### 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: 01.01.2024

No. of Certificate: 3802/A3/2021

Exportin	g (certifyii	ng) country:	INDIA			
Importin	g (requesti	ng) country:	JORDAN			
1. Nam	e and dosa	ge form of the		OMYO OGET	CIN INJECTION USP 15	UNITS
1.1 Activ	ve Ingredie	ent (S)2 and amo	ounts (S) per uni	t dose <sup>3</sup>	:	
	Each Ly	ophilized vial c	ontains			
		in sulfate nt to Bleomyci	US n free base	P	15 IU 15 mg	
1.2		oduct licensed t s appropriate)		he mark	eet for use in the exporting cour	ntry? 5
	Yes	$\boxtimes$			No 🗆	
1.3	Is this pro	oduct actually o	on the market in	the exp	orting country?	
	Yes				No 🗆	Unknown
	If the ans	wer to 1.2 is ye	s, continue with	section	2A and omit section 2B.	
	If the ans	wer to 1.2 is no	o, omit section 2.	A and c	ontinue 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 l	icense holder (l	Name and addre	ss):	GLS PHARMA LIMITED Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, INDI	
2.A.3	Status of	product – licen	se holder8 (Key	is appr	opriate category as defined in r	note (8)
	a) 🛛			b) [		c) 🔲
2A.3.1	For categ	ories b and c th	e name and add	ress of t	the Manufacturer producing the	dosage form is 9?
	Yes 🗌			No [		Not applicable
2.A.4	Is summa	ary basis for app	proval appended	<sup>10</sup> ? (er	nclosed at the time of product a	approval)
	Yes 🛛			No [		Not applicable
2.A.5	Is the atta (key as	ached, officially appropriate)	approved produ	ict infoi	rmation complete and consonar	nt with the license? <sup>11</sup>
2. A.6	Yes 🛭 Applican	t for certificate	if different from	No [ n licens	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	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	Remark	cs: <sup>13</sup>					
3.		ne certifying authority arrang produced?	e for period	ic inspection of the manufact	uring plant in which the dosage		
	Yes	$\boxtimes$		No 🗆	Not applicable 14		
	If not o	or not applicable, proceed to	question 4.				
	Periodi	city of routine inspections (y	vears):	NOT LESS THA	AN ONCE A YEAR		
	Has the	e manufacturer of this type of	f dosage for	m been inspected Yes/No (Ke	ey in as appropriate)		
	Yes			No 🗌	Not applicable		
	Do the	facilities and operations con-	form to GM	P as recommended by the Wo	orld Health Organisation <sup>15</sup> ?		
	Yes			No 🗌	Not applicable		
4.		ne information submitted by acturer of the product ? <sup>16</sup>	the applican	at satisfy the certifying author	ity on all aspects of the		
	Yes			No 🗌	Not applicable		
	Addres	s of certifying authority		Office of the De Drugs Control Administr Hyderabad 500 038,	ration, Vengalarao Nagar,		
	Teleph	one and Fax numbers	55. 3.≢	TEL: +91 40 23814119	FAX: +91 40 23814360		
	Name o	of Authorized Person					
				JOINT D	VEEN KUMAR. DIRECTOR(FAC) ONTROLING AUTHORITY		
		Signature HYDERABAD JD(FAC) Stamp and Date	:	Joint Director (En Licensing & Controlling Drugs Control Ad Government of Hyderabad-50)	Pharm.,Ph.D forcement) 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: 14/02/2022

