



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. Mahendra Chemicals
B-1, 217 + 218/2, GIDC Estate, Naroda,
Ahmedabad -382330, Gujarat State, India

2. Manufacturer's licence number: G/25/296

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

List of API(s):

as per list enclosed as Annexures

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: 10.06.2025 & 11.06.2025

The Written Confirmation remains valid until: Three Year 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: Ranga Chandrashekar,
Joint Drugs Controller (India)

E-mail: ranga.cs@cdsco.nic.in;

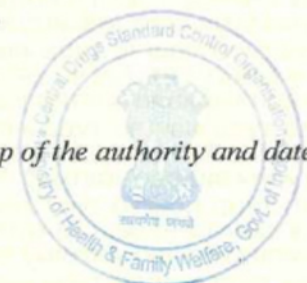
Telephone no.: +91-11-23236965

Fax no.: +91-11-23236973

Chandrashekar
06/10/25

Signature रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केन्द्रीय औषधि मानक नियंत्रण संगठन (गुजरात), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O.(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण विभाग / Ministry of Health and Family Welfare
एन सी रोड, कोटला रोड, नई दिल्ली 110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date



07 OCT 2025



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Ahmedabad -382330, Gujarat State, India

List of APIs:

S. No.	Active Substance(s)	Activity(ies)
1.	Lidocaine BP/USP/Ph.Eur.	Manufacturing & Packing
2.	Lidocaine Hydrochloride BP/USP/Ph.Eur.	Manufacturing & Packing

ITEM(S) TWO (02) ONLY

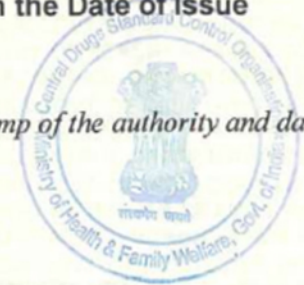
The Written Confirmation remains valid until: Three Year from the Date of Issue

Chandrasekhar

Signature

चंद्रशेखर रंगा/Chandrasekhar Ranga
जुट ड्रग्स नियंत्रक (भारत) / Joint Drugs Controller (India)
केन्द्रीय औषधि नियंत्रक संस्थान (मुंबई), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O.(HQ), Dte. General of Health Services
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एन टी रोड, कोटा रोड, संजिवली-110002 / FDA Bhawan, Kotha Road, New Delhi-110002

Stamp of the authority and date



07 OCT 2025