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: 28 JAN 2019

To

M/s. Shilpa Medicare Ltd., 100% EOU,
Plot No. 33, 33A, 40 to 47, Block C,D,E,H,I and AM,
Raichur Industrial Growth Center,
Chicksugar-584134, District-Raichur

SUB: - Written Conf rmation of M/s. Shilpa Medicare Ltd., 100% EOU, Plot No. 33, 33A, 40 to 47, Block C,D,E,H,I and AM, Raichur Industrial Growth Center, Chicksugar-584134, District-Raichur, 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	Valid upto
01	19	27/06/2016	02/07/2019
02	01	27/06/2016	02/07/2019
03	03	28 JAN 2019	02/07/2019
04	01	28 JAN 2019	02/07/2019

Yours faithfully,

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

15/01/19

15-01-19

Annexure-03

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

CERTIFICATE NO. : WC-0147

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 Ltd., 100% EOU, Plot No. 33, 33A, 40 to 47, Block C,D,E,H,I and AM, Raichur Industrial Growth Center, Chicksugar-584134, District-Raichur.**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1	Azacitidine IH	Manufacturing & Packing
2	Capecitabine Ph. Eur.	Manufacturing & Packing
3	Tranexamic Acid USP/ Ph. Eur.	Manufacturing & Packing

ITEM(S) Three (03) ONLY

The Written Confirmation remains valid until: 02/07/2019

Signature

a/c ency 15/01/19

Stamp of the authority and date

28 JAN 2019

Annexure-04

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

CERTIFICATE NO. : WC-0147

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 Ltd., 100% EOU, Plot No. 33, 33A, 40 to 47, Block C,D,E,H,I and AM, Raichur Industrial Growth Center, Chicksugar-584134, District-Raichur.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1	Prucalopride Succinate IH	Manufacturing & Packing

ITEM(S) One (01) ONLY

This certificate is being issued subject to condition that the firm shall obtained NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substance for the purpose of export only, as the above mentioned active substance is not approved for manufacture for sale in India

The Written Confirmation remains valid until: 02/07/2019

Signature

a/c encl 15/01/19

Stamp of the authority and date

28 JAN 2019