



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. LTD.**
Address : **PLOT NOS. 35 TO 37, 43 TO 45 CFC-B, DIWAN UDYOG NAGAR, ALIYALI, PALGHAR, THANE 401404 MAHARASHTRA STATE, INDIA**
- Licence No. : **KD656 In Form 25,
KD456 In Form 28**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Capsules	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
2	External Preparation (Ointments / Creams / Lotion/Gel)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
3	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 :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591954
IRIC1841035392021071
CIRON DRUGS & PHARMACEUTICALS PVT. LTD. -
NEW-WHO-
GMP/CERT/KD/103539/2021/11/36591

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:19 Jul 2021**





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.

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)
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

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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 authority:
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400051,
Maharashtra, INDIA.
Tel: +91-22-26592363
Fax: +91-22-2659195
1RIC18310275320210729
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**



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.

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
<u>12</u>			

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 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
1RIC18310275320210729
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**



FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051
CERTIFICATE OF A PHARMACEUTICAL PRODUCT ¹

This certificate conforms to the format recommended by the World Health Organisation
 (General instructions and explanatory notes attached)

No. of certificate : **COPP/CERT/KD/108627/2021/11/38204/187024** Valid Upto : **28 Jul 2024**
Exporting Country : **INDIA**
Importing Country : **As per Annexure**
1. Name and dosage form of product : **BECAINE-5 INJECTION**
BUPIVACAINE INJECTION BP 5MG/ML (PRESERVATIVE FREE)

1.1 Active ingredient(s)² and amount (s) per unit dose³: Each ml contains:

Bupivacaine Hydrochloride BP Eq. to **Anhydrous Bupivacaine Hydrochloride 5 mg**

For complete qualitative composition including excipients :⁴

1.2 Is this product licensed to be placed on the market for use in the exporting country ?⁵ Yes No
1.3 Is this product actually on the market in the exporting country ? Yes No Unknown

2A.1 Number of product license:⁷ **KD74 In Form 28**
 and date of issue: **09 Apr 2007**
2A.2 Product License holder (Name and address) :
CIRON DRUGS & PHARMACEUTICALS PVT. LTD. N-118,118/1,
119,119/1,119/2,113 MIDC, TARAPUR, BOISAR, PALGHAR
401506 MAHARASHTRA STATE, INDIA
2A.3 Status of product-license Holder :⁸
 A B C
2A.3.1 For categories b and c the name and address of the manufacturer
 producing the dosage form is:⁹
2A.4 Is summary basis of Approval appended ?¹⁰
 Yes No
2A.5 Is the attached, officially approved product information complete and
 consonant with the license ?¹¹
 Yes No Not Provided
2A.6 Applicant for certificate if different from License holder :¹²
Not Applicable

2B.1 Applicant for certificate (name and address) :
2B.2 Status of applicant :
 A B C
2B.2.1 For categories b and c the name and address of the manufacturer
 producing the dosage form is:⁹
2B.3. Why is marketing authorization lacking ?

 Not required Not requested Under Consideration Refused
2B.4 Remarks :¹³



3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced ?
 if no or not applicable proceed to question 4. Yes No Not Applicable¹⁴

3.1 Periodicity of routine inspections(years) : **Once a year**
3.2 Has the manufacture of this type of dosage form been inspected ? Yes No
3.3 Do the facilities and operations conform to GMP as recommended by World Health Organisation ?¹⁵
 Yes No Not Applicable ¹⁴
4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?¹⁶
 Yes No

If no, explain :
 Address of certifying authority :
 Food & Drug Administration, M.S.
 Bandra-kurla Complex,
 Bandra (E), Mumbai – 400 051.
 Maharashtra,INDIA.
 Tel: +91-22-26592363/64/65
 Fax: +91-22-26591959
 SRIC18310862720211126101

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: **26 Nov 2021**

Food & Drugs Administration, Maharashtra State, Mumbai 400051, India
Annexure to the Certificate of a Pharmaceutical Product

