**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:
08 JUN 2022

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 of M/s. Sun Pharmaceutical Industries Ltd., A-7/A-8, M.I.D.C Industrial Area, Ahmednagar-414 111,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 online application No. WC/RE/2022/2191 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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 | 67 | 08 JUN 2022 | 25.07.2025 |
| 02 | 02 | 08 JUN 2022 | 25.07.2025 |

**Yours faithfully,**

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

08.06.2022

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

CERTIFICATE NO. : 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**
**Ahmednagar-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

**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.

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**Date of Inspection of the plant**: 05.08.2021 & 06.08.2021

**The Written Confirmation remains valid until**: 25.07.2025

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

08 JUN 2022

*Signature* 08/06/2022

*Stamp of the authority and date*

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

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

CERTIFICATE NO. :

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**
**Ahmednagar-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. | AnastrozoleUSP/EP | Manufacturing and Packing |
| 5. | Atorvastatin Calcium USP | Manufacturing and Packing |
| 6. | Azacitidine IH | Manufacturing and Packing |
| 7. | BicalutamideUSP | Manufacturing and Packing |
| 8. | BortezomibIH | Manufacturing and Packing |
| 9. | Bupropion Hydrochloride USP | Manufacturing and Packing |
| 10. | Capecitabine USP | Manufacturing and Packing |
| 11. | Carboplatin USP/EP/BP | Manufacturing and Packing |
| 12. | Cisplatin USP/EP/BP | Manufacturing and Packing |
| 13. | Clopidrogrel Bisulfate USP | Manufacturing and Packing |
| 14. | Desloratadine IH | Manufacturing and Packing |
| 15. | Dabigatran EtexilateMesylate IH | Manufacturing and Packing |
| 16. | Decitabine IH | Manufacturing and Packing |
| 17. | Desmopressin Acetate USP | Manufacturing and Packing |
| 18. | Disodium Pamidronate USP/BP | Manufacturing and Packing |
| 19. | Divalproex Sodium USP | Manufacturing and Packing |
| 20. | Dobutamine Hydrochloride USP | Manufacturing and Packing |
| 21. | Donepezil Hydrochloride USP | Manufacturing and Packing |
| 22. | Dothiepin Hydrochloride / Dosulepin Hydrochloride EP/BP | Manufacturing and Packing |
| 23. | Erlotinib Hydrochloride IH | Manufacturing and Packing |
| 24. | Finasteride USP | Manufacturing and Packing |
| 25. | Flurbiprofen USP/EP/BP | Manufacturing and Packing |
| 26. | Fluvoxamine Maleate BP/USP | Manufacturing and Packing |
| 27. | Fulvestrant USP/EP | Manufacturing and Packing |

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08/06/2022

08 JUN 2022

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

CERTIFICATE NO. :

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. | Gabapentin USP | Manufacturing and Packing |
| 29. | Ganirelix IH | Manufacturing and Packing |
| 30. | Gemcitabine Hydrochloride USP/EP/BP | Manufacturing and Packing |
| 31. | Ibandronic Acid Monosodium Monohydrate IH | Manufacturing and Packing |
| 32. | Imatinib MesylateIH | Manufacturing and Packing |
| 33. | Lamotrigine USP | Manufacturing and Packing |
| 34. | LenalidomideIH | Manufacturing and Packing |
| 35. | Lercanidipine Hydrochloride IH | Manufacturing and Packing |
| 36. | Letrozole USP/EP/BP | Manufacturing and Packing |
| 37. | Leuprolide Acetate /Leuprorelin USP/BP | Manufacturing and Packing |
| 38. | Linagliptin IH | Manufacturing and Packing |
| 39. | Meloxicam USP/BP | Manufacturing and Packing |
| 40. | Memantine Hydrochloride USP | Manufacturing and Packing |
| 41. | Mesalamine/MesalazineUSP/EP | Manufacturing and Packing |
| 42. | Metformin Hydrochloride USP/EP | Manufacturing and Packing |
| 43. | Metoprolol Succinate USP/EP/BP | Manufacturing and Packing |
| 44. | Metoprolol Tartrate USP/EP/BP | Manufacturing and Packing |
| 45. | Naratriptan Hydrochloride USP | Manufacturing and Packing |
| 46. | Octreotide Acetate IH | Manufacturing and Packing |
| 47. | Olanzepine USP/EP | Manufacturing and Packing |
| 48. | Olopatadine Hydrochloride IH/USP | Manufacturing and Packing |
| 49. | Omeprazole EP/USP | Manufacturing and Packing |
| 50. | Oxaliplatin USP/EP/BP | Manufacturing and Packing |
| 51. | Pantoprazole Sodium BP/USP/EP | Manufacturing and Packing |
| 52. | Pemetrexed Disodium Heptahydrate IH/EP | Manufacturing and Packing |
| 53. | Prasugrel Hydrochloride IH | Manufacturing and Packing |
| 54. | Pregabalin IH | Manufacturing and Packing |
| 55 | Quetiapine Fumarate IH | Manufacturing and Packing |
| 56. | Risedronate Sodium USP | Manufacturing and Packing |
| 57 | Rivastigmine USP | Manufacturing and Packing |
| 58 | Rivastigmine Tartrate USP | Manufacturing and Packing |
| 59 | Sodium Valproate EP/BP | Manufacturing and Packing |
| 60 | Tadalafil USP/EP | Manufacturing and Packing |

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

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

CERTIFICATE NO. :

**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) |
|---|---|---|
| 61. | Temozolomide USP | Manufacturing and Packing |
| 62. | Teriparatide IH | Manufacturing and Packing |
| 63. | Terlipressin Acetate IH | Manufacturing and Packing |
| 64. | Tetrabenazine IH | 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 |

**ITEM(S) SIXTY SEVEN (67) ONLY**

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**The Written Confirmation remains valid until: 25.07.2025**

*Signature*

03-06-2022

*Stamp of the authority and date*

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

09 JUN 2022

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
Ahmednagar-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: 25.07.2025

*Signature*

*Stamp of the authority and date*

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

08 JUN 2022