AMENDED

7-5/2013/EU/WC-0077

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi -110002
Dated:
20 MAY 2024

To

M/S. AMOLI ORGANICS
(A DIVISION OF UMEDICA LABORATORIES PVT. LTD.)
BLOCK NO. 422, ECP CANAL ROAD, VILLAGE –LUNA,
TAL –PADRA, CITY –LUNA -391440,
DIST. –VADODARA, GUJARAT STATE, INDIA

Subject: Correction/Amendment in Written Confirmation Certificate of **M/S. AMOLI ORGANICS (A DIVISION of UMEDICA LABORATORIES PVT. LTD.), BLOCK NO. 422, ECP CANAL ROAD, VILLAGE –LUNA, TAL –PADRA, CITY –LUNA -391440, GUJARAT 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 this office for necessary amendment/correction in WC certificate issued by this office.

In this regard, kindly 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

Rajeev

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

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

Amended

CERTIFICATE NO. :

WC-0077

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. AMOLI ORGANICS**
   (A DIVISION OF UMEDICA LABORATORIES PVT. LTD.)
   BLOCK NO. 422, ECP CANAL ROAD, VILLAGE –LUNA,
   TAL –PADRA, CITY –LUNA -391440,
   DIST. –VADODARA, GUJARAT STATE, INDIA

2. **Manufacturer's License Number:** G/25/1518 & G/28/1100

The name of the manufacturing site mentioned in the Written Confirmation Certificate (**WC-0077 valid up to 12.08.2025**) is hereby amended as follows:

In place of:

M/s. Amoli Organics Pvt. Ltd.

Read as:

M/S. AMOLI ORGANICS (A DIVISION of UMEDICA LABORATORIES PVT. LTD.)

All other conditions of Written Confirmation Certificate will remain same.

Signature

20 MAY 2024

Stamp of the authority and date

Amended

7-5/2013/EU/WC-0077

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi -110002
Dated:

15 JAN 2024

To

M/S. AMOLI ORGANICS
(A DIVISION OF UMEDICA LABORATORIES PVT. LTD.)
BLOCK NO. 422, ECP CANAL ROAD, VILLAGE –LUNA,
TAL –PADRA, CITY –LUNA -391440,
DIST. –VADODARA, GUJARAT STATE, INDIA

Subject: Correction/Amendment in Written Confirmation Certificate of **M/S. AMOLI ORGANICS (A DIVISION of UMEDICA LABORATORIES PVT. LTD.), BLOCK NO. 422, ECP CANAL ROAD, VILLAGE –LUNA, TAL –PADRA, CITY –LUNA -391440, GUJARAT 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 this office for necessary amendment/correction in WC certificate issued by this office.

In this regard, kindly 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. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

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

CERTIFICATE NO. : **Amended**

WC-0077

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. AMOLI ORGANICS**
   (A DIVISION OF UMEDICA LABORATORIES PVT. LTD.)
   BLOCK NO. 422, ECP CANAL ROAD, VILLAGE –LUNA,
   TAL –PADRA, CITY –LUNA -391440,
   DIST. –VADODARA, GUJARAT STATE, INDIA

2. **Manufacturer's License Number:** G/25/1518 & G/28/1100

The name of the Active Substance mentioned in the Written Confirmation Certificate (**WC-0077**) issued on dated **09.06.2022** is hereby amended as follows:

In place of:

M/s. Amoli Organics Pvt. Ltd.

Read as:

M/S. AMOLI ORGANICS (A DIVISION of UMEDICA LABORATORIES PVT. LTD.)

All other conditions of Written Confirmation Certificate will remain same.

15 JAN 2024

Signature

Stamp of the authority and date

7-5/2013/EU/WC-0077
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 09 JUN 2022

To

M/s. Amoli Organics Pvt. Ltd.
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

SUB:- Written Confirmation of M/s. Amoli Organics Pvt. Ltd., Block No. 422, ECP Canal Road, Village - Luna, Tal – Padra, Dist – Vadodara, Gujarat 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/2022/3415 submitted to CDSCO, Ahmedabad Zone office, and the recommendation received from DDC (I), Ahmedabad 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	01	09 JUN 2022	12.08.2025

Yours faithfully,

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

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

CERTIFICATE NO. : **WC-0077**

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. Amoli Organics Pvt. Ltd.
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra, Dist – Vadodara
Gujarat State, India

