AMENDED

7-5/2013/EU/WC-0086
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Import and Registration Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 27 JUL 2026

To,

M/s. Anuh Pharma Limited (Public Limited),
E-17/3, E-17/4 & E 18, MIDC,
Tarapur, Boisar, Palghar, 401 506,
Maharashtra State, India.

Subject: -Correction/Amendment in Written Confirmation of M/s. Anuh Pharma Limited (Public Limited), E-17/3, E-17/4 & E 18, MIDC, Tarapur, Boisar, Palghar, 401 506, Maharashtra, India -reg.

Sir,

This is in reference to your email dated 13.07.2026 on the subject cited above.

The WC certificate no. 0086 (mentioned as WC-082) dated 18.03.2026 valid up to 17.03.2029 along with covering letter and annexure -1, is hereby amended as follows, subject to all the other conditions of WC certificate remaining the same:

Amendment in Certificate Issued on 18.03.2026		
	In place of	***Read as***
Covering letter	7-5/2026/EU/WC-082	7-5/2013/EU/WC-0086
WC certificate and Annnexure-1	WC-082	WC-0086

Yours faithfully,

27/7/26

(Dr. Annam Visala)
Joint Drugs Controller (India)

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

CERTIFICATE NO. : **AMENDED 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 (Public Limited), E-17/3, E-17/4 & E 18, MIDC, Tarapur, Boisar, Palghar, 401 506, Maharashtra State, India.**

The Written Confirmation Certificate No. 0086 (mentioned as WC-082) dated 18.03.2026 valid up to 17.03.2029 along with covering letter and annexure -1 is hereby amended as follows:

Amendment in Certificate Issued on 18.03.2026		
	In place of	***Read as***
Covering letter	7-5/2026/EU/WC-082	7-5/2013/EU/WC-0086
WC certificate and Annnexure-1	WC-082	WC-0086

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

Signature

21/7/26

डॉ. ए. विशाला / Dr. A. Visala
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 रोड़, नई दिल्ली–110002
FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

Central Drugs Standard Control Organisation * Ministry of Health & Family Welfare, Govt. of India

7-5/2026/EU/WC-082
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:
18 MAR 2026

To,

M/s. Anuh Pharma Limited (Public Limited)
E-17/3, E-17/4 & E 18, MIDC,
Tarapur, Boisar, Palghar, 401 506,
Maharashtra State, India

SUB:- Written Confirmation of **M/s. Anuh Pharma Limited (Public Limited), E-17/3, E-17/4 & E 18, MIDC, Tarapur, Boisar, Palghar, 401 506, Maharashtra, 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/2026/12416 dated 23.01.2026 submitted to CDSCO, DDC(I), West Zone, 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.

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 MAR 2026	Three years from the date of issue
1	15	18 MAR 2026	Three years from the date of issue

Yours faithfully,

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

WC-082

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

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: **Anuh Pharma Limited (Public Limited)**
E-17/3, E-17/4 & E 18, MIDC,
Tarapur, Boisar, Palghar, 401 506,
Maharashtra State, India

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

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 list enclosed as Annexure-01

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: 13.05.2024 & 14.05.2024

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

Signature

Stamp of the authority and date

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

18 MAR 2026

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

Annexure-1
WC-082

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: Anuh Pharma Limited (Public Limited)
E-17/3, E-17/4 & E 18, MIDC,
Tarapur, Boisar, Palghar, 401 506,
Maharashtra State, India.

List of API(s):

S. No.	Active substance(s)	Activity(ies)
1.	Chloramphenicol B.P/U.S.P/Ph.Eur	Manufacturing & Packing
2	Erythromycin stearate B.P/U.S.P/ Ph.Eur	Manufacturing & Packing
3.	Erythromycin estolate B.P/U.S.P/ Ph.Eur	Manufacturing & Packing
4.	Sulfadoxine B.P/U.S.P/ Ph.Eur	Manufacturing & Packing
5.	Chloramphenicol Palmitate B.P/U.S.P/ Ph.Eur	Manufacturing & Packing
6.	Pyrazinamide B.P/U.S.P/ Ph.Eur	Manufacturing & Packing
7.	Azithromycin B.P/U.S.P/ Ph.Eur.	Manufacturing & Packing
8.	Erythromycin Ethyl Succinate B.P/U.S.P/ Ph.Eur	Manufacturing & Packing
9.	Erythromycin Propionate F.P	Manufacturing & Packing
10.	Erythromycin B.P/U.S.P/ Ph.Eur	Manufacturing & Packing
11.	Ambroxol Hydrochloride B.P/ Ph.Eur	Manufacturing & Packing
12.	Pyrimethamine Ph.Eur.	Manufacturing & Packing
13.	Gliclazide Ph.Eur	Manufacturing & Packing
14.	Allopurinol Ph.Eur	Manufacturing & Packing
15.	Sulfadimethoxine B.P/Ph.Eur	Manufacturing & Packing

ITEM(S) FIFITEEN (15) ONLY

The Written Confirmation remains valid until: Three years from the date of issue

Signature

Stamp of the authority and date

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

18 MAR 2026