No. of Certificate

: COPP/CERT/KD/108627/2021/11/38204/187024
CIRON DRUGS & PHARMACEUTICALS PVT. LTD.
N-118,118/1, 119,119/1,119/2,113 MIDC, TARAPUR, BOISAR,
: PALGHAR 401506 MAHARASHTRA STATE, INDIA
Name of the Product
: BECAINE-5 INJECTION
: BUPIVACAINE INJECTION BP 5MG/ML (PRESERVATIVE FREE)

Valid up to: 28 Jul 2024

Name of the Product License Holder
Name of the Product

List of Countries For Export

Afghanistan	Bosnia and Herzegovina	Czechoslovakia	Grenada	Kosovo	Micronesia	Philippines	South Sudan	Turkey
Albania	Botswana	Denmark	Guatemala	Kurdistan	Moldova	Poland	Spain	Turkmenistan
Algeria	Brazil	Djibouti	Guinea	Kuwait	Monaco	Porte Rico	Sri Lanka	Turks and Calicos
Andorra	British Virgin	Dominica	Guinea-Bissau	Kyrgyzstan	Mongolia	Portugal	St. Kitties	Tuvalu
Anglia	Brunei	Dominican Republic	Guyana	LaO PDR	Monsterrat	Qatar	st. Kitties and Nevi	Uganda
Angola	Brunei Darussalam	DR Congo	Haiti	Laos	Montenegro	R.D. Congo	St. Lucia	Ukraine
Anguilla	Bulgaria	East Timor	Herzegovina	Latvia	Morocco	Rep. of Congo	St. Maarten	UNHCR
Antigua	Burkina Faso	Ecuador	Holland	Lebanon	Mozambique	Reunion	St. Vincent	UNICEF
Antigua and Barbuda	Burundi	Egypt	Holy See	Leone	Myanmar	RITES	St. Vincent and the Grenadines	United Arab Emirates
Argentina	Cabo Verde	El Salvador	Honduras	Lesotho	Namibia	Romania	Sudan	United Kingdom
Armenia	Cambodia	England	Hong-Kong	Liberia	Nauru	Russia	Sultanate of Oman	United State
Aruba	Cameroon	Equatorial Guinea	Hungary	Libya	Nepal	Rwanda	Suriname	UNOPS
Australia	Canada	Eritrea	Iceland	Liechtenstein	Netherlands	Samao	Swaziland	Uruguay
Austria	Cape Verde	Estonia	India	Lithuania	New Zealand	San Marino	Sweden	Uzbekistan
Azerbaijan	Cayman Island	Ethiopia	Indonesia	Luxembourg	Nicaragua	Sao Tome and Principe	switzerland	Vanuata
Bahamas	Central African Republic	Fiji	Iran	Macau	Niger	Saudi Arabia	Syria	Vatican City
Bahrain	Chad	Fiji Island	Iraq	Macedonia	Nigeria	Senegal	Taiwan	Venezuela
Bangladesh	Chile	Finland	Ireland	Madagascar	North Korea	Serbia	Tajikistan	Vietiane
Barbados	China	France	Israel	Malawi	Norway	Seychelles	Tanzania	Vietnam
Belarus	Colombia	French Guiana	Italy	Malaysia	Oman	Sierra Leone	Tchad	Western Samoa
Belgium	Comoros	Gabon	Ivory Coast	Maldives	PAHO	Singapore	Thailand	WHO
Belize	Congo	Gambia	Jamaica	Mali	Pakistan	Slovakia	The Netherlands	Yemen
Belorussia	Costa Rica	Georgia	Japan	Malta	Palau	Slovenia	Timor Leste	Yugoslavia
Benin	Croatia	Germany	Jordan	Marshal Island	Palestine	Solomom Island	Togo	Zaire
Bermuda	Cuba	Ghana	Kazakhstan	Mauritania	Panama	Somalia	Tongo	Zambia
Bhutan	Curacao	Global Fund		Mauritius	Papua New Guinea	South Africa	Trinidad & Tobago	Zanzibar
Bolivia	Cyprus	Grand Cayman	Kiribati	GM	Paraguay	South Korea	Tunisia	Zimbabwe
Bosnia	Czechia	Guinea	Korea	Malta	Peru			

Address of certifying authority
Food & Drug Administration, M
Bandra-kurla Complex,
Bandra (E), Mumbai - 400 051
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
SRIC18310862720211126101



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: 26 Nov 2021



Ciron Drugs
& Pharmaceuticals Pvt. Ltd.

