# GOVERNMENT OF TELANGANA DRUGS CONTROL ADMINISTRATION

Vengalarao Nagar, Hyderabad 500 038

## CERTIFICATE OF PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization (General Instructions and explanatory notes attached.)

Valid up to: 06/01/2022

No. of Certificate: 4912/DI/MLK/TST/COPP/05122020

Exporti	ng (certify	ing) country:	INDIA						
Importi	ng (reques	sting) country:	KAZAKHS	TAN					
1. Nan	ne and dos	sage form of the	product:	EPIRUE	BICIN HYDRO	OCHLORIDE	INJECTION U	SP 10 mg	10 mL/Vial
1.1 Acti	ive Ingred	ient (S)2 and amo	ounts (S) per u	mit dose <sup>3</sup>	:				
	Each m	L contains:							
		cin Hydrochlorid	le ph.Eur	TICD	5 mg				
	Excipien	Chloride nts		USP	9 mg q.s				
	Water fo	or Injection		USP	q.s				
1.2		roduct licensed to as appropriate)	be placed on	the mark	et for use in the	exporting count	ry? <sup>5</sup>		
	Yes	$\boxtimes$			No 🗆				
1.3	Is this pr	oduct actually or	n the market in	the expo	orting country?				
	Yes 🗵				No 🗌		Unknown		
	If the answer to 1.2 is yes, continue with section 2A and omit section 2B.								
	If the answer to 1.2 is no, omit section 2A and continue with section 2B6								
	SECTIO	ON 2A							
2.A.1	Number	of product Licen	ace <sup>7</sup> and date of	of issue:	22/RR/TS/201	5/F/G, Dated:	13.01.2015		
2.A.2	Product	license holder (N	Tame and addr	ess):	GLS PHARM Plot.No. 10,ID Jeedimetla, R.I Hyderabad, Te	A, Phase-I	A		
2.A.3	Status of	f product – licens	se holder <sup>8</sup> (Ke	y is appro	opriate category	as defined in no	ote (8)		
	a) 🛛			b) [	]	8	c) 🔲		
2A.3.1	For cate	gories b and c the	e name and ad	dress of the	he Manufacturer	producing the	dosage form is 9?		
	Yes			No [			Not applicable	$\boxtimes$	
2.A.4	Is summ	ary basis for app	roval appende	d <sup>10</sup> ? (er	closed at the tin	ne of product ap	proval)		
	Yes 🛛			No [			Not applicable [		
2.A.5		ached, officially appropriate)	approved pro	duct infor	mation complete	e and consonant	with the license?	.11	
2. A.6	Yes 🛭 Applicar	nt for certificate,	if different fro	No [ om license		& Address) <sup>12</sup>	Not applicable [		
	Yes 🗌			No [	⊠		Not applicable [		

2. B.1	Applicant for certificate (Name & address)								
2. B.2	2 Status of applicant: (Key in the appropriate category as defined in note 8)								
2. B.2.1	For cate	egories b and c the name and	address of	the manufacturer producing the	ne dosage from is <sup>9</sup> :				
2. B.3		marketing authorization lack uired / Not requested / under		on / Refused (Key in as appro	opriate)				
2. B.4	Remark	s: <sup>13</sup>							
3.		e certifying authority arrange produced?	e for period	ic inspection of the manufactu	uring plant in which the dosage				
	Yes			No 🗆	Not applicable 14				
	If not or	r not applicable, proceed to c	uestion 4.						
	Periodic	city of routine inspections (y	ears):	NOT LESS THA	N ONCE A YEAR				
	Has the	manufacturer of this type of	dosage for	m been inspected Yes/No (Ke	ey in as appropriate)				
	Yes			No 🗌	Not applicable				
	Do the	Do the facilities and operations conform to GMP as recommended by the World Health Organisation 15?							
	Yes			No 🗌	Not applicable				
4.	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacturer of the product ? <sup>16</sup>								
	Yes	$\boxtimes$		No 🗌	Not applicable				
	Address of certifying authority :			Office of the De Drugs Control Administr Hyderabad 500 038,	ation, Vengalarao Nagar,				
	Telepho	one and Fax numbers	:	TEL: +91 40 23814119	FAX: +91 40 23814360				
	Name of Authorized Person		:	Dr. B. VENKA	ΓESHWARLU				
	Signatu	re	<b>JO</b>	INT DIRECTOR & CI	ERTIFITING AUTHORITY				
	Stamp a	nd Date		المركبي Dr. B. VENKA	Stall20				
		STROLADMAN		JOINT DIRE					



DRUGS CONTROL ADMINISTRATION

# GOVERNMENT OF TELANGANA DRUGS CONTROL ADMINISTRATION

Vengalarao Nagar, Hyderabad 500 038

## CERTIFICATE OF PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization (General Instructions and explanatory notes attached.)

