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

CERTIFICATE NO. : **WC-0096**

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, G.I.D.C Estate,
Naroda, Ahmedabad-382330,
Gujarat, 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

Name of APIs as below:

S. No.	Active substance(s)	Activity(ies)
1.	Lidocaine BP/USP/EP/JP	Manufacturing & Packing
2.	Lidocaine Hydrochloride BP/EP/USP	Manufacturing & Packing

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: 11.07.2022 and 12.07.2022

The Written Confirmation remains valid until: **07.02.2025.**

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

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

08 FEB 2023

Signature

Stamp of the authority and date