7-5/2013/EU/WC-0054
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

11 AUG 2022

To,

M/s. Ami Lifesciences Pvt Ltd.,
Block No. 82/B, ECP Road,
At & Post. Karakhadi, Tal-Padra,
City Karakhadi -391450, Vadodara,
Gujarat, India

SUB:- Written Confirmation of M/s. Ami Lifesciences Pvt Ltd., Block No. 82/B, ECP Road, At & Post. Karakhadi, Tal-Padra, City Karakhadi, Vadodara – 391 450, 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 nos. WC/RE/2022/4459, WC/RE/2022/4461, WC/RE/2022/4481, WC/RE/2022/4574, WC/RE/2022/4575, WC/RE/2022/4584, WC/RE/2022/4587, WC/RE/2022/4589, WC/RE/2022/4601, WC/RE/2022/4572, WC/RE/2022/4573, WC/RE/2022/4380, WC/RE/2022/4516, WC/RE/2022/4586, WC/RE/2022/4588 & WC/RE/2022/4595 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
01	16	11 AUG 2022	26.06.2025

Yours faithfully,

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

7-5/2015/EU/WC-0054
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

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

To,

18 AUG 2022

M/s. Ami Lifesciences Pvt Ltd.
Block No. 82/B, ECP Road,
At & Post. Karakhadi, Tal-Padra,
City Karakhadi -391450, Vadodara,
Gujarat, India

SUB:- Application for amendment of the Written Confirmation of M/s. Ami Lifesciences Pvt Ltd. Block No. 82/B, ECP Road, At & Post. Karakhadi, Tal-Padra, City Karakhadi - 391450, Vadodara, 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 email dated 16.08.2022 for the necessary correction in the Written Confirmation Certificate issued by this office.

In this regard, kindly find the enclosed amended 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

CERTIFICATE NO. : **WC-0054**

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. Ami Lifesciences Pvt Ltd.**
Block No. 82/B, ECP Road,
At & Post. Karakhadi, Tal-Padra,
City Karakhadi -391450, Vadodara,
Gujarat, India

2. Manufacturer's licence number: G/25/1704

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 enclosed Annexure

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: **04.04.2022 & 05.04.2022**

The Written Confirmation remains valid until: **26.06.2025**

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

11 AUG 2022

Signature

Stamp of the authority and date

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

CERTIFICATE NO. : **Amended Annexure-01 WC-0054**

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. Ami Lifesciences Pvt Ltd.**
Block No. 82/B, ECP Road,
At & Post. Karakhadi, Tal-Padra,
City Karakhadi -391450, Vadodara,
Gujarat, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Azilsartan Medoxomil Potassium Salt IH	Manufacturing & Packing
2.	Benzonatate IH	Manufacturing & Packing
3.	Brivaracetam IH	Manufacturing & Packing
4.	Doxofylline IH	Manufacturing & Packing
5.	Febuxostat IH	Manufacturing & Packing
6.	Fimasartan Potassium Trihydrate IH	Manufacturing & Packing
7.	Flavoxate Hydrochloride BP/USP	Manufacturing & Packing
8.	Obeticholic Acid IH	Manufacturing & Packing
9.	Pamabrom USP	Manufacturing & Packing
10.	Rutoside Trihydrate Ph.Eur	Manufacturing & Packing
11.	Sevelamer Carbonate IH	Manufacturing & Packing
12.	Tadalafil Ph.Eur./BP/USP	Manufacturing & Packing
13.	Tranexamic Acid BP/USP/EP/JP	Manufacturing & Packing
14.	Vonoprazan Fumarate IH	Manufacturing & Packing
15.	Vildagliptin IH	Manufacturing & Packing
16.	Itopride Hydrochloride IH	Manufacturing & Packing

ITEM(S) Sixteen (16) ONLY

The Written Confirmation remains valid until: 26.06.2025

Signature

Stamp of the authority and date

18 AUG 2022

AMENDED

7-5/2013/EU/WC-0054
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 01 MAR 2024

To

M/s. Ami Life - Sciences Pvt. Ltd.,
Block No. 82/B, ECP Road,
At & Post Karakhadi, Tal - Padra,
City Karakhadi, Vadodara -391450, Gujarat, India

SUB:- Written Confirmation of M/s. Ami Life Sciences Pvt. Ltd., Block No. 82/B, ECP Road, At & Post Karakhadi, Tal - Padra, City Karakhadi, Vadodara -391450, 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 application no. WC/RE/2022/4507, WC/RE/2022/4532 and WC/RE/2022/4518 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.