CORPORATE OFFICE : C-1101 / 1102, Lotus Corporate Park, Graham Firth Steel Compound, Jay Coach Junction, Western Express Highway, Goregaon (East), Mumbai - 400 063.
Tel.: +91-22-33598000 | Email: mail@cironpharma.com | www.cironpharma.com
(UNIT1) N-118, N-119, N-113, M.I.D.C., Tarapur, Boisar, Dist. Palghar - 401 506. Maharashtra, INDIA.
(UNIT 2) 35-37, 43-45, CFC-B, Dewan Udyog Nagar, Afiyali, Palghar, Dist. Palghar - 401 404. Maharashtra, INDIA.



CIN-U24246MH1990PTC056735

12th September 2023

TO WHOMSOEVER IT MAY CONCERN

We **CIRON DRUGS & PHARMACEUTICALS PVT. LTD.** Manufacturer of **VALGANCICLOVIR TABLET USP 450 MG** and have these product already enlisted in the **WHO - GMP list.**

We will process for application of valid COPP with our FDA once the tender is awarded and will share the same upon receipt from the FDA.

Request you to kindly consider our application.

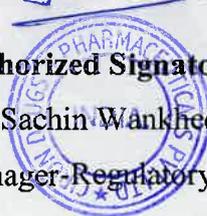
For Ciron Drugs and Pharmaceuticals Pvt. Ltd.

Sachin

Authorized Signatory

Mr. Sachin Wankhede

Manager-Regulatory Affairs



FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051

CERTIFICATE OF A PHARMACEUTICAL PRODUCT ¹

This certificate conforms to the format recommended by the World Health Organisation

(General instructions and explanatory notes attached)

No. of certificate : COPP/CERT/KD/109931/2022/11/38883/189855 Valid Upto :28 Jul 2024
Exporting Country : INDIA
Importing Country : As per Annexure
1. Name and dosage form of product : NITROGLYCERIN INJECTION USP

1.1 Active ingredient(s)² and amount (s) per unit dose³: Each ml contains

Diluted Nitroglycerin USP Eq. to Nitroglycerin 5 mg Ethanol USP 30 %

For complete qualitative composition including excipients :⁴

1.2 Is this product licensed to be placed on the market for use in the exporting country ?⁵ Yes [X] No []
1.3 Is this product actually on the market in the exporting country ? Yes [X] No [] Unknown []

2A.1 Number of product license:⁷ KD74 In Form 28 and date of issue: 10 Aug 2007
2A.2 Product License holder (Name and address) : CIRON DRUGS & PHARMACEUTICALS PVT. LTD. N-118,118/1, 119,119/1,119/2,113 MIDC, TARAPUR, BOISAR, PALGHAR 401506 MAHARASHTRA STATE, INDIA
2A.3 Status of product-license Holder :⁸ A [X] B [] C []
2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is:⁹
2A.4 Is summary basis of Approval appended ?¹⁰ Yes [] No [X]
2A.5 Is the attached, officially approved product information complete and consonant with the license ?¹¹ Yes [] No [] Not Provided [X]
2A.6 Applicant for certificate if different from License holder :¹² Not Applicable

2B.1 Applicant for certificate (name and address) :
2B.2 Status of applicant : A [] B [] C []
2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form is:⁹
2B.3. Why is marketing authorization lacking ? [] [] [] []
Not required Not requested Under Consideration Refused
2B.4 Remarks :¹³



3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced ? if no or not applicable proceed to question 4. Yes [X] No [] Not Applicable¹⁴ []

