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	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) ² and amounts (S) per	unit dose ³ :		
	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 ⁷ 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 ⁸	(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 ⁹ ?
	Yes	No [Not applicable
2.A.4	Is summary basis for approval appear	nded ¹⁰ ? (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) ¹²	Not applicable
	Yes	No [⊴	Not applicable

2. B.1	Applica	ant for certificate (Name & ac	ddress)							
2. B.2	Status o	of applicant: (Key in the appr	opriate cate	gory 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		marketing authorization lack uired / Not requested / under		on / Refused (Key in as appro	opriate)					
2. B.4	Remark	cs: 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 ¹⁵ ?					
	Yes			No 🗌	Not applicable					
4.		ne information submitted by t cturer of the product ? ¹⁶	he applicant	satisfy the certifying authori	ty on all aspects of the					
	Yes	\boxtimes		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					

ATTACHMENT TO COPP

Product Name: Leuprolide acetate for depot Injection USP 3.75 mg

Composition:

Each Lyophilized vial contains

Leuprolide acetate USP 3.75mg
Excipients q.s

2mL ampoule of solvent contains:

Sodium carboxy methyl cellulose	USP	5mg
Mannitol	USP	50mg
Polysorbate 80	USP	1 mg
Water for injection	USP	q.s

CERTIFICATE OF COMPOSITION

Ingredients	Qty/vial
Leuprolide acetate USP*	3.75 mg
PLGA(Polylacto Glycolic acid)	33.1 mg
Poly vinyl alcohol USP	60 mg
Gelatin USP	0.65 mg
Mannitol USP	6.60 mg
Methylene dichloride USP	0.825 mL
Water for Injection USP **	q.s

^{*} Actual quantity of drug to be taken to get 100% assay on as is basis

USP - United States Pharmacopeia

q.s - Quantity Sufficient



^{**} Loss in the process of Lyophilization

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: 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) ² and a	nounts (S)	per unit dose ³	:	
	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 ⁷ 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 ⁹ ?
	Yes []		No [Not applicable
2.A.4	Is sumn	nary basis for a	pproval app	pended 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) ¹²
	Yes 🗌			No	\boxtimes	Not applicable

2. B.1	Applica	ant for certificate (Name & ac	ddress)							
2. B.2	Status o	of applicant: (Key in the appr	opriate cate	gory 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		marketing authorization lack uired / Not requested / under		on / Refused (Key in as appro	opriate)					
2. B.4	Remark	cs: 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 ¹⁵ ?					
	Yes			No 🗌	Not applicable					
4.		ne information submitted by t cturer of the product ? ¹⁶	he applicant	satisfy the certifying authori	ty on all aspects of the					
	Yes	\boxtimes		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					

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: 14.02.2023

No. of Certificate: 3705/A3/2020

Exporting	g (certifyi	ng) country:	INDIA			
Importing	g (request	ing) country:	KENYA			
1. Name	e and dosa	age form of the	product: 7	TEMOZOLO	OMIDE CAPSULES 20 mg	g
1.1 Activ	- 5		3:	er unit dose ³ : USP	20 mg q.s	
1.2	Is this pr	Approved col oduct licensed as appropriate	to be placed	•	ll et for use in the exporting cour	ntry? 5
	Yes	\boxtimes			No 🗆	
1.3	Is this pr	oduct actually	on the mark	et in the expo	orting country?	
	Yes	\boxtimes			No 🗌	Unknown
	If the ans	swer to 1.2 is y	es, continue	with section	2A and omit section 2B.	
	If the ans	swer to 1.2 is r	o, omit sect	ion 2A and co	ontinue with section 2B6	
S	ECTION	2A				
2.A.1	Number	of product Lic	ence ⁷ and da	ate of issue:	22/RR/TS/2015/F/G, Dated	: 13.01.2015
2.A.2	Product l	icense holder	(Name and a	address):	GLS PHARMA LIMITED Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, IND	
2.A.3	Status of	product – lice	nse holder ⁸	(Key is appro	opriate category as defined in	note (8)
	a) 🛛			b) [1	c) 🔲
2A.3.1	For categ	gories b and c	he name and	d address of the	he Manufacturer producing the	e dosage form is ⁹ ?
	Yes 🗌			No [Not applicable
2.A.4	Is summa	ary basis for ap	proval appe	ended 10 ? (en	closed at the time of product a	approval)
	Yes 🛛			No [Not applicable
2.A.5	Is the atta (key as	ached, official appropriate)	y approved	product infor	mation complete and consona	nt with the license?11
2. A.6	Yes 🛛 Applican	at for certificate	e, if differen	No [t from license	holder (Name & Address) ¹²	Not applicable
	Yes 🗌			No 2	₃	Not applicable

