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

Amended

CERTIFICATE NO. : WC-0279

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. Medinex Laboratories Pvt. Ltd.,
Plot No. 2 & 3, Survey No. 277/1, Block No. 177/1,
Village: Ukharla- 364005, Tehsil: Ghogha
City: Ukharla, Dist: Bhavnagar, Gujarat

2. Manufacturer's licence number: G/25/210 & G/28/83 Dated 15.11.2016

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& 2

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: 29 – 30 May, 2017 & 05th August 2017.

The Written Confirmation remains valid until: 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

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

25 JUN 2018

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

Annexure-1
(Amended)

CERTIFICATE NO. : WC-0279

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Plot No. 2 & 3, Survey No. 277/1, Block No. 177/1,
Village: Ukharla- 364005, Tehsil: Ghogha
City: Ukharla, Dist: Bhavnagar, Gujarat, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Isoprenaline Hydrochloride (BP)	Manufacturing & Packing
2.	Isoproterenol Hydrochloride (USP)	Manufacturing & Packing
3.	Carbazochrome (JP)	Manufacturing & Packing
4.	Adrenochrome Monosemicarbazone (JP)	Manufacturing & Packing
5.	Hydrochlorothiazide (BP)	Manufacturing & Packing
6.	Hydrochlorothiazide (USP)	Manufacturing & Packing
7.	Hydrochlorothiazide (Ph. Eur)	Manufacturing & Packing
8.	Dimenhydrinate (USP)	Manufacturing & Packing
9.	Dimenhydrinate (BP)	Manufacturing & Packing
10.	Dimenhydrinate (Ph. Eur)	Manufacturing & Packing
11.	L-Glutamic Acid Hydrochloride (USP)	Manufacturing & Packing
12.	Diphenhydramine Hydrochloride (BP)	Manufacturing & Packing
13.	Diphenhydramine Hydrochloride (Ph. Eur)	Manufacturing & Packing
14.	Diphenhydramine Hydrochloride (USP)	Manufacturing & Packing

ITEM(S) Fourteen (14) ONLY

The Written Confirmation remains valid until: Three years from the date of issue

Signature

Stamp of the authority and date

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

25 JUN 2018

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

CERTIFICATE NO. :

Annexure-2
(Amended)

WC-0279

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. Medinex Laboratories Pvt. Ltd.,
Plot No. 2 & 3, Survey No. 277/1, Block No. 177/1,
Village: Ukharla- 364005, Tehsil: Ghogha
City: Ukharla, Dist: Bhavnagar, Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Hydrated Dihydralazine Sulphate (BP)	Manufacturing & Packing

ITEM(S) One (01) 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 substances for the purpose of export only, as the above mentioned active substances are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: Three years from the date of issue

Signature

Stamp of the authority and date

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

25 JUN 2018