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

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002
Dated 20 DEC 2022

To

M/s. MSN Life Sciences Private Limited,
Unit-II, Sy No * Parts of 454,455,457,458 & 459 Chandampet-Village,
Shankarampet-R Mandal, Medak District, Telangana Pin Code 502255

SUB:- Written Confirmation of M/s. MSN Life Sciences Private Limited, Unit-II, Sy No * Parts of 454,455,457,458 & 459 Chandampet-Village, Shankarampet-R Mandal, Medak District, Telangana Pin Code 502255as 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 received vide email dated 09.12.2022 on the subject cited above.

In this regard, please find the enclosed amended Written Confirmation Certificate. The condition of the 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 will remain same.

Please acknowledge the receipt.

Yours faithfully,

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

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

Amended
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 of site: **M/s. MSN Life Sciences Private Limited, Unit-II, Sy No * Parts of 454,455,457,458 & 459 Chandampet-Village, Shankarampet-R Mandal, Medak District, Telangana Pin Code 502255**

2. Manufacturer's Licence Number: 17/MD/TS/2014/B/R

The address of the manufacturer mentioned annexures 03 & 04 of Written Confirmation Certificate (WC-0383) granted on date 10.08.2022 is hereby amended as follows:

In place of:
"M/s. MSN Life Sciences Private Limited, Unit-II, Sy No 455/A, 455/AA,455/E and 455/EE Chandampet -Village, Shankarampet-R Mandal, Medak District, Telangana Pin Code 502255"
Read as:
"M/s. MSN Life Sciences Private Limited, Unit-II, Sy No * Parts of 454,455,457,458 & 459 Chandampet-Village, Shankarampet-R Mandal, Medak District, Telangana Pin Code 502255"

The products details may be read as follows:

Sr No	Annexure of WC-0383	Product name mentioned as	May be read as
1.	annexure 02 dated 08.08.2022	Pimavanserine IH	Pimavanserine Tartrate IH
2.	annexure 03 dated 10.08.2022	Tenofovir Alafenamide IH	Tenofovir Alafenamide Hemifumarate IH
3.	annexure 04 dated 10.08.2022	Fluphenazine Hydrochloride Ph. Int	Fluphenazine Hydrochloride USP
4.		Sodium Benzoate Ph. Int	Sodium Benzoate USP

All the other conditions of Written Confirmation Certificate will remain same.

Signature

Stamp of the authority and date

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

20 DEC 2022

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: 15 DEC 2022

To,

M/s MSN Life Sciences Private Limited, Unit-II,
Sy No. *Parts of 454, 455, 457, 458 & 459, Chandampet-Village,
Shankarampet-R Mandal, Medak District,
Pin code-502255, Telangana, India

Sub:- Application for amendment of the Written Confirmation of M/s MSN Life Sciences Private Limited, Unit-II, Sy No. *Parts of 454, 455, 457, 458 & 459, Chandampet-Village, Shankarampet-R Mandal, Medak District, Pin code-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 Ref. no. 04/AMND-EUWC/MSNLS-II/Aug/2022-23 dated 05.12.2022 received vide diary no. 11104 dated 07.12.2022 on the subject cited above.

In this regard, please find the enclosed amended Written Confirmation Certificate. The condition of the 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 will remain same.

Please acknowledge the receipt.

Yours faithfully,

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

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

Amended

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 of site:** M/s. MSN Life Sciences Private Limited, Unit-II, Sy No. *Parts of 454, 455, 457, 458 & 459, Chandampet-Village, Shankarampet-R Mandal, Medak District, Pin code-502255, Telangana, India.

2. **Manufacturer's License Number:** 17/MD/TS/2014/B/G

The address of the site mentioned in the certificate & Annexures of Written Confirmation Certificate (WC-0383) issued on date 08.08.2022 is hereby amended as follows:

In place of:

M/s MSN Life Sciences Private Limited, Unit-II, Sy No.455/A, 455/AA, 455/E and 455/EE, Chandampet-Village, Shankarampet-R Mandal, Medak District, Telangana, Pin code-502255, India

Read as:

M/s MSN Life Sciences Private Limited, Unit-II, Sy No. *Parts of 454, 455, 457, 458 & 459, Chandampet-Village, Shankarampet-R Mandal, Medak District, Pin code-502255, Telangana, India.