AMENDED

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
01	16	11.08.2022	**26.06.2025**
02-A	02	01 MAR 2024	**26.06.2025**
03-A	01	01 MAR 2024	**26.06.2025**
04-A	01	30.09.2022	**26.06.2025**
05	01	01.09.2022	**26.06.2025**
06	04	07.09.2022	**26.06.2025**
07	03	23.09.2022	**26.06.2025**
08	01	21.10.2022	**26.06.2025**
09	01	02.11.2022	**26.06.2025**
10	01	19.02.2024	**26.06.2025**

Yours faithfully,

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

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

AMENDED
Annexure-02

CERTIFICATE NO. : **WC-0054**

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. Ami Life - Sciences Pvt. Ltd.,**
Block No. 82/B, ECP Road,
At & Post Karakhadi, Tal - Padra,
City Karakhadi, Vadodara -391450,
Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Tapentadol Hydrochloride IH	Manufacturing & Packing
2.	Teneligliptin Hydrobromide Hydrate IH	Manufacturing & Packing

ITEM(S) TWO (02) ONLY

The Written Confirmation remains valid until: 26.06.2025

Signature

Stamp of the authority and date

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

01 MAR 2024

AMENDED
Annexure-03

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

CERTIFICATE NO. : WC-0054

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. Ami Life - Sciences Pvt. Ltd.,
Block No. 82/B, ECP Road,
At & Post Karakhadi, Tal - Padra,
City Karakhadi, Vadodara -391450,
Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Sacubitril Valsartan Trisodium Salt Hemipentahydrate 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: 26.06.2025

Signature

Stamp of the authority and date

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

01 MAR 2024

Amended

7-5/2013/EU/WC-0054
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated 30 SEP 2022

To

M/s. Ami Lifesciences Pvt. Ltd.
Address: Block No.: 82/B, ECP Road, At & Post: Karakhadi-391450
Karakhadi , Vadodara-391450, Gujarat India

SUB:- Written Confirmation of M/s Ami Lifesciences Pvt. Ltd. Address: Block No.: 82/B, ECP Road, At & Post: Karakhadi-391450 Karakhadi, Vadodara-391450, 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/2022/4570 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.

Amended

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	16	11.08.2022	26.06.2025
2	02	16.08.2022	26.06.2025
3	01	16.08.2022	26.06.2025
4	01	24.08.2022	26.06.2025

Yours faithfully,

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

Amended

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

Annexure-4

CERTIFICATE NO. :

WC-0054

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. Ami Lifesciences Pvt. Ltd.**
Address: Block No.: 82/B, ECP Road, At & Post: Karakhadi-391450 Karakhadi , Vadodara-391450, Gujarat India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Ambroxol Hydrochloride EP	Manufacturing & Packing

ITEM One (01) ONLY

The Written Confirmation remains valid until: 26.06.2025

Signature

Stamp of the authority and date

30 SEP 2022

7-5/2013/EU/WC-0054
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated
01 SEP 2022

To
M/s. Ami Lifesciences Pvt. Ltd.
Address: Block No.: 82/B, ECP Road, At & Post: Karakhadi-391450
Karakhadi , Vadodara-391450, Gujarat India

SUB:- Written Confirmation of M/s Ami Lifesciences Pvt. Ltd. Address: Block No.: 82/B, ECP Road, At & Post: Karakhadi-391450 Karakhadi, Vadodara-391450, 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/2022/4458 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	16	11.08.2022	26.06.2025
2	02	16.08.2022	26.06.2025
3	01	16.08.2022	26.06.2025
4	01	24.08.2022	26.06.2025
5	01	01 SEP 2022	26.06.2025

