**7-5/2013/EU/WC-0281**
**Government of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organisation**
**International Cell**

**Food and Drug Administration Bhawan**
**Kotla Road, New Delhi-110002**
**Dated** 15 APR 2020

**To**

**M/s. MSN Organics Pvt Ltd,**
**Sy. No. 224/A, Bibinagar (V & M),**
**Yadadri Bhuvanagiri (Dist),**
**Telangana State, Pincode -508126**

**SUB:- Written Confirmation of M/s. MSN Organics Pvt Ltd, Sy. No. 224/A, Bibinagar (V & M), Yadadri Bhuvanagiri (Dist),Telangana State, Pincode -508126 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, Zonal Office , Hyderabad and the recommendation received from DDC(I), Hyderabad Zonal 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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.

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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 | 17 | 15 APR 2020 | 19.05.2023 |
| 2 | 03 | 15 APR 2020 | 19.05.2023 |

**Yours faithfully,**

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

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

**CERTIFICATE NO. : WC-0281**

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 Organics Pvt Ltd,**
**Sy. No. 224/A, Bibinagar (V & M),**
**Yadadri Bhuvanagiri (Dist),**
**Telangana State, Pincode -508126**

2. **Manufacturer's licence number: 39/NL/AP/2009/B/R**

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 enclosed in Annexures**

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**: 13th & 14th February, 2020

**The Written Confirmation remains valid until**: **19th May, 2023**

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

*Signature*

*Stamp of the authority and date*

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

15 APR 2020

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

**Annexure-1**
**WC-0281**

**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. MSN Organics Pvt Ltd,**
**Sy. No. 224/A, Bibinagar (V & M),**
**Yadadri Bhuvanagiri (Dist),**
**Telangana State, Pincode -508126**

**List of APIs:**

| S. No. | Active substance(s) | Activity(ies) |
|---|---|---|
| 1. | Asenapine Maleate IH | Manufacturing & Packing |
| 2. | Atomoxetine Hydrochloride Ph.Eur/USP | Manufacturing & Packing |
| 3. | Cinacalcet Hydrochloride IH | Manufacturing & Packing |
| 4. | Clopidogrel Bisulfate USP | Manufacturing & Packing |
| 5. | Clopidogrel Hydrogen Sulfate Ph.Eur | Manufacturing & Packing |
| 6. | Dimethyl Fumarate IH | Manufacturing & Packing |
| 7. | Febuxostat IH | Manufacturing & Packing |
| 8. | Iloperidone IH | Manufacturing & Packing |
| 9. | Parecoxib Sodium IH | Manufacturing & Packing |
| 10. | Pioglitazone Hydrochloride (USP/Ph.Eur) | Manufacturing & Packing |
| 11. | Rivastigmine Hydrogen Tartrate Ph. Eur | Manufacturing & Packing |
| 12. | Rivastigmine Tartrate USP | Manufacturing & Packing |
| 13. | Sildenafil Citrate Ph. Eur/USP | Manufacturing & Packing |
| 14. | Tadalafil Ph.Eur/USP | Manufacturing & Packing |
| 15. | Tapentadol Hydrochloride IH | Manufacturing & Packing |
| 16. | Ticagrelor IH | Manufacturing & Packing |
| 17. | Topiramate USP | Manufacturing & Packing |

**ITEM(S) Seventeen (17) ONLY**

**The Written Confirmation remains valid until: 19.05.2023**

*Signature*

15/04/20

15.4.2020

*Stamp of the authority and date*

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

15 APR 2020

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

Annexure-2

CERTIFICATE NO. : WC-0281

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 Organics Pvt Ltd,**
**Sy. No. 224/A, Bibinagar (V & M),**
**Yadadri Bhuvanagiri (Dist),**
**Telangana State, Pincode -508126**

List of APIs:

| S. No. | Active substance(s) | Activity(ies) |
|---|---|---|
| 1. | Etifoxine Hydrochloride IH | Manufacturing & Packing |
| 2. | Tapentadol Tartrate IH | Manufacturing & Packing |
| 3. | Trientine Hydrochloride USP | Manufacturing & Packing |

**ITEM(S) Three (03) 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: **19.05.2023**

*Signature*

13/04/20

15.4.2020

*Stamp of the authority and date*

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

15 APR 2020