All other conditions of Written Confirmation Certificate will remain same.

Signature

Stamp of the authority and date

15 DEC 2022

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

08 AUG 2022

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

SUB:- 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 online application no. WC/RE/2022/4705 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.	40	08 AUG 2022	08.08.2025
2.	17	08 AUG 2022	08.08.2025

Yours faithfully,

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

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

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 & 455/EE,
Chandampet (Village), Shankarampet-R(Mandal),
Medak District-502255 Telangana, India

2. Manufacturer's licence number: 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

List of API(s):

As per Annexure 01 & 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: 05/07/2021 & 06/07/2021

The Written Confirmation remains valid until: 08.08.2025

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

08 AUG 2022

Signature

Stamp of the authority and date

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

Annexure- 01

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

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Dolutegravir Sodium IH	Manufacturing & Packing
2.	Pirfenidone In-house / Ph.Eur	Manufacturing & Packing
3.	Albendazole USP/Ph.Eur	Manufacturing & Packing
4.	Mebendazole USP/Ph.Eur	Manufacturing & Packing
5.	Empagliflozin IH	Manufacturing & Packing
6.	Sacubitril and Valsartan IH	Manufacturing & Packing
7.	Valsartan USP / Ph.Eur	Manufacturing & Packing
8.	Levofloxacin Hemihydrate USP/ Ph.Eur	Manufacturing & Packing
9.	Rufinamide USP	Manufacturing & Packing
10.	Eslicarbazepine Acetate IH	Manufacturing & Packing
11.	Dabigatran Etexilate Mesylate IH	Manufacturing & Packing
12.	Dexlansoprazole IH	Manufacturing & Packing
13.	Riociguat IH/ USP/Ph.Eur	Manufacturing & Packing
14.	Droxidopa IH	Manufacturing & Packing
15.	Aminocaproic Acid USP/Ph.Eur	Manufacturing & Packing
16.	Canagliflozin IH	Manufacturing & Packing
17.	Canagliflozin Hemihydrate IH	Manufacturing & Packing
18.	Clobazam IH /Ph.Eur	Manufacturing & Packing
19.	Darunavir Ethanolate IH	Manufacturing & Packing
20.	Desvenlafaxine Succinate IH /USP	Manufacturing & Packing
21.	Esomeprazole Magnesium USP/Ph.Eur	Manufacturing & Packing
22.	Esomeprazole Sodium IH /Ph.Eur	Manufacturing & Packing
23.	Etravirine IH	Manufacturing & Packing
24.	Oxcarbazepine USP/Ph.Eur	Manufacturing & Packing
25.	Sofosbuvir IH	Manufacturing & Packing
26.	Apremilast IH	Manufacturing & Packing
27.	Bilastine IH	Manufacturing & Packing
28.	Cangrelor Tetrasodium IH	Manufacturing & Packing
29.	Cobicistat IH	Manufacturing & Packing

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

08 AUG 2022

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

30.	Darunavir IH	Manufacturing & Packing
31.	Macitentan IH	Manufacturing & Packing
32.	Sacubitril Sodium IH	Manufacturing & Packing
33.	Bedaquiline Fumarate IH	Manufacturing & Packing
34.	Fluphenazine Decanoate USP/Ph.Eur	Manufacturing & Packing
35.	Haloperidol USP/Ph.Eur	Manufacturing & Packing
36.	Metolazone USP/Ph.Eur	Manufacturing & Packing
37.	Tiagabine Hydrochloride USP	Manufacturing & Packing
38.	Caspofungin Acetate In-house	Manufacturing & Packing
39.	Haloperidol Decanoate USP/Ph.Eur	Manufacturing & Packing
40.	Ziprasidone Mesylate Trihydrate Ph.Eur	Manufacturing & Packing

