7-5/2013/EU/WC-0021

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 07 JUL 2025

To

M/s MSN Laboratories Private Limited
Sy. Nos, 317,320,321,322,323,604 & 605,
Pincode-502329, Rudraram (Village), Patancheru (Mandal),
Sangareddy (Dist.), TELANGANA, INDIA

SUB:- Written Confirmation of **M/s MSN Laboratories Private Limited, Sy. Nos, 317,320,321,322,323,604 & 605, Pincode-502329, Rudraram (Village), Patancheru (Mandal), Sangareddy (Dist.), TELANGANA, 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/RE/2025/9706 submitted to CDSCO, Hyderabad Zone office, 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.

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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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

9. The manufacturer is required to comply with the provisions of GSR 20(E), dated 18.01.2022.

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
--	--	07 JUL 2025	14.07.2028
01	30	07 JUL 2025	14.07.2028
02	30	07 JUL 2025	14.07.2028
03	09	07 JUL 2025	14.07.2028
04	18	07 JUL 2025	14.07.2028

Yours faithfully,

Chandrashekar
04/07/25

Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

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

WC-0021

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 Laboratories Private Limited
Sy. Nos, 317,320,321,322,323,604 & 605,
Pincode-502329, Rudraram (Village),
Patancheru (Mandal), Sangareddy (Dist.),
Telangana, INDIA

2. Manufacturer's licence number: 10/MD/AP/2004/B/CC

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):

And as per the annexure(s) enclosed.

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: 16.10.2024 & 17.10.2024

The Written Confirmation remains valid until: 14.07.2028
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: Ranga Chandrashekar,
Joint Drugs Controller (India)

E-mail: ***ranga.cs@cdsco.nic.in;***
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

04/07/25

Signature
रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

07 JUL 2025

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

Annexure-01
WC-0021

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 Laboratories Private Limited**
Sy. Nos, 317,320,321,322,323,604 & 605,
Pincode-502329, Rudraram (Village),
Patancheru (Mandal), Sangareddy (Dist.),
Telangana, INDIA

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Alcaftadine IH	Manufacturing & Packing
2.	Alfuzosin Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
3.	Aliskiren Hemifumarate IH	Manufacturing & Packing
4.	Almotriptan Malate USP/IH/ Ph.Eur.	Manufacturing & Packing
5.	Alogliptin Benzoate IH	Manufacturing & Packing
6.	Ambrisentan IH	Manufacturing & Packing
7.	Apixaban IH	Manufacturing & Packing
8.	Arformoterol Tartrate IH	Manufacturing & Packing
9.	Azelastine Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
10.	Bosentan Monohydrate IH	Manufacturing & Packing
11.	Bepotastine Besilate IH	Manufacturing & Packing
12.	Bumetanide USP/Ph.Eur.	Manufacturing & Packing
13.	Clidinium Bromide USP	Manufacturing & Packing
14.	Clopidogrel Besylate IH/Ph.Eur.	Manufacturing & Packing
15.	Clopidogrel Bisulfate USP	Manufacturing & Packing
16.	Clopidogrel Hydrogen Sulphate Ph.Eur.	Manufacturing & Packing
17.	Dabigatran Etexilate Mesyalte IH	Manufacturing & Packing
18.	Dabigatran Etexilate Oxalate IH	Manufacturing & Packing
19.	Dapagliflozin (Amorphous) IH	Manufacturing & Packing
20.	Dapagliflozin Propanediol IH	Manufacturing & Packing
21.	Deferasirox IH/USP/Ph.Eur.	Manufacturing & Packing
22.	Diazoxide USP/Ph.Eur.	Manufacturing & Packing
23.	Dronedarone Hydrochloride IH/Ph.Eur.	Manufacturing & Packing
24.	Duloxetine Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
25.	Dutasteride IH/USP/Ph.Eur.	Manufacturing & Packing
26.	Edaravone IH	Manufacturing & Packing
27.	Ezetimibe IH	Manufacturing & Packing
28.	Eplerenone IH/Ph.Eur.	Manufacturing & Packing
29.	Esmolol Hydrochloride IH	Manufacturing & Packing
30.	Eltrombopag Olamine IH	Manufacturing & Packing

ITEM(s) Thirty (30) Only

The Written Confirmation remains valid until: 14.07.2028

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ डी ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Signature

Stamp of the authority and date

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

07 JUL 2025

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

CERTIFICATE NO. : **Annexure-02 WC-0021**

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 Sy. Nos, 317,320,321,322,323,604 & 605, Pincode-502329, Rudraram (Village), Patancheru (Mandal), Sangareddy (Dist.), Telangana, INDIA**

