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

Central 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

CERTIFICATE NO. : **Annexure-2 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