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

Table 1

Sr.No.	Dosage Form(s)	Categor(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 products 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[illegible]64
Fax: +91-22-2659[illegible]55
KOPRAN RESEARCH LABORATORIES LIMITED
WHO-GMP/CERT/KD/90630/2019/11/30326

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

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

05 DEC 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 guidelines and related materials . Good manufacturing practices and inspection. Volume 2, 1999. World Health Organization, Geneva and subsequent updates.

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE