



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. Endoc Lifecare Pvt. Ltd.,
Plot No. 4 - 7, Survey No. 53, and
Survey No. 52 / P3 & P1 (New Survey No.624 & 627),
Plot No. 1, B/H Saurashtra Paper Board Mill,
Shapar - Veraval Industrial Area, At-Shapar,
Tal Kotada Sangani, Dist. - Rajkot - 360024,
Gujarat, India.

2. Manufacturer's licence number: G/25/1621

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 Annexure(s) enclosed

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: 24.10.2024 & 25.10.2024

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: Ranga Chandrashekar,
Joint Drugs Controller (India)

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

Telephone no.: +91-11-23236965

Fax no.: +91-11-23236973

Chandrashekar
30/07/25
Signature of Ranga Chandrashekar Ranga

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



01 AUG 2025



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. Endoc Lifecare Pvt. Ltd.,
Plot No. 4 - 7, Survey No. 53, and
Survey No. 52 / P3 & P1 (New Survey No.624 & 627),
Plot No. 1, B/H Saurashtra Paper Board Mill,
Shapar - Veraval Industrial Area, At-Shapar,
Tal Kotada Sangani, Dist. - Rajkot - 360024,
Gujarat, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Fluconazole BP/USP/Ph.Eur.	Manufacturing & Packing
2.	Ornidazole IH	

ITEM(S) TWO (02) ONLY

The Written Confirmation remains valid until: Three Years from the date of Issue.

Signature *Chandrashekar Ranga* 30/07/25

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केंद्रीय औषधि मानक नियंत्रण संगठन (सुरक्षासूचक), स्वास्थ्य सेवा विभाग
C.D.S.C.O.(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण विभाग / Ministry of Health and Family Welfare
एन डी ए भवन, कोटा रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date



01 AUG 2025

