FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 11/5/2018

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/59163/2017/11/21723**

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.

This certificate remains valid until 05 Dec 2019 . 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: +91-22-26593764
Fax: +91-22-26591959

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:07 May 2018

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

07 MAY 2018

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.

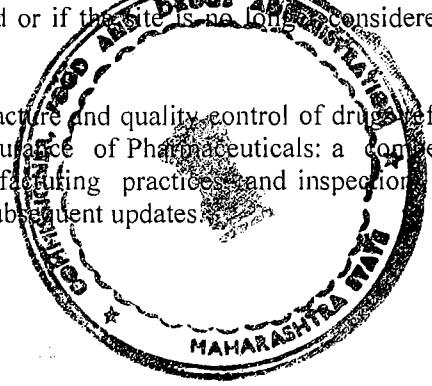
   Example - 2.

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.



LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

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Name of Manufactring Firm : KOPRAN RESEARCH LABORATORIES LIMITED
K-4/4, ADDITIONAL MIDC, POST BIRWADI, TAL. MAHAD, DIST. RAIGAD, RAIGAD 402302
MAHARASHTRA STATE, INDIA

Drug License No : KD265 In Form 25,
KD230 In Form 28

Sr.No.	Name of the Product	Composition
1	AMLODIPINE BESILATE BP	
2	AMLODIPINE BESILATE EP	
3	AMLODIPINE BESILATE IP	
4	AMLODIPINE BESYLATE USP	
5	ATENOLOL BP	
6	ATENOLOL EP	
7	ATENOLOL IP	
8	ATENOLOL USP	

1 2 3 4 5 6 7

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Fax: +91-22-26591959

Name of the Authorised person : A. T. NIKHADE

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
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Sr.No.	Name of the Product	Composition
9	AZITHROMYCIN BP	
10	AZITHROMYCIN EP	
11	AZITHROMYCIN IP	
12	AZITHROMYCIN USP	
13	CEFEPIME FOR INJECTION USP	
14	CEFEPIME INJECTION IP (STERILE)	
15	CEFOTAXIME SODIUM BP (STERILE)	
16	CEFOTAXIME SODIUM EP (STERILE)	
1 2 3 4 5 6 7		

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Sr.No.	Name of the Product	Composition
17	CEFOTAXIME SODIUM USP (STERILE)	
18	CEFOTAXIME SODIUM IP (STERILE)	
19	CEFTRIAXONE SODIUM BP (STERILE)	
20	CEFTRIAXONE SODIUM EP (STERILE)	
21	CEFTRIAXONE SODIUM IP (STERILE)	
22	CEFTRIAXONE SODIUM USP (STERILE)	
23	CLARITHROMYCIN CARBOMER COMPLEX COATED GRANULES 43.75%	Granules 43.75%
24	CLARITHROMYCIN EP	

1 2 3 4 5 6 7

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Sr.No.	Name of the Product	Composition
25	CLARITHROMYCIN GRANULES 27.5%	Granules 27.5%
26	CLARITHROMYCIN GRANULES 28%	Granules 28%
27	CLARITHROMYCIN GRANULES 33%	Granules 33%
28	CLARITHROMYCIN GRANULES 42%	Granules 42%
29	CLARITHROMYCIN GRANULES 43%	Granules 43%
30	CLARITHROMYCIN IP	
31	CLARITHROMYCIN USP	
32	DORIPENEM STERILE	

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Sr.No.	Name of the Product	Composition
33	LYMECYCLINE BP	
34	LYMECYCLINE EP	
35	MEROPENEM FOR INJECTION IP	
36	MEROPENEM FOR INJECTION USP	
37	METOPROLOL SUCCINATE BP	
38	METOPROLOL SUCCINATE EP	
39	METOPROLOL SUCCINATE IP	
40	METOPROLOL SUCCINATE USP	
1 2 3 4 5 6 7		

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Sr.No.	Name of the Product	Composition
41	METOPROLOL TARTRATE BP	
42	METOPROLOL TARTRATE EP	
43	METOPROLOL TARTRATE IP	
44	METOPROLOL TARTRATE USP	
45	OMEPRAZOLE BP	
46	OMEPRAZOLE IP	
47	OMEPRAZOLE PELLETS CONTAINING OMEPRAZOLE 8.5% W/W	Pellets 8.5% w/w
48	OMEPRAZOLE USP	

1 2 3 4 5 6 7

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Sr.No.	Name of the Product	Composition
49	PREGABALIN	
50	PREGABALIN BP	
51	PREGABALIN EP	
52	PREGABALIN IP	
53	ROXITHROMYCIN BP	
54	ROXITHROMYCIN EP	
55	ROXITHROMYCIN IP	
56	TICAGRELOR	

1 2 3 4 5 6 7

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