

Office of The Commissioner. Food & Drugs Administration M.S. Bandra - Kurla Complex, Bandra (E), Mumbai - 400 051 Date :-19 Jul 2021

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/103539/2021/11/36591

On the basis of the inspection carried out on 21.06.2021 & 22.06.2021 ,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.

Name of the Firm

CIRON DRUGS & PHARMACEUTICALS PVT.

Address

PLOT NOS. 35 TO 37, 43 TO 45 CFC-B, DIWAN

UDYOG NAGAR, ALIYALI, PALGHAR, THANE 401404 MAHARASHTRA STATE, INDIA

2. Licence No. KD656 In Form 25,

KD456 In Form 28

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies) Production, Filling, Packing, labelling, Quality Control, Quality Assurance	
1	Capsules	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)		
2	External Preparation (Ointments / Creams / Lotion/Gel)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance	
	Dry Powders for Suspensions/Syrups	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance	
4	Tablets	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance	
5 Liquid Orals		General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, 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 18 Jul 2024. 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:

Name of the Authorised person : D. R. GAHANE

Food & Drug Administration, M.S.

Bandra-kurla Complex,

Bandra (E), Mumbai - 400

Maharashtra, INDIA.

Tel: +91-22-2659236 Fax: +91-22-26591

1RIC1841035392021071 CIRON DRUGS & PHARN NEW-WHO-GMP/CERT/KD/103539

021/11/36591

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling

Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai. Maharashtra State, India

Date: 19 Jul 2021

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)		Print Model	
Tablets	Cytotoxic	Packaging	
HART	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	Signature and the		
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 grality control of drivereferred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a control of guidelines and related materials. Good manufacturing practices and inspection Volume 2, 1999. World Health Organization, Geneva and subsequent updates.



Office of The Commissioner, Food & Drugs Administration M.S. Bandra – Kurla Complex, Bandra (E), Mumbai – 400 051 Date:-29 Jul 2021

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/102753/2021/11/36838

On the basis of the inspection carried out on 01/07/2021&02/07/2021 ,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.

Name of the Firm

CIRON DRUGS & PHARMACEUTICALS PVT.

LTD

Address

N-118,118/1, 119,119/1,119/2,113 MIDC,

TARAPUR, BOISAR, PALGHAR 401506

MAHARASHTRA STATE, INDIA

2. Licence No.

KD80 In Form 25,

KD74 in Form 28, KD/3 in Form 28B

Table 1

Dosage Form(s)	Categor(jes)	Activity(ies)	
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	
Eye / Ear Drops	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance	
Eye Drops / Ophthalmic Preparations	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance	
Inhalation	General (Other than Cephalosporins, Penicillin,	Production, Filling, Packing, labelling, Quality Control, Quality Assurance	
Liquid Injection (SVP)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance	
iquid Orals	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance	
	External Preparation (Ointments / Creams / Lotion/Gel/Ear drop/Nasal drop/Spray) Eye / Ear Drops Eye Drops / Ophthalmic Preparations Inhalation Liquid Injection (SVP)	External Preparation (Ointments / Creams / Lotion/Gel/Ear drop/Nasal drop/Spray) General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones) General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	

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 28 Jul 2024. 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 authorities
Food & Drug Administration Vision

Bandra-kurla Complex, Bandra (E), Mumbai – 6051. Maharashtra.INDIA.

Tel: +91-22-26592363 Fax: +91-22-2659195

1RIC18310275320210729 CIRON DRUGS & PHARMACEU AND AVT. LTD. NEW-WHO-GMP/CERT/KD/102 2021/11 /36838 Name of the prised person : D. R. GAHANE

Signature :

and Date : Joint Commissioner (HQ) & Controlling

Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai. Maharashtra State, India

Date:29 Jul 2021



Office of The Commissioner, Food & Drugs Administration M.S. Bandra – Kurla Complex, Bandra (E), Mumbai – 400 051 Date:-29 Jul 2021

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(General instructions and explanatory notes attached).

Certificate No.: NEW-WHO-GMP/CERT/KD/102753/2021/11/36838

On the basis of the inspection carried out on 01/07/2021&02/07/2021 ,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, PALGHAR 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)
7	Lyophilised / Powder injectable	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
12			

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This certificate remains valid until 28 Jul 2024. 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: +91-22-26591959

TRIC18310275320210729
CIRON DRUGS & PHARMACEUTICALS PVT. LTD
NEW-WHO-GMP/CERT/KD/102753/2021/11

/36838

Name of the Authorised person: D. R. GAHANE

Signature:

Stamp and Date: Joint Commissioner (HQ) & Controlling

Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai. Maharashtra State, India

Date: 29 Jul 2021