No. of Certificate: 1012/DI/MLK/TST/COPP/15022020

Exportin	g (certifyii	ng) country:	INDIA			
Importin	g (requesti	ng) country:	CROATIA			
1. Nam	e and dosa	ge form of the	product: BICAL	UTAN	WIDE TABLETS USP 150	MG
1.1 Activ	ve Ingredie	ent (S) <sup>2</sup> and am	ounts (S) per unit	dose <sup>3</sup> :	Ð	
	Each film	coated tablet	s contains			
	Bicalutan		USP		) mg	
	Excipient Colour:	ts Fitanium Dioxi	de USP	q.s	<b>i</b>	
1.2		oduct licensed s appropriate		e mark	et for use in the exporting cour	ntry? 5
	Yes				No 🔲	
1.3	Is this pro	oduct actually	on the market in th	e expo	orting country?	
	Yes				No 🗌	Unknown
	If the ans	wer to 1.2 is ye	es, continue with s	ection	2A and omit section 2B.	
	If the ans	wer to 1.2 is no	o, omit section 2A	and co	ontinue with section 2B6	
	SECTIO	ON 2A				
2.A.1	Number of	of product Lice	ence <sup>7</sup> and date of i	ssue:	22/RR/TS/2015/F/G, Dated	: 13.01.2015
2.A.2	Product li	icense 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 – licer	nse holder <sup>8</sup> (Key i	s appro	opriate category as defined in	note (8)
	a) 🛛			b) [	]	c) 🔲
2A.3.1	For categ	ories b and c tl	ne name and addre	ss of t	he Manufacturer producing the	e dosage form is <sup>9</sup> ?
	Yes 🔲			No [		Not applicable
2.A.4	Is summa	ary basis for ap	proval appended <sup>1</sup>	<sup>0</sup> ? (er	nclosed at the time of product a	approval)
	Yes 🛛			No [		Not applicable
2.A.5		ached, officially appropriate)	y approved produc	t infor	mation complete and consona	nt with the license? <sup>11</sup>
2. A.6	Yes 🛭 Applican	t for certificate	, if different from	No [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			No 🗆	Not applicable <sup>14</sup> □		
	If not or	not applicable, proceed to qu	uestion 4.				
	Periodio	city of routine inspections (ye	ars):	NOT LESS THA	N ONCE A YEAR		
	Has the	manufacturer of this type of	dosage forr	n been inspected Yes/No (Ke	y in as appropriate)		
	Yes			No 🗌	Not applicable		
	Do the i	facilities and operations confo	orm to GMI	P as recommended by the Wo	orld Health Organisation <sup>15</sup> ?		
	Yes	$\boxtimes$		No 🗆	Not applicable		
4.		e information submitted by the cturer of the product ? <sup>16</sup>	ne applicant	t satisfy the certifying authori	ty on all aspects of the		
	Yes			No 🗌	Not applicable		
	Address	of certifying authority	3	Office of the De Drugs Control Administr Hyderabad 500 038,	ation, Vengalarao Nagar,		
	Telepho	one and Fax numbers	<b>:</b>	TEL: +91 40 23814119	FAX: +91 40 23814360		
	Name o	f Authorized Person	:	Dr. B. VENKA	ΓESHWARLU		
	Signatur	re	; ;	INT DIRECTOR & CI	ERTIFITING AUTHORITY		
	Stamp a			Dr. B. VENKAT	<b>TESHWARLU</b>		
		ROLADAM		JOIN! DIKE	JIUK(FAC)		



DRUGS CONTROL ADMINISTRATION

## 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: 4511/A3/2022			Valid up to: 20.03.2024
Exportin	g (certifying) country: INDIA			
Importin	g (requesting) country: EGYPT			
1. Name	e and dosage form of the product:	CHLORAMB CHLORAMAX	CONTRACTOR OF STREET, MANUFACTURE OF HIGH THE	
1.1 Activ	re Ingredient (S) <sup>2</sup> and amounts (S	per unit dose <sup>3</sup> :		
	Each film coated tablets contains Chlorambucil Excipients	USP 2 m	ng	
	Color: Iron Oxide of Yellow & Tit	anium Dioxide US	SP	
1.2	Is this product licensed to be pla (Key in as appropriate)	ced on the marke	et for use in the exporting cour	ntry? 5
	Yes 🛛		No 🗆	
1.3	Is this product actually on the m	arket in the expo	orting country?	
	Yes 🛛		No 🗆	Unknown
	If the answer to 1.2 is yes, contin	nue with section	2A and omit section 2B.	
	If the answer to 1.2 is no, omit so	ection 2A and co	ontinue with section 2B6	
S	ECTION 2A			
2.A.1	Number of product Licence <sup>7</sup> and	date of issue:	22/RR/TS/2015/F/G, Dated:	: 13.01.2015
2.A.2	Product license holder (Name an	d address):	GLS PHARMA LIMITED Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, INDI	
2.A.3	Status of product – license holde	r <sup>8</sup> (Key is appro	opriate category as defined in r	note (8)
	a) 🖾	b) [	Í	c) 🗌
2A.3.1	For categories b and c the name	and address of th	ne Manufacturer producing the	dosage form is <sup>9</sup> ?
	Yes	No [		Not applicable
2.A.4	Is summary basis for approval ap	ppended 10 ? (en	closed at the time of product a	approval)
	Yes 🛛	No [		Not applicable
2.A.5	Is the attached, officially approv (key as appropriate)	ed product infor	mation complete and consonar	nt with the license?11
2. A.6	Yes ⊠ Applicant for certificate, if diffe	No [rent 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	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 que	estion 4.				
	Periodic	ity of routine inspections (year	rs): NOT LESS THA	N ONCE A YEAR			
	Has the	manufacturer of this type of de	osage form been inspected Yes/No (Ke	y in as appropriate)			
	Yes	$\boxtimes$	No 🗌	Not applicable			
	Do the f	acilities and operations confor	m to GMP as recommended by the Wo	orld Health Organisation <sup>15</sup> ?			
	Yes	$\boxtimes$	No 🗌	Not applicable			
4.		e information submitted by the turer of the product ? <sup>16</sup>	applicant satisfy the certifying authori	ty on all aspects of the			
	Yes	$\boxtimes$	No 🗌	Not applicable			
	Address	of certifying authority	: Drug Control A Deputy Director (FAC) Licens Nizamabad , Hyderabad 500	sing & Controlling Authority			
	Telepho	ne and Fax numbers	: TEL: +91 40 23814119	FAX: +91 40 23814360			
	Name of	f Authorized Person		HAGYA LAXMI			
	Signatur	e		RECTOR (FAC) ROLLING AUTHORITY			
	Stamp a	nd Date	R. Swho	-pyaley 02/2			
	Ocputy Director	Nizamabad Region	Deputy I Licensing & C Drugs Contr Government	HAGYA LAXMI Director (FAC) Controlling Authority rol Administration ent of Telangana id-500 038, T.S.			