3.1 Periodicity of routine inspections(years) : Once a year
3.2 Has the manufacture of this type of dosage form been inspected ? Yes [X] No []
3.3 Do the facilities and operations conform to GMP as recommended by World Health Organisation ?¹⁵ Yes [X] No [] Not Applicable¹⁴ []
4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?¹⁶ Yes [X] No []

If no, explain :

Address of certifying authority : Food & Drug Administration, M.S. Bandra-kurla Complex, Bandra (E), Mumbai - 400 051. Maharashtra,INDIA. Tel: +91-22-26592363/64/65 Fax: +91-22-26591959 SRIC18310993120220116101

Name of the Authorised person : D. R. GAHANE

Signature : [Signature]
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority Food & Drug Administration, M.S. Bandra (E), Mumbai. Maharashtra State, India Date:16 Jan 2022

Food & Drugs Administration, Maharashtra State, Mumbai 400051, India
Annexure to the Certificate of a Pharmaceutical Product

No. of Certificate

: COPP/CERT/KD/109931/2022/11/38883/189855
CIRON DRUGS & PHARMACEUTICALS PVT. LTD.
 N-118,118/1, 119,119/1,119/2,113 MIDC, TARAPUR, BOISAR,

Valid up to: 28 Jul 2024

Name of the Product License Holder

: **PALGHAR 401506 MAHARASHTRA STATE, INDIA**

Name of the Product

: **NITROGLYCERIN INJECTION USP**

List of Countries For Export

Afghanistan	Bosnia and Herzegovina	Czechoslovakia	Grenada	Kosovo	Micronesia	Philippines	South Sudan	Turkey
Albania	Botswana	Denmark	Guatemala	Kurdistan	Moldova	Poland	Spain	Turkmenistan
Algeria	Brazil	Djibouti	Guinea	Kuwait	Monaco	Porte Rico	Sri Lanka	Turks and Calicos
Andorra	British Virgin	Dominica	Guinea-Bissau	Kyrgyzstan	Mongolia	Portugal	St. Kitties	Tuvalu
Anglia	Brunei	Dominican Republic	Guyana	LaO PDR	Monstserrat	Qatar	st. Kitties and Nevi	Uganda
Angola	Brunei Darussalam	DR Congo	Haiti	Laos	Montenegro	R.D. Congo	St. Lucia	Ukraine
Anguilla	Bulgaria	East Timor	Herzegovina	Latvia	Morocco	Rep. of Congo	St. Maarten	UNHCR
Antigua	Burkina Faso	Ecuador	Holland	Lebanon	Mozambique	Reunion	St. Vincent	UNICEF
Antigua and Barbuda	Burundi	Egypt	Holy See	Leone	Myanmar	RITES	St. Vincent and the Grenadines	United Arab Emirates
Argentina	Cabo Verde	El Salvador	Honduras	Lesotho	Namibia	Romania	Sudan	United Kingdom
Armenia	Cambodia	England	Hong-Kong	Liberia	Nauru	Russia	Sultanate of Oman	United State
Aruba	Cameroon	Equatorial Guinea	Hungary	Libya	Nepal	Rwanda	Suriname	UNOPS
Australia	Canada	Eritrea	Iceland	Liechtenstein	Netherlands	Samao	Swaziland	Uruguay
Austria	Cape Verde	Estonia	India	Lithuania	New Zealand	San Marino	Sweden	Uzbekistan
Azerbaijan	Cayman Island	Ethiopia	Indonesia	Luxembourg	Nicaragua	Sao Tome and Principe	switzerland	Vanuata
Bahamas	Central African Republic	Fiji	Iran	Macau	Niger	Saudi Arabia	Syria	Vatican City
Bahrain	Chad	Fiji Island	Iraq	Macedonia	Nigeria	Senegal	Taiwan	Venezuela
Bangladesh	Chile	Finland	Ireland	Madagascar	North Korea	Serbia	Tajikistan	Victiane
Barbados	China	France	Israel	Malawi	Norway	Seychelles	Tanzania	Vietnam
Belarus	Colombia	French Guiana	Italy	Malaysia	Oman	Sierra Leone	Tchad	Western Samoa
Belgium	Comoros	Gabon	Ivory Coast	Maldives	PAHO	Singapore	Thailand	WHO
Belize	Congo	Gambia	Jamaica	Mali	Pakistan	Slovakia	The Netherlands	Yemen
Belorussia	Costa Rica	Georgia	Japan	Malta	Palau	Slovenia	Timor Leste	Yugoslavia
Benin	Croatia	Germany	Jordan	Marshal Island	Palestine	Solomom Island	Togo	Zaire
Bermuda	Cuba	Ghana	Kazakhstan	Mauritania	Panama	Somalia	Tongo	Zambia
Bhutan	Curacao	Global Fund	Kenya	Mauritius	Papua New Guinea	South Africa	Trinidad & Tobago	Zanzibar
Bolivia	Cyprus	Grand Cayman	Kiribati	MCGM	Paraguay	South Korea	Tunisia	Zimbabwe
Bosnia	Czechia	Greece	Kuwait	Mexico	Peru			

