



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

Name and address of site: M/s. Rank Organics Chemical Pvt. Ltd.
Plot No. N-85 / N-86, Tarapur, M.I.D.C Boisar,
Tal & Dist: Palghar- 401506 Maharashtra, India

2. Manufacturer's licence number: 25-KD/202

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 enclosed 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: 13/02/2025 & 14/02/2025

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. Annam Visala,
Joint Drugs Controller (India)
E-mail: visala.annam@cdsco.nic.in
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

डॉ. ए. विशाला / Dr. A. Visala

संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केंद्रीय औषधि मानक नियंत्रण सभा (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O. (HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय
Ministry of Health and Family Welfare
एफ.डी.ए. भवन, कोटला रोड, नई दिल्ली-110002
FDA Bhawan, Kotla Road, New Delhi-110002

08 MAY 2026

Stamp of the authority and date





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

CERTIFICATE NO. :

Annexure-1
WC-0521

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

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Tal & Dist: Palghar- 401506 Maharashtra, India

2. List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Sodium Stearyl Fumarate USP	Manufacturing & Packing
2.	Sodium Stearyl Fumarate BP	Manufacturing & Packing
3.	Sodium Stearyl Fumarate Ph. Eur.	Manufacturing & Packing
4.	Triprolidine Hydrochloride USP	Manufacturing & Packing
5.	Triprolidine Hydrochloride BP	Manufacturing & Packing
6.	Iron (III) Hydroxy Polymaltose IHS	Manufacturing & Packing
7.	Naphazoline Hydrochloride USP	Manufacturing & Packing
8.	Naphazoline Hydrochloride Ph. Eur.	Manufacturing & Packing

ITEM(S) EIGHT (08) Only

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

Signature

डॉ. ए. विशाला / Dr. A. Visala

संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केंद्रीय औषधि मानक नियंत्रण समित्त (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O. (HQ), Dir. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय
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एफ डी सी ओ भवन कागला रोड नई दिल्ली-110002
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