FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 01 MAR 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/KD/82148/2019/11/27049**

On the basis of the inspection carried out on **06/12/2018, 07/12/2018 and 19/01/2019** ,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 : **EMIL PHARMACEUTICAL INDUSTRIES PVT. LTD.**
   Address : **101, MANGALUM, KULUPWADI, BORIVALI (EAST) MUMBAI 400066**
   Manufacturing At : **PLOT NO. J-76, M.I.D.C., TARAPUR, BOISAR, THANE 401506 MAHARASHTRA STATE, INDIA**
2. Licence No. : **KD669A In Form 25A, KD780A In Form 28A**

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	Oral Powders / Granules / Pellets	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

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 12 Feb 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
UIME133821402019022?
EMIL PHARMACEUTICAL INDUSTRIES PVT. LTD. -
NEW-WHO-GMP/CERT/KD/82148/2019/11
/27049

Name of the Authorised person : A. T. NIKHADE
Signature :
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:27 Feb 2019

61236

27 FEB 2019

ATTESTED

AUTHORISED SIGNATORY
IMC CHAMBER OF COMMERCE AND INDUSTRY
MUMBAI-INDIA

JIGNA KOTHARI
Asst. Director

IMC CHAMBER OF COMMERCE AND INDUSTRY
18 MAR 2019
MUMBAI, INDIA

TRYAMBAK DONGARDIVE
GOVT. OF INDIA
Reg. No. 10302.
NOTARY

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,

Use, whenever available. Internation... nonproprietary names.

5. The certificate remains valid until ... activities and/or categories certified ... compliance with GMP.

6. The requirements for good practic... the certificate are those included ... guidelines and related material... 1999. World Health Organization ...

भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
Country
INDIA
This public document of the type
COMMERCIAL DOCUMENT
is issued to EMIL PHARMACEUTICAL INDUSTRIES PVT. LTD.
has been signed by JIGNA KOTHARI
with the seal / stamp of ASST. DIRECTOR, IMC CHAMBER OF COMMERCE & INDUSTRY, MUMBAI-INDIA
Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 25-Mar-2019 at NEW DELHI, INDIA
with reference no. MHMC00072179 19
Seal / Stamp
(भावना शर्मा)
(Bhavana Sharma)
Signature

GOVT. OF INDIA Reg. No. 10302 FIVE RUPEES NOTARY

GOVT. OF INDIA Reg. No. 10302 TWENTY RUPEES NOTARY

BY ME

JAGDISH TRYAMBAK DONGARDIVE
Advocate & Notary, (Govt. Of India)
Saraswati Chawl, Kranti Nagar,
Zopadpatti, Akurli Road,
Kandivali (E), Mumbai-400 101
(Maharashtra)

18 MAR 2019