Address of certifying authority
 Food & Drug Administration, M.S.
 Bandra-kurla Complex,
 Bandra (E), Mumbai - 400 051,
 Maharashtra, INDIA.
 Tel: +91-22-26592363/34
 Fax: +91-22-26591959
 SRIC1831099312022011610



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: 16 Jan 2022

FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051

CERTIFICATE OF A PHARMACEUTICAL PRODUCT ¹

This certificate conforms to the format recommended by the World Health Organisation (General instructions and explanatory notes attached)

No. of certificate : COPP/CERT/KD/110803/2022/11/39193/191213 Valid Upto :28 Jul 2024
Exporting Country : INDIA
Importing Country : NIGERIA
1. Name and dosage form of product : VANCOMYCIN HYDROCHLORIDE FOR INJECTION USP 500MG

1.1 Active ingredient(s)² and amount (s) per unit dose³: Each vial contains:

Vancomycin Hydrochloride USP Equivalent to Vancomycin 500 mg

For complete qualitative composition including excipients :⁴

1.2 Is this product licensed to be placed on the market for use in the exporting country ?⁵ Yes [X] No []

1.3 Is this product actually on the market in the exporting country ? Yes [X] No [] Unknown []

2A.1 Number of product license:⁷ KD74 In Form 28 and date of issue: 27 Sep 2012
2A.2 Product License holder (Name and address) : CIRON DRUGS & PHARMACEUTICALS PVT. LTD. N-118,118/1, 119,119/1,119/2,113 MIDC, TARAPUR, BOISAR, PALGHAR 401506 MAHARASHTRA STATE, INDIA
2A.3 Status of product-license Holder :⁸ A [X] B [] C []
2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is:⁹
2A.4 Is summary basis of Approval appended ?¹⁰ Yes [] No [X]
2A.5 Is the attached, officially approved product information complete and consonant with the license ?¹¹ Yes [] No [] Not Provided [X]
2A.6 Applicant for certificate if different from License holder :¹² Not Applicable

2B.1 Applicant for certificate (name and address) :
2B.2 Status of applicant : A [] B [] C []
2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form is⁹
2B.3. Why is marketing authorization lacking ? [] [] [] []
Not required Not requested Under Consideration Refused
2B.4 Remarks :¹³



3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced if no or not applicable proceed to question 4. Yes [X] No [] Not Applicable¹⁴ []

3.1 Periodicity of routine inspections(years) : Once a year

3.2 Has the manufacture of this type of dosage form been inspected ? Yes [X] No []

3.3 Do the facilities and operations conform to GMP as recommended by World Health Organisation ?¹⁵ Yes [X] No [] Not Applicable¹⁴ []

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?¹⁶ Yes [X] No []

If no, explain :

Address of certifying authority : Food & Drug Administration, M.S. Bandra-kurla Complex, Bandra (E), Mumbai - 400 051. Maharashtra, INDIA. Tel: +91-22-26592363/64/65 Fax: +91-22-26591959 5RIC18311080320220224101

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:24 Feb 2022