



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

Amended  
WC-0136

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 of site: M/s. Dishman Carbogen Amcis Limited.  
2. Manufacturer's Licence Number: G/25/799

The name and address of the manufacturer mentioned in the Written Confirmation Certificate (WC-0136) granted on date 04.07.2016 is hereby amended as follows:

In place of:

"M/s. Dishman Pharmaceuticals and Chemicals Ltd., 1216/11, 12, 1216/20 to 26, GIDC Estate, Phase-IV, Naroda, Dist. Ahmedabad-382330, Gujarat India."

Read as:

"M/s. Dishman Carbogen Amcis Limited, 1216/11, 12, 1216/20 to 26, GIDC Estate, Phase-IV, Naroda, Dist. Ahmedabad-382330, Gujarat India."

OK All the other conditions of Written Confirmation Certificate will remain same.

Signature

Stamp of the authority and date



01 MAR 2018

43018  
12/3/18

**Central Drugs Standard Control Organisation  
Directorate General of Health Services  
Ministry of Health & Family Welfare**

**Food and Drug Administration Bhawan  
Kotla Road, New Delhi-110002**

No.: 7-5/2013/EU/WC-0136

Dated **04 JUL 2016**

To

**M/s. Dishman Pharmaceuticals and Chemicals Ltd.,  
1216/11, 12, 1216/20 to 26, GIDC Estate,  
Phase-IV, Naroda, Dist. Ahmedabad- 382 330, Gujarat**

**SUB:- Written Confirmation of for M/s. Dishman Pharmaceuticals and Chemicals Ltd., 1216/11, 12, 1216/20 to 26, GIDC Estate, Phase-IV, Naroda, Dist. Ahmedabad- 382 330, Gujarat, 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 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.

*Received original  
H.M. Pat  
09510022413*

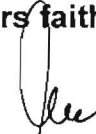
8. In the event of any drug found not of standard quality, the same shall be reported to this office within 7 days of receipt of report.

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.	Number of products	Issue date	Valid upto
01	07	04 JUL 2016	02.07.2019

Yours faithfully,



(Dr. G. N. Singh)

Drugs Controller General (India)

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*Amal*

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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 Pharmaceuticals and Chemicals Ltd.,  
1216/11, 12, 1216/20 to 26, GIDC Estate, Phase-IV,  
Naroda, Dist. Ahmedabad- 382 330, Gujarat

2. Manufacturer's licence number: G/25/799

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 enclosed as Annexure-1**

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: 15.09.2014 & 05.03.2015

The Written Confirmation remains valid until: 02<sup>nd</sup> July, 2019

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. G.N. Singh,  
Drugs Controller General (India)

E-mail: dci@nic.in,  
Telephone no.: +91-11-23236965  
Fax no.: +91-11-23236973

Signature

*[Handwritten signature]*

Stamp of the authority and date





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

CERTIFICATE NO. :

Annexure-1

WC-0136

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 Pharmaceuticals and Chemicals Ltd.,  
1216/11, 12, 1216/20 to 26, GIDC Estate, Phase-IV,  
Naroda, Dist. Ahmedabad- 382 330, Gujarat

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1	Cetrimide (BP/EP)	Manufacturing & Packing
2	Strong Cetrimide Solution (BP)	Manufacturing & Packing
3	Benzalkonium Chloride Solution (BP/USP/EP/JP)	Manufacturing & Packing
4	Cetylpyridinium Chloride (BP/USP/EP)	Manufacturing & Packing
5	Bisacodyl (BP/USP/EP)	Manufacturing & Packing
6	Sodium Picosulfate (BP/JP/EP)	Manufacturing & Packing
7	Benzethonium Chloride (USP)	Manufacturing & Packing

ITEM(S) Seven (07) ONLY

The Written Confirmation remains valid until: 02<sup>nd</sup> July, 2019

Signature

*[Handwritten signature]*  
o/c  
Arunesh

Stamp of the authority and date

