



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

01 MAR 2019

INSTITUTO DE SALUD PUBLICA

Certifico que la presente
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MINISTRO DE FE

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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: +91-22-26592363/94
Fax: +91-22-26591956
TIME 1330214020190227
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

JIGNA KOTHARI



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 act
country

भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
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. MFIMC0007218019
Seal / Stamp

certificate becomes invalid if the
is no longer considered to be in

quality control of drugs referred to in
pharmaceuticals: a compendium of
practices and inspection. Volume 2,
Tables.

ATTESTED BY ME

JACOB TRAMBAK DONGARDIVE
Advocate & Notary, (Govt. Of India)
Saraswati Chawl, Kranti Nagar,
Zopadpatti, Akurli Road
Kandivali (E), Mumbai - 400 017
(Maharashtra)

18 MAR 2019