FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :
31 AUG 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/AD/67318/2018/11/24741**

On the basis of the inspection carried out on **15/05/2018 & 16/05/2018** ,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 : **IPCA LABORATORIES LIMITED**
   Address : **H-4, MIDC, WALUJ AURANGABAD AURANGABAD 431136 MAHARASHTRA STATE, INDIA**
2. Licence No. : **AD070 In Form 25**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Active Pharmaceutical Ingredients (Bulk Drugs)	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 27 Aug 2021 . 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: +91-22-2659236[illegible]
Fax: +91-22-2659[illegible]
ICPI41367318201[illegible]

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:28 Aug 2018

28 AUG 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]

No. of certificate : NEW-WHO-GMP/CERT/AD/67318/2018/11 /24741 **VALID UP TO :27 Aug 2021**

Name of Manufactring Firm : IPCA LABORATORIES LIMITED
H-4, MIDC, WALUJ AURANGABAD
AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD070 In Form 25

Sr.No.	Name of the Product	Composition
1	Aceclofenac BP	
2	Aceclofenac IP	
3	Aceclofenac Ph. Eur.	
4	Allopurinol JP	
5	Allopurinol BP	
6	Allopurinol IP	
7	Allopurinol Ph. Eur.	
8	Allopurinol USP	

1 2 3 4 5

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1CPI4136731820180828

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Sr.No.	Name of the Product	Composition
9	Atenolol BP	
10	Atenolol IP	
11	Atenolol Ph.Eur.	
12	Atenolol USP	
13	Chlortalidone BP	
14	Chlortalidone Ph.Eur.	
15	Chlorthalidone IP	
16	Chlorthalidone USP	

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Sr.No.	Name of the Product	Composition
17	Flumequine BP	
18	Flumequine(Flumequinum)Ph.Eur.	
19	Lumefantrine Ph. Int.	
20	Metformin Hydrochloride BP	
21	Metformin Hydrochloride CP	
22	Metformin Hydrochloride IP	
23	Metformin Hydrochloride JP	
24	Metformin Hydrochloride Ph. Eur.	

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Sr.No.	Name of the Product	Composition
25	Metformin Hydrochloride USP	
26	Metoprolol Tartrate BP	
27	Metoprolol Tartrate IP	
28	Metoprolol Tartrate Ph.Eur.	
29	Metoprolol Tartrate USP	
30	Oxantel Pamoate	
31	Piperaquine Phosphate	
32	Propranolol Hydrochloride BP	

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Sr.No.	Name of the Product	Composition
33	Propranolol Hydrochloride IP	
34	Propranolol Hydrochloride Ph.Eur.	
35	Propranolol Hydrochloride USP	
36	Pyrantel Pamoate IP	
37	Pyrantel Pamoate USP	

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