FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 26 AUG 2019

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/PD/86231/2019/11/29218**

On the basis of the inspection carried out on **24/06/2019,25/06/2019 and 03/08/2019** ,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 : **EMCURE PHARMACEUTICALS LIMITED**
   Address : **PLOT NO. D-24 & D-24/1, KURKUMBH M.I.D.C., TAL. DAUND, PUNE 413802 MAHARASHTRA STATE, INDIA**
2. Licence No. : **PD164 In Form 25, PD25F01200910 In Form 25F, PD119 In Form 28**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Active Pharmaceutical Ingredients (Bulk Drugs)	Cytotoxics	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance
2	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 23 Aug 2022 . 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: +91-22-26591958
ICME31286231201908 24
EMCURE PHARMACEUTICALS LIMITED -
NEW-WHO-GMP/CERT/PD/86231/2019/11
Page 1 of 2

Name of the Authorised person : V. K. BIYANI
Signature :
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai,
Maharashtra State, India
Date:24 Aug 2019

FOOD AND DRUGS ADMINISTRATION COMMISSIONER MAHARASHTRA STATE

14 SEP 2021

MAHARASHTRA CHAMBER OF COMMERCE, INDUSTRY AND AGRICULTURE
PUNE
060966
14 SEP 2021
MAHARASHTRA (INDIA)

24 AUG 2019

P V SASIDHARAN
EXECUTIVE

SURAJ D. KHADE
ADVOCATE & NOTARY
GOVT. OF INDIA
198/569, Sant Tukaram Nagar,
Pimpri, Pune-18, Mob-9850696401

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 V K BIYANI

acting in the capacity of JT. COMMISSIONER

bears the seal/stamp of MAHRATTA CHAMBER OF COMMERCE, INDUSTRIES AND AGRICULTURE

Certified

at NEW DELHI, INDIA the 17-Sep-2021

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. MHMC0002054621

Seal / Stamp

Signature

Is issued to EMCURE PHARMACEUTICALS LTD.

The Ministry of External Affairs does not responsibility for the contents of the above documents

(अशोक कुमार)
(ASHOK KUMAR)
अवर सचिव (सत्यापन / ओ.आई.)
Under Secretary (Attestation/O I.)
सी.पी.वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi

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.

MAHARASHTRA CHAMBER OF COMMERCE, INDUSTRIES AND AGRICULTURE
PUNE
0 6 0 9 6 6
14 SEP 2021
MAHARASHTRA (INDIA)

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EXECUTIVE

14 SEP 2021

SURAJ D. KHADE
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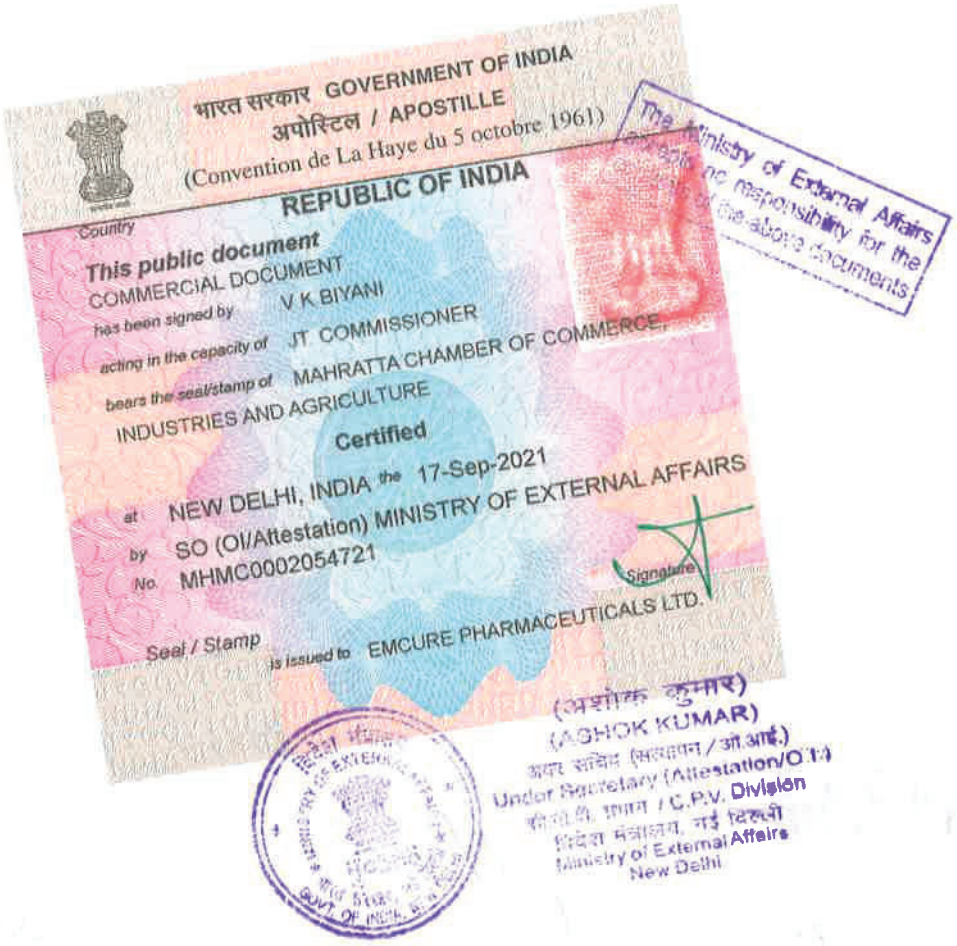
GOVT. OF INDIA
108/969, Sant Tukaram Nagar,
Pimpri, Pune-18. Mob-9850656405


