

7-5/2013/EU/WC-0100  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organisation  
(International Cell)

(Amended)

FDA Bhawan, Kotla Road,  
New Delhi-110002

Dated 22 JUL 2019

To

**M/s. Biocon limited - SEZ  
Plot No .2,3,4 & 5, Phase-IV,  
Bommasandra-Jigani Link Road,  
Bommasandra Post, Bengaluru – 560 099**

**SUB:-** Written Confirmation of M/s. Biocon limited - SEZ, Plot No .2,3,4 & 5, Phase-IV, Bommasandra-Jigani Link Road, Bommasandra Post, Bengaluru – 560 099 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 office, 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.

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	12	22 JUL 2019	02.07.2022
02	01	26.06.2019	02.07.2022

Yours faithfully,



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

o/c  
19.07.2019

f...  
14.7.19

19/07/19





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. Biocon limited - SEZ  
Plot No .2, 3, 4 & 5, Phase-IV,  
Bommasandra-Jigani Link Road,  
Bommasandra Post, Bengaluru – 560 099

2. Manufacturer's licence number: KTK/25/514/2005 & KTK/28/351/2005

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 1 & Annexure 2

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: 22.05.2019 & 23.05.2019

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

26 JUN 2019





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. Biocon Limited - SEZ  
Plot No .2, 3, 4 & 5, Phase-IV,  
Bommasandra-Jigani Link Road,  
Bommasandra Post, Bengaluru – 560099

List of APIs:

Sr. No.	Name of the Active substance (s)	Activitie(s)
1.	Simvastatin Ph.Eur/USP	Manufacturing & Packing
2.	Atorvastatin Calcium Trihydrate Ph. Eur	Manufacturing & Packing
3.	Atorvastatin Calcium IH	Manufacturing & Packing
4.	Atorvastatin Magnesium IH	Manufacturing & Packing
5.	Pravastatin Sodium Ph. Eur	Manufacturing & Packing
6.	Lovastatin Ph. Eur	Manufacturing & Packing
7.	Orlistat IH	Manufacturing & Packing
8.	Everolimus IH	Manufacturing & Packing
9.	Temsirolimus IH	Manufacturing & Packing
10.	Micafungin Sodium IH	Manufacturing & Packing
11.	Pioglitazone Hydrochloride IH	Manufacturing & Packing
12.	Vildagliptin IH	Manufacturing & Packing

**ITEM(S)Twelve (12) Only**


The Written Confirmation remains valid until: **02.07.2022**

  
Signature

Stamp of the authority and date



o/c  
19.7.2019

  
19.7.19  
Ad. 19/07/19





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. Biocon limited - SEZ**  
**Plot No .2, 3, 4 & 5, Phase-IV,**  
**Bommasandra-Jigani Link Road,**  
**Bommasandra Post, Bengaluru – 560 099**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Fidaxomicin 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 for sale in India.

The Written Confirmation remains valid until: 02.07.2022

Signature



Stamp of the authority and date

26 JUN 2019