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	ite 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 summ	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 consonal	nt with the license?11
2. A.6	Yes 🛭 Applican	t for certificate	e, if differen	No [t from license	holder (Name & Address) ¹²	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	For cate	egories b and c the name and	address of t	he manufacturer produ	ucing 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.	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	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/l	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	:				
				JO	INT DII	EEN KUMAR. RECTOR(FAC) NTROLING AUTHORI	TY
		Signature HYDERABAD JD(FAC) Stamp and Date	:	Joint Directo Licensing & Contr Drugs Contre 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	10		
	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	ontinu	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) :	Plot	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	matic	on complete and consonar	nt with the license? ¹¹
2. A.6	Yes 🛭 Applican	nt for certificat	e, if differe	No [ent from licens		der (Name & Address) ¹²	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 cate	egories b and c the name and	address of t	he manufacturer produ	ucing 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.	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	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/l	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	:				
				JO	INT DII	EEN KUMAR. RECTOR(FAC) NTROLING AUTHORI	TY
		Signature HYDERABAD JD(FAC) Stamp and Date	:	Joint Directo Licensing & Contr Drugs Contre 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

Exporting	g (certifyii	ng) country:	INDIA				
Importing	g (requesti	ng) country:	KENYA				
1. Name	e and dosa	ge form of the	product:	TEMOZO TEMOGE		IIDE CAPSULES 250 n	ng
1.1 Activ	e Ingredie	nt (S)2 and an	nounts (S) p	oer unit dose	:		
		psule contain	s:				
	Temozol			USP		250 mg	
	Excipien		larma maad	in consule at		Į.s	
1.2	Is this pro	Approved colloduct licensed s appropriate	to be place	•		r use in the exporting cour	ntry? 5
	Yes				No		
1.3	Is this pro	oduct actually	on the mar	ket in the exp	porting	g country?	
	Yes				No		Unknown
	If the ans	wer to 1.2 is y	es, continu	e with section	n 2A a	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 edimetla, 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 r	note (8)
	a) 🛛			b)			c) 🗌
2A.3.1	For categ	ories 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		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	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 cate	egories b and c the name and	address of t	he manufacturer produ	ucing 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.	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	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/l	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	:				
				JO	INT DII	EEN KUMAR. RECTOR(FAC) NTROLING AUTHORI	TY
		Signature HYDERABAD JD(FAC) Stamp and Date	:	Joint Directo Licensing & Contr Drugs Contre 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.)

No. of Certificate: 4506/A3/2022

No. of C	ertificate: 4506/A3/2	022			Valid up to: 10.02.2024
Exportin	g (certifying) country:	INDIA			
Importin	g (requesting) country:	MYANMAR			
1. Nam	e and dosage form of the	product: PACLI		EL INJECTION USP 260 260	mg 43.4 mL/vial
1.1 Activ	ve Ingredient (S)2 and an	nounts (S) per unit	dose ³ :		
	Each mL contains				
	Paclitaxel	USP		6 mg	
	Polyoxyl 35 castor o	il USP		527 mg	
	Dehydrated Alcohol	USP		49.7% v/v	
1.2	Is this product licensed (Key in as appropriate		e marke	et for use in the exporting cour	ntry? 5
	Yes 🛛			No 🗌	
1.3	Is this product actually	on the market in th	e expo	rting country?	
	Yes 🛛			No 🗆	Unknown
	If the answer to 1.2 is y	es, continue with s	ection	2A and omit section 2B.	
	If the answer to 1.2 is r	o, omit section 2A	and co	ntinue with section 2B6	
	SECTION 2A				
2.A.1	Number of product Lic	ence ⁷ and date of i	ssue:	22/RR/TS/2015/F/G, Dated	: 13.01.2015
				2	
2.A.2	Product license holder	Name and 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	s appro	priate category as defined in I	note (8)
	a) 🔀		b) 🔲		c) 🔲
2A.3.1	For categories b and c	he name and addre	ss of th	ne Manufacturer producing the	e dosage form is ⁹ ?
	Yes		No []	Not applicable
2.A.4	Is summary basis for ap	proval appended 10	⁰ ? (en	closed at the time of product a	approval)
	Yes 🖾		No [J	Not applicable
2.A.5	Is the attached, official (key as appropriate)	y approved produc	t infor	nation complete and consonar	nt with the license? ¹¹
2. A.6	Yes Applicant for certificate		No [license	holder (Name & Address) ¹²	Not applicable
	Yes 🗌		No [3	Not applicable