ITEM(S) Fourty (40) ONLY

The Written Confirmation remains valid until: 08.08.2025

Signature

Stamp of the authority and date

08 AUG 2022

Annexure-02

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

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 & 455/EE,
Chandampet(Village),Shankarampet-R(Mandal),
Medak District-502255 Telangana, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Monomethyl Fumarate IH	Manufacturing & Packing
2.	Tiopronin IH	Manufacturing & Packing
3.	Brexpiprazole IH	Manufacturing & Packing
4.	Tavaborole IH	Manufacturing & Packing
5.	Edoxaban Tosylate IH	Manufacturing & Packing
6.	Naloxegol Oxalate IH	Manufacturing & Packing
7.	Alvimopan Dihydrate IH	Manufacturing & Packing
8.	Crisaborole IH	Manufacturing & Packing
9.	Elvitegravir IH	Manufacturing & Packing
10.	Icatibant Acetate IH	Manufacturing & Packing
11.	Levomilnacipran Hydrochloride IH	Manufacturing & Packing
12.	Linaclotide IH	Manufacturing & Packing
13.	Pimavanserin IH	Manufacturing & Packing
14.	Sugammadex Sodium IH	Manufacturing & Packing
15.	Lifitegrast IH	Manufacturing & Packing
16.	Obeticholic Acid IH	Manufacturing & Packing
17.	Dofetilide USP	Manufacturing & Packing

ITEM(S) Seventeen (17) 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: 08.08.2025

Signature 08 AUG 2022

Stamp of the authority and date

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

7-5/2013/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:

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.

10 AUG 2022

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 online applications no. WC/FR/2021/778 submitted to CDSCO, Zonal office, Hyderabad and the recommendation received from DDC (I), 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
01	40	08.08.2022	08.08.2025
02	17	08.08.2022	08.08.2025
03	02	10 AUG 2022	08.08.2025
04	04	10 AUG 2022	08.08.2025

Yours faithfully,

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

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

Annexure-03

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.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Nitazoxanide IH	Manufacturing & Packing
2.	Tenofovir Alafenamide IH	Manufacturing & Packing

ITEM(S) TWO (02) ONLY

The Written Confirmation remains valid until: 08.08.2025.

Signature

Stamp of the authority and date

10 AUG 2022

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

Annexure-04

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.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Plecanatide IH	Manufacturing & Packing
2.	Fluphenazine Di Hydrochloride Ph.Eur.	Manufacturing & Packing
3.	Fluphenazine Hydrochloride Ph. Int.	Manufacturing & Packing
4.	Sodium Benzoate Ph. Int.	Manufacturing & Packing

ITEM(S) FOUR (04) ONLY

This certificate is being issued subject to condition that the firm shall obtained NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substance for the purpose of export only, as the above mentioned active substance is not approved for manufacture for sale in India

The Written Confirmation remains valid until: 08.08.2025.

Signature

Stamp of the authority and date

10 AUG 2022

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: 25 NOV 2022

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-502 255 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 online application no WC/ED/2022/5445 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	40	08.08.2022	08.08.2025
2	08	08.08.2022	08.08.2025
3	02	10.08.2022	08.08.2025
4	04	10.08.2022	08.08.2025
5	01	25 NOV 2022	08.08.2025

Yours faithfully,

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

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

Annexure-5
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.	Aviptadil IH	Manufacturing & Packing

ITEM(S) One (01) 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, 2025

Signature 25 NOV 2022

Stamp of the authority and date

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:

08 FEB 2023

To

M/s. MSN Life Sciences Private Limited,
Unit-II, Sy No. *Parts of 454, 455, 457, 458 & 459,
Chandampet-Village, Shankarampet-R Mandal, Medak District,
Pin code-502255, Telangana, India