## 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: 3824/A3/2021

Exportin	g (certifying) country:	INDIA		
Importin	g (requesting) country:	CROATIA		
1. Name	e and dosage form of the	product: CYTARABIN	NE INJECTION BP 1g 10 XX 1000	mL/Vial
1.1 Activ	e Ingredient (S) <sup>2</sup> and am	ounts (S) per unit dose <sup>3</sup> :		
	Each mL Contains: Cytarabine Water for injection	BP 100:	mg	
	water for injection	BP q.s		
1.2	Is this product licensed (Key in as appropriate		et for use in the exporting cou	untry? <sup>5</sup>
	Yes 🛮		No 🗆	
1.3	Is this product actually	on the market in the expo	orting country?	
	Yes 🛛		No 🗌	Unknown
	If the answer to 1.2 is y	es, continue with section	2A and omit section 2B.	
	If the answer to 1.2 is n	o, omit section 2A and co	ontinue with section 2B6	
s	ECTION 2A			
2.A.1	Number of product Lice	ence <sup>7</sup> and date of issue:	22/RR/TS/2015/F/G, Dated	d: 13.01.2015
	200			
2.A.2	Product license holder (	(Name and address):	GLS PHARMA LIMITEI Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, INI	)
2.A.2 2.A.3			Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist,	<b>)</b> DIA
			Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, IND opriate category as defined in	<b>)</b> DIA
	Status of product – liceral	nse holder <sup>8</sup> (Key is approb	Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, IND opriate category as defined in	DIA note (8) c)
2.A.3	Status of product – liceral	nse holder <sup>8</sup> (Key is approb	Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, IND opriate category as defined in [] he Manufacturer producing the	DIA note (8) c)
2.A.3	Status of product – licer  a)  For categories b and c to Yes	nse holder <sup>8</sup> (Key is approb) b) he name and address of the	Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, IND opriate category as defined in [] he Manufacturer producing the	DIA  note (8)  c)   e dosage form is <sup>9</sup> ?  Not applicable
2.A.3 2A.3.1	Status of product – licer  a)  For categories b and c to Yes	nse holder <sup>8</sup> (Key is approb) b) he name and address of the	Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, INI opriate category as defined in he Manufacturer producing the	DIA  note (8)  c)   e dosage form is <sup>9</sup> ?  Not applicable
2.A.3 2A.3.1	Status of product – licer  a)  For categories b and c t  Yes   Is summary basis for ap	he name and address of the proval appended <sup>10</sup> ? (er	Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, INI opriate category as defined in he Manufacturer producing the	DIA  note (8)  c)   ne dosage form is <sup>9</sup> ?  Not applicable   approval)  Not applicable
2.A.3 2A.3.1 2.A.4	Status of product – licer  a)  For categories b and c t  Yes  Is summary basis for ap  Yes  Is the attached, officiall (key as appropriate)  Yes  Yes	he name and address of the proval appended 10? (er No [y approved product infor No [	Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, INI opriate category as defined in he Manufacturer producing the	DIA  note (8)  c)   ne dosage form is <sup>9</sup> ?  Not applicable   approval)  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.		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	$\boxtimes$		No 🗌	Not applicable		
	Addres	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 (	Certificate: 3935/A3/	2021			Valid up to: 12.09.2023		
Exporti	ng (certifying) country:	INDIA					
Importi	ng (requesting) country:	ALGERIA					
1. Nan	ne and dosage form of the			ZINE FOR INJECTION VA 100 mg	USP 100 mg		
1.1 Acti	ive Ingredient (S)2 and an	nounts (S) per unit	dose <sup>3</sup> :				
	Each sterile lyophiliz	zed vial contains					
	Dacarbazine	USP	100 mg	3			
	Excipients		q.s				
1.2	Is this product licensed (Key in as appropriate		market	t for use in the exporting cou	ntry? 5		
	Yes 🛛			No 🗆			
1.3	Is this product actually	on the market in th	e expor	ting country?			
	Yes 🛛		,	No 🗆	Unknown		
	If the answer to 1.2 is y	es, continue with se	ection 2	A and omit section 2B.			
	If the answer to 1.2 is no	o, omit section 2A	and con	ntinue with section 2B6			
5	SECTION 2A						
2.A.1	Number of product Lice	ence <sup>7</sup> and date of is	ssue: 2	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, IND			
2.A.3	Status of product - licer	nse holder <sup>8</sup> (Key is	s approp	oriate category as defined in	note (8)		
	a) 🖂		b) 🔲		c) 🔲		
2A.3.1	For categories b and c the name and address of the Manufacturer producing the dosage form is <sup>9</sup> ?						
	Yes		No 🗌	I)	Not applicable		
2.A.4	Is summary basis for ap	proval appended 16	<sup>0</sup> ? (enc	closed at the time of product a	approval)		
	Yes 🛛		No 🗌	1	Not applicable		
2.A.5	Is the attached, officiall (key as appropriate)	y approved produc	t inform	nation complete and consona	nt with the license? <sup>11</sup>		
2. A.6	Yes Applicant for certificate		No 🔲	holder (Name & Address) <sup>12</sup>	Not applicable		
	Yes 🗌		No 🛛	10	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	gories b and c the name and a	address	s of the manufacturer producing t	he dosage from is <sup>9</sup> :	
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 or	not applicable, proceed to qu	estion	4.		
	Periodic	ity of routine inspections (ye	ars):	NOT LESS THA	AN ONCE A YEAR	
	Has the	manufacturer of this type of	dosage	form been inspected Yes/No (Ke	ey in as appropriate)	
	Yes	⊠		No 🏻	Not applicable	
		_		52000 1	F1000000	
	Do the f	acilities and operations confo	orm to	GMP as recommended by the W	orld Health Organisation <sup>15</sup> ?	
	Yes	$\boxtimes$		No 🗌	Not applicable	
4.		e information submitted by the cturer of the product ? <sup>16</sup>	e appl	icant satisfy the certifying author	ity on all aspects of the	
	Yes			No 🗌	Not applicable	
	Address	of certifying authority		Drug Control Deputy Director (FAC) Licen Nizamabad , Hyderabad 50		
	Telepho	ne and Fax numbers	:	TEL: +91 40 23814119	FAX: +91 40 23814360	
	Name of	f Authorized Person	i		BHAGYA LAXMI RECTOR (FAC)	
	Signatur	re	:		ROLLING AUTHORITY	
	Stamp a	nd Date		R. Swh	re pyr leg 09/2	
	puty Director	Nizamabad Region		Deputy Licensing & C Drugs Cont	HAGYA LAXMI Director (FAC) Controlling Authority rol Administration ent of Telangana	

