7-5/2013/EU/WC-0135

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 24 SEP 2025

To

M/s. Dishman Carbogen Amcis Limited
Survey No. -47 & 48, Paiki, Sub Plot No. -1,
Village -Lodariyal, Tal. -Sanand,
Dist. -Ahmedabad -382220, Gujarat, India

Subject: - Written Confirmation of **M/s. Dishman Carbogen Amcis Limited, Survey No. -47 & 48, Paiki, Sub Plot No. -1, Village -Lodariyal, Tal. -Sanand, Dist. -Ahmedabad -382220, 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/2025/10461** submitted to CDSCO, Ahmedabad Zone office on CDSCO Sugam Portal, 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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 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	24 SEP 2025	Three Year from the Date of Issue

Yours faithfully,

23/09/25

Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत)/Joint Drugs Controller(India)
केंद्रीय मानक औषध प्रयोगशाला (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

CERTIFICATE NO. : **WC-0135**

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. Dishman Carbogen Amcis Limited**
Survey No. -47 & 48, Paiki, Sub Plot No. -1,
Village -Lodariyal, Tal. -Sanand,
Dist. -Ahmedabad -382220, Gujarat, India

2. Manufacturer's licence number: **G/25/1445**

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):

S. No.	Active Substance(s)	Activity(ies)
1	Aripiprazole IH	Manufacturing & Packing

Item(s) One (01) Only

And as per list enclosed as Annexure(s)

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: 10.01.2024 & 11.01.2024

The Written Confirmation remains valid until: **Three Year from the Date of Issue**

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: Ranga Chandrashekar,
Joint Drugs Controller (India)

E-mail: ***ranga.cs@cdsco.nic.in;***
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केन्द्रीय 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
Ministry of Health & Family Welfare, Govt. of India
सत्यमेव जयते

24 SEP 2025

7-5/2013/EU/WC-0135
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 15 OCT 2025

To

M/s. Dishman Carbogen Amcis Limited
Survey No. -47 & 48, Paiki, Sub Plot No. -1,
Village -Lodariyal, Tal. -Sanand,
Dist. -Ahmedabad -382220, Gujarat, India

Subject: - Written Confirmation of **M/s. Dishman Carbogen Amcis Limited, Survey No. -47 & 48, Paiki, Sub Plot No. -1, Village -Lodariyal, Tal. -Sanand, Dist. -Ahmedabad -382220, 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/2025/10432** submitted to CDSCO, Ahmedabad Zone office on CDSCO Sugam Portal, 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 with the provisions of GSR 20(E), dated 18.01.2022

10. Benzocaine EP/BP, Lidocaine BP/USP, Lidocaine Hydrochloride BP/USP/EP, Ropivacaine Hydrochloride Monohydrate EP and Cinacalcet HCl IH have not been considered due to non-submission of requisite information.

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	15 OCT 2025	23.09.2028
1	11	15 OCT 2025	23.09.2028
2	03	15 OCT 2025	23.09.2028

Yours faithfully,

Chandrashekar 15/10/25

Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशेखर रंग/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

CERTIFICATE NO. :

Annexure-1
WC-0135

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. Dishman Carbogen Amcis Limited**
Survey No. -47 & 48, Paiki, Sub Plot No. -1,
Village -Lodariyal, Tal. -Sanand,
Dist. -Ahmedabad -382220, Gujarat, India

List of API(s):

S. No.	Active Substance(s)	Activity(ies)
1.	Bupivacaine Hydrochloride BP/USP/Ph.Eur.	Manufacturing & Packing
2.	Eprosartan Mesylate IH	Manufacturing & Packing
3.	Pralidoxime Chloride USP	Manufacturing & Packing
4.	Strontium Ranelate IH	Manufacturing & Packing
5.	Thioridazine Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
6.	Linezolid IH	Manufacturing & Packing
7.	Quetiapine Fumarate IH	Manufacturing & Packing
8.	Voriconazole IH	Manufacturing & Packing
9.	Tropicamide IH	Manufacturing & Packing
10.	Benzocaine USP	Manufacturing & Packing
11.	Bedaquiline Fumarate IH	Manufacturing & Packing

Item(s) Eleven (11) Only

The Written Confirmation remains valid until: 23.09.2028

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga 15/10/25
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 ★ Ministry of Health & Family Welfare, Govt. of India ★

15 OCT 2025

Annexure-2
WC-0135

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

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. Dishman Carbogen Amcis Limited**
Survey No. -47 & 48, Paiki, Sub Plot No. -1,
Village -Lodariyal, Tal. -Sanand,
Dist. -Ahmedabad -382220, Gujarat, India

List of API(s):

S. No.	Active Substance(s)	Activity(ies)
1.	Octenidine Hydrochloride IH	Manufacturing & Packing
2.	Ternidazole IH	Manufacturing & Packing
3.	Indigotindisulfonate Sodium USP	Manufacturing & Packing

Item(s) Three (03) 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 substance(s) for the purpose of export only, as the above-mentioned active substance(s) are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 23.09.2028

Chandrashekar

चंद्रशेखर रेगा/Chandrashekar Rega
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

Signature

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

Stamp of the authority and date

15 OCT 2025