



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: +91-22-26591959
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

LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/PD/86231/2019/11 VALID UP TO :23 Aug 2022
/29218
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
41	Ibandronate Sodium Monohydrate	Ibandronate Sodium Monohydrate
42	Ibutilide Fumarate	Ibutilide Fumarate
43	Irinotecan Hydrochloride USP	Irinotecan Hydrochloride USP
44	Iron Sucrose Complex	Iron Sucrose Complex
45	Iron Sucrose Complex Solution	Iron Sucrose Complex Solution
46	Ketorolac Trometamol Ph.Eur.	Ketorolac Trometamol Ph.Eur.
47	Ketorolac Tromethamine USP	Ketorolac Tromethamine USP
48	Leflunomide Ph.Eur.	Leflunomide Ph.Eur.

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



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Date: 24 Aug 2019

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