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

06 APR 2023

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 online application no. WC/RE/2022/5886 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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.

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	06 APR 2023	19.05.2026
2	03	06 APR 2023	19.05.2026

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
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: 04/05/2022 to 06/05/2022

The Written Confirmation remains valid until: **19th May, 2026**

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. Rajeev Singh Raghuvanshi,
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 • Ministry of Health & Family Welfare, Govt. of India •

06 APR 2023

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/Ph.Eur	Manufacturing & Packing

ITEM(S) Seventeen (17) ONLY

The Written Confirmation remains valid until: 19.05.2026

Rajan Singh
Signature

Stamp of the authority and date

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

06 APR 2023

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

Annexure-2
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.	Etifoxine Hydrochloride IH	Manufacturing & Packing
2.	Tapentadol Tartrate IH	Manufacturing & Packing
3.	Trientine Hydrochloride USP/Ph.Eur	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: 19.05.2026

Rajeev Singh

Signature

Stamp of the authority and date

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

06 APR 2023

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 15 JAN 2024

To,

M/s. MSN Organics Pvt. Ltd.,
Sy. No. 224/A, Bibinagar (V & M),
Yadadri Bhuvanagiri (Dist.), Pincode -808126,
Telangana State, India,

SUB:- Written Confirmation of M/s. **M/s. MSN Organics Pvt. Ltd., Sy. No. 224/A, Bibinagar (V & M), Yadadri Bhuvanagiri (Dist.), Pincode -808126, 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 online application no. WC/ED/2023/7522 submitted to CDSCO, DDC(I), Hyderabad Zone, and the recommendation received from DDC(I), Hyderabad Zone 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.

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5. The Written Confirmation will be withdrawn in the events of non compliance of Standards.

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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	17	06.04.2023	19.05.2026
02	03	06.04.2023	19.05.2026
03	02	15 JAN 2024	19.05.2026

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

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

CERTIFICATE NO. : **Annexure-03**

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.), Pincode -808126,
Telangana State, India,

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Perampanel IH	Manufacturing & Packing
2.	Ticagrelor Ph.Eur	Manufacturing & Packing

ITEM(S) Two (02) ONLY

The Written Confirmation remains valid until: 19.05.2026

Signature

Stamp of the authority and date

15 JAN 2024