7-5/2022/EU/WC-0086
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

To

M/s. Anuh Pharma Ltd.,
E-17/3, 17/4 & E 18 Boisar,
MIDC Tarapur, Tal. District-Palghar, 401 506,
Maharashtra State, India

18 APR 2023

Subject:- Written Confirmation of M/s. Anuh Pharma Ltd., E-17/3, 17/4 & E 18 Boisar, MIDC Tarapur, Tal. District-Palghar, 401 506 Maharashtra State, 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/2023/6572 submitted to CDSCO, West Zone office and the recommendation received from DDC(I), West zone office 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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.

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
1	09	18 APR 2023	01.03.2026
2	02	18 APR 2023	01.03.2026

Yours faithfully,

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

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

CERTIFICATE NO. : **WC-0086**

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. Anuh Pharma Ltd.,**
E-17/3, 17/4 & E 18 Boisar,
MIDC Tarapur, Tal. District-Palghar, 401 506,
Maharashtra State, India

2. **Manufacturer's licence number**: 25-KD/1194 & 28-KD/990

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

As per List enclosed as 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: 02.03.2023 to 02.03.2023

The Written Confirmation remains valid until: **01.03.2026**

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

18 APR 2023

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Govt.

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

Annexure-1
WC-0086

CERTIFICATE NO. :

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. Anuh Pharma Ltd.,**
E-17/3, 17/4 & E 18 Boisar,
MIDC Tarapur, Tal. District-Palghar, 401 506,
Maharashtra State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Ambroxol Hydrochloride BP/EP	Manufacturing & Packing
2.	Azithromycin BP/EP/USP	Manufacturing & Packing
3.	Chloramphenicol Palmitate BP/EP/USP	Manufacturing & Packing
4.	Chloramphenicol BP/EP/USP	Manufacturing & Packing
5.	Erythromycin BP/EP/USP	Manufacturing & Packing
6.	Erythromycin Stearate BP/EP/USP	Manufacturing & Packing
7.	Erythromycin Propionate FP	Manufacturing & Packing
8.	Pyrazinamide BP/EP/USP	Manufacturing & Packing
9.	Sulfadoxine BP/EP	Manufacturing & Packing

ITEM(S) Nine (09) Only

The Written Confirmation remains valid until: 01.03.2026.

Signature Rajan Singh

Stamp of the authority and date

Assistant Controller of Drugs, Standard Control Organization, Ministry of Health & Family Welfare, Govt. of India

18 APR 2023

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

Annexure-2

CERTIFICATE NO. : WC-0086

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

Name and address of site: **M/s. Anuh Pharma Ltd.,**
E-17/3, 17/4 & E 18 Boisar,
MIDC Tarapur, Tal. District-Palghar, 401 506,
Maharashtra State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Erythromycin Estolate BP/EP/USP	Manufacturing & Packing
2.	Erythromycin Ethyl Succinate BP/EP/USP	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: 01.03.2026

Signature

Stamp of the authority and date

18 APR 2023

7-5/2022/EU/WC-0086
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

To,

M/s. Anuh Pharma Limited
E-17/3 , E-17/4 & E-18, MIDC, Tarapur,
Boisar, Palghar-401506, Maharashtra, India

25 SEP 2023

SUB:- Written Confirmation to M/s. Anuh Pharma Limited, E-17/3 , E-17/4 & E-18, MIDC, Tarapur, Boisar, Palghar-401506, Maharashtra, 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/2023/7194 dated 06-JUN-2023 submitted to CDSCO, DDC(I), West Zone, Maharashtra, and the recommendation received from DDC(I), West 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.

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
1	09	18.04.2023	01.03.2026
2	02	18.04.2023	01.03.2026
3	03	25 SEP 2023	01.03.2026

Yours faithfully,

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

Annexure-03

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

CERTIFICATE NO. : WC-0086

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. Anuh Pharma Limited
E-17/3 , E-17/4 & E-18, MIDC, Tarapur,
Boisar, Palghar-401506, Maharashtra, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Gliclazide Ph.Eur	Manufacturing & Packing
2.	Pyrimethamine Ph.Eur	Manufacturing & Packing
3.	Allopurinol Ph.Eur	Manufacturing & Packing

ITEM(S) THREE (03) ONLY

The Written Confirmation remains valid until: 01.03.2026

Signature

Stamp of the authority and date

25 SEP 2023

7-5/2013/EU/WC-0086

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated
30 MAY 2025

To

M/s ANUH PHARMA LTD.,
E-17/3, E-17/4, & E-18, MIDC, Tarapur,
Boisar – 401506, District: Palghar Zone 3,
Maharashtra State, India

SUB: - Written Confirmation of **M/s ANUH PHARMA LTD., E-17/3, E-17/4, & E-18, MIDC, Tarapur, Boisar – 401506, District: Palghar Zone 3, Maharashtra State, 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/2024/9098 submitted to CDSCO, West Zone office, and the recommendation received from DDC (I), West 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.

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
--	--	18.04.2023	**01.03.2026**
01	09	18.04.2023	**01.03.2026**
02	02	18.04.2023	**01.03.2026**
03	03	25.09.2023	**01.03.2026**
04	01	30 MAY 2025	**01.03.2026**

Yours faithfully,

Chandrashekar 30/05/25

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.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

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

CERTIFICATE NO. : **Annexure -04**
WC -0086

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 ANUH PHARMA LTD.,**
E-17/3, E-17/4, & E-18, MIDC, Tarapur,
Boisar – 401506, District: Palghar Zone 3,
Maharashtra State, India.

List of API(s):

S. No.	Active Substance(s)	Activity(ies)
1	Sulfadimethoxine – EP/BP	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 01.03.2026

Chandrashekar

Signature 30/05/25

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.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

Stamp of the authority and date

Min. of Health & Family Welfare, Govt. of India * Central Drugs Standard Control Organization * सत्यमेव जयते

30 MAY 2025