

7-5/2014/EU/WC-0301
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated:

22 MAY 2024

To,

**M/s. Synnat Pharma Private Limited,
Plot No. 60A, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531019,
Andhra Pradesh, India**

SUB:- Written Confirmation of **M/s. Synnat Pharma Private Limited, Plot No. 60A, Jawaharlal Nehru Pharma City, 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/2023/6723 dated 12.03.2023 submitted to CDSCO, ADC(I), Visakhapatnam Sub-Zone, and the recommendation received from ADC(I), Visakhapatnam Sub-Zone, 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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 with the provisions 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
--	01	22 MAY 2024	07.02.2027

Yours faithfully,


(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (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. Synnat Pharma Private Limited,
Plot No. 60A, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531019,
Andhra Pradesh, India**

2. Manufacturer's licence number: **09/VP/AP/2013/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):

S. No.	Active substance(s)	Activity(ies)
1	Rocuronium Bromide BP/IP/USP/Ph. Eur	Manufacturing & Packing

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: 04.09.2023 & 05.09.2023

The Written Confirmation remains valid until: 07.02.2027

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. Rajeev Singh Raghuvanshi,
Drugs Controller General (India)

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973


Signature

22 MAY 2024



Stamp of the authority and date

7-5/2014/EU/WC-0301
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: 04 JUN 2024

To,

**M/s. Synnat Pharma Pvt. Ltd,
Plot No. 60A Jawaharlal Nehru Pharma City,
Parawada mandal, Anakapalli District-531019, Andhra Pradesh India.**

SUB:- Written Confirmation of M/s. Synnat Pharma Pvt. Ltd, Plot No. 60A Jawaharlal Nehru Pharma City, 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/RE/2024/7957 dated 23.01.2024 submitted to CDSCO, ADC(I), Visakhapatnam Sub-Zone, and the recommendation received from ADC(I), Visakhapatnam Sub-Zone 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
--	01	22.05.2024	07.02.2027
1	04	04 JUN 2024	07.02.2027
2	01	04 JUN 2024	07.02.2027

Yours faithfully,



(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)



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

Annexure-01

CERTIFICATE NO. : WC-0301

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. Synnat Pharma Pvt. Ltd.,
Plot No. 60A Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District-531019,
Andhra Pradesh India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Atracurium Besylate IP/BP/USP/Ph.Eur.,	Manufacturing & Packing
2.	Papaverine Hydrochloride BP/USP/Ph.Eur.,	Manufacturing & Packing
3.	Noscapine BP/USP/JP/Ph.Eur.,	Manufacturing & Packing
4.	Osetamivir Phosphate IP/BP/USP/Ph.Eur	Manufacturing & Packing

ITEM(S) FOUR (04) ONLY

The Written Confirmation remains valid until: 07.02.2027


Signature



04 JUN 2024



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. Synnat Pharma Pvt. Ltd,
Plot No. 60A Jawaharlal Nehru Pharma City,
Parawada mandal, Anakapalli District-531019,
Andhra Pradesh India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Noscapine Hydrochloride BP/USP/Ph.Eur.	Manufacturing & Packing

ITEM(S) ONE (01) 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 active substance for the purpose of export only, as the above-mentioned active substance is not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 07.02.2027


Signature

Stamp of the authority and date



04 JUN 2024

7-5/2014/EU/WC-0301
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: **14 JUN 2024**

To,

**M/s. Synnat Pharma Private Limited,
Plot No. 60A, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531019,
Andhra Pradesh, India**

SUB:- Written Confirmation of **M/s. Synnat Pharma Private Limited, Plot No. 60A, Jawaharlal Nehru Pharma City, 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/2023/7279 dated 24.06.2023 submitted to CDSCO, ADC(I), Visakhapatnam Sub-Zone, and the recommendation received from ADC(I), Visakhapatnam Sub-Zone, 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 with the provisions 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
--	01	22.05.2024	07.02.2027
1	04	04.06.2024	07.02.2027
2	01	04.06.2024	07.02.2027
3	02	14 JUN 2024	07.02.2027

Yours faithfully,


 (Dr. Rajeev Singh Raghuvanshi)
 Drugs Controller General (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. Synnat Pharma Private Limited,
Plot No. 60A, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531019,
Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Risedronate Sodium 2,5-hydrate- BP/Ph.Eur	Manufacturing & Packing
2.	Risedronate Sodium USP	Manufacturing & Packing

ITEM(S) Two (02) ONLY

The Written Confirmation remains valid until: 07.02.2027


Signature

Stamp of the authority and date



14 JUN 2024

7-5/2014/EU/WC-0301
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: 19 JUN 2024

To,

**M/s.Synnat Pharma Private Limited,
Plot No. 60A, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531019,
Andhra Pradesh, India**

SUB:-Written Confirmation of **M/s.Synnat Pharma Private Limited, Plot No. 60A, Jawaharlal Nehru Pharma City, 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/2023/6722 dated 12.03.2023 submitted to CDSCO, ADC(I), Visakhapatnam Sub-Zone, and the recommendation received from ADC(I), Visakhapatnam Sub-Zone, 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 with the provisions 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
--	01	22.05.2024	07.02.2027
1	04	04.06.2024	07.02.2027
2	01	04.06.2024	07.02.2027
3	02	14.06.2024	07.02.2027
4	01	19 JUN 2024	07.02.2027

Yours faithfully,


(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (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.Synnat Pharma Private Limited,
Plot No. 60A, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531019,
Andhra Pradesh, India**

List of API(s):

S. No.	Active substance(s)	Activity(ies)
1	Zoledronic Acid Monohydrate BP/IP/Ph.Eur	Manufacturing & Packing

ITEM ONE (01) ONLY

The Written Confirmation remains valid until: 07.02.2027


Signature



19 JUN 2024

7-5/2014/EU/WC-0301
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated **03 SEP 2025**

To

**M/s. Synnat Pharma Private Limited,
Plot No. 60A, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531019,
Andhra Pradesh, India**

Subject: Written Confirmation of **M/s. Synnat Pharma Private Limited, Plot No. 60A, Jawaharlal Nehru Pharma City, 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/2024/8767** submitted to CDSCO, Visakhapatnam Sub-Zone office, and the recommendation received from ADC (I), Visakhapatnam Sub-Zone 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 with the provisions 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
--	01	22.05.2024	07.02.2027
1	04	04.06.2024	07.02.2027
2	01	04.06.2024	07.02.2027
3	02	14.06.2024	07.02.2027
4	01	19.06.2024	07.02.2027
5	01	03 SEP 2025	07.02.2027

Yours faithfully,

Chandrashekar
02/09/25
Ranga Chandrashekar
Joint Drugs Controller (India)
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केन्द्रीय औषधि नियंत्रण संगठन (सुदय्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.(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



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. Synnat Pharma Private Limited,
Plot No. 60A, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531019,
Andhra Pradesh, India**

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Tetrabenazine IH	Manufacturing & Packing

ITEM(s) ONE (01) ONLY

The Written Confirmation remains valid until: **07.02.2027**

Chandrashekar
02/09/25

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केन्द्रीय 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.टी.ए.पल, कोटला रोड, नई दिल्ली-110002 / FDA Bldg., Kolla Road, New Delhi-110002

Stamp of the authority and date



03 SEP 2025