7-5/2013/EU/WC-0002
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002

Amended

Dated: 17 JUN 2019

To

M/s. Teva API India Private Limited,
Plot No. A-2, A-2/1, A-2/2,
UPSIDC Industrial Area-II, Bijnor Road,
Gajraula, Distt. Amroha (U.P), India

Subject:- Written Confirmation of M/s. Teva API India Private Limited, Plot No. A-2, A-2/1, A-2/2, UPSIDC Industrial Area-II, Bijnor Road, Gajraula, Distt. Amroha (U.P), 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, North Zone Ghaziabad and the recommendation received from DDC(I), North Zone Ghaziabad 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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.

ATESTED TRUE COPY
For Western U.P.Chamber of Commerce & Industry
S K DEY
Assistant Secretary
25/4/19

WESTERN U.P. CHAMBER OF COMMERCE & INDUSTRY MEERUT (U.P.INDIA)

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
1	16	17 JUN 2019	26.05.2022

Yours faithfully,

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

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For Western U.P.Chamber of Commerce & Industry
S K. DEY
Assistant Secretary

CHAMBER OF COMMERCE MEERUT (INDIA)

The Ministry of External Affairs accepts no responsibility for the contents of the above document.

भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)

Country: REPUBLIC OF INDIA

This public document
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has been signed by N/A
acting in the capacity of N/A
bears the seal/stamp of ASSTT. SECY, WESTERN UP CHAMBER OF COMMERCE & INDUSTRY

Certified
at NEW DELHI, INDIA the 24-Jul-2019
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. UPLU0007010219

Signature

Seal / Stamp

is issued to TEVA API INDIA PVT.LTD.

(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ. आई.)
Section Officer (OI)
सी. पी. वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

Amended

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

CERTIFICATE NO. : WC-0002

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 Private Limited,**
Plot No. A-2, A-2/1, A-2/2,
UPSIDC Industrial Area-II, Bijnor Road,
Gajraula, Distt. Amroha (U.P), India

2. Manufacturer's licence number: 21 of 1994 & 11/SC/P of 1998

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-1
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: 28.02.2019 & 01.03.2019

The Written Confirmation remains valid until: 26th May 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: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

Stamp of the authority and date

17 JUN 2019

ATESTED TRUE COPY
For Western U.P.Chamber of Commerce & Industry
S. K. DEY
Assistant Secretary
25/6/19

WESTERN U.P. CHAMBER OF COMMERCE & INDUSTRY MEERUT (U.P.INDIA)

भारत सरकार GOVERNMENT OF INDIA

अपोस्टिल / APOSTILLE

(Convention de La Haye du 5 octobre 1961)

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Country REPUBLIC OF INDIA

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Certified

at NEW DELHI, INDIA the 24-Jul-2019

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. UPLU0007010319

Seal / Stamp

Signature

is issued to TEVA API INDIA PVT.LTD.

(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (आ. आई.)
Section Officer (OI)
सी. पी. वी. प्रभाग / C.P.V Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

Amended

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

Annexure-1

CERTIFICATE NO. : WC-0002

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 Private Limited,
Plot No. A-2, A-2/1, A-2/2,
UPSIDC Industrial Area-II, Bijnor Road,
Gajraula, Distt. Amroha (U.P), India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Famciclovir USP/IH	Manufacturing & Packing
2.	Fluvastatin Sodium USP/IH/EP	Manufacturing & Packing
3.	Olanzapine USP/EP/IH	Manufacturing & Packing
4.	Irbesartan USP/EP/IH	Manufacturing & Packing
5.	Montelukast Sodium USP/EP/IH	Manufacturing & Packing
6.	Quetiapine Fumarate USP/IH	Manufacturing & Packing
7.	Diltiazem Hydrochloride USP/EP/IH	Manufacturing & Packing
8.	Ezetimibe USP/IH	Manufacturing & Packing
9.	Pioglitazone Hydrochloride USP/EP/IH	Manufacturing & Packing
10.	Valsartan USP/EP/IH	Manufacturing & Packing
11.	Losartan Potassium USP/EP/IH	Manufacturing & Packing
12.	Pregabalin USP/EP/IH	Manufacturing & Packing
13.	Atorvastatin Calcium USP/IH	Manufacturing & Packing
14.	Caspofungin Acetate IH	Manufacturing & Packing
15.	Eletriptan Hydrobromide IH	Manufacturing & Packing
16.	Rosuvastatin Calcium EP/IH	Manufacturing & Packing

