

7-5/2025/EU/WC-0603
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan, Kotla Road,
New Delhi-110002

Dated: 10 FEB 2025

To

M/s. Synthokem Labs Private Limited,
Unit-III, Plot No. 75, Jawaharlal Nehru Pharma City,
Thanam Village, Parawada Mandal,
Anakapalli District, Pincode-531019,
Andhra Pradesh, India.

Subject: -Written Confirmation of M/s. Synthokem Labs Private Limited, Unit-III, Plot No. 75, Jawaharlal Nehru Pharma City, Thanam Village, Parawada Mandal, Anakapalli District-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 online application no. **WC/FR/2024/8939 dated 05.09.2024** submitted to ADC(I), CDSCO, Sub-Zone office, Vishakhapatnam and the recommendation received from ADC (I), CDSCO, Sub Zone office, Vishakhapatnam 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.

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
--	--	10 FEB 2025	Three Years from the Date of Issue
01	02	10 FEB 2025	Three Years from the Date of Issue

Yours faithfully,

Chandrashekar
10/2/25
(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
एन.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. Synthokem Labs Private Limited,
Unit-III, Plot No. 75, Jawaharlal Nehru Pharma City,
Thanam Village, Parawada Mandal,
Anakapalli District, Pincode-531019,
Andhra Pradesh, India.

2. Manufacturer's licence number: 43/VSP/AP/2021/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 API(s):

As per Annexure-1

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: 22.01.2024 & 23.01.2024

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;

Telephone no.: +91-11-23236965

Fax no.: +91-11-23236973

Chandrashekar
10/2/25

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga

संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)

केंद्रीय औषधि पानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा परामर्शालय

C.D.S.C. (HQ) - Dte. General of Health Services

स्वास्थ्य सेवा परामर्शालय / Ministry of Health and Family Welfare

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



10 FEB 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. Synthokem Labs Private Limited,
Unit-III, Plot No. 75, Jawaharlal Nehru Pharma City,
Thanam Village, Parawada Mandal,
Anakapalli District, Pincode-531019,
Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Chlorphenesin IH	Manufacturing & Packing
02	Mephenesin IH	Manufacturing & Packing

ITEM(S) TWO (02) 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 substances for the purpose of export only, as the above-mentioned active substances are not approved for manufacture for sale in India.

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

Chandrashekar Ranga

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महाविद्यालय
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



10 FEB 2025

AMENDED

7-5/2025/EU/WC-0603
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002

Dated: 26 SEP 2025

To

M/s. Synthokem Labs Private Limited,
Unit-III, Plot No. 75, Jawaharlal Nehru Pharma City,
Thanam Village, Parawada Mandal,
Anakapalli District, Pincode-531019,
Andhra Pradesh, India.

Subject: -Correction/Amendment in Written Confirmation of **M/s. Synthokem Labs Private Limited, Unit-III, Plot No. 75, Jawaharlal Nehru Pharma City, Thanam Village, Parawada Mandal, Anakapalli District-531019, Andhra Pradesh, India** - regarding.

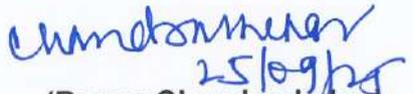
Sir,

This is with refer to your email, wherein you had requested for the amendment for the licence number in issued WC-0603 dated **10.02.2025**, which is valid upto 09.02.2028.

In this regard, please find the amended certificate with correct licence number.

Please acknowledge the receipt

Yours faithfully,


25/09/25
(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. Synthokem Labs Private Limited,
Unit-III, Plot No. 75, Jawaharlal Nehru Pharma City,
Thanam Village, Parawada Mandal,
Anakapalli District, Pincode-531019,
Andhra Pradesh, India.**

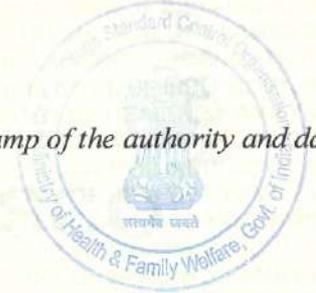
The licence number on the WC-0603 dated is hereby amended as follows:

<i>In place of</i>	<i>Read as</i>
43/VSP/AP/2021/B/R	43/VSP/AP/2021/B/G

All the other conditions of Written Confirmation Certificate will remain same.

Chandrasekhar
Signature
चंद्रशेखर रंगा/Chandrasekhar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केंद्रीय औषधि मानक नियंत्रण संगठन (सुझ्यालय), 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
एन सी ई बिल्डिंग, कोटा रोड, नई दिल्ली-110002 / FDA Building, Kotla Road, New Delhi-110002

Stamp of the authority and date



26 SEP 2025

7-5/2025/EU/WC-0603
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002

Dated: 19 JAN 2026

To

M/s. Synthokem Labs Private Limited,
Unit-III, Plot No. 75,
Jawaharlal Nehru Pharma City,
Thanam Village, Parawada Mandal,
Anakapalli District, Pincode-531019,
Andhra Pradesh, India.

Subject: -Written Confirmation of **M/s. Synthokem Labs Private Limited, Unit-III, Plot No. 75, Jawaharlal Nehru Pharma City, Thanam Village, Parawada Mandal, Anakapalli District-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 online application no. **WC/FR/2024/10068** submitted to ADC(I), CDSCO, Sub-Zone office, Vishakhapatnam and the recommendation received from ADC (I), CDSCO, Sub Zone office, Vishakhapatnam 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.
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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.

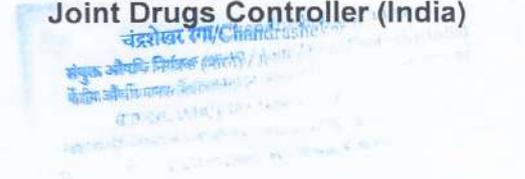
Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Upto
--	--	10.02.2025	09.02.2028
01	02	10.02.2025	09.02.2028
Amendment	--	26.09.2025	09.02.2028
02	01	19 JAN 2026	09.02.2028

Yours faithfully,

Chandrashekar
16/01/28

(Dr. 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. Synthokem Labs Private Limited,
Unit-III, Plot No. 75, Jawaharlal Nehru Pharma City,
Thanam Village, Parawada Mandal,
Anakapalli District, Pincode-531019,
Andhra Pradesh, India**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Drotaverine Hydrochloride IH	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 09.02.2028

Chandrashekar Ranga
Signature 16/01/26

Chandrashekar Ranga
Joint Drugs Controller (India)
Central Drugs Standard Control Organization
Ministry of Health and Family Welfare
New Delhi-110002



19 JAN 2026