2. Manufacturer's licence number: G/25/1518 & G/28/1100

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):

Sr. No.	Active substance (s)	Activity(ies)
1.	Ascorbic Acid IP/EP/BP/USP	Manufacturing & Packing

ITEM(S) ONE (21) ONLY

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: 10.03.3022 & 11.03.2022

The Written Confirmation remains valid until: 12.08.2025

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

Signature

Stamp of the authority and date

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

09 JUN 2022

7-5/2013/EU/WC-0077
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. Amoli Organics Pvt. Ltd.
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

15 JUN 2022

SUB:- Written Confirmation of M/s. Amoli Organics Pvt. Ltd., Block No. 422, ECP Canal Road, Village - Luna, Tal – Padra, Dist – Vadodara, Gujarat 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/2022/3170 submitted to CDSCO, Ahmedabad Zone office, and the recommendation received from DDC (I), Ahmedabad 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	01	09.06.2022	12.08.2025
2	01	15 JUN 2022	12.08.2025

Yours faithfully,

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

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

Annexure-2

CERTIFICATE NO. : WC-0077

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. Amoli Organics Pvt. Ltd.
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Ranolazine IH	Manufacturing & Packing

ITEM(S) ONE (21) ONLY

The Written Confirmation remains valid until: 12.08.2025

Signature

Stamp of the authority and date

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

15 JUN 2022

7-5/2013/EU/WC-0077
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

16 JUN 2022

To

M/s. Amoli Organics Pvt. Ltd.
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

SUB:- Written Confirmation ofM/s. Amoli Organics Pvt. Ltd., Block No. 422, ECP Canal Road, Village - Luna, Tal – Padra, Dist – Vadodara, Gujarat 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/2022/4209 submitted to CDSCO, Ahmedabad Zone office, and the recommendation received from DDC(I), Ahmedabad 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	01	09.06.2022	12.08.2025
2	01	15.06.2022	12.08.2025
3	01	16 JUN 2022	12.08.2025

Yours faithfully,

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

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

CERTIFICATE NO. :

Annexure-3

WC-0077

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. Amoli Organics Pvt. Ltd.
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Dimethyl Fumarate IH	Manufacturing & Packing

ITEM(S) ONE (21) ONLY

The Written Confirmation remains valid until: 12.08.2025

Signature

Stamp of the authority and date

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

15 JUN 2022

7-5/2013/EU/WC-0077
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. Amoli Organics Pvt. Ltd.
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

SUB:- Written Confirmation ofM/s. Amoli Organics Pvt. Ltd., Block No. 422, ECP Canal Road, Village - Luna, Tal – Padra, Dist – Vadodara, Gujarat 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/2022/4227 submitted to CDSCO, Ahmedabad Zone office, and the recommendation received from DDC(I), Ahmedabad 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	01	09.06.2022	12.08.2025
2	01	15.06.2022	12.08.2025
3	01	16.06.2022	12.08.2025
4	01	17 JUN 2022	12.08.2025

Yours faithfully,

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

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

Annexure-4

CERTIFICATE NO. :

WC-0077

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. Amoli Organics Pvt. Ltd.
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Sildenafil Citrate EP/USP	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 12.08.2025

Signature

Stamp of the authority and date

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

17 JUN 2022

7-5/2013/EU/WC-0077
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

24 JUN 2022

To

M/s. Amoli Organics Pvt. Ltd.
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

SUB:- Written Confirmation of M/s. Amoli Organics Pvt. Ltd., Block No. 422, ECP Canal Road, Village - Luna, Tal – Padra, Dist – Vadodara, Gujarat 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 applications no. WC/RE/2022/4378, WC/RE/2022/4230 WC/RE/2022/4381 and WC/RE/2022/4171 submitted to CDSCO, Ahmedabad Zone office, and the recommendation received from DDC (I), Ahmedabad 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	01	09.06.2022	12.08.2025
2	01	15.06.2022	12.08.2025
3	01	16.06.2022	12.08.2025
4	01	17.06.2022	12.08.2025
5	03	24 JUN 2022	12.08.2025
6	01	24 JUN 2022	12.08.2025

Yours faithfully,

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

Annexure-5

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

CERTIFICATE NO. : WC-0077

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. Amoli Organics Pvt. Ltd.**
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Atorvastatin Calcium Trihydrate IP/USP/BP/EP/JP	Manufacturing & Packing
2.	Venlafaxine Hydrochloride EP/USP/BP	Manufacturing & Packing
3.	Linezolid IH	Manufacturing & Packing