No. of C	Certificate	: 3825/A3/20	021			Valid up to: 1	1.01.2023
Exportin	ng (certify	ing) country: I	NDIA				
Importi	ng (reques	ting) country: M	IOLDOVA				
1. Nan	ne and dos	age form of the p	product: IFOS		E FOR INJECTION USP 1g		
1.1 Acti	ve Ingredi	ent (S) <sup>2</sup> and amo	ounts (S) per un	it dose <sup>3</sup> :	SI .		
	Each Via Ifosfami	l Contains: de	USP	1000 1	mg		
1.2		roduct licensed to as appropriate)	o be placed on	the mark	et for use in the exporting cour	ntry? 5	
	Yes	$\boxtimes$			No 🔲		
1.3	Is this p	oduct actually o	n the market in	the expo	orting country?		
	Yes	$\boxtimes$			No 🗌	Unknown	
	If the an	swer to 1.2 is ye	s, continue with	n section	2A and omit section 2B.		
	If the an	swer to 1.2 is no	, omit section 2	2A and co	ontinue with section 2B6		
5	SECTION	1 2A					
2.A.1	Number	of product Licer	nce <sup>7</sup> and date o	f issue:	22/RR/TS/2015/F/G, Dated	: 13.01.2015	
2.A.2	Product	license holder (N	Name and addre	ess):	GLS PHARMA LIMITED Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, IND		
2.A.3	Status of	f product – licen	se holder8 (Ke	y is appro	opriate category as defined in	note (8)	
	a) 🛛			b) [	]	c) 🔲	
2A.3.1	For cate	gories b and c th	e name and add	dress of th	he Manufacturer producing the	e dosage form is	9?
	Yes			No [		Not applicable	$\boxtimes$
2.A.4	Is summ	ary basis for app	proval appended	i <sup>10</sup> ? (en	closed at the time of product a	approval)	
	Yes 🛛			No [		Not applicable	
2.A.5	Is the att (key as	ached, officially appropriate)	approved prod	luct infor	mation complete and consonar	nt with the licens	se? <sup>11</sup>
2. A.6	Yes 🛭 Applicar		if different fro	No [ m license	holder (Name & Address) <sup>12</sup>	Not applicable	
	Yes 🗌			No 2	⊲	Not applicable	

2. B.1	Applicant for certificate (Name & address)						
2. B.2	Status of applicant: (Key in the appropriate category as defined in note 8)						
2. B.2.1	1 For categories b and c the name and address of the manufacturer producing the dosage from is 9:						
2. B.3	Why is marketing authorization lacking? Not required / Not requested / under consideration / Refused (Key in as appropriate)						
2. B.4	Remarks: 13						
3.		ne certifying authority arrange produced?	e for periodi	c inspection of the manufactu	uring plant in which the dosage		
	Yes	$\boxtimes$		No 🗆	Not applicable 14		
	If not o	r not applicable, proceed to q	uestion 4.				
	Periodi	city of routine inspections (ye	ears):	NOT LESS THA	N ONCE A YEAR		
	Has the	manufacturer of this type of	dosage form	n been inspected Yes/No (Ke	y in as appropriate)		
	Yes			No 🗌	Not applicable		
	Do the	facilities and operations conf	orm to GMI	as recommended by the Wo	rld Health Organisation <sup>15</sup> ?		
	Yes			No 🗌	Not applicable		
4.		ne information submitted by t cturer of the product ? <sup>16</sup>	he applicant	satisfy the certifying authori	ty on all aspects of the		
	Yes			No 🗌	Not applicable		
	Address	s of certifying authority	2	Office of the De Drugs Control Administr Hyderabad 500 038,	ation, Vengalarao Nagar,		
	Telepho	one and Fax numbers	:	TEL: +91 40 23814119	FAX: +91 40 23814360		
	Name o	of Authorized Person	:				
					/EEN KUMAR. IRECTOR(FAC)		
				LICENSING & CO	ONTROLING AUTHORITY		
		Signature HYDERABAD JD(FAC) Stamp and Date	:	Dr. Y. NAVEEN  Joint Director (Enf. Licensing & Controlling Drugs Control Adr. Government of Hyderabad-500	pharm.,Ph.D orcement) Authority (FAC) ministration		

## CERTIFICATE OF PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization (General Instructions and explanatory notes attached.)

