FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date 05 DEC 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.: **WHO-GMP/CERT/KD/90630/2019/11/30326**

On the basis of the inspection carried out on **23/10/2017, 24/10/2017 and 30/11/2017** 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 : **KOPRAN RESEARCH LABORATORIES LIMITED**

Address : **K-4/4, ADDITIONAL MIDC, POST BIRWADI, TAL. MAHAD, DIST. RAIGAD, RAIGAD 402302 MAHARASHTRA STATE, INDIA**

Licence No : **KD265 In Form 25, KD230 In Form 28**

Sr. No.	Dosage Form(s)	Category(ies)	Activity(ies)
1	Active Pharmaceutical Ingredients (Bulk Drugs)	Cephalosporins	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
3	Active Pharmaceutical Ingredients (Bulk Drugs)	Penems	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance
4	Granules	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance
5	Pellets	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 product manufactured through this process lies with the manufacturer.

The Certificate was valid upto 05 Dec 2019. The validity of this certificate has been extended for the period of six months and now the validity of this Certificate remains 05 Jun 2020. 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. +91-22-2659...
Fax. +91-22-26...

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 05 DEC 2019

J. D. RAWAL Notary Greater Mumbai

ATTESTED BY ME

05 DEC 2019

No 07791

IMC CHAMBER OF COMMERCE AND IN... 04 SEP 2020 MUMBAI, INDIA

ROHIT YADAV
Manager
ATTESTED
AUTHORISED SIGNATORY
IMC CHAMBER OF COMMERCE AND INDUSTRY
MUMBAI-INDIA

04 SEP 2020

Explanatory notes

1. This certificate which is in the format recommended by WHO, certifies the status of the facility 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 provided. Otherwise record "not applicable" in cases where there is no legal framework for the issuing of such 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 no longer considered to be in

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

The Ministry of External Affairs accepts no responsibility for the contents of above documents.

Country REPUBLIC OF INDIA

This public document
COMMERCIAL DOCUMENT
has been signed by V K BIYANI
acting in the capacity of JT. COMMISSIONER
bears the seal/stamp of IMC CHAMBER OF COMMERCE & INDUSTRY, MUMBAI-INDIA.

Certified
at NEW DELHI, INDIA the 11-Sep-2020
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. MHMC0003177720

Signature

Seal / Stamp

is issued to KOPRAN RESEARCH LABORATORIES LTD.

(SUNIL CHANAP)
अनुभाग अधिकारी (ओ. आई.)
Section Officer (OI)
सी. पी. वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

D. RAWAL NOTARY BOMBAY GREATER

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

7-5/2020/Misc/070
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi- 110002.
Dated:- 1/5/2020

To,

All States/UT Drugs Controllers

Subject: Extension of validity of WHO GMP/Certificate of Pharmaceutical Product (COPP) - Regarding

Sir/Madam

Certificate of Pharmaceutical Product (CoPP) is issued under the WHO GMP ...tification Scheme for the purpose of international commerce, i.e., for registration of ...ducts in foreign countries. Earlier the validity of CoPP was extended from 2 years to 3 ...rs vide Office Memorandum No. 7-5/2018/Misc/048 dated 08.05.2018.

This office has received representations from stakeholders requesting to extend ...dity of WHO GMP Certificate/CoPP whose validities are expiring between now and ...ust 2020 in view of COVID-19 outbreak.

The matter has been examined in light of current situation of COVID 19 outbreak and ...der to maintain the continuity of essential activities by the pharmaceutical industry, it has ...decided that validity of WHO GMP/CoPP expiring from March to August 2020 may be ...nded by 6 months from the date of expiry of the certificate as per WHO GMP ...ification guidelines..

No 07791

ATTESTED
AUTHORISED SIGNATORY
IMC CHAMBER OF COMMERCE AND INDUSTRY
MUMBAI-INDIA
ROHIT YADAV
Manager

IMC CHAMBER OF COMMERCE AND INDUSTRY
04 SEP 2020
MUMBAI, INDIA

Yours Faithfully,

Dr. V. G. Somani
...gs Controller General (India)

Copy to:

1- PS to JS (R), MoHFW, GOI, Nirman Bhawan, New Delhi
2- All Zonal, Sub-Zonal offices of CDSCO

ATTESTED BY ME
4 SEP 2020
J. D. RAWAL
Notary Greater Mumbai