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:

19 MAR 2020

To

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

Subject:- Written Confirmation of M/s. Teva API India Pvt. Ltd., Plot No. Q1 to Q4, Industrial Area, Ghirongi, Malanpur, Distt. Bhind (M.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, 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
1.	12	21.05.2019	20.05.2022
2.	01	21.05.2019	20.05.2022
3.	03	17.06.2019	20.05.2022
4.	05	19 MAR 2020	20.05.2022

O LC

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

16/07/2020

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, Ghirongi,
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

OIC

Signature

16/03/2020

Stamp of the authority and date

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

19 MAR 2020