FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration, M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-20 Sep 2024

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/138936/2024/11/51720**

On the basis of the inspection carried out on **25 & 26 July 2024** , 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 LTD**
   Address : **PLOT NO. P1 AND P2, I.T.B.T. PARK PHASE-II, M.I.D.C. HINJAWADI PUNE 411057 MAHARASHTRA STATE, INDIA**
2. Licence No. : **PD149 In Form 25, PD101 In Form 28**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Capsules	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
2	Liquid Injection (SVP)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
3	Tablets	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
4	Dry Powders for Suspensions/Syrups	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
5	Tablets	Hormones	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

MAHARASHTRA CHAMBER OF COMMERCE, INDUSTRIES & AGRICULTURE PUNE 05854 07 NOV 2024 MAHARASHTRA (INDIA)

MANDAR MOHAN MARATHE
MANAGER

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 19 Sep 2027 . 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
1CME111138936202411720
EMCURE PHARMACEUTICALS LTD - NEW-WHO-GMP/CERT/PD/138936/2024/11/51720

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

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:20 Sep 2024

FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

7 NOV 2024

SURAJ D KHADE
ADVOCATE & NOTARY
GOVT OF INDIA
198/969, Sant Tukaram Nagar
Pimpri, Pune-18. Mob. 9850566405

NOTARY GOVERNMENT OF INDIA SURAJ DHARMRAJ KHADE DISTRICT PUNE MAHARASHTRA


भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
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INDUSTRIES AND AGRICULTURE
Certified
at NEW DELHI, INDIA the 12-Nov-2024
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. MHMC0008020424
Seal / Stamp
Signature
is issued to EMCURE PHARMACEUTICALS LTD.
0I 2754901
विदेश मंत्रालय
MINISTRY OF EXTERNAL AFFAIRS
GOVT. OF INDIA, NEW DELHI
(पंकज कुमार)
(Pankal Kumar)
अनुभाग अधिकारी (सत्यापन / ओ.आई.)
Section Officer (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
05854
07 NOV 2024
MAHARASHTRA (INDIA)

MANDAR MOHAN MARATHE
MANAGER

7 NOV 2024

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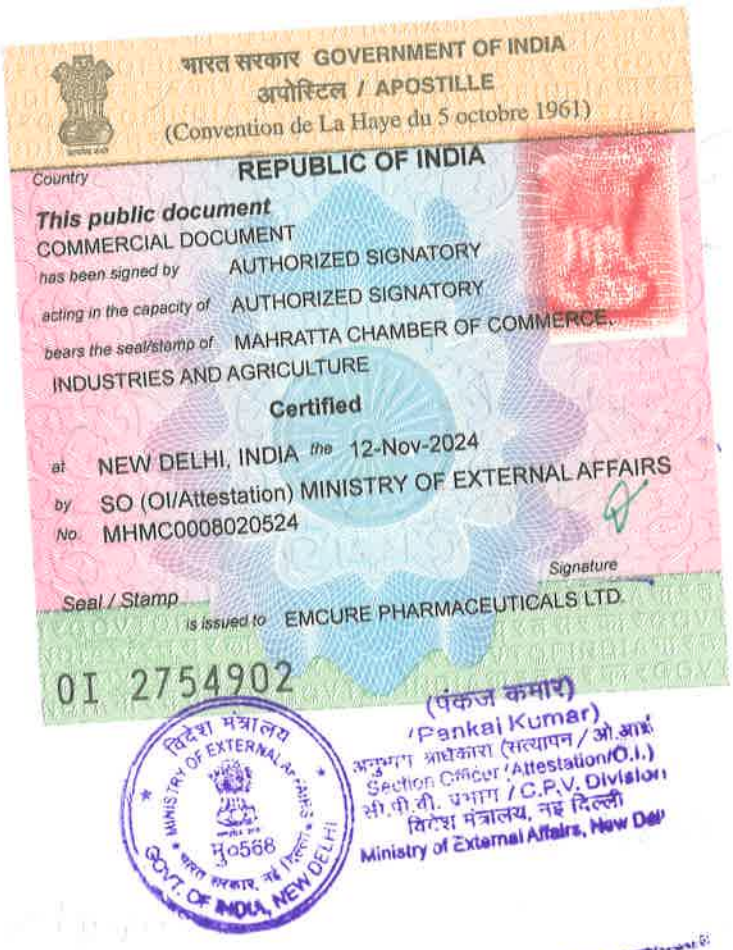
GOVT OF INDIA
198/969, Sant Tukaram Nagar
Pimpri, Pune-18, Mob-9850586405



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INDUSTRIES AND AGRICULTURE

Certified

at NEW DELHI, INDIA the 12-Nov-2024

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. MHMC0008020524

Signature

Seal / Stamp

is issued to EMCURE PHARMACEUTICALS LTD.

