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: 22 JUL 2019

To
M/s Dishman Carbogen Amics 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 Amics 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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 JUL 2019	Three years from the date of issue
02	06	22 JUL 2019	Three years from the date of issue

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

o/c
19.07.2019
19.7.19

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 Amics Limited,
Survey No.47,48, Paiki Sub Plot No.1,
Village -Lodariyal, Tal-Sanand,
Dist - Ahmedabad-382220,Gujarat,India.

2. Manufacturer's license 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

As per list Annexed

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: 19th & 20th Feb & 21st April 2018

The Written Confirmation remains valid until: (03) Three years 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: Dr.S.Eswara Reddy.
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

22 JUL 2019

o/c 19.07.2019 19.7.19

Annexure-01
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 Amics 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.	Glimepride 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

ITEM(S) Twenty Two (22) Only

The Written Confirmation remains valid until: (03) Three Years from the date of Issue

Signature

Stamp of the authority and date

22 JUL 2019

O/c
19.07.2019
19.7.19

Annexure-02
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 Amics 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	Eprosartan Acid IH	Manufacturing & Packing
2	Etofenamate Ph.Eur	Manufacturing & Packing
3	Frovatriptan Succinate IH	Manufacturing & Packing
4	Ocetenidine Hydrochloride IH	Manufacturing & Packing
5	Ternidazole IH	Manufacturing & Packing
6	Hexetidine Ph.Eur	Manufacturing & Packing

ITEM(S) Six (06) 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: (03)Three years from the date of Issue

Signature

Stamp of the authority and date

22 JUL 2019

O/C
19.07.2019.

19.7.19

19/07/19