ITEM(S) THREE (03) ONLY

The Written Confirmation remains valid until: 12.08.2025

Signature

Stamp of the authority and date

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

24 JUN 2022

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

Annexure-6

CERTIFICATE NO. : WC-0077

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. Amoli Organics Pvt. Ltd.
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1	Dihydralazine Mesylate 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: 12.08.2025

Signature

Stamp of the authority and date

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

24 JUN 2022

7-5/2013/EU/WC-0077
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. Amoli Organics Pvt. Ltd.
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India.

27 JUN 2022

SUB:- Written Confirmation of M/s. Amoli Organics Pvt. Ltd., Block No. 422, ECP Canal Road, Village - Luna, Tal – Padra, Dist – Vadodara, Gujarat 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 applications no. WC/FR/2022/4216, WC/FR/2022/4377 and WC/FR/2022/4383 submitted to CDSCO, Ahmedabad Zone office, and the recommendation received from DDC (I), Ahmedabad 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	01	09.06.2022	12.08.2025
2	01	15.06.2022	12.08.2025
3	01	16.06.2022	12.08.2025
4	01	17.06.2022	12.08.2025
5	03	24.06.2022	12.08.2025
6	01	24.06.2022	12.08.2025
7	03	27 JUN 2022	12.08.2025

Yours faithfully,

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

Annexure-7

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

CERTIFICATE NO. : WC-0077

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. Amoli Organics Pvt. Ltd.
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Sertraline Hydrochloride IP/EP/BP/USP	Manufacturing & Packing
2.	Aripiprazole USP	Manufacturing & Packing
3.	Oxcarbazepine IP/EP/BP/USP	Manufacturing & Packing

ITEM(S) THREE (03) ONLY

The Written Confirmation remains valid until: 12.08.2025

Signature VL

Stamp of the authority and date

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

27 JUN 2022

7-5/2013/EU/WC-0077
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

29 JUN 2022

To

M/s. Amoli Organics Pvt. Ltd.
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

SUB:- Written Confirmation ofM/s. Amoli Organics Pvt. Ltd., Block No. 422, ECP Canal Road, Village - Luna, Tal – Padra, Dist – Vadodara, Gujarat 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 applications no. WC/RE/2022/4353 submitted to CDSCO, Ahmedabad Zone office, and the recommendation received from DDC(I), AhmedabadZone 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	01	09.06.2022	12.08.2025
2	01	15.06.2022	12.08.2025
3	01	16.06.2022	12.08.2025
4	01	17.06.2022	12.08.2025
5	03	24.06.2022	12.08.2025
6	01	24.06.2022	12.08.2025
7	03	27.06.2022	12.08.2025
8	01	29 JUN 2022	12.08.2025

Yours faithfully,

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

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

Annexure-8

CERTIFICATE NO. : **WC-0077**

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. Amoli Organics Pvt. Ltd.**
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Tadalafil EP/BP/USP	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 12.08.2025

Signature

29 JUN 2022

Stamp of the authority and date

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

7-5/2013/EU/WC-0077
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated

06 JUL 2022

To

M/s. Amoli Organics Pvt.Ltd.
Address: ECP Canal Road, Village-Luna,Taluka-Padra
Vadodara , Vadodara-391440, Gujarat, India

SUB:- Written Confirmation of M/s Amoli Organics Pvt.Ltd. Address: ECP Canal Road, Village-Luna,Taluka-Padra Vadodara , Vadodara-391440, Gujarat, 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/RE/2022/4210, WC/RE/2022/4307 submitted to CDSCO, Ahmedabad Zonal office and the recommendation received from DDC(I), Ahmedabad 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	01	09.06.2022	12.08.2025
2	01	15.06.2022	12.08.2025
3	01	16.06.2022	12.08.2025
4	01	17.06.2022	12.08.2025
5	03	24.06.2022	12.08.2025
6	01	24.06.2022	12.08.2025
7	03	27.06.2022	12.08.2025
8	01	29.06.2022	12.08.2025
9	02	06 JUL 2022	12.08.2022

