FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 18 DEC 2018

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.
(General instructions and explanatory notes attached).
Certificate No.: **NEW-WHO-GMP/CERT/AMD/72144/2018/11/24392**

On the basis of the inspection carried out on **31/05/2018 , 01/06/2018 and 18/07/2018** ,we certify that the site indicated on this Certificate complies with **Good Manufacturing Practices** for the dosage forms, categories and activities listed in Table 1.

1. Name of the Firm : **CHAITANYA BIOLOGICALS PVT. LTD.**
   Address : **75/2, NATIONAL HIGHWAY NO. 06, MALKAPUR BYPASS, MALKAPUR BULDHANA 443101 MAHARASHTRA STATE, INDIA**
2. Licence No. : **AMD82003 In Form 25**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Active Pharmaceutical Ingredients (Bulk Drugs)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 05 Aug 2021 . It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959

Name of the Authorised person : **A. T. NIKHADE**
Signature :
Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:13 Dec 2018

13 DEC 2018

ASMECHEM
Mumbai

SANKARAN S. IYER
(AUTHORISED SIGNATORY)
Asmechem Chamber of Commerce & Industry of India.

Explanatory notes

1. This certificate which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.

2. The certification number should be traceable within the regulatory authority issuing the certificate.

3. Where the regulatory authority issues a licence for the site , this number should be specified record "not applicable" in cases where there is no legal framework for the issuing of a licence.

4. Table 1
   List the dosage forms, starting materials, categories and activities. Examples are given below.

   Example -1

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

   Example - 2.

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Starting material (s)2		
Paracetamol	Analgesic	Synthesis, Purification, Packing, Labelling.

   Use, whenever available. International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

5. The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.

6. The requirements for good practices the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials . Good manufacturing practices and inspection. Volume 2, 1999. World Health Organization, Geneva and subsequent updates.

ASMECHEM Mumbai

SANKARAN S. IYER
(AUTHORISED SIGNATORY)
Asmechem Chamber of Commerce
& Industry of India.

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AMD/72144 /2018/11/24392 **VALID UP TO :05 Aug 2021**

Name of Manufactring Firm : CHAITANYA BIOLOGICALS PVT. LTD.
75/2, NATIONAL HIGHWAY NO. 06, MALKAPUR BYPASS, MALKAPUR BULDHANA 443101
MAHARASHTRA STATE, INDIA

Drug License No : AMD82003 In Form 25

Sr.No.	Name of the Product	Composition
1	Ferrous Ascorbate	
2	Ferrous Bis Glycinate	
3	Ferrous Glycine Sulphate	
4	IRON (III) HYDROXIDE POLYMALTOSE COMPLEX 30-34%	
5	IRON (III) HYDROXIDE POLYSACCHARIDE COMPLEX	
6	IRON PROTEIN SUCCINYLATE	

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Fax: +91-22-26591959

Name of the Authorised person : **A. T. NIKHADE**

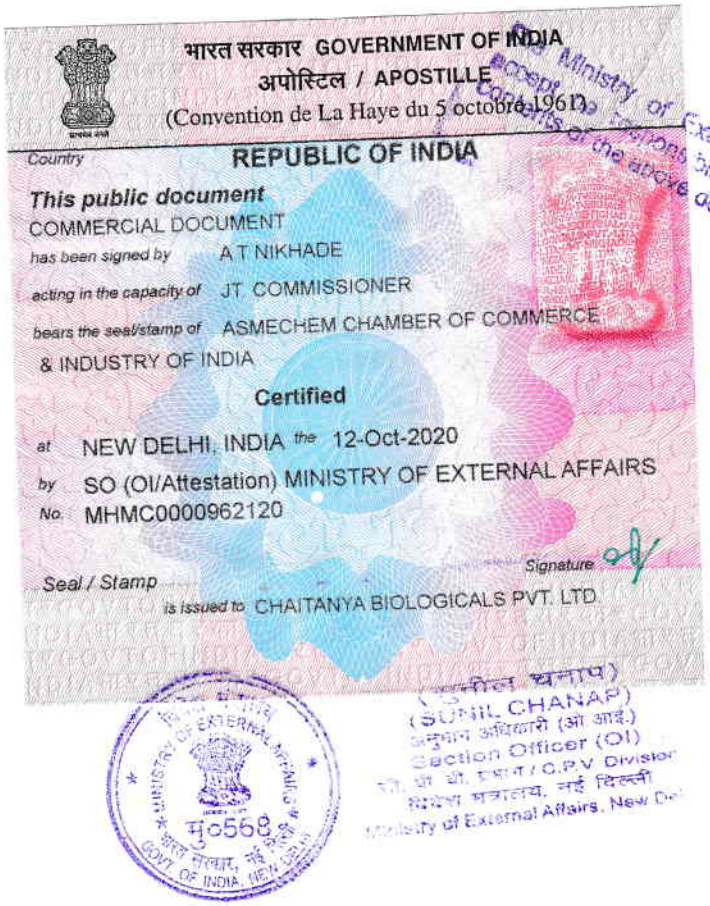
Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:13 Dec 2018

13 DEC 2018

ASMECHEM Chamber of Commerce & Industry of India Mumbai

SANKARAN S. IYER
(AUTHORISED SIGNATORY)
Asmechem Chamber of Commerce & Industry of India.



भारत सरकार GOVERNMENT OF INDIA

अपोस्टिल / APOSTILLE

(Convention de La Haye du 5 octobre 1961)

Country REPUBLIC OF INDIA

This public document

COMMERCIAL DOCUMENT

has been signed by A T NIKHADE

acting in the capacity of JT. COMMISSIONER

bears the seal/stamp of ASMECHEM CHAMBER OF COMMERCE & INDUSTRY OF INDIA

Certified

at NEW DELHI, INDIA the 12-Oct-2020

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. MHMC0000962120

Seal / Stamp

Signature

is issued to CHAITANYA BIOLOGICALS PVT. LTD.

MEA 568

(SUNIL CHANAP)
अनुभाग अधिकारी (आ आई.)
Section Officer (OI)
कौ. पा. प्र. / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

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