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/110176/2022/11/39022/190144** **Valid Upto :18 Jul 2024**

Exporting Country : INDIA

Importing Country : **As per Annexure**

1. Name and dosage form of product : **CO-MAGALDROX TABLETS BP (MAGNESIUM HYDROXIDE AND ALUMINIUM HYDROXIDE TABLETS BP) (400MG+400MG)**

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

Magnesium Hydroxide BP 400 mg	Dried Aluminium Hydroxide BP 400 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] **KD656 In Form 25**
and date of issue: **29 Sep 2020**

2A.2 Product License holder (Name and address) :
CIRON DRUGS & PHARMACEUTICALS PVT. LTD. PLOT NOS. 35 TO 37, 43 TO 45 CFC-B, DIWAN UDYOG NAGAR, ALIYALI, PALGHAR, THANE 401404 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

4RIC1841101762022013010 1

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:**30 Jan 2022**

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

Annexure to the Certificate of a Pharmaceutical Product

No. of Certificate : **COPP/CERT/KD/110176/2022/11/39022/190144**

Valid up to: 18 Jul 2024

Name of the Product License Holder : **CIRON DRUGS & PHARMACEUTICALS PVT. LTD. PLOT NOS. 35 TO 37, 43 TO 45 CFC-B, DIWAN UDYOG NAGAR, ALIYALI, PALGHAR, THANE 401404 MAHARASHTRA**

Name of the Product : **STATE, INDIA**

: **CO-MAGALDROX TABLETS BP (MAGNESIUM HYDROXIDE AND ALUMINIUM HYDROXIDE TABLETS BP) (400MG+400MG)**

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
4RIC18411017620220130101

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:**30 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/113245/2022/11/40335/196712** **Valid Upto :28 Jul 2024**

Exporting Country : INDIA

Importing Country : **ZIMBABWE**

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
5RIC18311324520220516101

Name of the Authorised person : **G. B. BYALE**

Signature :

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

Your partner in progress

Ciron Drugs
& Pharmaceuticals Pvt. Ltd.

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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, Aliyali, Palghar, Dist. Palghar - 401 404. Maharashtra, INDIA.
CIN-U24246MH1990PTC056735

Date: 09/12/2022

TO WHOMSOEVER IT MAY CONCERN

We **M/s. CIRON DRUGS & PHARMACEUTICALS PVT. LTD.** Manufacturer of below product

- **Rabeprazole Sodium for Injection 20 mg/vials**

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.

FOR CIRON DRUGS AND PHARMACEUTICALS PVT. LTD.

CIRON DRUGS & PHARMACEUTICALS PVT. LTD. INDIA.

Mrs. Vigy Jyth
Authorized Signatory