FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-**18 Jun 2024**

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/138078/2024/11/50635**

On the basis of the inspection carried out on **25.04.2024 AND 26.04.2024** ,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

1 2

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 17 Jun 2027 . 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: +91-22-26591979
1RIC183138078202406 8
CIRON DRUGS & PHARMACEUTICALS PVT. LTD. - NEW-WHO-GMP/CERT/KD/138078/2024/11/50635

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:**18 Jun 2024**

FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-**18 Jun 2024**

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.
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Certificate No.: **NEW-WHO-GMP/CERT/KD/138078/2024/11/50635**

On the basis of the inspection carried out on **25.04.2024 AND 26.04.2024** ,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
1 2			

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 17 Jun 2027 . 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
1RIC18313807820240618
CIRON DRUGS & PHARMACEUTICALS PVT. LTD. - NEW-WHO-GMP/CERT/KD/138078/2024/11/50635

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:**18 Jun 2024**

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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/140407/2024/11/51240/246132** **Valid Upto :17 Jun 2027**

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 dose [3]: 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 ☒ 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: **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 ☒ 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]

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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 Applicable**[14] ☐

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
5RIC1831404072024081497J

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:**14 Aug 2024**

Sri Lanka

Regulation 9

No. M-009765-FR

111607

National Medicines Regulatory Authority
Sri Lanka

Schedule III

CERTIFICATE OF REGISTRATION OF A MEDICINE

Generic Name : Verapamil Injection BP 2.5mg/ml

Brand Name : -

Dosage form : Injection Shelf Life : 24 Months

Pack Type : Amber Coloured Glass Ampoule

Pack Size(s) : 5 x 2ml, 10 x 2ml, 20 x 2ml

Name & Address of Manufacturer : Ciron Drugs & Pharmaceuticals Pvt.Ltd, No.118, 118/1, 119, 119/1, 119/2, 113, MIDC, Tharapur, Boisar, Dist Thane, 401506, Maharashtra State, India

Name & Address of Importer : Ceyoka (Pvt) Ltd, No.55, Negombo Rd, Peliyagoda

Registration No : M-009765-FR Date of Registration : 01.02.2022

Type of Registration : Full Period of Validity : From 01.02.2022 To 31.01.2027

Previous Registration No (if applicable) : M-005086-FR

Schedule : IIB

Maximum retail price per unit : LKR 717.00 per 2ml ampoule

Full registration shall be valid for a period of 5 years unless earlier suspended or cancelled.

Date of issue of certificate : 03.06.2022

Number and date of receipt for fees paid : T.I.N 056479
30.05.2022
M/2101/NP
IH

National Medicines Regulatory Authority

Chief Executive Officer
National Medicines Regulatory Authority
No.120, Norris Canal Road,
Colombo 10

This certificate is subject to conditions prescribed in Regulation 9 of the National Medicines (Registration and Licensing of

Sri Lanka

Regulation 9

No. M-012649-FR

157444

National Medicines Regulatory Authority
Sri Lanka

Schedule III

CERTIFICATE OF REGISTRATION OF A MEDICINE

Generic Name : Labetalol Hydrochloride Injection USP 5mg/ml

Brand Name : -

Dosage form : Solution for Injection Shelf Life : 36 Months

Pack Type : Amber Color Vial USP Type I

Pack Size(s) : 10 x 20 ml vial

Name & Address of Manufacturer : Ciron Drugs & Pharmaceuticals (Pvt) Ltd , N-118, 118/1, 119, 119/1, 119/2, 113 MIDC, Tarapur, Boisar, Palghar 401506, Maharashtra State, India

Name & Address of Importer : Ceyoka (Pvt) Ltd, No.55, Negombo Road, Peliyagoda,Sri Lanka

Registration No : M-012649-FR Date of Registration : 06.11.2023

Type of Registration : Full Period of Validity : From 06.11.2023 To 05.11.2028

Previous Registration No (if applicable) :

Schedule : IIB

Maximum retail price per unit : -

Full registration shall be valid for a period of 5 years unless earlier suspended or cancelled.

