No: 7-5/2013/EU/WC-0168
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. Sun Pharmaceutical Industries Ltd.,
Plot No. 24/2, & 25, Phase – IV, GIDC Industrial Zone,
At & Post – Panoli, Dist.- Bharuch - 394116, Gujarat, India

SUB: - Written Confirmation of M/s. Sun Pharmaceutical Industries Ltd., Plot No. 24/2, & 25, Phase – IV, GIDC Industrial Zone, At & Post – Panoli, Dist.- Bharuch - 394116, 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 application submitted to CDSCO, Ahmedabad Zone 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:-

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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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. of Products	Date of Issuance	Valid Upto
01	50	15 JUL 2019	Three years from the date of issue

Yours faithfully,

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

O/C
06.07.2019
8.7.19

WC-0168

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

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. Sun Pharmaceutical Industries Ltd., Plot No. 24/2, & 25, Phase – IV, GIDC Industrial Zone, At & Post – Panoli, Dist.- Bharuch - 394116, Gujarat, India**

2. Manufacturer's licence number: G/1199, G/1120 & G/47

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 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: **05th& 06th March, 2019**

The Written Confirmation remains valid until: **(03) Three years from the 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

Signature

Stamp of the authority and date

15 JUL 2019

06.07.2019

8.7.19

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

Annexure-01
WC-0168

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. Sun Pharmaceutical Industries Ltd.,
Plot No. 24/2, & 25, Phase – IV,
GIDC Industrial Zone,
At & Post – Panoli,
Dist - Bharuch - 394116,
Gujarat, India

List of APIs:

Sl.No.	Name of the Active Substances	Activitie(s)
1.	Alendronate Sodium IH/USP	Manufacturing and Packing
2.	Aripiprazole IH/USP/BP/Ph.Eur	Manufacturing and Packing
3.	Atomoxetine Hydrochloride IH/USP/BP/Ph.Eur.	Manufacturing and Packing
4.	Budesonide IP/EP/BP/USP	Manufacturing and Packing
5.	Buprenorphine Hydrochloride EP/BP/USP	Manufacturing and Packing
6.	Carvedilol IP/EP/BP/USP	Manufacturing and Packing
7.	Citalopram Hydrobromide IP/BP/USP	Manufacturing and Packing
8.	Clomipramine Hydrochloride IP/EP/BP/USP	Manufacturing and Packing
9.	Doxercalciferol IH	Manufacturing and Packing
10.	Drospirenone USP	Manufacturing and Packing
11.	Duloxetine Hydrochloride IH/USP/BP/Ph.Eur	Manufacturing and Packing
12.	Epinastine Hydrochloride IH/BP/Ph.Eur	Manufacturing and Packing
13.	Escitalopram Oxalate IH/USP/BP/Ph.eur	Manufacturing and Packing
14.	Esomeprazole Sodium IH	Manufacturing and Packing
15.	Fluticasone Propionate IP/EP/BP/USP	Manufacturing and Packing
16.	Fosphenytoin Sodium IH/USP	Manufacturing and Packing
17.	Granisetron Hydrochloride IH/BP	Manufacturing and Packing
18.	Hydroxyprogesterone Caproate USP	Manufacturing and Packing
19.	Levetiracetam IP/EP/USP	Manufacturing and Packing
20.	Levocetirizine Dihydrochloride IH	Manufacturing and Packing
21.	Losartan Potassium IP/BP/EP/USP	Manufacturing and Packing
22.	Loteprednol Etabonate IH	Manufacturing and Packing
23.	Methylphenidate Hydrochloride USP/Ph.Eur	Manufacturing and Packing
24.	Mirtazapine EP/BP/USP	Manufacturing and Packing

8-7-19

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

Annexure-01
WC-0168

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

Sl.No.	Name of the Active Substances	Activitie(s)
25	Naloxone Hydrochloride Dihydrate EP	Manufacturing and Packing
26	Naloxone Hydrochloride IP/USP	Manufacturing and Packing
27	Naltrexone Hydrochloride IP/EP/USP	Manufacturing and Packing
28	Ondansetron Hydrochloride Dihydrate EP/BP	Manufacturing and Packing
29	Ondansetron USP	Manufacturing and Packing
30	Oxcarbazepine IP/USP	Manufacturing and Packing
31	Paroxetine Hydrochloride Hemihydrate EP	Manufacturing and Packing
32	Paroxetine Hydrochloride IH	Manufacturing and Packing
33	Pentoxifylline EP/BP/USP	Manufacturing and Packing
34	Pramipexole Dihydrochloride USP	Manufacturing and Packing
35	Rasagiline Mesylate IH	Manufacturing and Packing
36	Repaglinide USP/Ph.Eur	Manufacturing and Packing
37	Riluzole IH	Manufacturing and Packing
38	Risperidone BP/USP	Manufacturing and Packing
39	Rizatriptan Benzoate IP/USP	Manufacturing and Packing
40	Sevelamer Carbonate IH	Manufacturing and Packing
41	Sodium Alendronate EP	Manufacturing and Packing
42	Sumatriptan Succinate IP/EP/BP/USP	Manufacturing and Packing
43	Tamsulosin Hydrochloride IP/USP/EP/BP	Manufacturing and Packing
44	Testosterone Cypionate USP	Manufacturing and Packing
45	Testosterone USP/Ph.Eur	Manufacturing and Packing
46	Tizanidine Hydrochloride IP/EP/USP	Manufacturing and Packing
47	Topiramate IP/USP	Manufacturing and Packing
48	Zolmitriptan IH/USP	Manufacturing and Packing
49	Zolpidem Tartrate IP/EP/BP/USP	Manufacturing and Packing
50	Zonisamide IH/USP	Manufacturing and Packing

ITEM(S) Fifty (50) Only

The Written Confirmation remains valid until: (03)Three Years from the date of Issue

Signature

Stamp of the authority and date

15 JUL 2019

06.07.2019.

8.7.19