



Office of The Commissioner,
Food & Drugs Administration, M.S.
Bandra - Kurla Complex,
Bandra (E),
Mumbai - 400 051
Date :- 07 Sep 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/PD/118897/2022/11/41919**

On the basis of the inspection carried out on **06.07.2022** and **07.07.2022**, 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.

- 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**
- 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 06 Sep 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.

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: 07 Sep 2022

12 SEP 2022

Tel: +91-22-26002363/64
Fax: +91-22-26691859
1CME3121188912020007
EMCURE PHARMACEUTICALS LIMITED - NEW-
WHO-GMP/CERT/PD/118897/2022/11/41919



**P V SASIDHARAN
EXECUTIVE**

**SURAJ D. KHADE
ADVOCATE & NOTARY
GOVT. OF INDIA
198/969, Sant Tukaram Nagar,
Pimpri, Pune-18. Mob-985066640**



भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)

Country

REPUBLIC OF INDIA

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has been signed by D R GAHANE

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 16-Sep-2022

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. MHMC0011354022

Seal / Stamp

is issued to

EMCURE PHARMACEUTICALS LTD.

Signature

OI 436039



(संदीप कुमार)

(Sandeep Kumar)

सुभाष अधिकारी (सत्यापन / ऑ. अ.)
Attention Officer (Attestation / O. A.)
वि. पी. अ. वि. / 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 in 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.

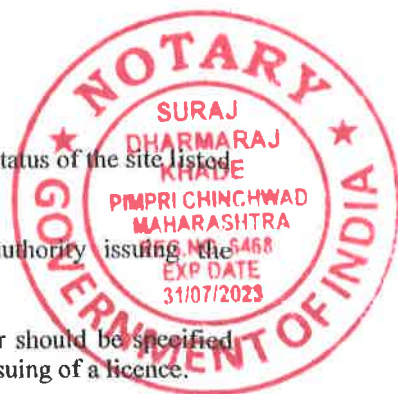
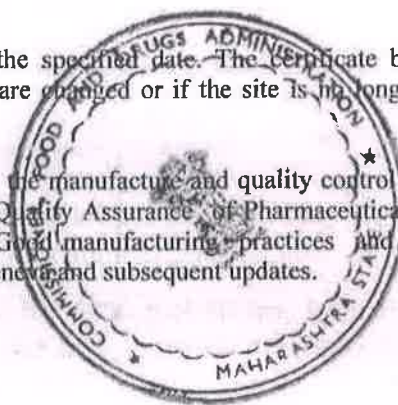
Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Starting material (s)2		
Paracetamol	Analgesic	Synthesis, Purification, Packing, Labelling.

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.



P V SASIDHARAN
EXECUTIVE



12 SEP 2022

SURAJ D. KHADE
ADVOCATE & NOTARY
GOVT. OF INDIA

198/969, Sant Tukaram Nagar,
Pimpri, Pune-18. Mob-9850666405



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D R GAHANE

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 16-Sep-2022

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. MHMC0011354122

Seal / Stamp

01 436040

is issued to

EMCURE PHARMACEUTICALS LTD.

Signature

(सतीश कुमार)
Sanjeev Kumar

सहायक अधिकारी (सत्यापन) / जॉ. ऑफ.
Section Officer (Attestation / O.T.)
सी. पी. डी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/PD/118897/2022/11 /41919
Name of Manufacturing 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
33	Benzphetamine Hydrochloride	Benzphetamine Hydrochloride
34	Bexarotene	Bexarotene
35	Busulfan Ph. Eur	Busulfan Ph. Eur
36	Busulfan USP	Busulfan USP
37	Carmustine Ph. Eur.	Carmustine Ph. Eur.
38	Carmustine USP	Carmustine USP
39	Cidofovir Dihydrate	Cidofovir Dihydrate
40	Cidofovir USP	Cidofovir USP



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

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Tel: +91-22-26592363/64
Fax: +91-22-26591959
1CME31211889720220907
EMCURE PHARMACEUTICALS LIMITED - NEW-
WHO-GMP/CERT/PD/118897/2022/11/41919

