महाराष्ट्र शासन
आयुक्त
अन्न वा औषध प्रशासन , महा. राज्य
३४१ , वांद्रे - कुर्ला संकुल , रिजर्व बँक
समोर, वांद्रे (पूर्व)
मुंबई - ४०० ०५१.

सत्यमेव जयते

FDA MAHARASHTRA
FOOD AND DRUG ADMINISTRATION

GOVERNMENT OF MAHARASHTRA
COMMISSIONER
Food and Drugs Administration (M.S.)
341, Bandra-Kurla Complex,
Opposite of RBI Buildings,
BAndra (E), Mumbai - 400 051
Tel : 022 - 26592362-65
E-Mail : comm.fda-mah@nic.in

क्र. NEW-WHO-GMP/CERT/KD/113007/2022/ 2651 /11 दिनांक. 19/7/2022

प्रति,

EMBIO LIMITED
RAIGAD

विषय - डब्लूएचओ - जीएमपी प्रमाणपत्र मंजुरीबाबत

संदर्भ - आपला प्रस्ताव क्रमांक 113007

महोदय,

सोबत डब्लूएचओ - जीएमपी प्रमाणपत्र / सीओपीपी (सर्टिफिकेट ऑफ फार्मास्युटिकल्स प्रॉडक्ट्स / स्टेटमेंट ऑफ लायसन्सिंग) स्टेटस प्रमाणपत्र क्रमांक डब्लूएचओ - जीएमपी/ KD/113007 (एकूण प्रमाणपत्रे 1) पाठवीण्यात येत आहेत

आपला

(डॉ. सं. ने. काले)
सहाय्यक आयुक्त (मुख्यालय) (डेस्क ११)
अन्न व औषध प्रशासन , म. राज्य.

FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-**19 Jul 2022**

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/KD/113007/2022/11/41406**

On the basis of the inspection carried out on **11.05.2022 to 12.05.2022** ,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 : **EMBIO LIMITED**
   Address : **PLOT NO. E-21, MIDC INDUSTRIAL ESTATE MAHAD RAIGAD 402309 MAHARASHTRA STATE, INDIA**
2. Licence No. : **1206 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)	Production, Filling, 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 18 Jul 2025 . 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
1BME37411300720220719
EMBIO LIMITED - NEW-WHO-GMP/CERT /KD/113007/2022/11/41406

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**19 Jul 2022**

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

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.

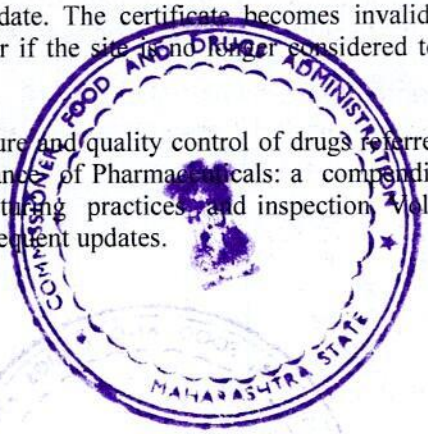
   Example - 2.

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.



LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/KD/113007/2022/11/41406 **VALID UP TO :18 Jul 2025**

Name of Manufacturing Firm : EMBIO LIMITED
PLOT NO. E-21, MIDC INDUSTRIAL ESTATE
MAHAD RAIGAD 402309 MAHARASHTRA
STATE, INDIA

Drug License No : 1206 In Form 25

Sr.No.	Name of the Product	Composition
1	Lisdexamphetamine Dimesylate	
2	Methadone Hydrochloride	
3	Cannabidiol-Synthetic	
4	Lisdexamphetamine Diadipate	
5	Methadone Hydrochloride BP	
6	Methadone Hydrochloride Ph Eur	
7	Methadone Hydrochloride USP	
8	dl-Methylephedrine Hydrochloride JP	

1 2 3

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

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
1BME37411300720220719
EMBIO LIMITED - NEW-WHO-GMP/CERT/KD/113007/2022/11/41406

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**19 Jul 2022**

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/KD/113007/2022/11/41406 **VALID UP TO :18 Jul 2025**

Name of Manufacturing Firm : EMBIO LIMITED
PLOT NO. E-21, MIDC INDUSTRIAL ESTATE
MAHAD RAIGAD 402309 MAHARASHTRA
STATE, INDIA

Drug License No : 1206 In Form 25

Sr.No.	Name of the Product	Composition
9	d-Norpseudoephedrine Hydrochloride (Cathine Hydrochloride)	
10	Ephedrine Hydrochloride - BP	
11	Ephedrine Hydrochloride - Ph.Eur	
12	Ephedrine Hydrochloride - USP	
13	Ephedrine Hydrochloride -IP	
14	Ephedrine Hydrochloride- JP	
15	Ephedrine Sulfate	
16	Pseudoephedrine Hydrochloride - JPC	

1 2 3

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

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
1BME37411300720220719
EMBIO LIMITED - NEW-WHO-GMP/CERT /KD/113007/2022/11/41406

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**19 Jul 2022**

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/KD/113007/2022/11 /41406 **VALID UP TO :18 Jul 2025**

Name of Manufacturing Firm : EMBIO LIMITED
PLOT NO. E-21, MIDC INDUSTRIAL ESTATE
MAHAD RAIGAD 402309 MAHARASHTRA
STATE, INDIA

Drug License No : 1206 In Form 25

Sr.No.	Name of the Product	Composition
17	Pseudoephedrine Hydrochloride - Ph.Eur	
18	Pseudoephedrine Hydrochloride BP	
19	Pseudoephedrine Hydrochloride IP	
20	Pseudoephedrine Hydrochloride USP	
21	Pseudoephedrine Sulfate USP --	
22	Selegiline Hydrochloride - Ph.Eur	
23	Selegiline Hydrochloride BP	
24	Selegiline Hydrochloride USP	
1 2 3		

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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
1BME37411300720220719
EMBIO LIMITED - NEW-WHO-GMP/CERT /KD/113007/2022/11/41406

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**19 Jul 2022**