Yours faithfully,

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

Annexure-9

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

CERTIFICATE NO. : WC-0077

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. Amoli Organics Pvt.Ltd.**
Address: ECP Canal Road, Village-Luna,Taluka-Padra Vadodara , Vadodara-391440, Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Pirfenidone Ph. Eur.	Manufacturing & Packing
2.	Sodium Ascorbate BP, IP, USP, Ph. Eur.	Manufacturing & Packing

ITEM(S) Two (02) ONLY

The Written Confirmation remains valid until: 12.08.2025

Signature

Stamp of the authority and date

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

06 JUL 2022

7-5/2013/EU/WC-0077
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated
07 JUL 2022

To

M/s. Amoli Organics Pvt.Ltd.
Address: ECP Canal Road, Village-Luna,Taluka-Padra
Vadodara , Vadodara-391440, Gujarat, India

SUB:- Written Confirmation of M/s Amoli Organics Pvt.Ltd. Address: ECP Canal Road, Village-Luna,Taluka-Padra Vadodara , Vadodara-391440, Gujarat, 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/2022/4382 submitted to CDSCO, Ahmedabad Zonal office and the recommendation received from DDC(I), Ahmedabad 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	01	09.06.2022	12.08.2025
2	01	15.06.2022	12.08.2025
3	01	16.06.2022	12.08.2025
4	01	17.06.2022	12.08.2025
5	03	24.06.2022	12.08.2025
6	01	24.06.2022	12.08.2025
7	03	27.06.2022	12.08.2025
8	01	29.06.2022	12.08.2025
9	02	06.07.2022	12.08.2022
10	01	07 JUL 2022	12.08.2022

Yours faithfully,

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

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

Annexure-10

CERTIFICATE NO. : WC-0077

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. Amoli Organics Pvt.Ltd.**
Address: ECP Canal Road, Village-Luna,Taluka-Padra Vadodara , Vadodara-391440, Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Telmisartan BP, EP, USP	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 12.08.2025

Signature

Stamp of the authority and date

07 JUL 2022

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

7-5/2013/EU/WC-0077
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. Amoli Organics Pvt. Ltd.
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India.

15 JUL 2022

Subject :- Written Confirmation of M/s. Amoli Organics Pvt. Ltd., Block No. 422, ECP Canal Road, Village - Luna, Tal – Padra, Dist – Vadodara, Gujarat 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 applications no. WC/RE/2022/4305, WC/RE/2022/4233 submitted to CDSCO, Ahmedabad Zone office, and the recommendation received from DDC (I), Ahmedabad 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	01	09.06.2022	12.08.2025
2	01	15.06.2022	12.08.2025
3	01	16.06.2022	12.08.2025
4	01	17.06.2022	12.08.2025
5	03	24.06.2022	12.08.2025
6	01	24.06.2022	12.08.2025
7	03	27.06.2022	12.08.2025
8	01	29.06.2022	12.08.2025
9	02	06.07.2022	12.08.2025
10	01	07.07.2022	12.08.2025
11	02	15 JUL 2022	12.08.2025

Yours faithfully,

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

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

Annexure-11

CERTIFICATE NO. : **WC-0077**

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. Amoli Organics Pvt. Ltd.**
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Levetiracetam EP/USP	Manufacturing & Packing
2.	Carbamazepine IP/BP/EP/USP/JP	Manufacturing & Packing

ITEM(S) TWO (02) ONLY

The Written Confirmation remains valid until: 12.08.2025

Signature

15 JUL 2022

Stamp of the authority and date

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

7-5/2013/EU/WC-0077
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated
23 JUL 2022

To

M/s. Amoli Organics Pvt. Ltd.
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

SUB:- Written Confirmation of M/s. Amoli Organics Pvt. Ltd., Block No. 422, ECP Canal Road, Village - Luna, Tal – Padra, Dist – Vadodara, Gujarat 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 applications no. WC/RE/2022/4318, WC/RE/2022/4316, WC/RE/2022/4309 submitted to CDSCO, Ahmedabad Zone office, and the recommendation received from DDC(I), Ahmedabad 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	01	09.06.2022	12.08.2025
2	01	15.06.2022	12.08.2025
3	01	16.06.2022	12.08.2025
4	01	17.06.2022	12.08.2025
5	03	24.06.2022	12.08.2025
6	01	24.06.2022	12.08.2025
7	03	27.06.2022	12.08.2025
8	01	29.06.2022	12.08.2025
9	02	06.07.2022	12.08.2025
10	01	07.07.2022	12.08.2025
11	02	15.07.2022	12.08.2025
12	03	23 JUL 2022	12.08.2025

