7-5/2013/EU/WC-0084
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002
Dated: 15 JUL 2019

To

M/s. Cadila Healthcare Ltd.,
Plot No. 26 to 29 & 31, Umraya Road,
Village - Dabhasa, Tal – Padra,
Dist. - Vadodara, India

Subject:- Written Confirmation of M/s. Cadila Healthcare Ltd., Plot No. 26 to 29 & 31, Umraya Road, Village - Dabhasa, Tal – Padra, Dist. - Vadodara, 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, Ahmedabad zone office and the recommendation received from DDC(I), Ahmedabad Zone 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:-

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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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	32	15 JUL 2019	Three (03) years from date of issue

OLC

Yours faithfully,

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

12/07/19

12.7.19

12/07/19

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

CERTIFICATE NO. : WC-0084

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. Cadila Healthcare Ltd.,
Plot No. 26 to 29 & 31, Umraya Road,
Village - Dabhasa, Tal – Padra,
Dist. - Vadodara, India

2. Manufacturer's licence number: G/1409

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: 15.09.2017 & 11.01.2018

The Written Confirmation remains valid until: **Three (03) years from 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: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

12-7-19

Signature

12/07/19

Stamp of the authority and date

15 JUL 2019

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

CERTIFICATE NO. : **Annexure-1**
WC-0084

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. Cadila Healthcare Ltd.,
Plot No. 26 to 29 & 31, Umraya Road, Village - Dabhasa,
Tal – Padra, Dist. - Vadodara, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Atenolol BP/USP/EP	Manufacturing & Packing
2.	Clopidogrel Besylate IH	Manufacturing & Packing
3.	Clopidogrel Bisulfate USP	Manufacturing & Packing
4.	Deferiprone IH	Manufacturing & Packing
5.	Donepezil Hydrochloride IH	Manufacturing & Packing
6.	Famotidine BP/USP/EP	Manufacturing & Packing
7.	Fluconazole BP	Manufacturing & Packing
8.	Olmesartan Medoxomil IH	Manufacturing & Packing
9.	Rabeprazole Sodium IP	Manufacturing & Packing
10.	Pramipexole Dihydrochloride Monohydrate IH	Manufacturing & Packing
11.	Midodrine Hydrochloride IH	Manufacturing & Packing
12.	Duloxetine Hydrochloride EP/USP	Manufacturing & Packing
13.	Hydroxychloroquine Sulfate USP	Manufacturing & Packing
14.	Clindamycin Phosphate BP/USP/EP	Manufacturing & Packing
15.	Naftopidil IH	Manufacturing & Packing
16.	Hydrochlorothiazide USP/EP	Manufacturing & Packing
17.	Irbesartan IH	Manufacturing & Packing
18.	Paroxetine Hydrochloride IH	Manufacturing & Packing
19.	Risperidone BP/EP	Manufacturing & Packing
20.	Tamsulosin Hydrochloride IH	Manufacturing & Packing
21.	Topiramate IH	Manufacturing & Packing
22.	Ziprasidone Hydrochloride Monohydrate IH	Manufacturing & Packing
23.	Ivabradine Hydrochloride IH	Manufacturing & Packing
24.	Aripiprazole IH	Manufacturing & Packing
25.	Azelastine Hydrochloride EP	Manufacturing & Packing
26.	Pitavastatin Calcium IH	Manufacturing & Packing
27.	Silodosin IH	Manufacturing & Packing
28.	Pioglitazone Hydrochloride USP/IP	Manufacturing & Packing
29.	Rivastigmine IH	Manufacturing & Packing
30.	Salmeterol Xinafoate IH	Manufacturing & Packing
31.	Tirofiban Hydrochloride IH	Manufacturing & Packing
32.	Apixaban IH	Manufacturing & Packing

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ITEM(S) Thirty Two (32) ONLY

The Written Confirmation remains valid until: Three (03) years from date of issue

Signature

12/07/19

12-7-19

Stamp of the authority and date

Central Drugs Standard Control Organization
Directorate General of Health Services Ministry of Health & Family Welfare Government of India

15 JUL 2019