Amended

7-5/2013/EU/WC-0074
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002
Dated

01 SEP 2022

To

M/s. Cadila Pharmaceuticals Ltd.
Address: 294, GIDC Estate Ankleshwar,
Bharuch-393002, Gujarat India

SUB:- Written Confirmation of M/s Cadila Pharmaceuticals Ltd. Address: 294, GIDC Estate Ankleshwar , Bharuch-393002, Gujarat 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 online application no. WC/RE/2022/1977 submitted to CDSCO, Ahmedabad Zonal office and the recommendation received from DDC(I), Ahmedabad Zonal 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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.

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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	45	01 SEP 2022	02.07.2025

Yours faithfully,

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

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

Amended

CERTIFICATE NO. :

WC-0074

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 Pharmaceuticals Ltd.**
Address: 294, GIDC Estate Ankleshwar,
Bharuch-393002, Gujarat India

2. Manufacturer's licence number: : G/450

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 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: 23/09/2021 & 24.09.2021

The Written Confirmation remains valid until: 02.07.2025

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

01 SEP 2022

Signature

Stamp of the authority and date

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

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

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CERTIFICATE NO. : WC-0074 **Annexure-1**

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 Pharmaceuticals Ltd.**
Address: 294, GIDC Estate Ankleshwar,
Bharuch-393002, Gujarat India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Paroxetine Hydrochloride Hemihydrate U.S.P.,Ph. Eur	Manufacturing & Packing
2.	Desvenlafaxine Succinate In House	Manufacturing & Packing
3.	Alendronate Sodium U.S.P.	Manufacturing & Packing
4.	Sodium Alendronate Ph.Eur	Manufacturing & Packing
5.	Amlodipine Besilate B.P.,U.S.P.,J.P.,Ph.Eur, IP	Manufacturing & Packing
6.	Aripiprazole IH/U.S.P/Ph.Eur	Manufacturing & Packing
7.	Atomoxetine Hydrochloride IH/U.S.P./Ph.Eur	Manufacturing & Packing
8.	Atorvastatin Calcium U.S.P.	Manufacturing & Packing
9.	Bosentan (as monohydrate) In House	Manufacturing & Packing
10.	Bupropion Hydrochloride U.S.P.	Manufacturing & Packing
11.	Carvedilol U.S.P.,Ph. Eur	Manufacturing & Packing
12.	Celecoxib IH/U.S.P./Ph.Eur	Manufacturing & Packing
13.	Chlorhexidine Dihydrochloride Ph. Eur	Manufacturing & Packing
14.	Chlorhexidine Hydrochloride B.P	Manufacturing & Packing
15.	Desloratadine IH/U.S.P./Ph.Eur	Manufacturing & Packing
16.	Escitalopram Oxalate IH/U.S.P.	Manufacturing & Packing
17.	Ethambutol Hydrochloride B.P.,U.S. P.,Ph.Eur	Manufacturing & Packing
18.	Fluoxetine Hydrochloride B.P.,U.S. P.,Ph.Eur	Manufacturing & Packing
19.	Glibenclamide IH/B.P./J.P./Ph.Eur	Manufacturing & Packing
20.	Glyburide U.S.P.	Manufacturing & Packing
21.	Loratadine B.P.,U.S. P.,Ph.Eur	Manufacturing & Packing
22.	Meloxicam U.S.P.,Ph. Eur	Manufacturing & Packing
23.	Nateglinide U.S.P.,Ph. Eur	Manufacturing & Packing
24.	Olanzapine IH/U.S.P./Ph.Eur	Manufacturing & Packing
25.	Olmesartan Medoxomil U.S.P.,Ph. Eur	Manufacturing & Packing
26.	Ondansetron Hydrochloride U.S.P.,Ph. Eur	Manufacturing & Packing
27.	Paliperidone IH/U.S.P.	Manufacturing & Packing
28.	Raloxifene Hydrochloride U.S.P.	Manufacturing & Packing
29.	Rupatadine Fumarate IH	Manufacturing & Packing
30.	Sildenafil Citrate IH/U.S.P./Ph.Eur	Manufacturing & Packing
31.	Valsartan U.S.P.	Manufacturing & Packing
32.	Venlafaxine Hydrochloride IH/B.P./U.S.P./Ph.Eur	Manufacturing & Packing
33.	Silodosin IH/J.P.	Manufacturing & Packing
34.	Chlorhexidine Gluconate Solution B.P.,U.S. P.,J.P.,Ph.Eur	Manufacturing & Packing
35.	Pregabalin IH	Manufacturing & Packing

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Central Drugs Standard Control Organization • Ministry of Health & Family Welfare, Govt. of India •

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1. Name and address of site: **M/s. Cadila Pharmaceuticals Ltd.**
Address: 294, GIDC Estate Ankleshwar,
Bharuch-393002, Gujarat India

36.	Hydralazine Hydrochloride U.S.P.	Manufacturing & Packing
37.	Itopride Hydrochloride In House	Manufacturing & Packing
38.	Nebivolol Hydrochloride In House	Manufacturing & Packing
39.	Pranlukast In House	Manufacturing & Packing
40.	Rabeprazole Sodium In House	Manufacturing & Packing
41.	Deferasirox In House	Manufacturing & Packing
42.	Labetalol Hydrochloride U.S.P.	Manufacturing & Packing
43.	Chlorhexidine Base In House	Manufacturing & Packing
44.	Gemfibrozil U.S.P.	Manufacturing & Packing
45.	Cilostazol IH/U.S.P./J.P.	Manufacturing & Packing

ITEM(S) Forty Five (45) ONLY

The Written Confirmation remains valid until: 02.07.2025

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Govt. of India

01 SEP 2022