2. B.1	Applica	int for certificate (Name & ad	dress)							
2. B.2	Status	of applicant: (Key in the appro	opriate cate	gory as defined in note	e 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		marketing authorization lacki uired / Not requested / under		on / Refused (Key in a	ıs approp	oriate)				
2. B.4	Remark	s: ¹³								
3.		e certifying authority arrange produced?	for periodi	c inspection of the ma	nufactur	ing plant in which the dosa	ge			
	Yes			No 🗆		Not applicable 14				
	If not or	r not applicable, proceed to qu	uestion 4.							
	Periodic	city of routine inspections (ye	ears):	NOT LES	S THAN	ONCE A YEAR				
	Has the	manufacturer of this type of	dosage form	n been inspected Yes/I	No (Key	in as appropriate)				
	Yes			No 🗆		Not applicable				
	Do the	facilities and operations confo	orm to GMI	as recommended by	the Worl	ld Health Organisation ¹⁵ ?				
	Yes	\boxtimes		No 🗆		Not applicable				
4.		e information submitted by the	ne applicant	satisfy the certifying	authority	on all aspects of the				
	Yes			No 🗌		Not applicable				
	Address	s of certifying authority	:	Drugs Control Adn	ninistra	uty Director tion, Vengalarao Nagar, elangana, INDIA.				
	Telepho	one and Fax numbers	1	TEL: +91 40 23814	119	FAX: +91 40 23814360				
	Name o	of Authorized Person	:							
				JOI	INT DII	EEN KUMAR. RECTOR(FAC) NTROLING AUTHORI	TY			
		Signature HYDERABAD JD(FAC) Stamp and Date	:	Dr. Y. NAVE Joint Directo Licensing & Contro Drugs Contro Governme Hyderaba	r (Enfo colling A ol Adm	inistration				

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: 14.02.2023

No. of Certificate: 3706/A3/2020

Exportin	g (certifyi	ng) country:	INDIA				
Importin	g (request	ing) country:	KENYA				
1. Nam	e and dosa	age form of the	product:	TEMOZOL TEMOGET		DE CAPSULES 100 m	ng
1.1 Activ	e Ingredie	ent (S)2 and an	nounts (S)	per unit dose ³	:		
	Each Ca	psule contain	s:				
	Temozo			USP	10	00 mg	
	Excipier		•			.S	
020020		5.5		in capsule she			5
1.2		oduct licensed as appropriate		ed on the mark	et for	use in the exporting cour	ntry? 3
	Yes	\boxtimes			No		
1.3	Is this pr	oduct actually	on the mai	rket in the exp	orting	; country?	
	Yes	\boxtimes			No		Unknown
	If the ans	swer to 1.2 is y	es, continu	e with section	2A a	and omit section 2B.	
	If the ans	swer to 1.2 is 1	no, omit see	ction 2A and c	ontini	ue with section 2B6	
s	ECTION	2A					
2.A.1	Number	of product Lic	ence ⁷ and 6	date of issue:	22/1	RR/TS/2015/F/G, Dated:	: 13.01.2015
2.A.2	Product l	icense holder	(Name and	l address) :	Plo	S PHARMA LIMITED t.No. 10,IDA, Phase-I dimetla, R.R.Dist, derabad, Telangana, INDI	
2.A.3	Status of	product – lice	nse holder	8 (Key is appr	opriat	te category as defined in r	note (8)
	a) 🛛			b) []		c) 🗌
2A.3.1	For categ	gories b and c	the name a	nd address of t	he M	anufacturer producing the	e dosage form is ⁹ ?
	Yes 🗌			No [Not applicable
2.A.4	Is summa	ary basis for a	pproval app	pended 10 ? (er	nclose	ed at the time of product a	approval)
	Yes 🛛			No [Not applicable
2.A.5	Is the atta (key as	ached, official appropriate)	ly approve	d product info	rmatic	on complete and consonar	nt with the license? ¹¹
2. A.6	Yes 🛮 Applican	t for certificat	e, if differe	No [ent from licens		der (Name & Address) ¹²	Not applicable
	Yes 🗌			No	\boxtimes		Not applicable

2. B.1	Applica	int for certificate (Name & ad	dress)							
2. B.2	Status	of applicant: (Key in the appro	opriate cate	gory as defined in note	e 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		marketing authorization lacki uired / Not requested / under		on / Refused (Key in a	ıs approp	oriate)				
2. B.4	Remark	s: ¹³								
3.		e certifying authority arrange produced?	for periodi	c inspection of the ma	nufactur	ing plant in which the dosa	ge			
	Yes			No 🗆		Not applicable 14				
	If not or	r not applicable, proceed to qu	uestion 4.							
	Periodic	city of routine inspections (ye	ears):	NOT LES	S THAN	ONCE A YEAR				
	Has the	manufacturer of this type of	dosage form	n been inspected Yes/I	No (Key	in as appropriate)				
	Yes			No 🗆		Not applicable				
	Do the	facilities and operations confo	orm to GMI	as recommended by	the Worl	ld Health Organisation ¹⁵ ?				
	Yes	\boxtimes		No 🗆		Not applicable				
4.		e information submitted by the	ne applicant	satisfy the certifying	authority	on all aspects of the				
	Yes			No 🗌		Not applicable				
	Address	s of certifying authority	:	Drugs Control Adn	ninistra	uty Director tion, Vengalarao Nagar, elangana, INDIA.				
	Telepho	one and Fax numbers	1	TEL: +91 40 23814	119	FAX: +91 40 23814360				
	Name o	of Authorized Person	:							
				JOI	INT DII	EEN KUMAR. RECTOR(FAC) NTROLING AUTHORI	TY			
		Signature HYDERABAD JD(FAC) Stamp and Date	:	Dr. Y. NAVE Joint Directo Licensing & Contro Drugs Contro Governme Hyderaba	r (Enfo colling A ol Adm	inistration				

