

7-5/2013/EU/WC-0003
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated **27 JUN 2025**

To

**M/s. Synthimed Labs Private Limited,
Village Bhagwanpur, Barwala Road,
Derabassi -140507, District S.A.S Nagar (Mohali),
Punjab, India**

SUB:- Written Confirmation of **M/s. Synthimed Labs Private Limited, Village Bhagwanpur, Barwala Road, Derabassi -140507, District S.A.S Nagar (Mohali), Punjab, 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/RE/2025/9769** submitted to CDSCO, Zonal Office Baddi, and the recommendation received from DDC (I), CDSCO, Zonal Office Baddi 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 conform 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.

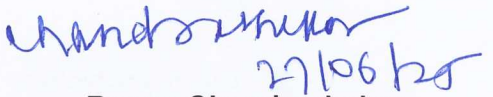
6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.
7. In the event of any Non-Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt 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.

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
--	--	27 JUN 2025	27.05.2028
01	25	27 JUN 2025	27.05.2028
02	02	27 JUN 2025	27.05.2028

Yours faithfully,



Ranga Chandrashekar
Joint Drugs Controller (India)
चंद्रशेखर रंगा/Chandrashekar Ranga

संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केंद्रीय औषधि मानक नियंत्रण 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
एफ.डी.ए. भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, 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. Synthimed Labs Private Limited,**
Village Bhagwanpur, Barwala Road,
Derabassi -140507, District S.A.S Nagar (Mohali),
Punjab, India

2. Manufacturer's licence number: **1610-OSP & 1615-B**

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):

and as per list enclosed as 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: 13.05.2025 & 14.05.2025

The Written Confirmation remains valid until: 27.05.2028

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

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga

संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केंद्रीय औषधि यानक निबंधन 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
एफ.डी.ए. भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date



27 JUN 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. Synthimed Labs Private Limited,
Village Bhagwanpur, Barwala Road,
Derabassi -140507, District S.A.S Nagar (Mohali),
Punjab, India

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Acamprosate Calcium Ph.Eur.	Manufacturing & Packing
2.	Anastrozole USP/Ph.Eur./IH	Manufacturing & Packing
3.	Aripiprazole USP/Ph.Eur./IH	Manufacturing & Packing
4.	Atorvastatin Calcium Trihydrate USP/Ph.Eur./JP	Manufacturing & Packing
5.	Cinacalcet Hydrochloride IH	Manufacturing & Packing
6.	Clarithromycin Citrate IH	Manufacturing & Packing
7.	Clarithromycin USP/Ph.Eur./JP	Manufacturing & Packing
8.	Clarithromycin Granules 27.5%, 33 %, 42 % (IH)	Manufacturing & Packing
9.	Clopidogrel Hydrogen Sulphate or Clopidogrel Bisulfate USP/Ph.Eur.	Manufacturing & Packing
10.	Donepezil Hydrochloride Monohydrate Ph. Eur.	Manufacturing & Packing
11.	Donepezil Hydrochloride USP/IH/JP/Ph.Eur.	Manufacturing & Packing
12.	Ezetimibe IH/USP	Manufacturing & Packing
13.	Fexofenadine Hydrochloride USP/Ph.Eur./JP	Manufacturing & Packing
14.	Imatinib Mesylate IH	Manufacturing & Packing
15.	Ivabradine Hydrochloride IH	Manufacturing & Packing
16.	Ivabradine Oxalate IH	Manufacturing & Packing
17.	Nateglinide USP	Manufacturing & Packing
18.	Pazopanib Hydrochloride IH	Manufacturing & Packing
19.	Pioglitazone Hydrochloride USP/Ph.Eur./JP/IH	Manufacturing & Packing
20.	Quetiapine Fumarate USP/Ph.Eur./IH/JP	Manufacturing & Packing
21.	Risedronate Sodium 2.5 Hydrate USP/Ph.Eur./JP	Manufacturing & Packing
22.	Ropinirole Hydrochloride USP/IH/Ph.Eur.	Manufacturing & Packing
23.	Saxagliptin Monohydrate IH	Manufacturing & Packing
24.	Temozolomide USP	Manufacturing & Packing
25.	Valganciclovir Hydrochloride USP	Manufacturing & Packing

ITEM(S) Twenty-Five (25) ONLY

The Written Confirmation remains valid until: 27.05.2028

Signature

2106125

Dr. Chandrashekar Ranga
Joint Drugs Controller (India)
Ministry of Health and Family Welfare
D.S.C.(HQ), Dir. General of Health Services
New Delhi-110002 / PDA Bhawan, Kaila Road, New Delhi-110002



Stamp of the authority and date

27 JUN 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. Synthimed Labs Private Limited,
Village Bhagwanpur, Barwala Road,
Derabassi -140507, District S.A.S Nagar (Mohali),
Punjab, India

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Mecloxamine Citrate IH	Manufacturing & Packing
2.	Lisdexamfetamine Dismesylate IH	Manufacturing & Packing
3.	Clopidogrel Besilate Ph. Eur	Manufacturing & Packing

ITEM(S) Two (03) ONLY

This certificate is being issued subject to condition that the firm shall obtain NOC from the Competent Authority, on case to case basis, to manufacture the above-mentioned active substance(s) for the purpose of export only, as the above-mentioned active substance(s) are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 27.05.2028

Chandrashekar Ranga
Signature: चंद्रशेखर रंगा/Chandrashekar Ranga
27/06/25

संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
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



27 JUN 2025