FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 21 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/KD/72365/2018/11/24339**

On the basis of the inspection carried out on **07/06/18 , 08/07/18 and 18/07/2018** ,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 : **CIRON DRUGS & PHARMACEUTICALS PVT. LTD.**
   Address : **N-118,118/1, 119,119/1,119/2,113 MIDC, TARAPUR, BOISAR, DIST. THANE 401506 MAHARASHTRA STATE, INDIA**
2. Licence No. : **KD80 in Form 25, KD74 in Form 28, KD/3 in Form 28B**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	External Preparation (Ointments / Creams / Lotion/Gel/Ear drop/Nasal drop/Spray)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
2	Eye / Ear Drops	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
3	Eye Drops / Ophthalmic Preparations	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
4	Inhalation	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
5	Liquid Injection (SVP)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
6	Liquid Orals	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
12			

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 01 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: +91-22-26592363/64
Fax: +91-22-26591558

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:16 Aug 2018

16 AUG 2018

NOTARY
Name G. H. Shukla
Area Gr. Mumbai
Reg. No. 121/84
GOVT. OF MAHARASHTRA

BOMBAY CHAMBER OF COMMERCE AND INDUSTRY
BOMBAY CHAMBER
1836

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.

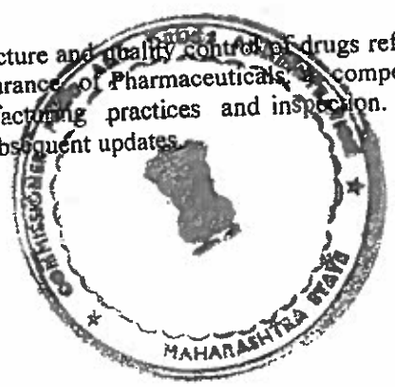
Example - 2.

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.



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2. Licence No. : **KD80 In Form 25, KD74 In Form 28, KD/3 In Form 28B**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
7	Lyophilised / Powder injectable	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
1 2			

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Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
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:16 Aug 2018

16 AUG 2018
A copy of this document / CERTIFICATE has been recorded with the Chamber

Authorised Signatory
Bombay Chamber of Commerce and Industry
Regn. No. 76 Date 2 APR 2019

Mr. [illegible] INFO
ASSISTANT MANAGER

H. Shukla Mumbai 121/84

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Example - 2.

Pharmaceutical Product (s)1	Category (ies)
Starting material (s)2	
Paracetamol	

Use, whenever availabl ise national nonproprietary names.

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