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: 14.02.2023

No. of Certificate: 3707/A3/2020

Exportin	g (certifyii	ng) country:	INDIA				
Importin	g (requesti	ng) country:	KENYA				
1. Name	e and dosa	ge form of the	product:	TEMOZO TEMOGE		IIDE CAPSULES 250 I	ng
1.1 Activ	e Ingredie	ent (S)2 and an	nounts (S) p	oer unit dose ³	:		
		psule contain	s:				
	Temozo			USP		250 mg	
	Excipien		larma maad	in agnaula ah		l.s	
1.2	Is this pro	Approved colloduct licensed as appropriate	to be place	•		r use in the exporting cour	ntry? 5
	Yes	\boxtimes			No		
1.3	Is this pro	oduct actually	on the mar	ket in the exp	ortin	g country?	
	Yes				No	. 🗖	Unknown
	If the ans	wer to 1.2 is y	es, continu	e with sectio	n 2A	and omit section 2B.	
	If the ans	wer to 1.2 is 1	no, omit sec	tion 2A and	contin	ue with section 2B6	
S	ECTION	2A					
2.A.1	Number	of product Lic	ence ⁷ and d	late of issue	: 22/	RR/TS/2015/F/G, Dated	: 13.01.2015
2.A.2	Product l	icense holder	(Name and	address):	Plo Jee	LS PHARMA LIMITED ot.No. 10,IDA, Phase-I dimetla, R.R.Dist, derabad, Telangana, INDI	
2.A.3	Status of	product – lice	nse holder ⁸	(Key is app	ropria	te category as defined in I	note (8)
	a) 🛮			b) [c) 🔲
2A.3.1	For categ	gories b and c	the name ar	nd address of	the M	Ianufacturer producing the	dosage form is ⁹ ?
	Yes 🗌			No			Not applicable
2.A.4	Is summa	ary basis for a	oproval app	ended 10 ? (e	enclos	ed at the time of product a	approval)
	Yes 🛛			No			Not applicable
2.A.5	Is the atta (key as	ached, official appropriate)	ly approved	I product info	ormati	on complete and consonar	nt with the license?11
2. A.6	Yes 🛭 Applican	t for certificat	e, if differe	No nt from licen	se hol	der (Name & Address) ¹²	Not applicable
	Yes 🗌			No	\boxtimes		Not applicable

2. B.1	Applica	int for certificate (Name & ad	dress)							
2. B.2	Status	of applicant: (Key in the appro	opriate cate	gory as defined in note	e 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		marketing authorization lacki uired / Not requested / under		on / Refused (Key in a	ıs approp	oriate)				
2. B.4	Remark	s: ¹³								
3.		e certifying authority arrange produced?	for periodi	c inspection of the ma	nufactur	ing plant in which the dosa	ge			
	Yes			No 🗆		Not applicable 14				
	If not or	r not applicable, proceed to qu	uestion 4.							
	Periodic	city of routine inspections (ye	ears):	NOT LES	S THAN	ONCE A YEAR				
	Has the	manufacturer of this type of	dosage form	n been inspected Yes/I	No (Key	in as appropriate)				
	Yes			No 🗆		Not applicable				
	Do the	facilities and operations confo	orm to GMI	as recommended by	the Worl	ld Health Organisation ¹⁵ ?				
	Yes	\boxtimes		No 🗆		Not applicable				
4.		e information submitted by the	ne applicant	satisfy the certifying	authority	on all aspects of the				
	Yes			No 🗌		Not applicable				
	Address	s of certifying authority	:	Drugs Control Adn	ninistra	uty Director tion, Vengalarao Nagar, elangana, INDIA.				
	Telepho	one and Fax numbers	1	TEL: +91 40 23814	119	FAX: +91 40 23814360				
	Name o	of Authorized Person	:							
				JOI	INT DII	EEN KUMAR. RECTOR(FAC) NTROLING AUTHORI	TY			
		Signature HYDERABAD JD(FAC) Stamp and Date	:	Dr. Y. NAVE Joint Directo Licensing & Contro Drugs Contro Governme Hyderaba	r (Enfo colling A ol Adm	inistration				