



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

11 8 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/78624/2019/11/27239**

On the basis of the inspection carried out on 13/12/2018, 14/12/2018 and 15/02/2019, 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.

- Name of the Firm : **KREMOINT PHARMA PVT. LTD.**
Address : **PLOT NO. B-8, ADDITIONAL AMBERNATH, MIDC, AMBERNATH (EAST), THANE 421806 MAHARASHTRA STATE, INDIA**
- Licence No. : **KD171 In Form 25, KD146 In Form 28**



Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	External Preparation (Ointments / Creams / Lotion/Gel)	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 13 Mar 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.

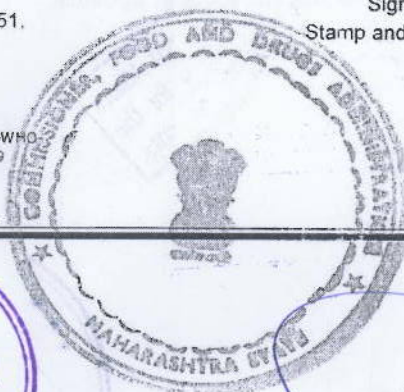
Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051,
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1ERK2057862420190314
KREMOINT PHARMA PVT. LTD. - NEW-WHO-GMP/CERT/KD/78624/2019/11/27239

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: 14 Mar 2019**



ATTESTED

AUTHORISED SIGNATORY
IMC CHAMBER OF COMMERCE AND INDUSTRY
MUMBAI-INDIA

SANJAY A. WAKHAR
Deputy Director



11 4 MAR 2019

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 g practices and inspection, Volume 2, at updates.

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 **KREMOINT PHARMA PVT LTD**

has been signed by **SANJAY A WAKHAR**

with the seal / stamp of **DY DIRECTOR, IMC CHAMBER OF COMMERCE, AND INDUSTRY, MUMBAI- INDIA**

Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 25-Apr-2019 at NEW DELHI, INDIA

Reference no. **MHMC0010102019**
(भावना शर्मा)
(Bhavana Sharma)
अधिकांश अधिकारी (ओ आई)
Section Officer (OI)
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

ATTESTED BY ME
S. M. H. ZAIDI
NOTARY
Government of India
Mumbai & Thane Dist.

13 0 APR 2019