Subject:- Written Confirmation of M/s MSN Life Sciences Private Limited, Unit-II, Sy No. *Parts of 454, 455, 457, 458 & 459, Chandampet-Village, Shankarampet-R Mandal, Medak District, Pin code-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 online application No. WC/ED/2022/1903 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	40	08.08.2022	08.08.2025
2	08	08.08.2022	08.08.2025
3	02	10.08.2022	08.08.2025
4	04	10.08.2022	08.08.2025
5	01	28.11.2022	08.08.2025
6	01	08 FEB 2023	08.08.2025

Yours faithfully,

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

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

Annexure - 6
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 Private Limited, Unit-II, Sy No. *Parts of 454, 455, 457, 458 & 459, Chandampet-Village, Shankarampet-R Mandal, Medak District, Pin code-502255, Telangana, India**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Remdesvir IH	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 08.08.2025

Signature

Stamp of the authority and date

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

08 FEB 2023

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 16 MAY 2024

To

M/s. MSN Life Sciences Private Limited,
Unit – II, Sy. No. *Parts of 454, 455, 457, 458 & 459,
Chandampet-Village, Shankarampet-R Mandal, Medak District,
Pin Code -502255, Telangana, India

SUB:- Written Confirmation of **M/s. MSN Life Sciences Private Limited, Unit – II, Sy. No. *Parts of 454, 455, 457, 458 & 459, Chandampet-Village, Shankarampet-R Mandal, Medak District, Pin Code -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 online application no. WC/ED/2022/5783 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.

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
--	--	08.08.2022	**08.08.2025**
1	40	08.08.2022	**08.08.2025**
2	08	08.08.2022	**08.08.2025**
3	02	10.08.2022	**08.08.2025**
4	04	10.08.2022	**08.08.2025**
5	01	28.11.2022	**08.08.2025**
6	01	08.02.2023	**08.08.2025**
7	02	16 MAY 2024	**08.08.2025**
8	02	16 MAY 2024	**08.08.2025**

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

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

CERTIFICATE NO. :

Annexure-7
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. *Parts of 454, 455, 457, 458 & 459,
Chandampet-Village, Shankarampet-R Mandal, Medak District, Pin Code -502255, Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Losartan Potassium USP	Manufacturing & Packing
02	Micafungin Sodium IH	Manufacturing & Packing

ITEM(S) TWO (02) ONLY

The Written Confirmation remains valid until: 08.08.2025

Signature

1 ... 2024

Stamp of the authority and date

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

Annexure-8
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. *Parts of 454, 455, 457, 458 & 459,
Chandampet-Village, Shankarampet-R Mandal, Medak District, Pin Code -502255, Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Stiripentol IH	Manufacturing & Packing
02	Sodium phenyl acetate IH	Manufacturing & Packing

ITEM(S) TWO (02) 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: 08.08.2025

Signature

16 ... 2024

Stamp of the authority and date

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 25 JUL 2024

To

M/s. MSN Life Sciences Private Limited,
Unit – II, Sy. No. *Parts of 454, 455, 457, 458 & 459,
Chandampet-Village, Shankarampet-R Mandal, Medak District,
Pin Code -502255, Telangana, India

SUB:-Written Confirmation of **M/s. MSN Life Sciences Private Limited, Unit – II, Sy. No. *Parts of 454, 455, 457, 458 & 459, Chandampet-Village, Shankarampet-R Mandal, Medak District, Pin Code -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 online application no. WC/ED/2023/7839 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.

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
--	--	08.08.2022	**08.08.2025**
1	40	08.08.2022	**08.08.2025**
2	08	08.08.2022	**08.08.2025**
3	02	10.08.2022	**08.08.2025**
4	04	10.08.2022	**08.08.2025**
5	01	28.11.2022	**08.08.2025**
6	01	08.02.2023	**08.08.2025**
7	02	16.05.2024	**08.08.2025**
8	02	16.05.2024	**08.08.2025**
9	01	25 JUL 2024	**08.08.2025**

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Annexure-9

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. *Parts of 454, 455, 457, 458 & 459,
Chandampet-Village, Shankarampet-R Mandal, Medak District,Pin Code -502255, Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Ferric Carboxy Maltose IH	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 08.08.2025

Signature

Stamp of the authority and date

25 JUL 2024