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 V K BIYANI
acting in the capacity of JT COMMISSIONER
bears the seal/stamp of MAHRATTA CHAMBER OF COMMERCE,
INDUSTRIES AND AGRICULTURE
Certified
at NEW DELHI, INDIA the 17-Sep-2021
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. MHMC0002054721
Signature
Seal / Stamp
is issued to EMCURE PHARMACEUTICALS LTD.
The Ministry of External Affairs
no responsibility for the
the above documents.
(अशोक कुमार)
(ASHOK KUMAR)
अवर सचिव (सत्यापन / ओ.आई.)
Under Secretary (Attestation/O.I.)
कॉन्सुलर प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/PD/86231/2019/11 /29218 **VALID UP TO:23 Aug 2022**

Name of Manufactring Firm : EMCURE PHARMACEUTICALS LIMITED
PLOT NO. D-24 & D-24/1, KURKUMBH M.I.D.C.,
TAL. DAUND, PUNE 413802 MAHARASHTRA
STATE, INDIA

Drug License No : PD164 In Form 25,
PD25F01200910 In Form
25F, PD119 In Form 28

Sr.No.	Name of the Product	Composition
49	Leflunomide USP	Leflunomide USP
50	Melphalan Hydrochloride	Melphalan Hydrochloride
51	Memantine Hydrochloride	Memantine Hydrochloride
52	Metoclopramide Hydrochloride USP	Metoclopramide Hydrochloride USP
53	Midodrine Hydrochloride USP	Midodrine Hydrochloride USP
54	Mycophenolate Mofetil Ph. Eur.	Mycophenolate Mofetil Ph. Eur.
55	Mycophenolate Mofetil USP	Mycophenolate Mofetil USP
56	Mycophenolate Sodium	Mycophenolate Sodium

1 2 3 4 5 6 7 8 9 10 ...

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Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1CME3128623120190824
EMCURE PHARMACEUTICALS LIMITED -
NEW-WHO-GMP/CERT/PD/86231/2019/11
/29218

Name of the Authorised person : **V. K. BIYANI**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:24 Aug 2019

24 AUG 2019

MAHARASHTRA CHAMBER OF COMMERCE, INDUSTRIES AND AGRICULTURE
PUNE
96096
14 SEP 2021
MAHARASHTRA (INDIA)

P V SASIDHARAN
EXECUTIVE

14 SEP 2021

SURAJ D. KHADE
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GOVT. OF INDIA
193/969, Sant Tukaram Nagar,
Pimpri, Pune-18, Mob-9850666401

14 SEP 2021

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ADVOCATE & NOTARY
GOVT. OF INDIA
198/969, Sant Tukaram Nagar,
Pimpri, Pune-18, Mob.-9850656404

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No. MHMC0002054821

Signature

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अवर सचिव (अटेस्टेशन / ओ.आई.)
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