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: 03 DEC 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.

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 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 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	22	22.07.2019	21.07.2022
02	06	22.07.2019	21.07.2022
02	01	16.08.2019	21.07.2022
03	08	04.10.2019	21.07.2022
04	02	04.10.2019	21.07.2022
05	01	03 DEC 2019	21.07.2022
01	23	03 DEC 2019	21.07.2022

Yours faithfully,

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

29.11.19

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

(Amended)
Annexure-01
WC-0135

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.	Bosentan Monohydrate IH	Manufacturing and Packing
2.	Bupivacaine Hydrochloride BP/USP/Ph. Eur.	Manufacturing and Packing
3.	Cinacalcet Hydrochloride IH	Manufacturing and Packing
4.	Eprosartan Mesylate IH	Manufacturing and Packing
5.	Fenofibrate BP/USP/Ph. Eur	Manufacturing and Packing
6.	Gemcitabine Hydrochloride BP/USP/Ph. Eur	Manufacturing and Packing
7.	Glimepiride BP/USP/Ph. Eur	Manufacturing and Packing
8.	Indapamide BP/USP/Ph. Eur	Manufacturing and Packing
9.	Lidocaine BP/USP	Manufacturing and Packing
10.	Lidocaine Hydrochloride BP/Ph.Eur/USP	Manufacturing and Packing
11.	Milnacipran Hydrochloride IH	Manufacturing and Packing
12.	Omeprazole BP/Ph.Eur/USP	Manufacturing and Packing
13.	Omeprazole Magnesium IH	Manufacturing and Packing
14.	Pantoprazole Sodium Ph. Eur	Manufacturing and Packing
15.	Pralidoxime Chloride Ph.Eur	Manufacturing and Packing
16.	Ropivacaine Hydrochloride Monohydrate Ph.Eur	Manufacturing and Packing
17.	Strontium Ranelate IH	Manufacturing and Packing
18.	Thioridazine Hydrochloride Ph.Eur/USP	Manufacturing and Packing
19.	Tramodol Hydrochloride Ph.Eur	Manufacturing and Packing
20.	Valganciclovir Hydochloride USP	Manufacturing and Packing
21.	Venlafaxine Hydrochloride BP/Ph.Eur	Manufacturing and Packing
22.	Xipamide IH	Manufacturing and Packing
23.	Tropicamide IH	Manufacturing and Packing

ITEM(S) Twenty Three (23) Only

The Written Confirmation remains valid until: **21.07.2022**

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India

0 3 DEC 2019

29.11.19

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

Annexure-05
WC-0135

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,
Lodariyal, Sanand,
Ahmedabad-382220,
Gujarat, India

List of APIs:

Sl. No.	Name of the Active substance(s)	Activitie(s)
1	Cholesterol HP IH	Manufacturing & Packing

ITEM(S) One (01) 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

Stamp of the authority and date

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

03 DEC 2019

29.11.19