

7-5/2013/EU/WC-0001
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: 21 MAY 2019

To,

M/s. Teva API India Pvt. Ltd.,
Plot No. Q1 to Q4, Industrial Area, Ghirongi,
Malanpur Distt. Bhind (M.P.)

SUB:- Written Confirmation of M/s. Teva API India Pvt. Ltd., Plot No. Q1 to Q4, Industrial Area, Ghirongi, Malanpur Distt. Bhind (M.P.) 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 Indore and the recommendation received from ADC(I), Sub Zone Indore 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	21 MAY 2019	Three years from the date of issue
02	01	21 MAY 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-0001

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. Teva API India Pvt. Ltd.,
Plot No. Q1 to Q4, Industrial Area, Ghirongi,
Malanpur Distt. Bhind (M.P.)

2. Manufacturer's licence number: 25/03/2009

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 enclosed as Annexure- 01 & 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: 09.04.2019 & 10.04.2019

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:

Telephone no.:

Fax no.:

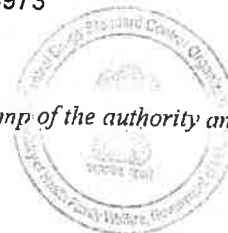
dcj@nic.in,

+91-11-23236965

+91-11-23236973

Signature

Stamp of the authority and date



21 MAY 2019



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

Annexure – 01

CERTIFICATE NO. : WC-0001

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. Teva API India Pvt. Ltd.,
Plot No. Q1 to Q4, Industrial Area, Ghirongi,
Malanpur Distt. Bhind (M.P.)

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Clopidogrel Bisulfate EP/USP	Manufacturing & Packing
2.	Olmesartan Medoxomil IH	Manufacturing & Packing
3.	Sofosbuvir IH	Manufacturing & Packing
4.	Losartan Potassium EP	Manufacturing & Packing
5.	Atorvastatin Calcium EP	Manufacturing & Packing
6.	Quetiapine Fumarate IH	Manufacturing & Packing
7.	Sitagliptin Phosphate IH	Manufacturing & Packing
8.	Sitagliptin Malate IH	Manufacturing & Packing
9.	Dabigatran Etxilate Mesylate IH	Manufacturing & Packing
10.	Ticagrelor IH	Manufacturing & Packing
11.	Desvenlafaxine Base	Manufacturing & Packing
12.	Desfesoterodine Succinate IH	Manufacturing & Packing

ITEM(S) Twelve (12) ONLY

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


Signature


Stamp of the authority and date

21 MAY 2019



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

Annexure-02

CERTIFICATE NO. :

WC-0001

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. Teva API India Pvt. Ltd.,
Plot No. Q1 to Q4, Industrial Area, Ghirongi,
Malanpur Dist. Bhind (M.P.)

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Edoxaban Tosylate 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: Three years from the date of issue.

Signature

Stamp of the authority and date



21 MAY 2019



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

Annexure – 03

CERTIFICATE NO. : WC-0001

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. Teva API India Pvt. Ltd.,
Plot No. Q1 to Q4, Industrial Area, Ghirongi,
Malanpur Distt. Bhind (M.P.)

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Clarithromycin EP	Manufacturing & Packing
2.	Irbesartan EP	Manufacturing & Packing
3.	Clopidogrel Bisulphate Form II IH	Manufacturing & Packing

ITEM(S) Three (03) ONLY

The Written Confirmation remains valid until: 20.05.2022


Signature


Stamp of the authority and date

17 JUN 2019



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

CERTIFICATE NO. :

Annexure-4
WC-0001

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

Name and address of site: M/s. Teva API India Pvt. Ltd.,
Plot No. Q1 to Q4,
Industrial Area, Ghrongi,
Malanpur, Distt. Bhind (M.P.), India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Amitriptyline Hydrochloride Ph.Eur	Manufacturing & Packing
2.	Solifinacin Succinate Ph.Eur	Manufacturing & Packing
3.	Doxepin Hydrochloride Ph.Eur	Manufacturing & Packing
4.	Imipramine Hydrochloride Ph.Eur	Manufacturing & Packing
5.	Potassium Citrate USP	Manufacturing & Packing

ITEM(S) Five (05) ONLY

The Written Confirmation remains valid until: 25.05.2022

o/c

Signature

14/05/2020

Stamp of the authority and date



19 MAR 2020