No. of C	ertificate : 3826/A3/2021			Valid up to: 11.01.2023			
Exportin	g (certifying) country: INDIA						
Importin	g (requesting) country: MOLDOV	A					
1. Nam	e and dosage form of the product: L	EUPROLID ROLEMAX		NJECTION 3.75 mg			
1.1 Activ	e Ingredient (S) <sup>2</sup> and amounts (S) per	unit dose <sup>3</sup> :					
	Each Lyophilized vial contains						
	Leuprolide Acetate		75 mg				
	Excipients  1 mL Ampoule of Solvent contains	q.s	5				
	Each Sterile ampoule contains:	TIOD .					
	Sodium Carboxymethyl Cellulose Mannitol		mg mg				
	Polysorbate 80 Water for Injection		mg				
62020	70	1		- 5			
1.2	Is this product licensed to be placed (Key in as appropriate)	on the marke	et for use in the exporting cour	ntry?			
	Yes		No 🗌				
1.3	Is this product actually on the marke	et in the expo	orting country?				
	Yes 🛛		No 🗌	Unknown			
	If the answer to 1.2 is yes, continue with section 2A and omit section 2B.						
	If the answer to 1.2 is no, omit secti	on 2A and co	ontinue with section 2B6				
S	ECTION 2A						
2.A.1	Number of product Licence <sup>7</sup> and da	te of issue:	22/RR/TS/2015/F/R, Dated:	19.04.2018			
2.A.2	Product license holder (Name and a	ddress):	GLS PHARMA LIMITED Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, INDI				
2.A.3	Status of product – license holder <sup>8</sup>	(Key is appro	opriate category as defined in a	note (8)			
	a) 🔀	b) [	]	c) 🔲			
2A.3.1	For categories b and c the name and	address of th	he Manufacturer producing the	e dosage form is <sup>9</sup> ?			
	Yes	No [		Not applicable			
2.A.4	Is summary basis for approval appear	nded <sup>10</sup> ? (en	aclosed at the time of product a	approval)			
	Yes 🛛	No [		Not applicable			
2.A.5	Is the attached, officially approved p (key as appropriate)	product infor	mation complete and consonar	nt with the license?11			
2. A.6	Yes Applicant for certificate, if different	No [ from license	holder (Name & Address) <sup>12</sup>	Not applicable			
	Yes	No [	⊴	Not applicable			

2. B.1	Applicant for certificate (Name & address)						
2. B.2	Status of applicant: (Key in the appropriate category as defined in note 8)						
2. B.2.1	1 For categories b and c the name and address of the manufacturer producing the dosage from is 9:						
2. B.3	Why is marketing authorization lacking? Not required / Not requested / under consideration / Refused (Key in as appropriate)						
2. B.4	Remarks: 13						
3.		ne certifying authority arrange produced?	e for periodi	c inspection of the manufactu	uring plant in which the dosage		
	Yes	$\boxtimes$		No 🗆	Not applicable 14		
	If not o	r not applicable, proceed to q	uestion 4.				
	Periodi	city of routine inspections (ye	ears):	NOT LESS THA	N ONCE A YEAR		
	Has the	manufacturer of this type of	dosage form	n been inspected Yes/No (Ke	y in as appropriate)		
	Yes			No 🗌	Not applicable		
	Do the	facilities and operations conf	orm to GMI	as recommended by the Wo	rld Health Organisation <sup>15</sup> ?		
	Yes			No 🗌	Not applicable		
4.		ne information submitted by t cturer of the product ? <sup>16</sup>	he applicant	satisfy the certifying authori	ty on all aspects of the		
	Yes			No 🗌	Not applicable		
	Address	s of certifying authority	2	Office of the De Drugs Control Administr Hyderabad 500 038,	ation, Vengalarao Nagar,		
	Telepho	one and Fax numbers	:	TEL: +91 40 23814119	FAX: +91 40 23814360		
	Name o	of Authorized Person	:				
					/EEN KUMAR. IRECTOR(FAC)		
				LICENSING & CO	ONTROLING AUTHORITY		
		Signature HYDERABAD JD(FAC) Stamp and Date	:	Dr. Y. NAVEEN  Joint Director (Enf. Licensing & Controlling Drugs Control Adr. Government of Hyderabad-500	pharm.,Ph.D orcement) Authority (FAC) ministration		

## CERTIFICATE OF PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization (General Instructions and explanatory notes attached.)

