No:7-5/2013/EU/WC-0159
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 02 DEC 2019

To
M/s. Sun Pharmaceutical Industries Ltd.,
A-7/A-8, M.I.D.C Industrial Area
Ahmed Nagar-414111,
Maharashtra,India.

SUB:- Written Confirmation ofM/s. Sun Pharmaceutical Industries Ltd., A-7/A-8, M.I.D.C Industrial Area, Ahmednagar-414111,Maharashtra,Indiaasper 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, West Zone office and the recommendation received from DDC(I), West Zone, Mumbai 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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.

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
01	70	26.07.2019	25.07.2022
02	02	26.07.2019	25.07.2022
01	70	02 DEC 2019	25.07.2022

Yours faithfully,

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

29.11.2019

7-5/2013/EU/WC-0159
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 26 JUL 2019

To
M/s. Sun Pharmaceutical Industries Ltd.,
A-7/A-8, M.I.D.C Industrial Area
Ahmed Nagar-414 111,
Maharashtra, India.

SUB:- Written Confirmation of M/s. Sun Pharmaceutical Industries Ltd., A-7/A-8, M.I.D.C Industrial Area, Ahmednagar- 414111, 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, West Zone office and the recommendation received from DDC(I), West Zone , Mumbai 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.

WC-0159

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.,**
A-7/A-8, M.I.D.C Industrial Area
Ahmed Nagar- 414111,
Maharashtra, India.

2. Manufacturer's licence number: **NKD/32 & NKD/39**

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: **28th & 29th May 2018**

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

26 JUL 2019

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

CERTIFICATE NO. :

(Amended)
Annexure-01
WC-0159

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.,
A-7/A-8, M.I.D.C Industrial Area
Ahmed Nagar- 414111,
Maharashtra, India.

List of APIs:

Sl. No.	Name of the active substances	Activitie(s)
1.	Abiraterone Acetate IH	Manufacturing and Packing
2.	AcitretinUSP	Manufacturing and Packing
3.	AmifostineUSP	Manufacturing and Packing
4.	AmisulprideEP	Manufacturing and Packing
5.	AnastrozoleUSP/EP	Manufacturing and Packing
6.	Atorvastatin Calcium USP	Manufacturing and Packing
7.	Azacitidine IH	Manufacturing and Packing
8.	BicalutamideUSP	Manufacturing and Packing
9.	BortezomibIH	Manufacturing and Packing
10.	Bupropion Hydrochloride USP	Manufacturing and Packing
11.	Capecitabine USP	Manufacturing and Packing
12.	Carboplatin USP/EP/BP	Manufacturing and Packing
13.	Cisplatin USP/EP/BP	Manufacturing and Packing
14.	Clopidrogrel Bisulfate USP	Manufacturing and Packing
15.	Desloratadine IH	Manufacturing and Packing
16.	Desmopressin Acetate USP	Manufacturing and Packing
17.	Disodium Pamidronate USP/BP	Manufacturing and Packing
18.	Divalproex Sodium USP	Manufacturing and Packing
19.	Dobutamine Hydrochloride USP	Manufacturing and Packing
20.	Donepezil Hydrochloride USP	Manufacturing and Packing
21.	Dothiepin Hydrochloride /Dosulepin Hydrochloride EP/BP	Manufacturing and Packing
22.	Finasteride USP	Manufacturing and Packing
23.	FlurbiprofenUSP/EP/BP	Manufacturing and Packing
24.	Fluvoxamine Maleate BP/USP	Manufacturing and Packing
25.	FulvestrantUSP/EP	Manufacturing and Packing
26.	Gabapentin USP	Manufacturing and Packing
27.	GanirelixIH	Manufacturing and Packing

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

CERTIFICATE NO. :

(Amended)
Annexure-01
WC-0159

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)
28	Gemcitabine Hydrochloride USP/EP/BP	Manufacturing and Packing
29	IbandronicAcid Monosodium Monohydrate IH	Manufacturing and Packing
30	ImatinibMesylateIH	Manufacturing and Packing
31	Isotretinoin USP	Manufacturing and Packing
32	Lamotrigine USP	Manufacturing and Packing
36	LenalidomideIH	Manufacturing and Packing
33	Lercanidipine Hydrochloride IH	Manufacturing and Packing
34	LetrozoleUSP/EP/BP	Manufacturing and Packing
35	Leuprolide Acetate USP/BP	Manufacturing and Packing
37	Meloxicam USP/EP	Manufacturing and Packing
38	Memantine Hydrochloride USP	Manufacturing and Packing
39	Mesalamine/MesalazineUSP/EP	Manufacturing and Packing
40	Metformin Hydrochloride USP/EP	Manufacturing and Packing
41	Metoprolol Succinate USP/EP/BP	Manufacturing and Packing
42	Metoprolol Tartrate USP/EP/BP	Manufacturing and Packing
43	Naratriptan Hydrochloride USP	Manufacturing and Packing
44	Octreotide Acetate IH	Manufacturing and Packing
45	OlanzepineUSP/EP	Manufacturing and Packing
46	Olopatadine Hydrochloride IH/USP	Manufacturing and Packing
47	Omeprazole EP/USP	Manufacturing and Packing
48	OxaliplatinUSP/EP/BP	Manufacturing and Packing
49	Oxpentifylline/PentoxifyllineUSP/EP/BP	Manufacturing and Packing
50	Pantoprazole sodium BP/USP/EP	Manufacturing and Packing
51	Pemetrexed Disodium HeptahydrateIH/EP	Manufacturing and Packing
52	Prasugrel Hydrochloride IH	Manufacturing and Packing
53	PregabalinIH	Manufacturing and Packing
54	Quetiapine Fumarate IH	Manufacturing and Packing
55	Risedronate Sodium USP	Manufacturing and Packing
56	Rivastigmine USP	Manufacturing and Packing
57	Rivastigmine Tartrate USP	Manufacturing and Packing
58	Sodium Valproate EP/BP	Manufacturing and Packing
59	Linagliptin IH	Manufacturing and Packing

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

CERTIFICATE NO. :

(Amended)
Annexure-01
WC-0159

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)
60	Tadalafil USP/EP	Manufacturing and Packing
61	Temozolomide USP	Manufacturing and Packing
62	Teriparatide IH	Manufacturing and Packing
63	Terlipressin Acetate IH	Manufacturing and Packing
64	TetrabenazineIH	Manufacturing and Packing
65	Tramadol Hydrochloride EP/USP	Manufacturing and Packing
66	Valporic Acid EP	Manufacturing and Packing
67	Venlafaxine Hydrochloride USP/EP	Manufacturing and Packing
68	Dabigatran EtexilateMesylate IH	Manufacturing and Packing
69	Decitabine IH	Manufacturing and Packing
70	Erlotinib Hydrochloride IH	Manufacturing and Packing

ITEM(S) Seventy (70) Only

The Written Confirmation remains valid until: 25.07.2022

Stamp of the authority and date

Signature

0 2 DEC 2019

29.11.2019

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

CERTIFICATE NO. :

Annexure-02
WC-0159

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.,
A-7/A-8, M.I.D.C Industrial Area
Ahmed Nagar- 414111,
Maharashtra, India.

List of APIs:

S. No.	Name of the Active substance(s)	Activitie(s)
1	Bivalirudin IH	Manufacturing & Packing
2	Phentermine Hydrochloride USP	Manufacturing & Packing

ITEM(S) Two (02) Only

This certificate is being issued subject to condition that the firm shall obtained NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substance for the purpose of export only, as the above mentioned active substance is not approved for manufacture for sale in India

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

Signature

Stamp of the authority and date

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

26 JUL 2019