**Central Drugs Standard Control Organization**
**Directorate General of Health Services**
**Ministry of Health & Family Welfare**

**Food and Drug Administration Bhawan,**
**Kotla Road, New Delhi-110002,**
**Dated:** 11 JUN 2018

No.: 7-5/2015/EU/WC-0349

To

**M/s. MSN Laboratories Private Limited (Unit- II),**
**Sy. No. 50, Kardanur (Village), Patti (Post),**
**Patancheru (Mandal), Sangareddy Dist, Telangana.**

**SUB:- Written Confirmation of M/s. MSN Laboratories Private Limited (Unit- II), Sy. No. 50, Kardanur (Village), Patti (Post), Patancheru (Mandal), Sangareddy Dist , Telangana State, 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, South Zone office and the recommendation received from DDC(I), South Zone, Hyderabad, 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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 noncompliance 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 | 18 | 07.12.2015 | 06/12/2018 |
| 2 | 04 | 07.12.2015 | 06/12/2018 |
| 3 | 21 | 11 JUN 2018 | 06/12/2018 |
| 4 | 06 | 11 JUN 2018 | 06/12/2018 |

**Yours faithfully,**

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

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

Annexure - 3

**CERTIFICATE NO. :** WC-0349

**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. MSN Laboratories Private Limited (Unit- II),
Sy. No. 50, Kardanur (Village), Patti (Post),
Patancheru (Mandal), Sangareddy Dist, Telangana.

**List of APIs:**

| S. No. | Active substance(s) | Activity(ies) |
|---|---|---|
| 1. | Tafluprost (IH) | Manufacturing & Packing |
| 2. | Carfilzomib (IH) | Manufacturing & Packing |
| 3. | Axitinib (IH) | Manufacturing & Packing |
| 4. | Regorafenib (IH) | Manufacturing & Packing |
| 5. | Sorafenib Hemi Tosylate (Monohydrate) | Manufacturing & Packing |
| 6. | Enzalutamide (IH) | Manufacturing & Packing |
| 7. | Sorafenib Tosylate (IH) | Manufacturing & Packing |
| 8. | Ibrutinib (IH) | Manufacturing & Packing |
| 9. | Lenalidomide (IH) | Manufacturing & Packing |
| 10. | Plerixafor (IH) | Manufacturing & Packing |
| 11. | Dasatinib (IH) | Manufacturing & Packing |
| 12. | Carmustine (USP) | Manufacturing & Packing |
| 13. | Azacitidine (IH) | Manufacturing & Packing |
| 14. | Afatinib Dimaleate (IH) | Manufacturing & Packing |
| 15. | Capecitabine (Ph. Eur) | Manufacturing & Packing |
| 16. | Imatinib Mesylate (Ph. Eur) | Manufacturing & Packing |
| 17. | Palonosetron Hydrochloride (USP) | Manufacturing & Packing |
| 18. | Docetaxel Anhydrous (Ph. Eur) | Manufacturing & Packing |
| 19. | Docetaxel Trihydrate (Ph. Eur) | Manufacturing & Packing |
| 20. | Gefitinib (Ph. Eur) | Manufacturing & Packing |
| 21. | Pemetrexed Disodium Heptahydrate (Ph. Eur) | Manufacturing & Packing |

**ITEM(S) Twenty One (21) ONLY**

**The Written Confirmation remains valid until: 06.12.2018**

*Signature*

*Stamp of the authority and date*

11 JUN 2018

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

Annexure-4

**CERTIFICATE NO. : WC-0349**

**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. MSN Laboratories Private Limited (Unit- II), Sy. No. 50, Kardanur (Village), Patti (Post), Patancheru (Mandal), Sangareddy Dist, Telangana

**List of APIs:**

| S. No. | Active substance(s) | Activity(ies) |
|---|---|---|
| 1. | Bexarotene (IH) | Manufacturing & Packing |
| 2. | Bosutinib (IH) | Manufacturing & Packing |
| 3. | Pomalidomide (IH) | Manufacturing & Packing |
| 4. | Thiotepa (USP) | Manufacturing & Packing |
| 5. | Bosutinib Monohydrate (IH) | Manufacturing & Packing |
| 6. | Aclidinium Bromide (IH) | Manufacturing & Packing |

**ITEM(S) Six (06) 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: 06.12.2018**

*Signature*

*Stamp of the authority and date*

Central Drugs Standard Control Organization, Ministry of Health Family Welfare, Government of India

11 JUN 2018