Valid up to: 11.01.2023

No. of Certificate: 3827/A3/2021

Exportir	ng (certify	ing) country:	INDIA			
Importin	ng (reques	ting) country:	VENEZU	ELA		
1. Nam	ne and dos	age form of th		LOMUSTIN LOMCAP 4	E CAPSULES 40 n	ng
1.1 Acti	ve Ingredi	ient (S) <sup>2</sup> and a	nounts (S)	per unit dose <sup>3</sup>	£	
	Each ca	psule contain	WE 1722			
	Lomust			40 mg		
	Excipeir	nts		q.s		
1.2		roduct license as appropriat		ed on the mark	et for use in the expor	rting country? 5
	Yes				No 🔲	
1.3	Is this p	roduct actually	on the mar	ket in the expe	orting country?	
	Yes	$\boxtimes$			No 🗌	Unknown
	If the an	swer to 1.2 is	yes, continu	e with section	2A and omit section	2B.
	If the an	swer to 1.2 is	no, omit sec	ction 2A and co	ontinue with section 2	B6
5	SECTION	N 2A				
2.A.1	Number	of product Lie	cence <sup>7</sup> and o	late of issue:	22/RR/TS/2015/F/C	G, Dated: 13.01.2015
2.A.2	Product	license holder	(Name and	address):	GLS PHARMA LI Plot.No. 10,IDA, Ph Jeedimetla, R.R.Dis Hyderabad, Telanga	nase-I t,
2.A.3	Status o	f product – lic	ense holder	Key is appr	opriate category as de	fined in note (8)
	a) 🛛			b) [	Ī	c) 🔲
2A.3.1	For cate	gories b and c	the name a	nd address of t	he Manufacturer prod	ucing the dosage form is <sup>9</sup> ?
	Yes [	]		No [		Not applicable
2.A.4	Is sumn	nary basis for a	pproval app	ended 10 ? (er	nclosed at the time of	product approval)
	Yes 🗵	1		No [	⊐	Not applicable
2.A.5	Is the at (key as	tached, officia appropriate)	lly approved	d product infor	rmation complete and	consonant with the license?11
2. A.6	Yes ⊠ Applica		te, if differe	No [ nt from license	a holder (Name & Ad	Not applicable  dress) <sup>12</sup>
	Yes 🗌			No	$\boxtimes$	Not applicable

2. B.1	Applicant for certificate (Name & address)						
2. B.2	Status of applicant: (Key in the appropriate category as defined in note 8)						
2. B.2.1	1 For categories b and c the name and address of the manufacturer producing the dosage from is 9:						
2. B.3	Why is marketing authorization lacking? Not required / Not requested / under consideration / Refused (Key in as appropriate)						
2. B.4	Remarks: 13						
3.		ne certifying authority arrange produced?	e for periodi	c inspection of the manufactu	uring plant in which the dosage		
	Yes	$\boxtimes$		No 🗆	Not applicable 14		
	If not o	r not applicable, proceed to q	uestion 4.				
	Periodi	city of routine inspections (ye	ears):	NOT LESS THA	N ONCE A YEAR		
	Has the	manufacturer of this type of	dosage form	n been inspected Yes/No (Ke	y in as appropriate)		
	Yes			No 🗌	Not applicable		
	Do the	facilities and operations conf	orm to GMI	as recommended by the Wo	rld Health Organisation <sup>15</sup> ?		
	Yes			No 🗌	Not applicable		
4.		ne information submitted by t cturer of the product ? <sup>16</sup>	he applicant	satisfy the certifying authori	ty on all aspects of the		
	Yes			No 🗌	Not applicable		
	Address	s of certifying authority	2	Office of the De Drugs Control Administr Hyderabad 500 038,	ation, Vengalarao Nagar,		
	Telepho	one and Fax numbers	:	TEL: +91 40 23814119	FAX: +91 40 23814360		
	Name o	of Authorized Person	:				
					/EEN KUMAR. IRECTOR(FAC)		
				LICENSING & CO	ONTROLING AUTHORITY		
		Signature HYDERABAD JD(FAC) Stamp and Date	:	Dr. Y. NAVEEN  Joint Director (Enf. Licensing & Controlling Drugs Control Adr. Government of Hyderabad-500	charm.,Ph.D corcement) Authority (FAC) ministration		

## CERTIFICATE OF PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization (General Instructions and explanatory notes attached.)

Valid up to: 11.01.2023

No. of Certificate: 3828/A3/2021

				45.G				
Exportin	g (certifying) country:	INDIA						
Importin	Importing (requesting) country: MOLDOVA							
1. Name	e and dosage form of the	product: MESNA I MESNA 4	INJECTION 400 mg 4 mL/ An 400	npoule				
1.1 Activ	e Ingredient (S) <sup>2</sup> and an	nounts (S) per unit do	$se^3$ :					
	Each mL Contains							
	Mesna	Ph.Eur	100 mg					
	Disodium Editate Benzyl Aclohol	USP USP	0.25 mg 10.4 mg					
	Water for Injection	USP	q.s					
1.2	Is this product licensed (Key in as appropriate		narket for use in the exporting cour	ntry? 5				
	Yes 🛛		No 🗆					
1.3	Is this product actually	on the market in the	exporting country?					
	Yes 🛛		No 🗆	Unknown				
	If the answer to 1.2 is yes, continue with section 2A and omit section 2B.							
	If the answer to 1.2 is a	no, omit section 2A ar	nd continue with section 2B6					
S	ECTION 2A							
2.A,1	Number of product Lic	ence <sup>7</sup> and date of issu	ue: 22/RR/TS/2015/F/G, Dated	: 13.01.2015				
2.A.2	Product license holder	(Name and address):	GLS PHARMA LIMITED Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, INDI					
2.A.3	Status of product - lice	ense holder <sup>8</sup> (Key is a	appropriate category as defined in a	note (8)				
	a) 🖾	b)		c) 🔲				
2A.3.1	For categories b and c	the name and address	of the Manufacturer producing the	e dosage form is <sup>9</sup> ?				
	Yes 🔲	N	о 🗆	Not applicable				
2.A.4	Is summary basis for a	pproval appended 10 ?	(enclosed at the time of product a	approval)				
	Yes 🖂	N	о 🗆	Not applicable				
2.A.5	Is the attached, official (key as appropriate)	ly approved product is	nformation complete and consonar	nt with the license? <sup>11</sup>				
2. A.6	Yes Applicant for certificat		o	Not applicable				
	Yes 🗌	N	o 🗵	Not applicable				

