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/109932/2022/11/38912/189854** **Valid Upto :28 Jul 2024**

Exporting Country : INDIA

Importing Country : **As per Annexure**

1. Name and dosage form of product : **ACICLOVIR SODIUM FOR INTRAVENOUS INFUSION BP**

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

Aciclovir Sodium	Equivalent to Aciclovir BP 250 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: **13 Apr 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
4RIC18310993220220123101

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:**23 Jan 2022**

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

Annexure to the Certificate of a Pharmaceutical Product

No. of Certificate : COPP/CERT/KD/109932/2022/11/38912/189854

Valid up to: 28 Jul 2024

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 : ACICLOVIR SODIUM FOR INTRAVENOUS INFUSION 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 :
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Fax: +91-22-26591959
4RIC18310993220220123101

Name of the Authorised person : D. R. GAHANE

Signature :

Stamp and Date :

FOOD AND DRUGS ADMINISTRATION COMMISSIONER MAHARASHTRA STATE

Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:23 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/109929/2022/11/38751/189664** **Valid Upto :28 Jul 2024**

Exporting Country : INDIA

Importing Country : **As per Annexure**

1. Name and dosage form of product : **LAREN**
CLARITHROMYCIN IV INJECTION

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

Clarithromycin BP 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: **09 Jul 2013**

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 :
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Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64/65
Fax: +91-22-26591959
4RIC18310992920220105101

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:**05 Jan 2022**

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

Annexure to the Certificate of a Pharmaceutical Product

Valid up to: 28 Jul 2024

No. of Certificate : **COPP/CERT/KD/109929/2022/11/38751/189664**

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 : **LAREN**

: **CLARITHROMYCIN IV INJECTION**

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	Kazakfistan	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			

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:**05 Jan 2022**

Address of certifying authority
Food & Drug Administration, M.S.
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4RIC18310992920220105101

