
5.	Bortezomib IH	Manufacturing and Packing
6.	Busulfan Ph.Eur/USP	Manufacturing and Packing
7.	Capecitabine USP/Ph.Eur	Manufacturing and Packing
8.	Decitabine IH	Manufacturing and Packing
9.	Erlotinib Hydrochloride IH	Manufacturing and Packing
10.	Imatinib Mesylate IH	Manufacturing and Packing
11.	Letrozole USP	Manufacturing and Packing
12.	Pemetrexed Disodium IH	Manufacturing and Packing
13.	Prucalopride Succinate IH	Manufacturing and Packing
14.	Tenofovir Disoproxil Fumarate IH	Manufacturing and Packing
15.	Tranexamic Acid USP/Ph.Eur	Manufacturing and Packing
16.	Sorafenib IH	Manufacturing and Packing
17.	Zoledronic Acid IH	Manufacturing and Packing

**ITEM(S) Seventeen (17) Only**

The Written Confirmation remains valid until: 02.07.2022

  
Signature

Stamp of the authority and date



05 JUL 2019

etc 28-06-2019

  
01/07/19