2. B.1	Applicant for certificate (Name & address)						
2. B.2	Status of applicant: (Key in the appropriate category as defined in note 8)						
2. B.2.1	1 For categories b and c the name and address of the manufacturer producing the dosage from is 9:						
2. B.3	Why is marketing authorization lacking? Not required / Not requested / under consideration / Refused (Key in as appropriate)						
2. B.4	Remarks: 13						
3.		ne certifying authority arrange produced?	e for periodi	c inspection of the manufactu	uring plant in which the dosage		
	Yes	$\boxtimes$		No 🗆	Not applicable 14		
	If not o	r not applicable, proceed to q	uestion 4.				
	Periodi	city of routine inspections (ye	ears):	NOT LESS THA	N ONCE A YEAR		
	Has the	manufacturer of this type of	dosage form	n been inspected Yes/No (Ke	y in as appropriate)		
	Yes			No 🗌	Not applicable		
	Do the	facilities and operations conf	orm to GMI	as recommended by the Wo	rld Health Organisation <sup>15</sup> ?		
	Yes			No 🗌	Not applicable		
4.		ne information submitted by t cturer of the product ? <sup>16</sup>	he applicant	satisfy the certifying authori	ty on all aspects of the		
	Yes			No 🗌	Not applicable		
	Address	s of certifying authority	2	Office of the De Drugs Control Administr Hyderabad 500 038,	ation, Vengalarao Nagar,		
	Telepho	one and Fax numbers	:	TEL: +91 40 23814119	FAX: +91 40 23814360		
	Name o	of Authorized Person	:				
					/EEN KUMAR. IRECTOR(FAC)		
				LICENSING & CO	ONTROLING AUTHORITY		
		Signature HYDERABAD JD(FAC) Stamp and Date	:	Dr. Y. NAVEEN  Joint Director (Enf. Licensing & Controlling Drugs Control Adr. Government of Hyderabad-500	charm.,Ph.D corcement) Authority (FAC) ministration		

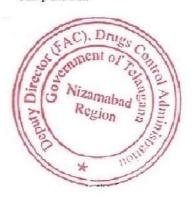
# CERTIFICATE OF PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization (General Instructions and explanatory notes attached.)

No. of	Certificate: 3925	/A3/2021			Valid up to: 1	1.12.2023
Exporti	ng (certifying) coun	try: INDIA				
Importi	ng (requesting) cour	ntry: ALGERIA				
1. Nar	me and dosage form			EXATE INJECTION USI T 500 mg	2 500 mg 20 m	nL/Vial
1.1 Act	ive Ingredient (S)2 a	nd amounts (S) per u	mit dose <sup>3</sup> :			
	Each mL contains: Methorexate Sodium Chloride Benzoyl Alcohol Water for injection Sodium hydroxide	USP USP USP USP	25 mg 0.0049 m 0.0090 m q.s q.s			
1.2	Is this product lice (Key in as approp		the marke	t for use in the exporting cour	ntry? 5	
	Yes 🛛			No 🔲		
1.3	Is this product actu	ually on the market in	n the expo	rting country?		
	Yes			No 🗆	Unknown	
	If the answer to 1.2	2 is yes, continue wit	th section 2	2A and omit section 2B.		
	If the answer to 1.	2 is no, omit section	2A and co	ntinue with section 2B6		
	SECTION 2A					
2.A.1	Number of produc	t Licence <sup>7</sup> and date of	of issue:	22/RR/TS/2015/F/G, Dated	: 13.01.2015	
2.A.2	Product license ho	lder (Name and addr	ress):	GLS PHARMA LIMITED Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, IND		
2.A.3	Status of product -	- license holder <sup>8</sup> (Ke	ey is appro	priate category as defined in I	note (8)	
	a) 🔯		b) 🔲		c) 🔲	
2A.3.1	For categories b ar	nd c the name and ad	dress of th	e Manufacturer producing the	dosage form is	<sup>9</sup> ?
	Yes		No [	]	Not applicable	$\boxtimes$
2.A.4	Is summary basis	for approval appende	ed 10 ? (end	closed at the time of product a	approval)	
	Yes 🛛		No [	]	Not applicable	
2.A.5	Is the attached, off (key as appropri		duct inform	nation complete and consonar	nt with the licens	e? <sup>11</sup>
2. A.6	Yes Applicant for certi	ficate, if different fro	No [om license	holder (Name & Address) <sup>12</sup>	Not applicable	
	Yes 🗌		No 🗵		Not applicable	