Date of issue of certificate : 15.11.2023

Number and date of receipt for fees paid : T.I.N.120171
13.11.2023
M/4556/RR-D/2023
IH

National Medicines Regulatory Authority

Deepika Bulathsinhala, MSc
Chief Executive Officer (Acting)
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

This certificate is subject to conditions prescribed in Regulation 9 of the National Medicines (Registration and Licensing of

Sri Lanka

Regulation 9

No. M-013496-FR

174940

National Medicines Regulatory Authority
Sri Lanka

Schedule III

CERTIFICATE OF REGISTRATION OF A MEDICINE

Generic Name : Metoprolol Injection BP 1 mg / ml

Brand Name : Xyprol - T

Dosage form : Injection Shelf Life : 24 Months

Pack Type : USP Type I Clear glass Ampoule

Pack Size(s) : 5 x 5ml

Name & Address of Manufacturer : Ciron Drugs and Pharmaceuticals (Pvt) Ltd, N-118, 118/1, 119, 119/1, 119/2, 113, MIDC, Tarapur, Boisar, Palghar, 401506, Maharashtra State, India.

Name & Address of Importer : Ceyoka (Pvt) Ltd., No 55, Negombo Road, Peliyagoda, Sri Lanka

Registration No : M-013496-FR Date of Registration : 11.05.2024

Type of Registration : Full Period of Validity : From 11.05.2024 To 10.05.2029

Previous Registration No (if applicable) :

Schedule : IIB

Maximum retail price per unit : -

Full registration shall be valid for a period of 5 years unless earlier suspended or cancelled.

Date of issue of certificate : 07.06.2024

Number and date of receipt for fees paid : T.I.N. 144005
27.05.2024
M/4531/RR-D/2023
DIL

National Medicines Regulatory Authority

Dr. Saveen Semage
MBBS, MSc, MD
Chief Executive Officer
National Medicines Regulatory Authority
120, Norris Canal Road,
Colombo 10.

This certificate is subject to conditions prescribed in Regulation 9 of the National Medicines (Registration and Licensing of Medicine) Regulations, 2019 made under the National Medicines Regulatory Authority Act, No. 5 of 2015 and shall be in force

DATOS GENERALES DEL PRODUCTO

Número de Registro Sanitario:	F000405012023
Nombre Comercial:	NITROGLICERINA CIRON 5 mg/mL SOLUCIÓN INYECTABLE
Estado:	Activo
Categoría:	Especialidades
Titular:	CIRON DRUGS & PHARMACEUTICALS PVT. LTD.

FABRICANTES

Nombre de Fabricante	País	Tipo	Anualidad	Renovación
CIRON DRUGS AND PHARMACEUTICALS PVT. LTD.(2)	INDIA	Principal	2023/12/31	2028/01/05

LABORATORIOS ACONDICIONADORES

NO SE ENCONTRARON DATOS

CLASIFICACIÓN

Clasificación:	VASODILATADOR USADO EN ENFERMEDAD CARDIACA, NITRATO ORGANICO

DATOS DE INTERES DEL PRODUCTO

PRINCIPIOS ACTIVOS

Principio Activo	**Unidad de medida**	**Concentración**
Nitroglicerina	mg.	5

FORMAS FARMACÉUTICAS

Forma Farmacéutica :	SOLUCION INYECTABLE
Indicaciones terapéuticas:	Cirugía: La inyección de nitroglicerina está indicada para: El control rápido de la hipertensión durante la cirugía cardíaca. Reducir la presión arterial y mantener la hipotensión controlada durante los procedimientos quirúrgicos. Controlar la isquemia miocárdica durante y después de la cirugía cardiovascular. Insuficiencia cardíaca congestiva que no responde: El trinitrato de glicerilo se puede usar para tratar insuficiencia cardíaca congestiva que no responde a infarto secundario agudo de miocardio. Angina inestable: El trinitrato de glicerilo se puede usar para tratar la angina inestable que es refractaria al tratamiento con betabloqueantes y nitratos sublinguales.
Mecanismo Acción:	
Régimen Dosificación:	
Farmacocinética:	
Efectos Adversos:	
Contraindicaciones:	
Precauciones:	
Principales Interacciones:	
Vida Útil:	24 MESES
Via de Administracíón:	INFUSION-INTRAVENOSA

PRESENTACIONES COMERCIALES	
Presentacion :	CAJA X 1 VIAL DE VIDRIO TIPO I AMBAR X 10 mL (PRESENTACIÓN COMERCIAL) + INSERTO, CON TAPON DE GOMA DE BROMOBUTILO GRIS CON SELLO AZUL
Presentacion :	CAJA X 10 AMPOLLA DE VIDRIO TIPO I AMBAR X 10 mL (PRESENTACIÓN COMERCIAL) + INSERTO

