7-5/2013/EU/WC-0115
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 08 JUL 2019

To,

M/s. Fresenius Kabi Oncology Ltd.,
D-35, Industrial Area, Kalyani,
Dist-Nadia-741235, West Bengal

SUB:- Written Confirmation of M/s. Fresenius Kabi Oncology Ltd., D-35, Industrial Area, Kalyani, Dist-Nadia-741235, West Bengal 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, East Zone office and the recommendation received from ADC(I), East 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	20	08 JUL 2019	Three years from the date of issue
02	02	08 JUL 2019	Three years from the date of issue

Yours faithfully,

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

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

CERTIFICATE NO. : WC-0115

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. Fresenius Kabi Oncology Ltd.,
D-35, Industrial Area, Kalyani,
Dist-Nadia-741235, West Bengal

2. Manufacturer's licence number: DL-1501-M

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- 01 & Annexure- 02

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: 17-18/06/2019

The Written Confirmation remains valid until: Three years from the date of issue

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: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

Stamp of the authority and date

08 JUL 2019

Annexure – 01

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

CERTIFICATE NO. : WC-0115

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. Fresenius Kabi Oncology Ltd.,
D-35, Industrial Area, Kalyani,
Dist-Nadia-741235, West Bengal

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Anastrozole USP	Manufacturing & Packing
2.	Busulfan USP/BP/EP	Manufacturing & Packing
3.	Docetaxel anhydrous IH	Manufacturing & Packing
4.	Docetaxel Trihydrate Ph.Eur	Manufacturing & Packing
5.	Docetaxel USP	Manufacturing & Packing
6.	Gemcitabine Hydrochloride Ph.Eur/USP	Manufacturing & Packing
7.	Letrozole Ph.Eur/BP/USP	Manufacturing & Packing
8.	Paclitaxel (Semisynthetic) Ph.Eur	Manufacturing & Packing
9.	Paclitaxel (Semisynthetic Test-2) USP	Manufacturing & Packing
10.	Bicalutamide USP	Manufacturing & Packing
11.	Carboplatin Ph.Eur/USP	Manufacturing & Packing
12.	Irinotecan Hydrochloride trihydrate USP	Manufacturing & Packing
13.	Oxaliplatin USP/Ph.Eur/ BP	Manufacturing & Packing
14.	Pemetrexed Disodium IH	Manufacturing & Packing
15.	Decitabine IH	Manufacturing & Packing
16.	Imatinib Mesylate IP	Manufacturing & Packing
17.	Gefitinib IP	Manufacturing & Packing
18.	Erlotinib Hydrochloride IH	Manufacturing & Packing
19.	Bendamustine Hydrochloride IH	Manufacturing & Packing
20.	Bortezomib IH	Manufacturing & Packing

ITEM(S) Twenty (20) ONLY

The Written Confirmation remains valid until: Three years from the date of issue

Signature

Stamp of the authority and date

08 JUL 2019

Annexure-02

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

CERTIFICATE NO. : WC-0115

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. Fresenius Kabi Oncology Ltd.,
D-35, Industrial Area, Kalyani,
Dist-Nadia-741235, West Bengal

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Levobupivacaine Hydrochloride IH	Manufacturing & Packing
2.	Belinostat IH	Manufacturing & Packing

ITEM(S) Two (02) 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: **Three years from the date of issue**

Signature

Stamp of the authority and date

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

08 JUL 2019