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
04 JUN 2025

To

M/s. Teva API India Pvt. Ltd.,
Plot No. Q1 to 4 Industrial Area, Ghirongi,
Malanpur, District -Bhind (M.P.), India

SUB:- Written Confirmation of **M/s. Teva API India Pvt. Ltd., Plot No. Q1 to 4 Industrial Area, Ghirongi, Malanpur, District -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 no. WC/RE/2025/10186 submitted to CDSCO, DDC(I), Indore Sub-Zone office, and the recommendation received from DDC(I), Indore Sub-Zone 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.

9. The manufacturer is required to comply to the provision of GSR 20(E) dated 18.01.2022.

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
--	--	04 JUN 2025	20.05.2028
01	20	04 JUN 2025	20.05.2028
02	02	04 JUN 2025	20.05.2028

Yours faithfully,

04/06/25

Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन / स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O./HQs, Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

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 4 Industrial Area, Ghirongi,
Malanpur, District -Bhind (M.P.), India

2. Manufacturer's licence number: **25/3/2009 & 28/38/2009**

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 the annexure(s) enclosed

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: 09.05.2025 & 10.05.2025

The Written Confirmation remains valid until: **20.05.2028**

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: Ranga Chandrashekar,
Joint Drugs Controller (India)

E-mail: ***ranga.cs@cdsco.nic.in;***
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Chandrashekar
04/06/25

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

Ministry of Health & Family Welfare, Govt. of India * Central Drugs Standard Control Organisation *
सत्यमेव जयते

0 4 JUN 2025

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

CERTIFICATE NO. : Annexure-01 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 4 Industrial Area, Ghirongi,
Malanpur, District -Bhind (M.P.), India

List of API(s):

S. No.	Active substance (s)	Activity(ies)
1.	Amitriptyline Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
2.	Atorvastatin Calcium USP/Ph.Eur.	Manufacturing & Packing
3.	Clarithromycin USP/Ph.Eur.	Manufacturing & Packing
4.	Clopidogrel Bisulfate IH/USP/Ph.Eur.	Manufacturing & Packing
5.	Clopidogrel Bisulphate (Form II) IH	Manufacturing & Packing
6.	Dabigatran Etexilate Mesylate IH	Manufacturing & Packing
7.	Desfesoterodine Succinate IH	Manufacturing & Packing
8.	Desvenlafaxine Base	Manufacturing & Packing
9.	Doxepin Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
10.	Edoxaban Tosylate IH	Manufacturing & Packing
11.	Imipramine Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
12.	Irbesartan USP/Ph.Eur.	Manufacturing & Packing
13.	Losartan Potassium USP/Ph.Eur.	Manufacturing & Packing
14.	Olmesartan Medoxomil IH	Manufacturing & Packing
15.	Potassium Citrate USP	Manufacturing & Packing
16.	Quetiapine Fumarate IH/USP	Manufacturing & Packing
17.	Sitagliptin Malate IH	Manufacturing & Packing
18.	Sofosbuvir IH	Manufacturing & Packing
19.	Solifenacin Succinate USP/Ph.Eur.	Manufacturing & Packing
20.	Ticagrelor IH	Manufacturing & Packing

ITEM(S) Twenty (20) ONLY

The Written Confirmation remains valid until: 20.05.2028

Chandrashekhar 04/06/25

Signature
चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ डी ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date
Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare, Govt. of India
सत्यमेव जयते
04 JUN 2025

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

Annexure-02
WC-0001

CERTIFICATE NO. :

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 4 Industrial Area, Ghirongi,
Malanpur, District -Bhind (M.P.), India

List of API(s):

S. No.	Active substance (s)	Activity(ies)
1.	Ferric Citrate IH	Manufacturing & Packing
2.	Ferric Oxyhydroxide IH	Manufacturing & Packing

ITEM(S) TWO (02) 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 substance(s) for the purpose of export only, as the above-mentioned active substance(s) are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 20.05.2028

Signature 04/06/25

चंद्रशेखर रेगा/Chandrashekar Rega
संयुक्त औषधि [illegible] Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare, Govt. of India
सत्यमेव जयते

04 JUN 2025

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
20 JUN 2025

To

M/s. Teva API India Pvt. Ltd.,
Plot No. Q1 to 4 Industrial Area, Ghirongi,
Malanpur, District -Bhind (M.P.), India

SUB:- Written Confirmation of **M/s. Teva API India Pvt. Ltd., Plot No. Q1 to 4 Industrial Area, Ghirongi, Malanpur, District -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 no. WC/ED/2024/8273 submitted to CDSCO, DDC(I), Indore Sub-Zone office, and the recommendation received from DDC(I), Indore Sub-Zone 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.

9. The manufacturer is required to comply to the provision of GSR 20(E) dated 18.01.2022.

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
--	--	04.06.2025	**20.05.2028**
01	20	04.06.2025	**20.05.2028**
02	02	04.06.2025	**20.05.2028**
03	01	20 JUN 2025	**20.05.2028**

Yours faithfully,

Chandrashekar
20/06/25

Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

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

CERTIFICATE NO. :

Annexure-03
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 4 Industrial Area, Ghirongi,
Malanpur, District -Bhind (M.P.), India

List of API(s):

S. No.	Active substance (s)	Activity(ies)
1.	Trazodone Hydrochloride USP/BP	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 20.05.2028

Chandrashekar

Signature

20/06/25

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भा.प्र.से.)/Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O.(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

Ministry of Health & Family Welfare, Govt. of India
सत्यमेव जयते

20 JUN 2025