2. B.1	Applicant for certificate (Name & address)								
2. B.2	Status o	f applicant: (Key in the appr	opriate	category as defined in note 8)					
2. B.2.1	For cate	gories b and c the name and	addres	s of the manufacturer producing t	the dosage from is 9:				
2. B.3		marketing authorization lack uired / Not requested / under		leration / Refused (Key in as appr	ropriate)				
2. B.4	Remark	s: <sup>13</sup>							
3.	Dose the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?								
	Yes			No 🗆	Not applicable 14				
	If not or	not applicable, proceed to q	uestio	n 4.					
	Periodic	rity of routine inspections (ye	ears):	NOT LESS THE	AN ONCE A YEAR				
	Has the	manufacturer of this type of	dosage	e form been inspected Yes/No (K	form been inspected Yes/No (Key in as appropriate)				
	Yes			No 🗆	Not applicable				
	Do the f	acilities and operations conf	orm to	GMP as recommended by the W	orld Health Organisation <sup>15</sup> ?				
	Yes			No 🗌	Not applicable				
4.		e information submitted by t cturer of the product ? <sup>16</sup>	he app	licant satisfy the certifying author	rity on all aspects of the				
	Yes	$\boxtimes$		No 🗆	Not applicable				
	Address	of certifying authority	:		Administration sing & Controlling Authority 0 038, Telanagana, INDIA				
	Telepho	one and Fax numbers	:	TEL: +91 40 23814119	FAX: +91 40 23814360				
	Name o	f Authorized Person	:		LA SARALA				
	Signatur	re	:		RECTOR (FAC) ROLLING AUTHORITY				
					0.				

Stamp and Date



PATLOLLA SARALA
DEPUTY DIRECTOR & CERTIFYING AUTHORITY
NIZAMABAD

## CERTIFICATE OF PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization (General Instructions and explanatory notes attached.)

Valid up to: 11.01.2023

No. of Certificate: 3929/A3/2021

						2000			
Exportin	ng (certify	ing) country:	INDIA						
Importin	ng (reques	ting) country:	MOLDOVA						
1. Nam	ne and dos	age form of the		LIDON LIMAX	IIDE CAPSULES USP 100	mg			
1.1 Acti	ve Ingredi	ent (S) <sup>2</sup> and am	ounts (S) per un	it dose <sup>3</sup>	:				
	Each C	apsules contain	is:						
	Thalido		USP	100 1	mg				
	Excipie	nts		q.s					
1.2		roduct licensed as appropriate		the mark	et for use in the exporting cour	ntry? 5			
	Yes	$\boxtimes$			No 🗆				
1.3	Is this pr	Is this product actually on the market in the exporting country?							
	Yes	$\boxtimes$			No 🗆	Unknown			
	If the an	If the answer to 1.2 is yes, continue with section 2A and omit section 2B.							
	If the an	swer to 1.2 is n	o, omit section 2	A and co	ontinue with section 2B6				
s	SECTION	2A							
2.A.1	Number	of product Lice	ence <sup>7</sup> and date of	issue:	22/RR/TS/2015/F/G, Dated	: 13.01.2015			
2.A.2	Product license holder (Name and address):  GLS PHARMA LIMITED  Plot.No. 10,IDA, Phase-I  Jeedimetla, R.R.Dist,  Hyderabad, Telangana, INDIA								
2.A.3	Status of product – license holder <sup>8</sup> (Key is appropriate category as defined in note (8)								
	a) 🛛			b) [	Ī	c) 🗌			
2A.3.1	For categories b and c the name and address of the Manufacturer producing the dosage form is 9?								
	Yes 🗌			No [		Not applicable			
2.A.4	Is summ	ary basis for ap	proval appended	l <sup>10</sup> ? (er	nclosed at the time of product a	approval)			
	Yes 🛛			No [		Not applicable			
2.A.5	Is the att	ached, officiall appropriate)	y approved prod	uct infor	rmation complete and consonar	nt with the license?11			
2. A.6	Yes 🛭 Applicar		, if different from	No [ m license	e holder (Name & Address) <sup>12</sup>	Not applicable			
	Yes 🗌			No [	$\boxtimes$	Not applicable			