OI 2754902

(पंकज कुमार)
(Pankaj Kumar)
अनुभाग अधिकारी (सत्यापन / ओ.आई.)
Section Officer (Attestation/O.I.)
सी.पी.वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

विदेश मंत्रालय MINISTRY OF EXTERNAL AFFAIRS
Mo568
भारत सरकार, नई दिल्ली GOVT. OF INDIA, NEW DELHI

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/PD/138936/2024/11/51720 **VALID UP TO :19 Sep 2027**

Name of Manufacturing Firm : EMCURE PHARMACEUTICALS LTD
PLOT NO. P1 AND P2, I.T.B.T. PARK PHASE-II,
M.I.D.C. HINJAWADI PUNE 411057
MAHARASHTRA STATE, INDIA

Drug License No : PD149 In Form 25, PD101 In Form 28

Sr.No.	Name of the Product	Composition
121	Foseal – 800 Sevelamer Hydrochloride Tablets 800 mg	Each film coated tablet contains Sevelamer Hydrochloride 800 mg Excipients qs
122	Funguard 100 Itraconazole Capsules USP 100 mg	Each capsule contains Itraconazole USP 100 mg Excipients qs Colour:Approved colours used in the capsule shell.
123	Gamo S (-) Pantoprazole Tablets 20 mg	Each enteric coated tablet contains S (-) Pantoprazole Sodium Equivalent to S (-) Pantoprazole 20 mg Excipients qs Colour:Red Oxide of Iron, Yellow Oxide of Iron & Titanium Dioxide USP
124	Hongoitra 100 Itraconazole Capsules USP 100 mg	Each capsule contains Itraconazole USP 100 mg Excipients qs Colour:Approved colours used in the capsule shell.
125	INBEC Abacavir, Dolutegravir and Lamivudine Tablets (600/50/300 mg)	Each film coated tablet contains: Abacavir Sulphate USP equivalent to Abacavir 600 mg Dolutegravir Sodium equivalent to Dolutegravir 50 mg Lamivudine USP 300 mg Excipients qs Colour:Titanium Dioxide USP, Indigo Carmine Aluminum Lake
126	Infen-25 mg Dexketoprofen Tablets 25 mg	Each Film Coated Tablet Contains Dexketoprofen Trometamol equivalent to Dexketoprofen 25 mg Excipients qs Colour:Titanium Dioxide USP
127	INSTGRA Dolutegravir Tablets 50mg	Each Film Coated Tablet Contains Dolutegravir Sodium Equivalent to Dolutegravir 50 mg Excipients qs Colour:Titanium Dioxide USP, Indigo Carmine Aluminum Lake
128	Itraconazole Emcure Itraconazole Capsules USP 100mg	Each hard gelatin capsule contains Itraconazole USP 100 mg Excipients qs Colour:Approved colours used in the capsule shell.

... 11 12 13 14 15 16 17 18 19 20 ...

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Tel: +91-22-26592363/64
Fax: +91-22-26591959

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:**20 Sep 2024**

1CME11113893620240920
EMCURE PHARMACEUTICALS LTD - NEW-WHO-GMP/CERT/PD/138936/2024/11/51720

MAHARASHTRA CHAMBER OF COMMERCE INDUSTRIES & AGRICULTURE PUNE 058543 07 NOV 2024 MAHARASHTRA (INDIA)

M.M.Marathe MANDAR MOHAN MARATHE MANAGER

NOTARY GOVERNMENT OF INDIA SURAJ DHARMARAJ KHADE DISTRICT PUNE MAHARASHTRA

7 NOV 2024

SURAJ D KHADE
ADVOCATE & NOTARY
GOVT OF INDIA
198/969, Sant Tukaram Nagar
Pimpri, Pune-18, Mob 9890966405


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Signature
OI 2754903
(पंकज कमार)
(Pankaj Kumar)
अनुभाग अधिकारी (सत्यापन / ओ.आई.)
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GOVT. OF INDIA, NEW DELHI

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M.I.D.C. HINJAWADI PUNE 411057
MAHARASHTRA STATE, INDIA

Drug License No : PD149 In Form 25, PD101 In Form 28

Sr.No.	Name of the Product	Composition
193	Vonavir Efavirenz, Emtricitabine and Tenofovir Disoproxil Fumarate Tablets 600/200/300 mg)	Each film coated tablet contains Efavirenz USP 600 mg Emtricitabine 200 mg Tenofovir Disoproxil Fumarate ....300 mg Equivalent to Tenofovir Disoproxil 245 mg Excipients qs Colour:Titanium Dioxide USP
194	Xcepta Mycophenolate mofetil 500 mg film-coated tablets	Each film coated tablet contains Mycophenolate Mofetil Ph.Eur 500 mg Excipients qs Colour:Black Iron Oxide, Red Iron Oxide, Yellow Iron Oxide & Titanium Dioxide Ph. Eur.

... 16 17 18 19 20 21 22 23 24 25

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EMCURE PHARMACEUTICALS LTD - NEW-WHO-GMP/CERT/PD/138936/2024/11/51720

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:**20 Sep 2024**

NOTARY
SURAJ DHARMARAJ KHADE
DISTRICT PUNE
MAHARASHTRA
REG.NO.6468
EXP DATE 31/07/2028
GOVERNMENT OF INDIA

FOOD AND DRUG ADMINISTRATION
COMMISSIONER
MAHARASHTRA STATE

MAHARASHTRA CHAMBER OF COMMERCE, INDUSTRIES AND AGRICULTURE
PUNE
05 85 43
07 NOV 2024
MAHARASHTRA (INDIA)

M.M.Marathe

MANDAR MOHAN MARATHE
MANAGER

7 NOV 2024

SURAJ D KHADE
ADVOCATE & NOTARY
GOVT OF INDIA
198/869, Sant Tukaram Nagar
Pimpri, Pune-18, Mob-9850656495

17 NOV 2024

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Pimpri, Pune-18, Mob-9850666405

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Signature
OI 2754904

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मु०568

(पंकज कुमार)
(Pankaj Kumar)
अनुभाग अधिकारी (सत्यापन / ओ.आर.)
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