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/140120/2024/11/51159/245520** **Valid Upto :17 Jun 2027**

Exporting Country : INDIA

Importing Country : **As per Annexure**

1. Name and dosage form of product : **CLINDAMYCIN INJECTION BP**

1.1 Active ingredient(s)[2] and amount (s) per unit dose [3]: Each ml contains

Clindamycin phosphate BP Eq. to Clindamycin 150 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: **06 Oct 2017**

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 Applicable**[14] ☐

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
5RIC18314012020240802971

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:**02 Aug 2024**

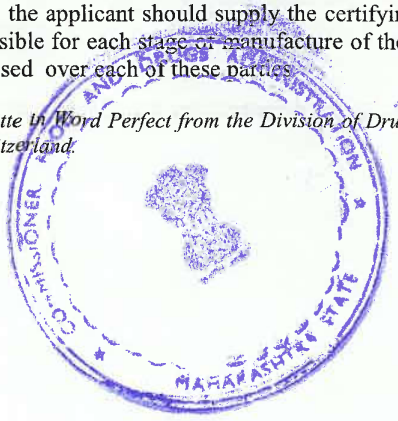
GENERAL INSTRUCTION :

Please refer to the guidelines for full instruction on how to complete this form and information on the implementation of the scheme.The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than hand written.Additional sheets should be appended, as necessary, to accommodate remarks and explanations .

EXPLANATORY NOTES :

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country .It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Names (INNS) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-Licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution, or administration of the product that is specified in the product Licence.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the Licence is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market :
   (a) manufactures the dosages form
   (b) packages and / or labels a dosage form manufactured by an independent company : or
   (c) is involved in none of the above .
9. This information can be provided only with the consent of the product - Licence holder or, in the case of non-registered products, the applicant . Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information.It should be noted that information concerning the site of production is part of the product Licence. If the production site is changed the Licence must be updated or it will cease to be valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as a summary of product characteristics (SPC).
12. In this circumstance, permission for issuing the certificate is required from the product Licence holder. This permission must be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration:
    (a) the product has been developed exclusively for the treatment of conditions – particularly tropical diseases – not endemic in the country of export:
    (b) the product has been reformulated with a view to improving its stability under tropical conditions:
    (c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import:
    (d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient
    (e) any other reason, please specify.
14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and Inspection is conducted under the aegis of the country of manufacture.
15. The requirements for good practices in the manufacture and quality control of drugs referred to the certificate are those included in the thirty- second report of the Expert Committee on specifications for Pharmaceutical Preparations (WHO Technical Report Series, No.823 , 1992 , Annex 1) Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series , No . 822, 1992, Annex 1).
16. The Section is to be completed when the product - licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product . In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form and the extent and nature of any controls exercised over each of these parties.

The layout for this Model Certificate is available on diskette in Word Perfect from the Division of Drug Management and Policies. World Health Organization, 1211 Geneva 27, Switzerland.



27-A

Food & Drugs Administration, Maharashtra State, Mumbai 400051, India

Annexure to the Certificate of a Pharmaceutical Product

No. of Certificate : COPP/CERT/KD/140120/2024/11/51159/245520 **Valid up to: 17 Jun 2027**

Name of the Product License Holder : 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 : CLINDAMYCIN INJECTION BP

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	Swedan	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	Kenya	Mauritius	Papua New Guinea	South Africa	Trinidad & Tobago	Zanzibar
Bolivia	Cyprus	Grand Cayman	Kiribati	MCGM	Paraguay	South Korea	Tunisia	Zimbabwe
Bosnia	Czechia	Greece	Korea	Mexico	Peru			

Address of certifying authority
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
5RIC18314012020240802977

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:02 Aug 2024

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/140120/2024/11/51159/245513** **Valid Upto :17 Jun 2027**

Exporting Country : INDIA

Importing Country : **As per Annexure**

1. Name and dosage form of product : **AMPHOTERICIN B FOR INJECTION USP**

1.1 Active ingredient(s)[2] and amount (s) per unit dose [3]: Each Lyophilized vial contains

Amphotericin B USP 50 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: **10 Feb 2010**

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 Applicable**[14] ☐

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
5RIC1831401202024080297J

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:**02 Aug 2024**

GENERAL INSTRUCTION :

Please refer to the guidelines for full instruction on how to complete this form and information on the implementation of the scheme.The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than hand written.Additional sheets should be appended, as necessary, to accommodate remarks and explanations .