2. B.1	Applicant for certificate (Name & address)							
2. B.2	Status of applicant: (Key in the appropriate category as defined in note 8)							
2. B.2.1	For categories b and c the name and address of the manufacturer producing the dosage from is $^9$ :							
2. B.3	Why is marketing authorization lacking?  Not required / Not requested / under consideration / Refused (Key in as appropriate)							
2. B.4	Remarks: <sup>13</sup>							
3.	Dose the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?							
	Yes	$\boxtimes$		No 🗆	Not applicable 14			
	If not o	r not applicable, proceed to q	uestion 4.					
	Periodi	city of routine inspections (ye	ears):	NOT LESS THA	N ONCE A YEAR			
	Has the	manufacturer of this type of	dosage form	n been inspected Yes/No (Ke	y in as appropriate)			
	Yes			No 🗌	Not applicable			
	Do the	facilities and operations conf	orm to GMI	as recommended by the Wo	rld Health Organisation <sup>15</sup> ?			
	Yes			No 🗌	Not applicable			
4.	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacturer of the product ? <sup>16</sup>							
	Yes			No 🗌	Not applicable			
	Addres	s of certifying authority	2	Office of the Deputy Director Drugs Control Administration, Vengalarao Nagar, Hyderabad 500 038, Telangana, INDIA.				
	Telepho	one and Fax numbers	:	TEL: +91 40 23814119	FAX: +91 40 23814360			
	Name o	of Authorized Person	:					
	Dr. Y. NAVEEN KUMAR. JOINT DIRECTOR(FAC)							
		ONTROLING AUTHORITY						
		Signature HYDERABAD JD(FAC) Stamp and Date	:	Dr. Y. NAVEEN  Joint Director (Enf. Licensing & Controlling Drugs Control Adr. Government of Hyderabad-500	charm.,Ph.D corcement) Authority (FAC) ministration			

## CERTIFICATE OF PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization (General Instructions and explanatory notes attached.)

Valid up to: 11.01.2023

No. of Certificate: 3930/A3/2021

						.73
Exportin	g (certifyi	ng) country:	INDIA			
Importin	g (requesti	ing) country:	MOLDO	VA		
1. Name	e and dosa	ge form of the			INE SULFATE FOR INJE INE -GLS	CTION USP 10 mg
1.1 Activ	e Ingredie	ent (S)2 and am	nounts (S) pe	r unit dose <sup>3</sup>	:	
	Each via	l contains				
	Mannito	ine sulfate or Injection		USP USP USP	10 mg q.s q.s	
1.2		oduct licensed as appropriate		on the mark	ket for use in the exporting cou	ntry? 5
	Yes	$\boxtimes$			No 🗆	
1.3	Is this pr	oduct actually	on the mark	et in the exp	porting country?	
	Yes	$\boxtimes$			No 🗌	Unknown
	If the ans	swer to 1.2 is y	es, continue	with section	n 2A and omit section 2B.	
	If the ans	swer to 1.2 is n	o, omit sect	on 2A and c	continue with section 2B6	
s	ECTION	2A				
2.A.1	Number	of product Lice	ence <sup>7</sup> and da	te of issue:	22/RR/TS/2015/F/G, Dated	: 13.01.2015
2.A.2	Product license holder (Name and address):  GLS PHARMA LIMITED  Plot.No. 10,IDA, Phase-I  Jeedimetla, R.R.Dist,  Hyderabad, Telangana, INDIA					
2.A.3	Status of	product – lice	nse holder <sup>8</sup>	(Key is appr	ropriate category as defined in	note (8)
	a) 🛛			b) [		c) 🔲
2A.3.1	For categ	gories b and c t	he name and	address of	the Manufacturer producing the	e dosage form is 9?
	Yes 🗌			No		Not applicable
2.A.4	Is summa	ary basis for ap	proval appe	nded <sup>10</sup> ? (e	enclosed at the time of product	approval)
	Yes 🛚			No		Not applicable
2.A.5	Is the atta (key as	ached, officiall appropriate)	y approved	product info	rmation complete and consona	nt with the license? <sup>11</sup>
2. A.6	Yes 🛭 Applican	t for certificate	e, if differen	No from licens	se holder (Name & Address) <sup>12</sup>	Not applicable
	Yes 🗌			No	$\boxtimes$	Not applicable

2. B.1	Applicant for certificate (Name & address)							
2. B.2	Status of applicant: (Key in the appropriate category as defined in note 8)							
2. B.2.1	For categories b and c the name and address of the manufacturer producing the dosage from is $^9$ :							
2. B.3	Why is marketing authorization lacking?  Not required / Not requested / under consideration / Refused (Key in as appropriate)							
2. B.4	Remarks: <sup>13</sup>							
3.	Dose the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?							
	Yes	$\boxtimes$		No 🗆	Not applicable 14			
	If not o	r not applicable, proceed to q	uestion 4.					
	Periodi	city of routine inspections (ye	ears):	NOT LESS THA	N ONCE A YEAR			
	Has the	manufacturer of this type of	dosage form	n been inspected Yes/No (Ke	y in as appropriate)			
	Yes			No 🗌	Not applicable			
	Do the	facilities and operations conf	orm to GMI	as recommended by the Wo	rld Health Organisation <sup>15</sup> ?			
	Yes			No 🗌	Not applicable			
4.	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacturer of the product ? <sup>16</sup>							
	Yes			No 🗌	Not applicable			
	Addres	s of certifying authority	2	Office of the Deputy Director Drugs Control Administration, Vengalarao Nagar, Hyderabad 500 038, Telangana, INDIA.				
	Telepho	one and Fax numbers	:	TEL: +91 40 23814119	FAX: +91 40 23814360			
	Name o	of Authorized Person	:					
	Dr. Y. NAVEEN KUMAR. JOINT DIRECTOR(FAC)							
		ONTROLING AUTHORITY						
		Signature HYDERABAD JD(FAC) Stamp and Date	:	Dr. Y. NAVEEN  Joint Director (Enf. Licensing & Controlling Drugs Control Adr. Government of Hyderabad-500	charm.,Ph.D corcement) Authority (FAC) ministration			

## CERTIFICATE OF PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization (General Instructions and explanatory notes attached.)