CIR/KD/656/22-27/03

23.	TRAPAMEDIC / ACETAMINOPHEN AND TRAMADOL HYDROCHLORIDE TABLETS USP		Export (USP)
638918	*Each film coated tablet contains:*	*- Acetaminophen USP (325 mg)* *- Tramadol Hydrochloride USP (37.5 mg)* *- Colour : Approved colour used (-)*	
24.	PARACIR / ACETAMINOPHEN ORAL SOLUTION USP (PARACETAMOL DROPS 100MG/ML)		Export (USP)
731648	*Each ml contains:*	*- Acetaminophen USP (100 mg)* *- Colour : Approved colour used (-)*	
25.	ACETAMINOPHEN ORAL SUSPENSION IP (PARACETAMOL DROPS) 100mg/ml		Domestic (IP (USP~P.C~ACETAMINOPHEN ORAL SUSPENSION USP(PARACETAMOL DROPS) 100mg/ml))
646462	*Each ml contains:*	*- Paracetamol IP (100 mg/ml)* *- Carmoisine / Ponceau 4R / Tartrazine / Sunset Yellow (In House) (-)* *- In Flavored syrup base (-)*	
26.	ACETAMINOPHEN TABLETS USP		Export (USP)
67797	*Each uncoated tablet contains:*	*- Acetaminophen USP (500 mg)*	
27.	ACETAZOLAMIDE TABLETS USP		Export (USP)
103974	*Each uncoated tablet contains:*	*- Acetazolamide USP (250 mg)*	
28.	ACETYLCYSTEINE GRANULES		Domestic (IHS(In House))
68318	*Each sachet contains:*	*- Acetylcysteine BP (200 mg)*	
29.	ACICLOVIR CREAM BP		Export (BP)
595529	*Composition:*	*- Aciclovir BP (5 % W/W)*	
30.	CIROVIR – 200 TABLETS / ACICLOVIR TABLETS BP		Export (BP)
66583	*Each tablet contains:*	*- Aciclovir BP (200 mg)*	
31.	CIROVIR – 400 TABLETS / ACICLOVIR TABLETS BP		Export (BP)
66586	*Each tablet contains:*	*- Aciclovir BP (400 mg)*	
32.	ACICLOVIR TABLETS IP		Domestic (IP)
161819	*Each uncoated tablet contains:*	*- Aciclovir IP (200 mg)*	
33.	ACICLOVIR TABLETS IP		Domestic (IP)
161822	*Each uncoated tablet contains:*	*- Aciclovir IP (400 mg)*	
34.	ACYCLOVIR ORAL SUSPENSION IP 400MG/5ML		Domestic (IP)
519206	*Each 5 ml contains:*	*- Acyclovir IP (400 mg)* *- Carmoisine/Tartrazine/Sunset Yellow/Ponceau 4R (In House) (-)*	
35.	ACYCLOVIR TABLETS I.P. 800MG		Domestic (IP)
91909	*Each film coated tablets contains:*	*- Acyclovir IP (800 MG)* *- Colour : Titanium Dioxide*	
36.	Adefovir Dipivoxil Tablets IP 10mg		Domestic (IP)
522693	*Each uncoated tablet contains:*	*- Adefovir Dipivoxil IP (10 mg)*	
37.	ALBAZOL / ALBENDAZOLE ORAL SUSPENSION USP		Export (USP)
596859	*Each 5 ml contains:*	*- Albendazole USP (200 mg)*	
38.	WORMAZOLE SD / ALBENDAZOLE SUSPENSION 200MG/5ML		Export (IHS(In House))
811387	*Each 5ml contains:*	*- Albendazole USP (200 mg)*	
39.	ALBAZOL-200 / ALBENDAZOLE TABLETS		Export (IHS(In House))
1073	*Each chewable tablet contains:*	*- Albendazole USP (200 mg)*	
40.	REBOKZOL / ALBENDAZOLE TABLETS		Export (IHS(In House))
191056	*Each chewable tablet contains:*	*- Albendazole (400 mg)*	
41.	ALBENDAZOLE TABLETS IP 400MG		Domestic (IP)
659334	*Each uncoated chewable tablet contains:*	*- Albendazole IP (400 mg)* *- Colour : Erythrosine/Tartrazine/Sunset yellow/Ponceau 4R (-)*	
42.	ALBAZOL – 400 / ALBENDAZOLE TABLETS USP		Export (USP)
66590	*Each uncoated tablet contains:*	*- Albendazole USP (400 mg)*	
43.	ALBENDAZOLE TABLETS.		Export (IHS(In House))
66589	*Each chewable tablet Contains:*	*- Albendazole USP (400 MG)*	
44.	ALENDRONATE SODIUM TABLETS USP		Domestic (USP)
68049	*Each uncoated tablet contains:*	*- Sodium Alendronate USP* *- Eq. to Alendronic acid (70 MG)*	
45.	ALENDRONATE SODIUM TABLETS USP		Domestic (USP)
162175	*Each uncoated tablet contains:*	*- Sodium Alendronate USP (--)* *- Eq. to Alendronic acid (35 mg)*	
46.	ALLOPURINOL TABLETS BP		Export (BP)
16938	*Each uncoated tablet contains:*	*- Allopurinol BP (300 MG)*	
47.	ALLOPURINOL TABLETS BP		Export (BP)
66624	*Each uncoated tablet contains:*	*- Allopurinol BP (100 MG)*	
48.	ALLOPURINOL TABLETS I.P. 300MG		Domestic (IP)
91912	*Each uncoated tablet contains:*	*- Allopurinol IP (300 MG)*	
49.	ALLOPURINOL TABLETS IP		Domestic (IP)
68051	*Each uncoated tablet contains:*	*- Allopurinol IP (100 MG)*	
50.	ALPRAZOLAM TABLETS IP 0.25MG		Domestic (IP)

Fee Payment(s) : DB-Id: 433917 - 09/08/2022 (Amt: 935250) (Retention of kd-656 2022-2027) ,Balance : 21500

