

**7-5/2025/EU/WC-0611**  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organisation  
(International Cell)

**FDA Bhawan, Kotla Road,  
New Delhi-110002**

**Dated**

**08 JUL 2025**

To

**M/s. ENANTI LABS PRIVATE LIMITED,  
Plot No. 60 D, Jawaharlal Nehru Pharma City,  
Thanam (V), Paravada (M), District: Anakapalli- 531019,  
Andhra Pradesh, India.**

**SUB:-** Request for correction of address of manufacturer in WC certificate-reg.

Sir,

This is with reference to your letter dated 03.07.2025, wherein you have requested for correction of address of the manufacturer in WC No. 0611 issued by this office on 30-06-2025.

In this regard, your application has been reviewed by this office and it is noted there is typo error in the address of the manufacturer in WC certificate No.0611 issued on 30.06.2025. Accordingly amended WC certificate has been enclosed for your information.

**Yours faithfully,**

**Ranga Chandrashekar  
Joint Drugs Controller (India)**



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. ENANTI LABS PRIVATE LIMITED,  
Plot No. 60 D, Jawaharlal Nehru Pharma City,  
Thanam (V), Paravada (M),  
District: Anakapalli- 531019,  
Andhra Pradesh, India.

2. Manufacturer's licence number: 10/VP/AP/2014/B/R

The name of the manufacturer mentioned in the Written confirmation certificate (WC-0611) granted on 30-06-2025 is hereby amended as follow-

In place of	Read as
M/s. ENANTI LABS PRIVATE LIMITED, Plot No. 60 D, Jawaharlal Nehru Pharma City, Thanam (C), Paravada (M), District: Anakapalli- 531019, Andhra Pradesh, India	M/s. ENANTI LABS PRIVATE LIMITED, Plot No. 60 D, Jawaharlal Nehru Pharma City, Thanam (V), Paravada (M), District: Anakapalli- 531019, Andhra Pradesh, India

All the other conditions of WC certificate dated 30-06-2025 will remain same.

Signature *Chandrashekar Ranga*  
08/07/25  
चंद्रशेखर रंगा/Chandrashekar Ranga  
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)  
केंद्रीय औषधि मानक नियंत्रण समूह (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 सी भवन, कोटला रोड, नई दिल्ली-110002/ FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date  
  
08 JUL 2025

**7-5/2025/EU/WC-0611**  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organisation  
(International Cell)

FDA Bhawan, Kotla Road,  
New Delhi-110002

Dated: 30 JUN 2025

To,

**M/s. ENANTI LABS PRIVATE LIMITED,  
Plot No. 60 D, Jawaharlal Nehru Pharma City,  
Thanam (V), Paravada (M), District: Anakapalli- 531019,  
Andhra Pradesh, India.**

**Subject:-** Written Confirmation of M/s. Enanti Labs Private Limited, Plot No. 60 D, Jawaharlal Nehru Pharma City, Thanam (V), Paravada (M), District- Anakapalli-531019, Andhra Pradesh, India, as per requirement of EU for import of 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 from India-Reg.

Sir,

Please refer to your application no. **WC/FR/2025/10712** dated 30-APR-2025 submitted to CDSCO, CDSCO, Sub-Zone, Visakhapatnam and the recommendation received from ADC(I), CDSCO, Sub-Zone, Visakhapatnam, on the above noted subject.

Written Confirmation as required 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 from India is herewith granted subject to the following conditions: -

1. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).
2. The manufacturer 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 equivalent to that in the EU.
3. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.
4. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.
5. The Written Confirmation will be withdrawn in the events of non-compliance of Standards.

6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.
7. In the event of any Non-Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt of report.
8. In the event of any drug found not of standard quality, the same shall be reported to this office within 7 days of receipt of report.
9. The manufacturer is required to comply to the provision of GSR 20(E) dated 18.01.2022.
10. The manufacturer shall obtain NOC from the respective CDSCO office on case to case basis for manufacture of active substance for export purpose, if active substance is falling under Unapproved/Banned/ New drug in India.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Upto
--	01	30 JUN 2025	Three years from the date of issue.

Yours faithfully,

*Chandrashekar*  
30/06/25

**Ranga Chandrashekar**  
**Joint Drugs Controller (India)**

चंद्रशेखर रंगा/Chandrashekar Ranga  
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)  
केन्द्रीय औषधि मानक विवेक संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय  
C.D.S.C.(HQ), Dte. General of Health Services  
स्वास्थ्य और परिवार कल्याण विभाग / Ministry of Health and Family Welfare  
ए.बी.ए. भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhabna, Kotla Road, New Delhi: 110002



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. ENANTI LABS PRIVATE LIMITED,  
Plot No. 60 D, Jawaharlal Nehru Pharma City,  
Thanam (C), Paravada (M), District: Anakapalli-531019,  
Andhra Pradesh, India.

2. Manufacturer's licence number: 10/VP/AP/2014/B/R

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Pregabalin Ph.Eur.	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: 08.01.2024 & 09.01.2024

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.

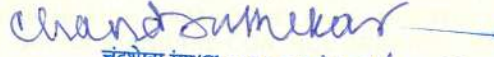
Address of the issuing regulatory authority: Central Drugs Standard Control Organisation  
FDA Bhawan, Kotla Road,  
New Delhi- 110 002, India

Name and function of responsible person: Ranga Chandrashekar,  
Joint Drugs Controller (India)

E-mail: [ranga.cs@cdsco.nic.in](mailto:ranga.cs@cdsco.nic.in);

Telephone no.: +91-11-23236965

Fax no.: +91-11-23236973

  
चंद्रशेखर रंगा/Chandrashekar Ranga  
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)  
Signature  
आयुर्विज्ञान विभाग संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय  
C.D.S.C.(HQ), Dte. General of Health Services  
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare,  
एन.टी.ए. भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