Yours faithfully,

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

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

Annexure-12

CERTIFICATE NO. : WC-0077

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. Amoli Organics Pvt. Ltd.**
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Celecoxib EP/USP	Manufacturing & Packing
2.	Olmesartan Medoxomil BP/EP/USP	Manufacturing & Packing
3.	Rosuvastatin Calcium IP/EP/USP	Manufacturing & Packing

ITEM(S) THREE (03) ONLY

The Written Confirmation remains valid until: 12.08.2025

Signature

Stamp of the authority and date

23 JUL 2022

7-5/2013/EU/WC-0077
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 2022

To

M/s. Amoli Organics Pvt. Ltd.
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

SUB:- Written Confirmation of M/s. Amoli Organics Pvt. Ltd., Block No. 422, ECP Canal Road, Village - Luna, Tal – Padra, Dist – Vadodara, Gujarat 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 applications no. WC/RE/2022/4244 & WC/RE/2022/4370 submitted to CDSCO, Ahmedabad Zone office, and the recommendation received from DDC(I), Ahmedabad 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	01	09.06.2022	12.08.2025
2	01	15.06.2022	12.08.2025
3	01	16.06.2022	12.08.2025
4	01	17.06.2022	12.08.2025
5	03	24.06.2022	12.08.2025
6	01	24.06.2022	12.08.2025
7	03	27.06.2022	12.08.2025
8	01	29.06.2022	12.08.2025
9	02	06.07.2022	12.08.2025
10	01	07.07.2022	12.08.2025
11	02	15.07.2022	12.08.2025
12	03	23.07.2022	12.08.2025
13	02	26 JUL 2022	12.08.2025

Yours faithfully,

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

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

Annexure-13

CERTIFICATE NO. : **WC-0077**

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. Amoli Organics Pvt. Ltd.**
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Hydrochlorothiazide EP/USP/BP	Manufacturing & Packing
2.	Solifenacin Succinate EP/IH	Manufacturing & Packing

ITEM(S) TWO (02) ONLY

The Written Confirmation remains valid until: 12.08.2025

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization

26 JUL 2022

7-5/2013/EU/WC-0077
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

12 AUG 2022

To

M/s. Amoli Organics Pvt. Ltd.
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India.

Subject :- Written Confirmation of M/s. Amoli Organics Pvt. Ltd., Block No. 422, ECP Canal Road, Village - Luna, Tal – Padra, Dist – Vadodara, Gujarat 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 applications no. WC/RE/2022/4245 and WC/RE/2022/4282 submitted to CDSCO, Ahmedabad Zone office, and the recommendation received from DDC (I), Ahmedabad 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	01	09.06.2022	12.08.2025
2	01	15.06.2022	12.08.2025
3	01	16.06.2022	12.08.2025
4	01	17.06.2022	12.08.2025
5	03	24.06.2022	12.08.2025
6	01	24.06.2022	12.08.2025
7	03	27.06.2022	12.08.2025
8	01	29.06.2022	12.08.2025
9	02	06.07.2022	12.08.2025
10	01	07.07.2022	12.08.2025
11	02	15.07.2022	12.08.2025
12	03	23.07.2022	12.08.2025
13	02	26.07.2022	12.08.2025
14	01	12 AUG 2022	12.08.2025
15	01	12 AUG 2022	12.08.2025

Yours faithfully,

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

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

Annexure-14

CERTIFICATE NO. : WC-0077

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. Amoli Organics Pvt. Ltd.**
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Chlorthalidone EP/IP/USP	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 12.08.2025

Signature

12 AUG 2022

Stamp of the authority and date

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

Annexure-15

CERTIFICATE NO. : WC-0077

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. Amoli Organics Pvt. Ltd.**
Block No. 422, ECP Canal Road
Village - Luna, Tal – Padra Dist – Vadodara
Gujarat State, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Ascorbic Acid Coated 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: 12.08.2025

Signature

12 AUG 2022

Stamp of the authority and date

Central Drugs Standard Control Organization

7-5/2013/EU/WC-0077

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 19 JUN 2024

To

M/s. AMOLI ORGANICS
(A DIVISION OF UMEDICA LABORATORIES PVT. LTD.)
BLOCK NO. 422, ECP CANAL ROAD, VILLAGE - LUNA,
TAL – PADRA DIST: VADODARA-391440, GUJARAT STATE, INDIA