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: 07 Sep 2022



P V SASIDHARAN
EXECUTIVE

12 SEP 2022

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INDUSTRIES AND AGRICULTURE

Certified

at NEW DELHI, INDIA the 16-Sep-2022

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. MHMC0011354222

Signature

Seal / Stamp

is issued to EMCURE PHARMACEUTICALS LTD

OI 436041



(संजीव कुमार)
(Sanjeev Kumar)
Section Officer (Attestation) (O.I.)
ओ.पी.डी. प्रभाग / O.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

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/41919

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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



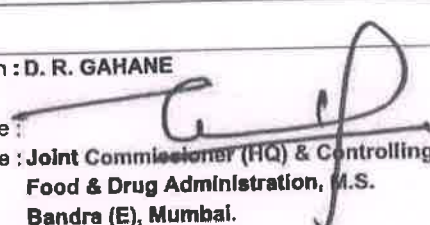
Sr.No.	Name of the Product	Composition
41	Cyclophosphamide USP	Cyclophosphamide USP
42	Decitabine Monohydrate.	Decitabine Monohydrate.
43	Dexketoprofen Trometamol	Dexketoprofen Trometamol
44	Dexmedetomidine Hydrochloride	Dexmedetomidine Hydrochloride
45	Docetaxel Trihydrate Ph.Eur	Docetaxel Trihydrate Ph.Eur
46	Docetaxel Trihydrate USP	Docetaxel Trihydrate USP
47	Dolutegravir Sodium	Dolutegravir Sodium
48	Esomeprazole Sodium	Esomeprazole Sodium



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

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Fax: +91-22-26591959
1CME31211889720220907
EMCURE PHARMACEUTICALS LIMITED - NEW-
WHO-GMP/CERT/PD/118897/2022/11/41919

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: 07 Sep 2022



P V SASIDHARAN
EXECUTIVE

12 SEP 2022

SURAJ D. KHADI
ADVOCATE & NOTARY
GOVT. OF INDIA
198/969, Sant Tukaram Nag
Pimpri, Pune-18. Mob-985066



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INDUSTRIES AND AGRICULTURE

Certified

at NEW DELHI, INDIA the 16-Sep-2022

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. MHMC0011354322

Seal / Stamp

is issued to

EMCURE PHARMACEUTICALS LTD.

Signature

01 436042



(संदीप कुमार)
(Sandeep Kumar)
एग. अधिकारी (सत्यापन / ओ.आई.)
Attestation Officer (Attestation / O.I.)
सी.पी.डी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

NOTARY
SURAJ
DHARMARAJ
KHADGE
D. R. GHANSHWAD
MAHARASHTRA
REG. NO. 6468
EXP. DATE
31/07/2023
GOVERNMENT OF INDIA

LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/PD/118897/2022/11 VALID UP TO: 06 Sep 2025
/41919

Name of Manufacturing 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,
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25F, PD119 In Form 28

Sr.No.	Name of the Product	Composition
49	Eszopiclone	Eszopiclone
50	Ethacrynic Acid USP	Ethacrynic Acid USP
51	Etodolac USP	Etodolac USP
52	Febuxostat	Febuxostat
53	Fingolimod Hydrochloride	Fingolimod Hydrochloride
54	Flecainide Acetate Ph.Eur.	Flecainide Acetate Ph.Eur.
55	Flecainide Acetate USP	Flecainide Acetate USP
56	Foscarnet Sodium Hexahydrate Ph.Eur.	Foscarnet Sodium Hexahydrate Ph.Eur.

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

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Fax: +91-22-26591959
1CME31211889720220907
EMCURE PHARMACEUTICALS LIMITED - NEW-
WHO-GMP/CERT/PD/118897/2022/11/41919

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: 07 Sep 2022



P V SASIDHARAN
EXECUTIVE

12 SEP 2022

SURAJ D. KHADGE
ADVOCATE & NOTARY
GOVT. OF INDIA

198/969, Sant Tukaram Nagar,
Pimpri, Pune-18. Mob-9850666405



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INDUSTRIES AND AGRICULTURE

Certified

at NEW DELHI, INDIA the 16-Sep-2022

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. MHMC0011354422

Seal / Stamp

is issued to

EMCURE PHARMACEUTICALS LTD.