2. B.1	Applica	ant for certificate (Name & a	ddress)						
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: 13								
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	question	14.					
	Periodi	city of routine inspections (y	ears):	NOT LESS TH	AN ONCE A YEAR				
	Has the	manufacturer of this type of	f dosage	form been inspected Yes/No (K	ey in as appropriate)				
	Yes			No 🗆	Not applicable				
	Do the	facilities and operations con	form to	GMP as recommended by the W	orld Health Organisation ¹⁵ ?				
	Yes			No 🗌	Not applicable				
4.	Does th	e information submitted by cturer of the product ? ¹⁶	the appl	icant satisfy the certifying author	ity on all aspects of the				
	Yes			No 🗆	Not applicable				
	Addres	s 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	of Authorized Person	:	PATLOL	LA SARALA				
					RECTOR (FAC) ROLLING AUTHORITY				
	Signatu	re	:	LICENSING & CONT	ROLLING AUTHORITY				
					a Du a				

Stamp and Date



PATLOLLA SARALA
DEPUTY DIRECTOR & CERTIFYING AUTHORITY
NIZAMABAD

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	Certificat	te: 2564/DI	MLK/TST/COP	P/1005	520	Valid up to: 0	9/05/2022
Exporti	ng (certi	fying) country:	INDIA				
Importi	ng (requ	esting) country:	KENYA				
1. Nar	ne and de	osage form of th	ne product: SORA	FENI	B TABLETS 200 mg		
1.1 Act	ive Ingre	edient (S) ² and a	mounts (S) per uni	t dose ³	E .		
	Each f	ilm coated tabl	et contains:				
		nib Tosylate Ilent to Sorafen	ib	200	mg		
	Excipi	ents		q.s			
	Colou	r: Iron Oxide o	f Red & Titanium	Dioxide	USP		
1.2		product licenseen as appropriat		e mark	et for use in the exporting cour	ntry? 5	
	Yes	\boxtimes			No 🗆		
1.3	Is this	product actually	on the market in t	he expo	orting country?		
	Yes	\boxtimes			No 🗆	Unknown	
	If the a	nswer to 1.2 is	yes, continue with	section	2A and omit section 2B.		
	If the a	nswer to 1.2 is	no, omit section 2/	and co	ontinue with section 2B6		
5	SECTIO	N 2A					
2.A.1	Numbe	er of product Lie	cence ⁷ and date of	issue :	22/RR/TS/2015/F/G, Dated	: 13.01.2015	
2.A.2	Produc	t license holder	(Name and addres	s):	GLS PHARMA LIMITED Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, IND		
2.A.3	Status	of product – lic	ense holder ⁸ (Key	is appro	opriate category as defined in 1	note (8)	
	a) 🛛			b) [1	c) 🔲	
2A.3.1	For cat	egories b and c	the name and addr	ess of tl	he Manufacturer producing the	dosage form is	?
	Yes [No []	Not applicable	
2.A.4	Is sum	mary basis for a	approval appended	¹⁰ ? (en	closed at the time of product a	ipproval)	
	Yes 2	⊴		No [Not applicable	
2.A.5	Is the a			ct infor	mation complete and consonar	nt with the license	e? ¹¹
2. A.6	Yes Applic		te, if different from	No [holder (Name & Address) ¹²	Not applicable	
	Yes [ľ		No D	⊲	Not applicable	П

2. B.1	Applica	nt 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: ¹³								
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 question 4.						
	Periodic	ity of routine inspection	s (years):	NOT LESS THA	N ONCE A YEAR				
	Has the	manufacturer of this typ	e of dosage form	n been inspected Yes/No (Ke	y in as appropriate)				
	Yes	\boxtimes		No 🗌	Not applicable				
	Do the f	acilities and operations	conform to GMI	P as recommended by the Wo	orld Health Organisation ¹⁵ ?				
	Yes			No 🗌	Not applicable				
4.		e information submitted eturer of the product ? ¹⁶	by the applicant	t satisfy the certifying authori	ity on all aspects of the				
	Yes	\boxtimes		No 🗌	Not applicable				
	Address	of certifying authority	3:	Office of the De Drugs Control Administr Hyderabad 500 038,	ation, Vengalarao Nagar,				
	Telepho	ne and Fax numbers	*	TEL: +91 40 23814119	FAX: +91 40 23814360				
	Name o	f Authorized Person	8	Dr. B. VENKA	ΓESHWARLU				
	Signatur	re .	; ;	INT DIRECTOR & C	ERTIFITING AUTHORITY				
	Stamp ar	and Date		Dr. B. VENKA	FESHWARLU				



DRUGS CONTROL ADMINISTRATION