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

CERTIFICATE NO. : **Amended WC-0416**

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. Nuray Chemicals Pvt Ltd.,**
Plot No. 111, SIDCO Industrial Estate,
Kakkalur, Thiruvallur-602003
Tamil Naidu, India

2. **Manufacturer's licence number:** **Form-25 TN 00003314 dated 25.03.2013**
Form-28 TN 00003315 dated 25.03.2013

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 in 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: 06th & 07th January, 2021

The Written Confirmation remains valid until: 06th December, 2023

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

Stamp of the authority and date

Central Drugs Standard Control Organization · Ministry of Health & Family Welfare, Govt. of India

Signature

25 MAR 2021