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: 15 JUL 2019

To,

M/s. MSN Laboratories Private Limited,
Sy. No. 317 & 323, Rudraram (Village),
Patancheru (Mandal), Sangareddy District-502329,
Telangana State, India

SUB:- Written Confirmation of M/s. MSN Laboratories Private Limited, Sy. No. 317 & 323, Rudraram (Village), Patancheru (Mandal), Sangareddy District-502329, 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, 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
01	59	15 JUL 2019	Three years from the date of issue
02	09	15 JUL 2019	Three years from the date of issue

Yours faithfully,

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

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. No. 317 & 323, Rudraram (Village), Patancheru (Mandal), Sangareddy District-502329, 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

As per list enclosed as Annexure- 01 and Annexure- 02

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: 03-04/06/2019

The Written Confirmation remains valid until: Three years from the date of issue

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. S Eswara Reddy,
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

15 JUL 2019

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

Annexure-01

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. No. 317 & 323, Rudraram (Village), Patancheru (Mandal), Sangareddy District-502329, Telangana State, India**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Ramelteon IH	Manufacturing & Packing
2.	Clidinium Bromide USP	Manufacturing & Packing
3.	Almotriptan Malate USP	Manufacturing & Packing
4.	Paliperidone Palmitate IH	Manufacturing & Packing
5.	Neostigmine Metilsulfate Ph.Eur	Manufacturing & Packing
6.	Neostigmine Methylsulfate USP	Manufacturing & Packing
7.	Dapagliflozin (Amorphous) IH	Manufacturing & Packing
8.	Prasugrel IH	Manufacturing & Packing
9.	Arformoterol Tartrate IH	Manufacturing & Packing
10.	Aliskiren Hemifumarate IH	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 IH	Manufacturing & Packing
19.	Clopidogrel Bisulfate USP	Manufacturing & Packing
20.	Clopidogrel Hydrogen Sulphate Ph.Eur	Manufacturing & Packing
21.	Esmolol Hydrochloride IH	Manufacturing & Packing
22.	Eplerenone IH	Manufacturing & Packing
23.	Duloxetine Hydrochloride USP / Ph.Eur	Manufacturing & Packing
24.	Olmesartan Medoxomil Ph.Eur	Manufacturing & Packing
25.	Pitavastatin Calcium IH	Manufacturing & Packing
26.	Alfuzosin Hydrochloride USP / Ph.Eur	Manufacturing & Packing
27.	Dutasteride IH/ Ph. Eur/USP	Manufacturing & Packing
28.	Azelastine Hydrochloride Ph.Eur / USP	Manufacturing & Packing
29.	Voriconazole Ph.Eur / USP	Manufacturing & Packing
30.	Solifenacin succinate IH	Manufacturing & Packing
31.	Bosentan Monohydrate IH	Manufacturing & Packing
32.	Paliperidone IH	Manufacturing & Packing

8.7.19

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. No. 317 & 323, Rudraram (Village), Patancheru (Mandal), Sangareddy District-502329, Telangana State, India**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
33.	Pramipexole di hydro chloride monohydrate Ph.Eur	Manufacturing & Packing
34.	Pramipexole di hydro chloride USP	Manufacturing & Packing
35.	Olopatadine Hydrochloride IH/USP	Manufacturing & Packing
36.	Prasugrel Hydrochloride IH	Manufacturing & Packing
37.	Clopidogrel Besylate IH	Manufacturing & Packing
38.	Rosuvastatin Calcium IH	Manufacturing & Packing
39.	Ambrisentan IH	Manufacturing & Packing
40.	Deferasirox IH	Manufacturing & Packing
41.	Terbinafine IH	Manufacturing & Packing
42.	Dronedarone Hydrochloride IH	Manufacturing & Packing
43.	Silodosin IH	Manufacturing & Packing
44.	Almotriptan Malate IH	Manufacturing & Packing
45.	Trospium Chloride Ph.Eur	Manufacturing & Packing
46.	Roflumilast IH	Manufacturing & Packing
47.	Rivaroxaban IH	Manufacturing & Packing
48.	Tolvaptan IH	Manufacturing & Packing
49.	Rifaximin Ph.Eur	Manufacturing & Packing
50.	Formoterol Fumarate USP	Manufacturing & Packing
51.	Apixaban IH	Manufacturing & Packing
52.	Posaconazole IH	Manufacturing & Packing
53.	Dabigatran Etexilate Mesylate IH	Manufacturing & Packing
54.	Fosaprepitant Dimeglumine IH	Manufacturing & Packing
55.	Rosuvastatin Calcium USP/Ph.Eur	Manufacturing & Packing
56.	Formoterol Fumarate Dihydrate Ph.Eur.	Manufacturing & Packing
57.	Dapagliflozin Propanediol IH	Manufacturing & Packing
58.	Eltrombopag Olamine IH	Manufacturing & Packing
59.	Zileuton USP	Manufacturing & Packing

ITEM(S) FIFTY NINE (59) ONLY

The Written Confirmation remains valid until: Three years from date of issue

Signature

Stamp of the authority and date

15 JUL 2019

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

Annexure-02

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. No. 317 & 323, Rudraram (Village),
Patancheru (Mandal), Sangareddy District-502329,
Telangana State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Azilsartan Kamedoxomil IH	Manufacturing & Packing
2.	Bazedoxifin Acetate IH	Manufacturing & Packing
3.	Vigabatrin Ph.Eur	Manufacturing & Packing
4.	Phytonadione USP	Manufacturing & Packing
5.	Dexlansoprazole IH	Manufacturing & Packing
6.	Vigabatrin USP	Manufacturing & Packing
7.	Avanafil IH	Manufacturing & Packing
8.	Mirabegron IH	Manufacturing & Packing
9.	Teriflunomide IH	Manufacturing & Packing

ITEM(S) Nine (09) 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: <u>Three years from date of issue</u>

Signature

Stamp of the authority and date

15 JUL 2019