EXPLANATORY NOTES :

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country .It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Names (INNS) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-Licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution, or administration of the product that is specified in the product Licence.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the Licence is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market :
   (a) manufactures the dosages form
   (b) packages and / or labels a dosage form manufactured by an independent company : or
   (c) is involved in none of the above .
9. This information can be provided only with the consent of the product - Licence holder or, in the case of non-registered products, the applicant . Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information.It should be noted that information concerning the site of production is part of the product Licence. If the production site is changed the Licence must be updated or it will cease to be valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as a summary of product characteristics (SPC).
12. In this circumstance, permission for issuing the certificate is required from the product Licence holder. This permission must be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration:
    (a) the product has been developed exclusively for the treatment of conditions – particularly tropical diseases – not endemic in the country of export:
    (b) the product has been reformulated with a view to improving its stability under tropical conditions:
    (c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import:
    (d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient
    (e) any other reason, please specify.
14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and Inspection is conducted under the aegis of the country of manufacture.
15. The requirements for good practices in the manufacture and quality control of drugs referred to the certificate are those included in the thirty- second report of the Expert Committee on specifications for Pharmaceutical Preparations (WHO Technical Report Series, No.823 , 1992 , Annex 1) Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series , No . 822, 1992, Annex 1).
16. The Section is to be completed when the product - licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product . In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form and the extent and nature of any controls exercised over each of these parties.

The layout for this Model Certificate is available on diskette in Word Perfect from the Division of Drug Management and Policies. World Health Organization, 1211 Geneva 27, Switzerland.

Food & Drugs Administration, Maharashtra State, Mumbai 400051, India

Annexure to the Certificate of a Pharmaceutical Product

No. of Certificate : COPP/CERT/KD/140120/2024/11/51159/245513 **Valid up to: 17 Jun 2027**

Name of the Product License Holder : 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 : AMPHOTERICIN B FOR 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	Swedan	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	Kenya	Mauritius	Papua New Guinea	South Africa	Trinidad & Tobago	Zanzibar
Bolivia	Cyprus	Grand Caytnan	Kiribati	MCGM	Paraguay	South Korea	Tunisia	Zimbabwe
Bosnia	Czechia	Greece	Korea	Mexico	Peru			

FOOD AND DRUGS ADMINISTRATION COMMISSIONER MAHARASHTRA STATE

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
5RIC18314012020240802970

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:**02 Aug 2024**

Your partner in progress

Ciron Drugs
& Pharmaceuticals Pvt. Ltd.

REGISTERED OFFICE : C-1101 / 1102, Lotus Corporate Park, Graham Firth Steel Compound, Jay Coach Junction, Western Express Highway, Goregaon (East), Mumbai - 400 063.
Tel.: +91-22-62748000 | Email: mail@cironpharma.com | www.cironpharma.com
(UNIT1) N-118, N-119, N-113, N-119/1 & N-119/2 M.I.D.C., Tarapur, Boisar, Dist. Palghar-401 506. Maharashtra, INDIA.
(UNIT2) 35-37, 43-45, CFC-B, Dewan Udyog Nagar, Aliyali, Palghar, Dist. Palghar - 401 404. Maharashtra, INDIA.
(RND CENTER) Plot No. W-198, TTC Ind. Area, MIDC Khairane, Navi Mumbai - 400709.
CIN-U24246MH1990PTC056735

TO WHOMSOEVER IT MAY CONCERN

Date: September 06th, 2024

DECLARATION FOR COPP

We, **Ciron Drugs & Pharmaceuticals Pvt. Ltd.** Manufacturer of following finished product.

1. Chlorhexidine Solution 50mg 100ml
2. Haloperidol decanoate injection 50mg
3. Vasopressin injection 20IU

Declare herewith that, currently we are unable to provide the COPP. 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 within 3-4 weeks.

Request you to kindly consider our application.

Thanking you.

Yours faithfully,

Ciron Drugs & Pharmaceuticals Pvt. Ltd.

INDIA.

Mr. Sachin Wankhede
Manager – Regulatory Affairs