This License/Certificate is eSIGNED. Physical Signature is NOT Required

No. of Products: 1243 , No. of Ingredients: 2246

Division	MFG ID No	Type:License Renewal	License No	Issue Date
KONKAN (PL2)	705122	RNW-208075-09/08/2022	25-KD/656	22/08/2022

CIR/KD/74/22-26/62

681791	*Each ml contains:*	*- Paracetamol IP (75 mg)* *- Benzyl Alcohol IP (As preservative) (1 % V/V)*
1022. 36455	**PARACETAMOL IV SOLUTION (50ML VIAL)** *Each ml contains:*	**Export (IHS(In House) (~))** *- Paracetamol BP (1 % W/V)*
1023. 591824	**Pethidine Hydrochloride Injection IP 50mg/ml** *Each ml contains:*	**Domestic (IP)** *- Pethidine Hydrochloride IP (50 mg)* *- Water for injection IP (- QS)*
1024. 36214	**PHENIRAMINE MALEATE INJECTION IP** *Each ml contains:*	**Domestic (IP (IP~P.C))** *- Pheniramine Maleate IP (22.75 MG)*
1025. 36223	**PHENOBARBITAL INJECTION BP** *Each ml contains:*	**Export (BP (BP~P.C))** *- Phenobarbital Sodium BP (200 MG)*
1026. 682040	**MEDIBARB-30 / PHENOBARBITAL INJECTION BP** *Each ml contains:*	**Export (BP)** *- Phenobarbital Sodium BP (30 mg)*
1027. 36247	**PHENOBARBITAL SODIUM INJECTION USP** *Each ml contains:*	**Export (USP (~))** *- Phenobarbital Sodium USP (40 MG)*
1028. 36248	**PHENOBARBITAL SODIUM INJECTION USP** *Each ml contains:*	**Export (USP (~))** *- Phenobarbital Sodium USP (100 MG)*
1029. 703834	**PHENOBARBITAL SODIUM INJECTION USP 120MG/ML** *Each ml contains:*	**Export (USP)** *- Phenobarbital Sodium USP (120 mg)*
1030. 703835	**PHENOBARBITAL SODIUM INJECTION USP 30MG/ML** *Each ml contains:*	**Export (USP)** *- Phenobarbital Sodium USP (30 mg)*
1031. 63951	**PHENOBARBITONE SODIUM INJECTION IP** *Each ml contains:*	**Domestic (IP (~))** *- Phenobarbital Sodium IP (200 MG)*
1032. 121539	**PHENOBARBITONE SODIUM INJECTION IP** *Each ml Contains:*	**Domestic (IP (~))** *- Phenobarbitone Sodium IP (130 mg)*
1033. 35049	**PHENYLEPHRINE EYE DROPS BP** *Each ml contains:*	**Export (BP (BP~P.C))** *- Phenylephrine Hydrochloride BP (2.5 %)* *- Benzalkonium Chloride BP (0.01 %)*
1034. 574913	**PHENYLEPHRINE EYE DROPS BP** *Each ml contains:*	**Export (BP)** *- Phenylephrine Hydrochloride BP (10.0 % W/V)* *- Benzalkonium chloride NF (0.01 % W/V)*
1035. 35391	**Phenylephrine Eye Drops IP** *Each ml contains:*	**Domestic (IP (BP~P.C~PHENYLEPHRINE EYE DROPS BP))** *- Phenylephrine Hydrochloride IP (10.0 % W/V)* *- Benzalkonium Chloride IP (0.01 % W/V)*
1036. 37962	**PHENYLEPHRINE HYDROCHLORIDE INJECTION IP** *Each ml contains:*	**Domestic (IP (~))** *- Phenylephrine Hydrochloride IP (10 MG)*
1037. 36633	**PHENYLEPHRINE HYDROCHLORIDE INJECTION USP** *Each ml contains:*	**Export (USP (~))** *- Phenylephrine Hydrochloride USP (10 MG)*
