

F. No. 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: 04 OCT 2019

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.

SUB: 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 application submitted to CDSCO, 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 conform 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	22	22.07.2019	21.07.2022
02	06	22.07.2019	21.07.2022
03	08	04 OCT 2019	21.07.2022
04	02		

Yours faithfully,

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

11/10/19

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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 APIs:

Sl.No.	Name of the Active Substances	Activitie(s)
1.	Aripiprazole IH	Manufacturing and Packing
2.	Benzocaine BP/USP/Ph.Eur	Manufacturing and Packing
3.	Cetirizine Hydrochloride BP/USP/Ph.Eur	Manufacturing and Packing
4.	Desloratadine IH	Manufacturing and Packing
5.	Fluvastatin sodium USP	Manufacturing and Packing
6.	Linezolid IH	Manufacturing and Packing
7.	Quetiapine Fumarate IH	Manufacturing and Packing
8.	Voriconazole IH	Manufacturing and Packing

ITEM(S) Eight (08) Only

The Written Confirmation remains valid until: 21.07.2022

Signature

Via

01. 9/10/19

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Stamp of the authority and date



04 OCT 2019



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 Ltd.,
Survey No.47,48,Paiki sub Plot No.1,
Lodariyal, Sanand,
Ahmedabad-382220,
Gujarat, India

List of APIs:

Sl. No.	Name of the Active substance(s)	Activitie(s)
1	Niraparib Tosylate Monohydrate IH	Manufacturing & Packing
2	Dihydrotachysterol IH	Manufacturing & Packing

ITEM(S) Two (02) Only

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

The Written Confirmation remains valid until: 21.07.2022

Signature

01/10/19

[Handwritten signature]

Stamp of the authority and date



04 OCT 2019