No.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-110 002

15 OCT 2019

To

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

SUB:Written Confirmation of M/s. MSN Life Sciences Pvt. Ltd., Unit – II, Sy. No. 455/A, 455/AA, 455/E, and 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, Zone Office, Hyderabad and the recommendation received from DDC (I), Zonal Office, Hyderabad 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.

S.No.	Annexure	No. of Products	Date of Issue	Valid up to
1	01	12	26.07.2019	08.08.2022
2	02	08	26.07.2019	08.08.2022
3	03	11	15 OCT 2019	08.08.2022
4	04	14	15 OCT 2019	08.08.2022

Yours faithfully,

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

10-10-19

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

Annexure-03
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

1. Name and address of site: M/s. MSN Life Sciences Pvt. Ltd.,
Unit – II, Sy. No. 455/A, 455/AA, 455/E, and 455/EE, Chandampet (Village),
Shankarampet-R(Mandal),
Medak District-502 255,
Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Aminocaproic Acid USP	Manufacturing & Packing
2.	Canagliflozin IH	Manufacturing & Packing
3.	Canagliflozin Hemihydrate IH	Manufacturing & Packing
4.	Clobazam IH	Manufacturing & Packing
5.	Darunavir Ethanolate IH	Manufacturing & Packing
6.	Desvenlaflaxine Succinate IH	Manufacturing & Packing
7.	Esomeprazole Magnesium USP	Manufacturing & Packing
8.	Esomeprazole Sodium IH	Manufacturing & Packing
9.	Etravirine IH	Manufacturing & Packing
10.	Oxcarbazepine USP	Manufacturing & Packing
11.	Sofosbuvir IH	Manufacturing & Packing

ITEM(S) Elevan (11) Only

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

Signature

Stamp of the authority and date

Drugs Standard Control Organization
सत्यमेव जयते
Ministry of Health Family Welfare, Government of India

15 OCT 2019

10.10.19

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

CERTIFICATE NO. : **Annexure-04**
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, and 455/EE,
Chandampet (Village),
Shankarampet R-(Mandal),
Medak District -502255,
Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Alvimopan Dihydrate IH	Manufacturing & Packing
2.	Apremilast IH	Manufacturing & Packing
3.	Bilastine IH	Manufacturing & Packing
4.	Cangrelor Tetrasodium IH	Manufacturing & Packing
5.	Cobicistat IH	Manufacturing & Packing
6.	Crisaborole IH	Manufacturing & Packing
7.	Darunavir IH	Manufacturing & Packing
8.	Elvitegravir IH	Manufacturing & Packing
9.	Icatibant Acetate IH	Manufacturing & Packing
10.	Levomilnacipran Hydrochloride IH	Manufacturing & Packing
11.	Linaclotide IH	Manufacturing & Packing
12.	Macitentan IH	Manufacturing & Packing
13.	Pimavanserine Tartrate IH	Manufacturing & Packing
14.	Sacubitril Sodium IH	Manufacturing & Packing

Item(S) Fourteen (14) 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 Aug 2022

Signature

Stamp of the authority and date

15 OCT 2019