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:
17 JUN 2022

To,

**M/s MSN Laboratories Private Limited,**
**Sy. Nos: 317, 320, 321, 322, 323, 604 & 605,**
**Rudraram (Village), Patancheru (Mandal),**
**Sangareddy District -502 329**
**Telangana State, India**

**SUB:-** Written Confirmation of M/s MSN Laboratories Private Limited, Sy. Nos: 317, 320, 321, 322, 323, 604 & 605, Rudraram (Village), Patancheru (Mandal), Sangareddy District -502 329, 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/RE/2022/2064 submitted to CDSCO, Hyderabad Zone office 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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 | 67 | 17 JUN 2022 | 14.07.2025 |
| 2 | 13 | 17 JUN 2022 | 14.07.2025 |

**Yours faithfully,**

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

17-06-2022

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

CERTIFICATE NO. : 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,
Rudraram (Village), Patancheru (Mandal),
Sangareddy District -502 329
Telangana State, 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):

List as per Enclosed 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: 07.04.2022 & 08.04.2022

The Written Confirmation remains valid until: 14.07.2025

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

17 JUN 2022

*Signature*

17-06-2022

*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

**Annexure-1**

**CERTIFICATE NO. :** **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,**
**Rudraram (Village), Patancheru (Mandal),**
**Sangareddy District -502 329**
**Telangana State, India**

**List of APIs:**

| Sr. No. | Active substance (s) | Activity(ies) |
|---|---|---|
| 1. | Ramelteon In-House | Manufacturing & Packing |
| 2. | Clidinium Bromide USP | Manufacturing & Packing |
| 3. | Almotriptan Malate USP | Manufacturing & Packing |
| 4. | Paliperidone Palmitate In-House | Manufacturing & Packing |
| 5. | Neostigmine Metilsulfate Ph.Eur | Manufacturing & Packing |
| 6. | Neostigmine Methylsulfate USP | Manufacturing & Packing |
| 7. | Dapagliflozin (Amorphous) In-House | Manufacturing & Packing |
| 8. | Prasugrel In-House | Manufacturing & Packing |
| 9. | Arformoterol Tartrate In-House | Manufacturing & Packing |
| 10. | Aliskiren Hemifumarate In-House | Manufacturing & Packing |
| 11. | Terbinafine Hydrochloride USP / Ph.Eur | Manufacturing & Packing |
| 12. | Salmeterol Xinafoate Ph.Eur | Manufacturing & Packing |
| 13. | Ketorolac Tromethamine USP | Manufacturing & Packing |
| 14. | Ketorolac Trometamol Ph.Eur | Manufacturing & Packing |
| 15. | Pantoprazole Sodium Sesquihydrate Ph.Eur | Manufacturing & Packing |
| 16. | Pantoprazole Sodium USP | Manufacturing & Packing |
| 17. | Finasteride USP / Ph.Eur | Manufacturing & Packing |
| 18. | Ezetimibe In-House | Manufacturing & Packing |
| 19. | Clopidogrel Bisulfate USP | Manufacturing & Packing |
| 20. | Clopidogrel Hydrogen Sulphate Ph.Eur | Manufacturing & Packing |
| 21. | Esmolol Hydrochloride In-House | Manufacturing & Packing |
| 22. | Eplerenone In-House | Manufacturing & Packing |
| 23. | Duloxetine Hydrochloride USP / Ph.Eur | Manufacturing & Packing |
| 24. | Olmesartan Medoxomil Ph.Eur | Manufacturing & Packing |
| 25. | Pitavastatin Calcium In-House | Manufacturing & Packing |
| 26. | Alfuzosin Hydrochloride USP / Ph.Eur | Manufacturing & Packing |
| 27. | Dutasteride In-House/USP/ Ph.Eur | Manufacturing & Packing |
| 28. | Azelastine Hydrochloride Ph.Eur / USP | Manufacturing & Packing |
| 29. | Voriconazole Ph.Eur / USP | Manufacturing & Packing |
| 30. | Solifenacin Succinate In-House | Manufacturing & Packing |
| 31. | Bosentan Monohydrate In-House | Manufacturing & Packing |



