7-5/2013/EU/WC-0011
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002
Dated: 03 JUN 2019

To

M/s. Sun Pharmaceutical Industries Limited,
Village Toansa, P.O. Rail Majra,
District Shaheed Bhagat Singh Nagar, Panjab, India

Subject:- Written Confirmation of M/s. Sun Pharmaceutical Industries Limited, Village Toansa, P.O. Rail Majra,District Shaheed Bhagat Singh Nagar, Panjab, IndiaIndia 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, Sub-Zone Baddi and the recommendation received from DDC(I), Sub-Zone Baddi 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
1	43	03 JUN 2019	Three (03) years from date of issue
2	01	03 JUN 2019	Three (03) years from date of issue

Yours faithfully,

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

31/05/19

31-5-19

31/05/19

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

CERTIFICATE NO. : WC-0011

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 Limited,
Village Toansa, P.O. Rail Majra,
District Shaheed Bhagat Singh Nagar, Panjab, India

2. Manufacturer's licence number: 1313-OSP-Pb and 1245-B-Pb

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 & 2
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: 02.05.2019 & 03.05.2019

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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

Signature

Stamp of the authority and date

31/05/19

21-5-19

03 JUN 2019

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

CERTIFICATE NO. : **WC-0011**

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

Name and address of site: M/s. Sun Pharmaceutical Industries Limited,
Village Toansa, P.O. Rail Majra,
District Shaheed Bhagat Singh Nagar, Panjab, India

1. **List of APIs:**

S. No.	Active substance(s)	Activity(ies)
1.	Amorolfine Hydrochloride Ph.Eur/IH	Manufacturing & Packing
2.	Atorvastatin Calcium Trihydrate USP/Ph.Eur	Manufacturing & Packing
3.	Benazepril Hydrochloride USP/Ph.Eur	Manufacturing & Packing
4.	Bosentan Monohydrate IH	Manufacturing & Packing
5.	Candesartan Cilexetil Ph.Eur/IH	Manufacturing & Packing
6.	Celiprolol Hydrochloride Ph.Eur	Manufacturing & Packing
7.	Desloratadine Ph.Eur/IH	Manufacturing & Packing
8.	Donepezil Hydrochloride USP/IH	Manufacturing & Packing
9.	Entecavir Monohydrate Ph.Eur/IH	Manufacturing & Packing
10.	Eslicarbazepine Acetate IH	Manufacturing & Packing
11.	Fexofenadine Hydrochloride USP/ Ph.Eur/IH	Manufacturing & Packing
12.	Fluvastatin Sodium Ph.Eur/IH	Manufacturing & Packing
13.	Febuxostat IH	Manufacturing & Packing
14.	Irbesartan USP/ Ph.Eur	Manufacturing & Packing
15.	Isotretinoin USP/ Ph.Eur	Manufacturing & Packing
16.	Lacosamide Ph.Eur/IH	Manufacturing & Packing
17.	Lansoprazole USP/Ph.Eur	Manufacturing & Packing
18.	Levofloxacin USP	Manufacturing & Packing
19.	Midazolam USP/ Ph.Eur	Manufacturing & Packing
20.	Nevirapine USP/ Ph.Eur	Manufacturing & Packing
21.	Ofloxacin USP/ Ph.Eur	Manufacturing & Packing
22.	Olanzapine USP/ Ph.Eur/IH	Manufacturing & Packing
23.	Omeprazole Magnesium USP/ Ph.Eur	Manufacturing & Packing
24.	Pantoprazole Sodium (Sesquihydrate) Ph.Eur	Manufacturing & Packing
25.	Pantoprazole Sodium USP	Manufacturing & Packing
26.	Rabeprazole Sodium IH	Manufacturing & Packing
27.	Rabeprazole Sodium Hydrate Ph.Eur	Manufacturing & Packing
28.	Ramipril USP/ Ph.Eur	Manufacturing & Packing
29.	Repaglinide USP/ Ph.Eur	Manufacturing & Packing
30.	Sertraline Hydrochloride USP/ Ph.Eur	Manufacturing & Packing
31.	Simvastatin USP/ Ph.Eur	Manufacturing & Packing
32.	Solifenacin Succinate Ph.Eur/IH	Manufacturing & Packing

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

CERTIFICATE NO. : **WC-0011**

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

Name and address of site: M/s. Sun Pharmaceutical Industries Limited,
Village Toansa, P.O. Rail Majra,
District Shaheed Bhagat Singh Nagar, Panjab, India

S. No.	Active substance(s)	Activity(ies)
33.	Tamsulosin Hydrochloride USP/ Ph.Eur	Manufacturing & Packing
34.	Telmisartan USP/ Ph.Eur	Manufacturing & Packing
35.	Tramadol Hydrochloride Ph.Eur	Manufacturing & Packing
36.	Valganciclovir Hydrochloride USP/IH	Manufacturing & Packing
37.	Venlafaxine Hydrochloride Ph.Eur	Manufacturing & Packing
38.	Voriconazole Ph.Eur	Manufacturing & Packing
39.	Atorvastatin Calcium Amorphous IH	Manufacturing & Packing
40.	Esomeprazole Magnesium Amorphous USP/IH	Manufacturing & Packing
41.	Metoprolol Tartrate Ph.Eur/USP/BP	Manufacturing & Packing
42.	Metoprolol Succinate Ph.Eur	Manufacturing & Packing
43.	Rosuvastatin Calcium Ph.Eur	Manufacturing & Packing

ITEM(S) Forty three (43) ONLY

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

Signature

Stamp of the authority and date

03 JUN 2019

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

Annexure-2

CERTIFICATE NO. : **WC-0011**

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. Sun Pharmaceutical Industries Limited,
Village Toansa, P.O. Rail Majra,
District Shaheed Bhagat Singh Nagar, Panjab, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Cilazapril Ph.Eur	Manufacturing & Packing

ITEM(S) One (01) 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 for sale in India.

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

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Signature

Stamp of the authority and date

03 JUN 2019

31/05/19

31-5-19

31/05/19