Valid up to: 11.01.2023

No. of Certificate: 3937/A3/2021

						177
Exportin	g (certifyi	ng) country:	INDIA			
Importin	g (request	ing) country:	JAMAICA			
1. Name	e and dosa	age form of the	product: VINC	RISTIN	E SULFATE INJECTION	N USP 1mg 1mL/ Vial
1.1 Activ	e Ingredi	ent (S) <sup>2</sup> and amo	ounts (S) per unit	dose <sup>3</sup> :		
	Each m	L contains:				
	Mannito	ine Sulfate I or Injection	USP USP USP		mg 00 mg .s	
1.2	Is this pr	3		-	t for use in the exporting cour	try? 5
	Yes	$\boxtimes$			No 🗌	
1.3	Is this pr	oduct actually o	on the market in t	he expor	ting country?	
	Yes	$\boxtimes$			No 🗌	Unknown
	If the ans	swer to 1.2 is ye	es, continue with	section 2	2A and omit section 2B.	
	If the an	swer to 1.2 is no	o, omit section 2A	and cor	ntinue with section 2B6	
S	ECTION	2A				
2.A.1	Number	of product Lice	nce <sup>7</sup> and date of	issue:	22/RR/TS/2015/F/G, Dated:	13.01.2015
2.A.2	Product license holder (Name and address):  GLS PHARMA LIMITED  Plot.No. 10,IDA, Phase-I  Jeedimetla, R.R.Dist,  Hyderabad, Telangana, INDIA					
2.A.3	Status of	product – licen	se holder <sup>8</sup> (Key	is approp	priate category as defined in n	ote (8)
	a) 🛛			b) 🗌		c) 🗌
2A.3.1	For cate	gories b and c th	e name and addr	ess of the	e Manufacturer producing the	dosage form is 9?
	Yes 🗌			No [	]	Not applicable
2.A.4	Is summ	ary basis for app	proval appended	<sup>10</sup> ? (enc	closed at the time of product a	pproval)
	Yes 🛛			No [	1	Not applicable
2.A.5	Is the att (key as	ached, officially appropriate)	approved produ	ct inforn	nation complete and consonar	t with the license? <sup>11</sup>
2. A.6	Yes 🛭 Applicar		if different from	No L	] holder (Name & Address) <sup>12</sup>	Not applicable
	Yes 🗌			No 🗵	]	Not applicable

2. B.1	Applicant for certificate (Name & address)							
2. B.2	Status of applicant: (Key in the appropriate category as defined in note 8)							
2. B.2.1	For categories b and c the name and address of the manufacturer producing the dosage from is $^9$ :							
2. B.3	Why is marketing authorization lacking?  Not required / Not requested / under consideration / Refused (Key in as appropriate)							
2. B.4	Remarks: <sup>13</sup>							
3.	Dose the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?							
	Yes	$\boxtimes$		No 🗆	Not applicable 14			
	If not o	r not applicable, proceed to q	uestion 4.					
	Periodi	city of routine inspections (ye	ears):	NOT LESS THA	N ONCE A YEAR			
	Has the	manufacturer of this type of	dosage form	n been inspected Yes/No (Ke	y in as appropriate)			
	Yes			No 🗌	Not applicable			
	Do the	facilities and operations conf	orm to GMI	as recommended by the Wo	rld Health Organisation <sup>15</sup> ?			
	Yes			No 🗌	Not applicable			
4.	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacturer of the product ? <sup>16</sup>							
	Yes			No 🗌	Not applicable			
	Addres	s of certifying authority	2	Office of the Deputy Director Drugs Control Administration, Vengalarao Nagar, Hyderabad 500 038, Telangana, INDIA.				
	Telepho	one and Fax numbers	:	TEL: +91 40 23814119	FAX: +91 40 23814360			
	Name o	of Authorized Person	:					
	Dr. Y. NAVEEN KUMAR. JOINT DIRECTOR(FAC)							
		ONTROLING AUTHORITY						
		Signature HYDERABAD JD(FAC) Stamp and Date	:	Dr. Y. NAVEEN  Joint Director (Enf. Licensing & Controlling Drugs Control Adr. Government of Hyderabad-500	charm.,Ph.D corcement) Authority (FAC) ministration			