F.No:7-5/2013/EU/WC-0214
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated:

14 FEB 2020

To
M/s Mehta API Pvt Ltd.,
Gut No. 546,571,519 and 520,
Village-Kumbhavali, Tarapur, Boisar,
Tal & Dist-Palghar, Pin-401506,
Maharashtra, India.

SUB: Written Confirmation of M/s Mehta API Pvt Ltd., Gut No. 546,571,519 and 520, Village Kumbhavali, Tarapur, Boisar, Tal & Dist-Palghar, Pin-401506, Maharashtra, 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, zonal office West Zone and the recommendation received from DDC (I), West Zone Mumbai 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	Validity
01	17	14 FEB 2020	02.07.2022
02	03	14 FEB 2020	02.07.2022

Yours faithfully,

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

D/c
13.2.2020
13-2-2020

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

WC-0214

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. Mehta API Pvt Ltd.,**
Gut No. 546,571,519 and 520,
Village-Kumbhavali, Tarapur,
Boisar, Tal & Dist-Palghar, Pin-401506
Maharashtra, India.

2. **Manufacturer's license Number: 25-KD/659 & 28-KD/458**

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 Annexed

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: 02nd & 03rd July 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.V.G.Somani**
Drugs Controller General (India).

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

13.2.2020

Stamp of the authority and date

14 FEB 2020

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

Annexure- 01
CERTIFICATE NO. : WC 0214

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 Mehta API Pvt Ltd.,**
Gut No. 546,571,519 and 520,
Village- Kumbhavali, Tarapur,
Boisar, Tal & Dist- Palghar, Pin-401506
Maharashtra, India.

List of APIs:

Sl.No.	Active Substance(s)	Activitie(s)
1.	Agomelatine IH	Manufacturing & Packing
2.	Aprepitant IH/USP/EP	Manufacturing & Packing
3.	Azithromycin BP/EP/USP	Manufacturing & Packing
4.	Bisoprolol Fumarate USP/EP	Manufacturing & Packing
5.	Cinacalcet Hydrochloride IH	Manufacturing & Packing
6.	Chloramphenicol BP/EP/USP	Manufacturing & Packing
7.	Chloramphenicol Palmitate BP/EP/USP	Manufacturing & Packing
8.	Droperidol BP/Ph.Eur/USP	Manufacturing & Packing
9.	Esmolol Hydrochloride IH/USP	Manufacturing & Packing
10.	Erythromycin BP/EP/USP	Manufacturing & Packing
11.	Erythromycin Stearate EP/USP	Manufacturing & Packing
12.	Erythromycin Estolate BP/EP/USP	Manufacturing & Packing
13.	Erythromycin Ethyl Succinate BP/EP/USP	Manufacturing & Packing
14.	Fluvoxamine Maleate BP/USP	Manufacturing & Packing
15.	Prochlorperazine Maleate BP/Ph.Eur/USP	Manufacturing & Packing
16.	Prochlorperazine Mesylate BP	Manufacturing & Packing
17.	Rivaroxaban IH	Manufacturing & Packing

ITEM(S) Seventeen (17) Only

The Written Confirmation remains valid until: 02.07.2022

Signature

Stamp of the authority and date

14 FEB 2020

13-2-2020

13-2-2020

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

Annexure – 02
WC-0214

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. 1. Name and address of site: M/s Mehta API Pvt Ltd.,
   Gut No. 546,571,519 and 520,
   Village- Kumbhavali, Tarapur,
   Boisar, Tal & Dist-Palghar, Pin-401506,
   Maharashtra, India.
2. List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Anagrelide Hydrochloride IH	Manufacturing & Packing.
2.	Landiolol IH	Manufacturing & Packing
3.	Treprostinil Monohydrate IH	Manufacturing & Packing

ITEM(S) Three (03) 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 or sale in India.

The Written Confirmation remains valid until: 02.07.2022

Signature

Stamp of the authority and date

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

14 FEB 2020

O/C 13.2.2020.

13.2.2020