17-6-2022

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

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

**List of APIs:**

| Sr. No. | Active substance (s) | Activity(ies) |
|---|---|---|
| 32. | Paliperidone In-House | Manufacturing & Packing |
| 33. | Pramipexole di hydrochloride monohydrate Ph.Eur | Manufacturing & Packing |
| 34. | Pramipexole di hydro chloride USP | Manufacturing & Packing |
| 35. | Olopatadine Hydrochloride In-House/USP | Manufacturing & Packing |
| 36. | Prasugrel Hydrochloride In-House | Manufacturing & Packing |
| 37. | Clopidogrel Besylate In-House | Manufacturing & Packing |
| 38. | Rosuvastatin Calcium In-House | Manufacturing & Packing |
| 39. | Ambrisentan In-House | Manufacturing & Packing |
| 40. | Deferasirox In-House | Manufacturing & Packing |
| 41. | Terbinafine In-House | Manufacturing & Packing |
| 42. | Dronedarone Hydrochloride In-House | Manufacturing & Packing |
| 43. | Silodosin In-House | Manufacturing & Packing |
| 44. | Almotriptan Malate In-House | Manufacturing & Packing |
| 45. | Trospium Chloride Ph.Eur | Manufacturing & Packing |
| 46. | Roflumilast In-House | Manufacturing & Packing |
| 47. | Rivaroxaban In-House | Manufacturing & Packing |
| 48. | Tolvaptan In-House | Manufacturing & Packing |
| 49. | Rifaximin Ph.Eur | Manufacturing & Packing |
| 50. | Formoterol Fumarate USP | Manufacturing & Packing |
| 51. | Apixaban In-House | Manufacturing & Packing |
| 52. | Posaconazole In-House | Manufacturing & Packing |
| 53. | Dabigatran Etexilate Mesylate In-House | Manufacturing & Packing |
| 54. | Fosaprepitant Dimeglumine In-House | Manufacturing & Packing |
| 55. | Rosuvastatin Calcium USP/Ph.Eur. | Manufacturing & Packing |
| 56. | Formoterol Fumarate Dihydrate Ph.Eur. | Manufacturing & Packing |
| 57. | Dapagliflozin Propanediol In-House | Manufacturing & Packing |
| 58. | Eltrombopag Olamine In-House | Manufacturing & Packing |
| 59. | Zileuton USP | Manufacturing & Packing |
| 60. | Bumetanide USP | Manufacturing & Packing |
| 61. | Tofacitinib Citrate In-House | Manufacturing & Packing |
| 62. | Alogliptin Benzoate In-House | Manufacturing & Packing |
| 63. | Edaravone In-House | Manufacturing & Packing |
| 64. | Alcaftadine In-House | Manufacturing & Packing |
| 65. | Dabigatran Etexilate Oxalate In-House | Manufacturing & Packing |
| 66. | Vilanterol Trifenatate In-House | Manufacturing & Packing |
| 67. | Glycerol Phenyl Butyrate In-House | Manufacturing & Packing |

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

**The Written Confirmation remains valid until: 14.07.2025**

*Signature*

17-06-2022

17 JUN 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

**Annexure-2**

**CERTIFICATE NO. : 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,**
**Rudraram (Village), Patancheru (Mandal),**
**Sangareddy District -502 329**
**Telangana State, India**

**List of APIs:**

| Sr. No. | Active substance (s) | Activity(ies) |
|---|---|---|
| 1. | Azilsartan Kamedoxomil In-House | Manufacturing & Packing |
| 2. | Bazedoxin Acetate In-House | Manufacturing & Packing |
| 3. | Vigabatrin Ph.Eur/USP | Manufacturing & Packing |
| 4. | Phytonadione USP | Manufacturing & Packing |
| 5. | Dexlansoprazole In-House | Manufacturing & Packing |
| 6. | Avanafil In-House | Manufacturing & Packing |
| 7. | Mirabegron In-House | Manufacturing & Packing |
| 8. | Teriflunomide In-House | Manufacturing & Packing |
| 9. | Lorcaserin Hydrochloride Hemihydrate In-House | Manufacturing & Packing |
| 10. | Mirabegron Hydrochloride In-House | Manufacturing & Packing |
| 11. | Tafamidis Meglumine In-House | Manufacturing & Packing |
| 12. | Netupitant In-House | Manufacturing & Packing |
| 13. | Lofexidine Hydrochloride In-House | Manufacturing & Packing |

**ITEM(S) THIRTEEN (13) 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: 14.07.2025**

*Signature*

17-06-2022

17 JUN 2022

*Stamp of the authority and date*

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