SUB:-Written Confirmation of **M/s. AMOLI ORGANICS, (A DIVISION OF UMEDICA LABORATORIES PVT. LTD.) BLOCK NO. 422, ECP CANAL ROAD, VILLAGE - LUNA, TAL – PADRA DIST: VADODARA-391440, GUJARAT 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/FR/2024/8082 submitted to CDSCO, Ahmedabad Zone office on CDSCO Sugam Portal, and the recommendation received from DDC(I), AhmedabadZone 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
1	01	09.06.2022	**12.08.2025**
2	01	15.06.2022	**12.08.2025**
3	01	16.06.2022	**12.08.2025**
4	01	17.06.2022	**12.08.2025**
5	03	24.06.2022	**12.08.2025**
6	01	24.06.2022	**12.08.2025**
7	03	27.06.2022	**12.08.2025**
8	01	29.06.2022	**12.08.2025**
9	02	06.07.2022	**12.08.2025**
10	01	07.07.2022	**12.08.2025**
11	02	15.07.2022	**12.08.2025**
12	03	23.07.2022	**12.08.2025**
13	02	26.07.2022	**12.08.2025**
14	01	12.08.2022	**12.08.2025**
15	01	12.08.2022	**12.08.2025**
16	04	19 JUN 2024	**12.08.2025**

Yours faithfully,

(Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

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

ANNEXURE-16

CERTIFICATE NO. : WC-0077

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. AMOLI ORGANICS
(A DIVISION OF UMEDICA LABORATORIES PVT. LTD.)
BLOCK NO. 422, ECP CANAL ROAD, VILLAGE - LUNA,
TAL – PADRA DIST: VADODARA-391440,
GUJARAT STATE, INDIA

List of APIs:

S. No.	Active substances	Activity(ies)
1.	Apixaban IH	Manufacturing & Packing
2.	Apremilast IH	Manufacturing & Packing
3.	Mirabegron IH	Manufacturing & Packing
4.	Rivaroxaban IH	Manufacturing & Packing

ITEM(S) FOUR (04) ONLY

The Written Confirmation remains valid until: 12.08.2025

Signature

Stamp of the authority and date

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

19 JUN 2024

7-5/2013/EU/WC-0077

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 20 SEP 2024

To,

M/s Amoli Organics (a division of umedica Laboratories Pvt. Ltd.),
Block No. 422, ECP Canal Road,
Village - Luna, Tal: Padra, Dist: Vadodara – 391440,
Gujarat, India

SUB:- Written Confirmation of M/s Amoli Organics (a division of umedica Laboratories Pvt. Ltd.), Block No. 422, ECP Canal Road, Village - Luna, Tal: Padra, Dist: Vadodara – 391440, Gujarat, 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/FR/2024/8411 dated 23.05.2024 submitted to CDSCO, DDC(I), Ahmedabad Zone, and the recommendation received from DDC(I), Ahmedabad 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.
9. The manufacturer is required to comply to the provision 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
1.	01	09.06.2022	12.08.2025
2.	01	15.06.2022	12.08.2025
3.	01	16.06.2022	12.08.2025
4.	01	17.06.2022	12.08.2025
5.	03	24.06.2022	12.08.2025
6.	01	24.06.2022	12.08.2025
7.	03	27.06.2022	12.08.2025
8.	01	29.06.2022	12.08.2025
9.	02	06.07.2022	12.08.2025
10.	01	07.07.2022	12.08.2025
11.	02	15.07.2022	12.08.2025
12.	03	23.07.2022	12.08.2025
13.	02	26.07.2022	12.08.2025
14.	01	12.08.2022	12.08.2025
15.	01	12.08.2022	12.08.2025
16.	04	19.06.2024	12.08.2025
17.	01	20 SEP 2024	12.08.2025

Yours faithfully,

Chandrasekhar 20/09/24

(Ranga Chandrashekar)
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

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

Annexure-17
WC-0077

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 Amoli Organics
(A division of umedica Laboratories Pvt. Ltd.),
Block No. 422, ECP Canal Road,
Village - Luna, Tal: Padra, Dist: Vadodara – 391440,
Gujarat, India

List of API(s):

S. No.	Active substance(s)	Activity(ies)
1.	Dapagliflozin Propanediol Monohydrate IH	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 12.08.2025

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

20 SEP 2024