7-5/2016/EU/WC/0383
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan,Kotla Road,
New Delhi-110002
Dated: 26 JUL 2019

To

M/s. MSN Life Sciences Pvt. Ltd.,
Unit-II, Sy. No 455/A, 455/AA, 455/E & 455/EE,
Chandampet (Village), Shankarampet-R (Mandal),
Medak District-502255 Telangana, India

Subject:- Written Confirmation of M/s. MSN Life Sciences Pvt. Ltd., Unit-II, Sy. No 455/A, 455/AA, 455/E & 455/EE, Chandampet (Village), Shankarampet-R (Mandal), Medak District-502255 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 application 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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.

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	12	26 JUL 2019	08.08.2022
2	8	26 JUL 2019	08.08.2022

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-0383

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 Life Sciences Pvt. Ltd., Unit-II, Sy. No 455/A, 455/AA, 455/E & 455/EE, Chandampet (Village), Shankarampet-R (Mandal), Medak District-502255 Telangana, India

2. Manufacturer's licence number: form 25 No. 17/MD/TS/2014/B/G

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-1 & 2
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: 12.06.2019 & 13.06.2019

The Written Confirmation remains valid until: **08th August, 2022**

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**
OIC
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

24/07/19

24.7.19

Stamp of the authority and date

26 JUL 2019

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

Annexure-1
WC-0383

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

Name and address of site: **M/s MSN Life Sciences Pvt. Ltd., Unit-II, Sy. No 455/A, 455/AA, 455/E & 455/EE, Chandampet (Village), Shankarampet-R (Mandal), Medak District-502255 Telangana, India**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Dolutegravir Sodium In-house	Manufacturing & Packing
2.	Pirfenidone In-house/Ph.Eur	Manufacturing & Packing
3.	AlbendazoleUSP/Ph.Eur	Manufacturing & Packing
4.	Mebendazole USP/Ph.Eur	Manufacturing & Packing
5.	Empagliflozin In-house	Manufacturing & Packing
6.	Sacubitril and valsartan In-house	Manufacturing & Packing
7.	Valsartan USP/Ph.Eur	Manufacturing & Packing
8.	Levofloxacin Hemihydrate USP	Manufacturing & Packing
9.	Rufinamide USP	Manufacturing & Packing
10.	Eslicarbazepine Acetate In-house	Manufacturing & Packing
11.	Dabigatran Etexilate Mesylate In-house	Manufacturing & Packing
12.	Dexlansoprazole In-house	Manufacturing & Packing

ITEM(S) Twelve (12) ONLY

The Written Confirmation remains valid until: 08th August, 2022

Signature

Stamp of the authority and date

26 JUL 2019

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

Annexure-2
WC-0383

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

Name and address of site: M/s MSN Life Sciences Pvt. Ltd.,
Unit-II, Sy. No 455/A, 455/AA, 455/E & 455/EE,
Chandampet (Village), Shankarampet-R (Mandal),
Medak District-502255 Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Riociguat In-house	Manufacturing & Packing
2.	Droxidopa In-house	Manufacturing & Packing
3.	Monomethyl Fumarate In-house	Manufacturing & Packing
4.	Tiopronin In-house	Manufacturing & Packing
5.	Brexpiprazole In-house	Manufacturing & Packing
6.	Tavaborole In-house	Manufacturing & Packing
7.	Edoxaban Tosylate In-house	Manufacturing & Packing
8.	Naloxegol Oxalate In-house	Manufacturing & Packing

ITEM(S) Eight (08) 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: 08th August, 2022

Signature

Stamp of the authority and date

26 JUL 2019