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Finasteride USP/Ph.Eur.	Manufacturing & Packing
2.	Formoterol Fumarate Dihydrate Ph.Eur.	Manufacturing & Packing
3.	Formoterol Fumarate USP	Manufacturing & Packing
4.	Fosapripitant Dimeglumine IH	Manufacturing & Packing
5.	Glycerol Phenyl Butyrate IH	Manufacturing & Packing
6.	Ketorolac Trometamol Ph.Eur.	Manufacturing & Packing
7.	Ketorolac Tromethamine USP	Manufacturing & Packing
8.	Neostigmine Methylsulfate USP	Manufacturing & Packing
9.	Neostigmine Metisulfate Ph.Eur.	Manufacturing & Packing
10.	Olmesartan Medoxomil Ph.Eur.	Manufacturing & Packing
11.	Olopatadine Hydrochloride IH/USP	Manufacturing & Packing
12.	Paliperidone IH	Manufacturing & Packing
13.	Paliperidone Palmitate IH	Manufacturing & Packing
14.	Pantoprazole Sodium Sesquihydrate Ph.Eur.	Manufacturing & Packing
15.	Pantoprazole Sodium USP	Manufacturing & Packing
16.	Pitavastatin Calcium IH	Manufacturing & Packing
17.	Posaconazole IH	Manufacturing & Packing
18.	Pramipexole Dihydrochloride USP	Manufacturing & Packing
19.	Pramipexole Dihydrochloride monohydrate EP	Manufacturing & Packing
20.	Prasugrel Hydrochloride IH	Manufacturing & Packing
21.	Prasugrel IH	Manufacturing & Packing
22.	Phytonadione USP	Manufacturing & Packing
23.	Ramelteon IH	Manufacturing & Packing
24.	Rifaximin Ph.Eur.	Manufacturing & Packing
25.	Rivaroxaban Ph.Eur./IH	Manufacturing & Packing
26.	Roflumilast IH	Manufacturing & Packing
27.	Rosuvastatin Calcium IH/USP/Ph.Eur.	Manufacturing & Packing
28.	Salmeterol Xinafoate Ph.Eur.	Manufacturing & Packing
29.	Silodosin IH	Manufacturing & Packing
30.	Solifenacin succinate IH	Manufacturing & Packing

ITEM(s) Thirty (30) Only

The Written Confirmation remains valid until: 14.07.2028

Signature 04/07/25
चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

07 JUL 2025

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

CERTIFICATE NO. :

Annexure-03
WC-0021

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**
Sy. Nos, 317,320,321,322,323,604 & 605,
Pincode-502329, Rudraram (Village),
Patancheru (Mandal), Sangareddy (Dist.),
Telangana, INDIA

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Terbinafine Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
2.	Terbinafine IH	Manufacturing & Packing
3.	Tolvaptan IH	Manufacturing & Packing
4.	Trospium Chloride Ph.Eur.	Manufacturing & Packing
5.	Tofacitinib Citrate IH	Manufacturing & Packing
6.	Vigabatrin USP/Ph.Eur.	Manufacturing & Packing
7.	Vilanterol Trifenatate IH	Manufacturing & Packing
8.	Voriconazole USP/Ph.Eur.	Manufacturing & Packing
9.	Zileuton USP	Manufacturing & Packing

ITEM(s) Nine (09) Only

The Written Confirmation remains valid until: 14.07.2028

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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Ministry of Health & Family Welfare, Govt. of India

07 JUL 2025

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

CERTIFICATE NO. : **Annexure-04 WC-0021**

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 Sy. Nos, 317,320,321,322,323,604 & 605, Pincode-502329, Rudraram (Village), Patancheru (Mandal), Sangareddy (Dist.), Telangana, INDIA**

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Avanafil IH	Manufacturing & Packing
2.	Azilsartan Kamedoxomil IH	Manufacturing & Packing
3.	Baricitinib IH	Manufacturing & Packing
4.	Bazedoxifene Acetate IH	Manufacturing & Packing
5.	Cariprazine Hydrochloride IH	Manufacturing & Packing
6.	Dexlansoprazole IH	Manufacturing & Packing
7.	Ivacaftor IH	Manufacturing & Packing
8.	Lofexidine Hydrochloride IH	Manufacturing & Packing
9.	Lorcoserin Hydrochloride Hemihydrate IH	Manufacturing & Packing
10.	Mirabegron Hydrochloride IH	Manufacturing & Packing
11.	Mirabegron IH	Manufacturing & Packing
12.	Molnupiravir IH	Manufacturing & Packing
13.	Naftifine Hydrochloride USP	Manufacturing & Packing
14.	Netupitant IH	Manufacturing & Packing
15.	Rufinamide IH	Manufacturing & Packing
16.	Tafamidis IH	Manufacturing & Packing
17.	Tafamidis Meglumine IH	Manufacturing & Packing
18.	Teriflunomide IH/Ph.Eur.	Manufacturing & Packing

ITEM(s) Eighteen (18) 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 substance(s) for the purpose of export only, as the above-mentioned active substance(s) are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 14.07.2028

Signature चंद्रशेखर रंगा/Chandrashekar Ranga 04/07/25
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date
Central Drugs Standard Control Organisation
सत्यमेव जयते
Ministry of Health & Family Welfare, Govt. of India

07 JUL 2025