01 436043

Signature



(Sandeep Kumar)
(नाम अधिकारी (सत्यापन / ओ. ए. ए.))
Section Officer (Attestation / O. E. A.)
ओ. ए. ए. विभाग / O. P. V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/PD/118897/2022/11 /41919

Name of Manufacturing 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
65	Leflunomide	Leflunomide
66	Leflunomide Ph.Eur.	Leflunomide Ph.Eur.
67	Leflunomide USP	Leflunomide USP
68	Lisinopril USP	Lisinopril USP
69	Melphalan Hydrochloride	Melphalan Hydrochloride
70	Metoclopramide Hydrochloride USP	Metoclopramide Hydrochloride USP
71	Midodrine Hydrochloride USP	Midodrine Hydrochloride USP
72	Mycophenolate Mofetil Ph. Eur.	Mycophenolate Mofetil Ph. Eur.



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

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
ICME31211889720220907
EMCURE PHARMACEUTICALS LIMITED - NEW -
WHO-GMP/CERT/PD/118897/2022/11/41919

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: 07 Sep 2022



P V SASIDHARAN
EXECUTIVE

12 SEP 2022

SURAJ D. KHAD
ADVOCATE & NOTARY
GOVT. OF INDIA
198/969, Sant Tukaram Nag
Pimpri, Pune-18, Mob-985066



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INDUSTRIES AND AGRICULTURE

Certified

at

NEW DELHI, INDIA the 16-Sep-2022

by

SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No.

MHMC0011354522

Seal / Stamp

is issued to

EMCURE PHARMACEUTICALS LTD.

Signature

(संदीप कुमार)

(Sandeep Kumar)

नृपाग अधिकारी (संस्थान / अ. अ.)
Section Officer (Attestation / C.O.)

जी.पी.ओ. विभाग / C.P.O. Division

विदेश मंत्रालय, नई दिल्ली

Ministry of External Affairs, New Delhi



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No. of certificate : NEW-WHO-GMP/CERT/PD/118897/2022/11 VALID UP TO 06 Sep 2023
/41919

Name of Manufacturing 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,
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Sr.No.	Name of the Product	Composition
81	Ritonavir USP	Ritonavir USP
82	Rizatriptan Benzoate Ph.Eur.	Rizatriptan Benzoate Ph.Eur.
83	Rizatriptan Benzoate USP	Rizatriptan Benzoate USP
84	Ropivacaine Hydrochloride USP	Ropivacaine Hydrochloride USP
85	S(-)Amlodipine Besilate Hemipentahydrate	S(-) Amlodipine Besilate Hemipentahydrate
86	S(-)Atenolol	S(-)Atenolol
87	S(-)Metoprolol Succinate	S(-)Metoprolol Succinate
88	S(-)Pantoprazole Sodium	S(-)Pantoprazole Sodium



... 4 5 6 7 8 9 10 11 12 13

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Fax: +91-22-26591959
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WHO-GMP/CERT/PD/118897/2022/11/41919

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
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P V SASIDHARAN
EXECUTIVE

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SURAJ D. KHADE
ADVOCATE & NOTARY
GOVT. OF INDIA
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No. MHMC0011354622

Seal / Stamp

Signature

is issued to EMCURE PHARMACEUTICALS LTD.

01 436045



(सतीश कुमार)
(Satish Kumar)
Section Officer (Attestation / O.T.)
ओ.पी.ओ. प्रभाग / O.P.V. Division
विदेश मंत्रालय, नई दिल्ली
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: 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,
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Sr.No.	Name of the Product	Composition
97	Trimethobenzamide Hydrochloride USP	Trimethobenzamide Hydrochloride USP
98	Zileuton USP	Zileuton USP
99	Zoledronic Acid	Zoledronic Acid
100	Zoledronic Acid Monohydrate Ph.Eur.	Zoledronic Acid Monohydrate Ph.Eur.
101	Zolmitriptan	Zolmitriptan



... 4 5 6 7 8 9 10 11 12 13

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Certified
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by **SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS**
No. **MHMC0011354722**

Seal / Stamp is issued to **EMCURE PHARMACEUTICALS LTD.**

Signature **(संदीप कुमार)**

01 436046



(संदीप कुमार)
Sandeep Kumar
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