

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

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

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 28 Jul 2024 . It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP

Address of certifying authors Food & Drug Administration M.S.

Bandra-kurla Complex, Bandra (E), Mumbai – 10051.

Maharashtra,INDIA. Tel: +91-22-26592363 Fax: +91-22-2659195

Fax: +91-22-2659195 1RIC18310275320210729 CIRON DRUGS & PHARMACEUT 1475 AVT. LTD. -NEW-WHO-GMP/CERT/KD/1027 /2021/11 /36838 Name of the person : D. R. GAHANE

Signature:

and Date : Joint Commissioner (HQ) & Controlling

Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai. Maharashtra State, India Date:29 Jul 2021



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

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1. Name of the Firm

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LTD.

Address

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

TARAPUR, BOISAR, PALGHAR 401506

MAHARASHTRA STATE, INDIA

2. Licence No.

KD80 In Form 25,

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

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
7	Lyophilised / Powder injectable	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
12			<u>*</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

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) Valid Upto:28 Jul 2024 COPP/CERT/KD/125892/2023/11/45254/219460 No. of certificate **Exporting Country** INDIA Importing Country DOBUTAMINE INJECTION USP 1. Name and dosage form of product 1.1 Active ingredient(s)² and amount (s) per unit dose ³: Each ml contains Dobutamine Hydrochloride USP Eq. to Dobutamine 12.5 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 2B.1 Applicant for certificate (name and address) : and date of issue: 24 Mar 2019 2A.2 Product License holder (Name and address) 2B.2 Status of applicant: CIRON DRUGS & PHARMACEUTICALS PVT. LTD. N-118,118/1, 119,119/1,119/2,113 MIDC, TARAPUR, BOISAR, PALGHAR $A \square B \square C \square$ 401506 MAHARASHTRA STATE, INDIA 2B.2.1 For categories b and c the name and address of the manufacturer 2A.3 Status of product-license Holder :8 producing the dosage form is9 $A \boxtimes B \sqcup C \sqcup$ 2B.3. Why is marketing authorization lacking? 2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is:9 Not required Not requested Under Consideration Refused 2B.4 Remarks : 13 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** 3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the 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: Name of the Authorised person : MR BHUSHAN PATIL Address of certifying authority: Food & Drug Administration, M.S. Bandra-kurla Complex, Signature: Bandra (E), Mumbai - 400 051. Stamp and Date: Joint Commissioner (HQ) & Controlling Maharashtra, INDIA. Authority Tel: +91-22-26592363/64/65 Food & Drug Administration, M.S. Fax: +91-22-26591959 Bandra (E), Mumbai. 5RIC18312589220230515101 Maharashtra State, India Date:15 May 2023

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)

COPP/CERT/KD/106298/2021/11/37254/182461

No. of certificate

77	106298/2021/11/37254/182461 Valid Upto :28 Jul 2024
Exporting Country : INDIA	
Importing Country : As per Annexure 1. Name and dosage form of product : XYPROL-T INJEC METOPROLOL II	
1.1 Active ingredient(s) ² and amount (s) per unit dose ³ : Each ml c	
Metoproloi Tartrate BP 1 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 co	ountry ?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: RD74 In Form 28 and date of issue: 17 Sep 2004 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: A B C C 2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is: 2A.4 Is summary basis of Approval appended? 2A.5 Is the attached, officially approved product information complete and consonant with the license? Yes No Not Provided	2B.1 Applicant for certificate (name and address): 2B.2 Status of applicant: A B C 2 2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form is 2B.3. Why is marketing authorization lacking? Not required Not requested Under Consideration Refused 2B.4 Remarks: 13
2A.6 Applicant for certificate if different from License holder: 12 Not Applicable 3. Does the certifying authority arrange for periodic inspection of the manufacturi if no or not applicable proceed to question 4. Yes No Not Applicable 1.	
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 F. Yes No Not Applicable 14 4. Does the information submitted by the applicant satisfy the certifying authority Yes No No 	
If no, explain:	
Address of certifying authority: Name of the Author Food & Drug Administration, M.S. Bandra-kurla Complex, Bandra (E) Mumbai. 400 051	Signature: Inp and Date: Joint Commissioner (HQ) & Controlling Authority Food & Drug Administration, M.S. Bandra (E), Mumbai. Maharashtra State, India Date:16 Sep 2021
* 2	

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

No. of Certificate

: COPP/CERT/KD/106298/2021/11/37254/182461

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 License Holder Name of the Product

: XYPROL-T INJECTION : METOPROLOL INJECTION BP Valid up to: 28 Jul 2024

List of Countries For Export

			List of	Countries Fo	r 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	РАНО	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		Zanzibar
Bolivia	Cyprus	Grand Cayman		MCGM	Paraguay	1		Zimbabwe
Bosnia	Czechia	Greece	Korea	ferico	Peru		N	