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-0054

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. Ami Lifesciences Pvt. Ltd.**
Address: Block No.: 82/B, ECP Road, At & Post: Karakhadi-391450 Karakhadi,
Vadodara-391450, Gujarat India

List of APIs:

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

ITEM One (01) ONLY

The Written Confirmation remains valid until: 26.06.2025

Signature

Stamp of the authority and date

01 SEP 2022

7-5/2013/EU/WC-0054
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi- 110 002.
Dated:

07 SEP 2022

To

M/s Ami Lifesciences Pvt. Ltd,
Block No 82/B, ECP Road, At & Post Karakhadi,
Tal-Padra, City Karakhadi, Vadodara-391450,
Gujarat, India.

Subject :- Written Confirmation M/s Ami Lifesciences Pvt. Ltd, Block No 82/B, ECP Road, At & Post Karakhadi, Tal-Padra, City Karakhadi, Vadodara-391450, 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-Regarding.

Sir,

Please refer to your online application no. WC/RE/2022/4583, WC/RE/2022/4360, WC/RE/2022/4480 and WC/RE/2022/4367 submitted to CDSCO, Ahemdabad zone office and the recommendation received from DDC (I), Ahemdabad 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 event 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 up to
01	16	11.08.2022	26.06.2025
02	02	16.08.2022	26.06.2025
03	01	16.08.2022	26.06.2025
04	01	24.08.2022	26.06.2025
05	01	01.09.2022	26.06.2025
06	04	07 SEP 2022	26.06.2025

Yours faithfully,

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

Annexure-06

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

CERTIFICATE NO. : WC-0054

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 Ami Lifesciences Pvt. Ltd, Block No 82/B, ECP Road, At & Post Karakhadi, Tal-Padra, City Karakhadi, Vadodara-391450, Gujarat, India**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Betahistine Dihydrochloride EP	Manufacturing & Packing
2.	Acebrophylline IH	Manufacturing & Packing
3.	Sevelamer HCl IH	Manufacturing & Packing
4.	Diacerein IH/BP/EP	Manufacturing & Packing

ITEM(S) FOUR (04) ONLY

The Written Confirmation remains valid until: 26/06/2025.

Signature

Stamp of the authority and date

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

07 SEP 2022

7-5/2013/EU/WC-0054
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated
23 SEP 2022

To
M/s. Ami Lifesciences Pvt. Ltd.
Address: Block No.: 82/B, ECP Road, At & Post: Karakhadi-391450
Karakhadi , Vadodara-391450, Gujarat India

SUB:- Written Confirmation of M/s Ami Lifesciences Pvt. Ltd. Address: Block No.: 82/B, ECP Road, At & Post: Karakhadi-391450 Karakhadi, Vadodara-391450, 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 nos. WC/RE/2022/4199, WC/RE/2022/4576 & WC/RE/2022/4368 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	16	11.08.2022	26.06.2025
2	02	16.08.2022	26.06.2025
3	01	16.08.2022	26.06.2025
4	01	24.08.2022	26.06.2025
5	01	01.09.2022	26.06.2025
6	04	07 SEP 2022	26.06.2025
7	03	23 SEP	26.06.2025

23 SEP 2022

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-0054

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. Ami Lifesciences Pvt. Ltd.**
Address: Block No.: 82/B, ECP Road, At & Post: Karakhadi-391450 Karakhadi,
Vadodara-391450, Gujarat India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Benfotiamine IH	Manufacturing & Packing
2.	Levocloperastine Fendizoate IH	Manufacturing & Packing
3.	Dapoxetine Hydrochloride IH	Manufacturing & Packing

ITEM Three (03) ONLY

The Written Confirmation remains valid until: 26.06.2025

Signature

Stamp of the authority and date

23 SEP 2022

7-5/2013/EU/WC-0054
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi- 110 002.
Dated:
21 OCT 2022

To

M/s Ami Lifesciences Pvt. Ltd,
Block No 82/B, ECP Road, At & Post Karakhadi,
Tal-Padra, City Karakhadi, Vadodara-391450,
Gujarat, India.