ITEM(S) Sixteen (16) ONLY

The Written Confirmation remains valid until: 26th May 2022

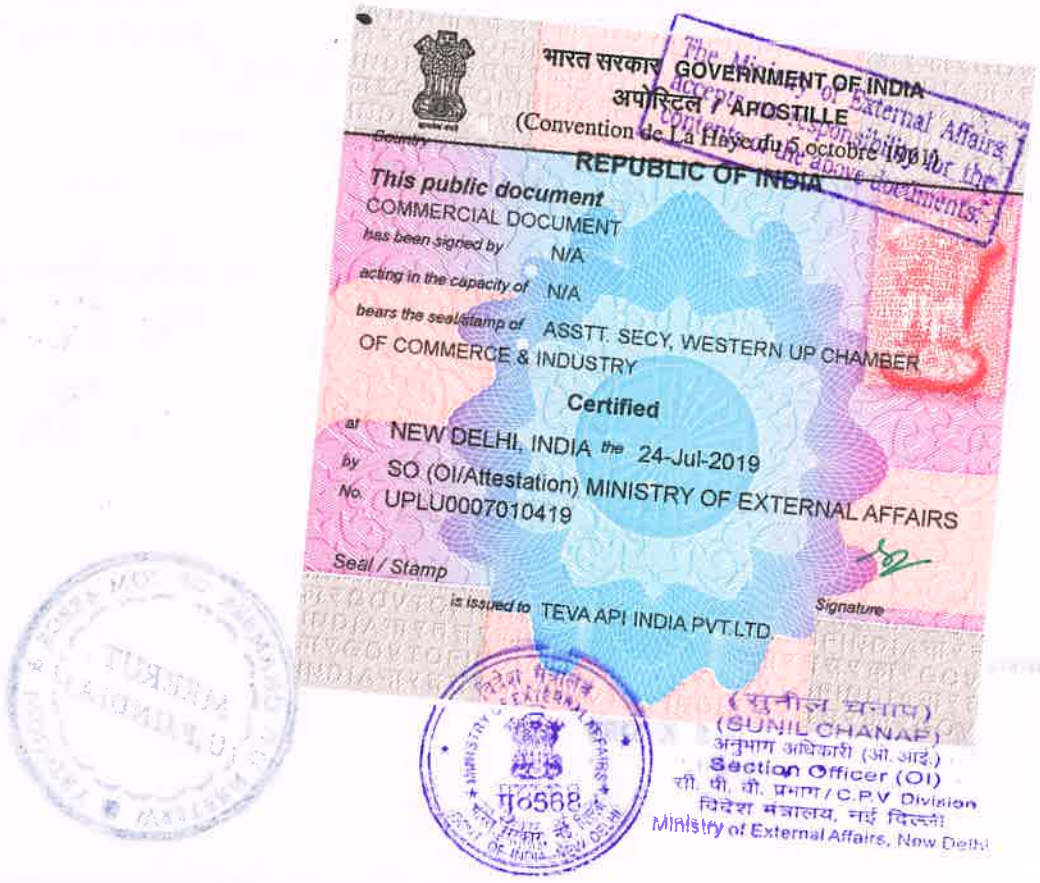
Signature

Stamp of the authority and date

17 JUN 2019

ATESTED TRUE COPY
For Western U.P. Chamber of Commerce & Industry
S K DEY
Assistant
25/4/19

WESTERN U.P. CHAMBER OF COMMERCE & INDUSTRY MEERUT (U.P. INDIA)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(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ. आई.)
Section Officer (OI)
सी. पी. वी. प्रभाग / C.P.V. Division
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Ministry of External Affairs, New Delhi