1038. 35587	**PHENYLEPHRINE HYDROCHLORIDE OPHTHALMIC SOLUTION USP** *Each ml contains:*	**Export (USP (~))** *- Phenylephrine Hydrochloride USP (10.0 % W/V)* *- Benzalkonium Chloride NF (0.01 % W/V)*
1039. 37070	**PHENYLEPHRINE HYDROCHLORIDE OPHTHALMIC SOLUTION USP** *Composition:*	**Domestic (USP (~))** *- Phyenylephrine Hydrochloride IP (10 % W/V)* *- In buffered aqueous base (- QS)* *- Benzalkonium Chloride IP (0.01 % W/V)*
1040. 573961	**PHENYLEPHRINE HYDROCHLORIDE OPHTHALMIC SOLUTION USP** *Composition:*	**Export (USP)** *- Phenylephrine Hydrochloride USP (10 % W/V)* *- In buffered aqueous base (- QS)* *- Benzalkonium Chloride NF (0.01 % W/V)*
1041. 732297	**PHENYLEPHRINE HYDROCHLORIDE OPHTHALMIC SOLUTION USP 5% (PHENYLEPHRINE HYDROCHLORIDE EYE DROPS)** *Each ml contains:*	**Export (USP)** *- Phenylephrine Hydrochloride USP (50 mg)* *- Benzalkonium Chloride USP / NF (As Preservative) (0.1 mg)*
1042. 116299	**PHENYLEPHRINE HYDROCHLORIDE, NAPHAZOLINE HYDROCHLORIDE,MENTHOL AND CAMPHOR OPHTHALMIC SOLUTION.** *composition:*	**Domestic (IHS(In House) (~))** *- Phenylephrine Hydrochloride IP (0.12 % W/V)* *- Naphazoline hydrochloride USP (0.05 % W/V)* *- Menthol IP (0.005 % W/V)* *- Camphor IP (0.01 % W/V)* *- Benzalkonium Chloride Solution IP (0.01 % W/V)* *- (as preservative)* *- Sterile isotonic aqueous base (QS)*
1043. 737121	**PHENYTOIN (DIPHENYLHYDANTOIN) SODIUM POWDER FOR INJECTION 250MG** *Each vial contains:*	**Export (IHS(In House))** *- Phenytoin Sodium BP (250 mg)*
1044. 34639	**CIROTOIN INJECTION / PHENYTOIN INJECTION BP** *Each ml contains:*	**Export (BP (~))** *- Phenytoin Sodium BP (50 MG)* *- Propylene Glycol BP (40 % W/V)* *- ethanol BP (10 % V/V)* *- WATER FOR INJECTION BP (QS)*

Fee Payment(s) : DB-Id: 415748 - 11/12/2021 (Amt: 1653500) (CIRON RETENTION OF LIC KD-74 FROM 01.01.2022 TO 31.12.2026) ,Balance : 13450

This License/Certificate is eSIGNED. Physical Signature is NOT Required

No. of Products: 1318 , No. of Ingredients: 3488

Division	MFG ID No	Type:License Renewal	License No	Issue Date
KONKAN (TZ4)	705331	RNW-188238-11/12/2021	28-KD/74	03/01/2022

Your partner in progress

Ciron Drugs
& Pharmaceuticals Pvt. Ltd.

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(UNIT 2) 35-37, 43-45, CFC-B, Dewan Udyog Nagar, Aliyali, Palghar, Dist. Palghar - 401 404. Maharashtra, INDIA.

CIN-U24246MH1990PTC056735

01.02.2023

TO WHOMSOEVER IT MAY CONCERN

We **CIRON DRUGS & PHARMACEUTICALS PVT. LTD.** Manufacturer of
ALLOPURINOL TABLETS BP 100 mg & PHENYLEPHRINE INJECTION 10 mg

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.

Saevin
01/02/2023

Authorized Signatory