Subject :- Written Confirmation M/s Ami Lifesciences Pvt. Ltd, Block No 82/B, ECP Road, At & Post Karakhadi, Tal-Padra, City Karakhadi, Vadodara-391450, 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-Regarding.

Sir,

Please refer to your online application no. WC/RE/2022/4365 submitted to CDSCO, Ahemdabad zone office and the recommendation received from DDC (I), Ahemdabad 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 event 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 up to
01	16	11.08.2022	26.06.2025
02	02	16.08.2022	26.06.2025
03	01	16.08.2022	26.06.2025
04	01	24.08.2022	26.06.2025
05	01	01.09.2022	26.06.2025
06	04	07.09.2022	26.06.2025
07	03	23.09.2022	26.06.2025
08	01	21 OCT 2022	26.06.2025

Yours faithfully,

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

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

Annexure-08

CERTIFICATE NO. : **WC-0054**

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 Ami Lifesciences Pvt. Ltd, Block No 82/B, ECP Road, At & Post Karakhadi, Tal-Padra, City Karakhadi, Vadodara-391450, Gujarat, India**

List of APIs:

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

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: **26/06/2025.**

Signature

Stamp of the authority and date

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

21 OCT 2022

7-5/2013/EU/WC-0054
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 02 NOV 2022

To

M/s. Ami Lifesciences Pvt Ltd.
Block No. 82/B, ECP Road,
At & Post. Karakhadi, Tal-Padra,
City Karakhadi, Vadodara – 391 450,
Gujarat, India

SUB:- Written Confirmation of M/s. Ami Lifesciences Pvt Ltd., Block No. 82/B, ECP Road, At & Post. Karakhadi, Tal-Padra, City Karakhadi, Vadodara – 391 450, 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/2022/4458 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
01	16	11.08.2022	26.06.2025
02	02	16.08.2022	26.06.2025
03	01	16.08.2022	26.06.2025
04	01	24.08.2022	26.06.2025
05	01	01.09.2022	26.06.2025
06	04	07.09.2022	26.06.2025
07	03	23.09.2022	26.06.2025
08	01	21.10.2022	26.06.2025
09	01	02 NOV 2022	26.06.2025

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-09**
WC-0054

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. Ami Lifesciences Pvt Ltd.**
Block No. 82/B, ECP Road,
At & Post. Karakhadi, Tal-Padra,
City Karakhadi -391450, Vadodara,
Gujarat, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Desvenlafaxine Succinate IH/USP	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 26.06.2025

Signature

Stamp of the authority and date

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

0 2 NOV 2022

7-5/2013/EU/WC-0054
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

19 FEB 2024

To

M/s. Ami Life - Sciences Pvt. Ltd.,
Block No. 82/B, ECP Road,
At & Post Karakhadi, Tal - Padra,
City Karakhadi, Vadodara -391450, Gujarat, India

SUB:- Written Confirmation of M/s. Ami Life Sciences Pvt. Ltd., Block No. 82/B, ECP Road, At & Post Karakhadi, Tal - Padra, City Karakhadi, Vadodara -391450, 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 application no. WC/FR/2023/7510 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.

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
01	16	11.08.2022	26.06.2025
02	02	16.08.2022	26.06.2025
03	01	16.08.2022	26.06.2025
04	01	24.08.2022	26.06.2025
05	01	01.09.2022	26.06.2025
06	04	07.09.2022	26.06.2025
07	03	23.09.2022	26.06.2025
08	01	21.10.2022	26.06.2025
09	01	02.11.2022	26.06.2025
10	01	19 FEB 2024	26.06.2025

Yours faithfully,

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

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

Annexure-10

CERTIFICATE NO. : WC-0054

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. Ami Life - Sciences Pvt. Ltd.,
Block No. 82/B, ECP Road,
At & Post Karakhadi, Tal - Padra,
City Karakhadi, Vadodara -391450,
Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Alpha Lipoic Acid USP	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 26.06.2025

Signature

Stamp of the authority and date

19 FEB 2024