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 5RIC18310629820210916101

Name of the Authorised person : D. R. GAHANE

Signature.

p and Date: Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai. Maharashtra State, India

Date:16 Sep 2021

FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051

	A PHARMACEUTICAL PRODUCT 1
	rmat recommended by the World Health Organisation tions and explanatory notes attached)
	RT/KD/109928/2022/11/38725/189660 Valid Upto :28 Jul 2024
Exporting Country : INDIA	1112), 103, 201 and 121 and 12
Importing Country : As per Ann	eviire
	IIL INJECTION BP 2.5MG/ML
1.1 Active ingredient(s) ² and amount (s) per unit dose ³ : Ea	
Verapamil Hydrochloride BP 2.5 mg	
For complete qualitative composition including excipients: ⁴	
1.2 Is this product licensed to be placed on the market for use in the ex	coorting country ? ⁵ Yes No
1.3 Is this product actually on the market in the exporting country? Yes	es 🖾 No 🗀 Unknown 🗀
2A.1 Number of product license: 7 KD74 In Form 28	2B.1 Applicant for certificate (name and address):
and date of issue: 18 Feb 2005	
2A.2 Product License holder (Name and address): CIRON DRUGS & PHARMACEUTICALS PVT. LTD. N-118,118	2B.2 Status of applicant :
119,119/1,119/2,113 MIDC, TARAPUR, BOISAR, PALGHAF	
401506 MAHARASHTRA STATE, INDIA	2B.2.1 For categories b and c the name and address of the manufacturer
2A.3 Status of product-license Holder .8	producing the dosage form is ⁹
A ⊠ B L C L	3D 2 Why is marketing outhorization looking 2
2A.3.1 For categories b and c the name and address of the manufactur	er 2B.3. Why is marketing authorization lacking?
producing the dosage form is:9	Not required Not requested Under Consideration Refused
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	2B.4 Remarks: 13
2A.4 Is summary basis of Approval appended? ¹⁰	
Yes No 2A.5 Is the attached, officially approved product information complete	te and
consonant with the license ? ¹¹	ic and
Yes No Not Provided	
2A.6 Applicant for certificate if different from License holder: 12	
Not Applicable	
3. Does the certifying authority arrange for periodic inspection of the n	
if no or not applicable proceed to question 4. Yes No Not A	pplicable ¹⁴
3.1 Periodicity of routine inspections(years) : Once a year	STATE STATE
3.2 Has the manufacture of this type of dosage form been inspected ? \mathbf{Y}	
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	ag authority on all aspects of the manufacture of the product ?16
Yes No	5
If no, explain:	A
Address of certifying authority : Name of t	he Authorised person : D. R. GAHANE
Food & Drug Administration, M.S.	P (1)
Bandra-kurla Complex,	Signature.
Bandra (E), Mumbai – 400 051.	Stamp and Date : Joint Commissioner (HQ) & Controlling
Maharashtra, INDIA.	Authority

Fax: +91-22-26591959

5RIC18310992820220105101

Food & Drug Administration, M.S.

Bandra (E), Mumbai. Maharashtra State, India

Date:05 Jan 2022

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

No. of Certificate

: COPP/CERT/KD/109928/2022/11/38725/189660

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 License Holder Name of the Product

: VERAPAMIL INJECTION BP 2.5MG/ML

Valid up to: 28 Jul 2024

List of Countries For Export

			LIST OF	Countries Fo	r 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	Swedań	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	Taṇzania	Vietnam
Belarus	Colombia	French Guiana	Italy	Malaysia	Oman	Sierra Leone	Tchad	Western Samoa
Belgium	Comoros	Gabon	Ivory Coast	Maldives	РАНО	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	OD AND	Mauritius	Papua New Guinea	South Africa	Trinidad & Tobago	Zanzibar
Bolivia	Cyprus	Grand Cayman	Kiribati -	CGM	Paraguay	South Korea	Tunisia	Zimbabwe
Bosnia	Czechia	Greek		Mèxico	Peru			

Address of certifying authority

Food & Drug Administration, M

Bandra-kurla Complex,

Bandra (E), Mumbai - 400 05

Maharashtra, INDIA.

Tel: +91-22-26592363/64 Fax: +91-22-26591959

5RIC18310992820220105101

Name of the phorised person : D. R. GAHANE

Signatu :

np and Date: Joint Commissioner (HO) & Controlling Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai.

Maharashtra State, India

Date: 05 Jan 2022









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, Bolsar, 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.

Date: 14th August 2023

CIN-U24246MH1990PTC056735

TO WHOMSOEVER IT MAY CONCERN

We, Ciron Drugs & Pharmaceuticals Pvt. Ltd. Manufacturer of below enlisted product:

- 1. Propranolol Injection BP 1 mg/ml
- 2. Vasopressin Injection USP 20 IU/ml

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.

Authorized Signat

Mr. Sachin Wankhede

Manager - Regulatory Affairs Department.