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

**CERTIFICATE NO. : WC-0479**

**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. Vav Lipids Private Limited,**
**Plot No.C-76, Mirjole Industrial Estate,**
**MIDC, Ratnagiri - 415 612,**
**Maharashtra, India**

**2. Manufacturer's licence number: FORM:25: MH/102313**

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 an 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: 16th & 17th December 2019**

**The Written Confirmation remains valid until: (03) 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:*** **Dr. V.G. Somani**
**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*

03 AUG 2020