Hvderabad-500 038, T.S.

### 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: 20.03.2024

No. of Certificate: 4516/A3/2022

Exporti	ng (certifying) country: INDIA		
Importi	ng (requesting) country: TURK	EY	
1. Nan	ne and dosage form of the product	DECITABINE FOR INJECTIO	N 50mg
1.1 Acti	ve Ingredient (S) <sup>2</sup> and amounts (S	) per unit dose <sup>3</sup> :	
	Each Lyophilized vial contains		
	Decitabine Excipients	50 mg q.s	
1,2	Is this product licensed to be place (Key in as appropriate)	ced on the market for use in the exporting	g country? 5
	Yes 🛛	No 🗆	
1.3	Is this product actually on the ma	arket in the exporting country?	
	Yes 🛛	№ □	Unknown
	If the answer to 1.2 is yes, contin	nue with section 2A and omit section 2B.	
	If the answer to 1.2 is no, omit so	ection 2A and continue with section 2B6	
5	SECTION 2A		
2.A.1		date of issue: 22/RR/TS/2015/F/G, I	Notad: 13 01 2015
2.A.1	Number of product Electice and	date of 188de . 22/RR/18/2013/F/G, 1	7ateu. 15.01.2015
2.A.2	Product license holder (Name an	d address): GLS PHARMA LIMI Plot.No. 10,IDA, Phase Jeedimetla, R.R.Dist, Hyderabad, Telangana,	e-I
2.A.3	Status of product – license holde	r8 (Key is appropriate category as define	ed in note (8)
	a) 🖾	b) 🔲	c) 🔲
2A.3.1	For categories b and c the name	and address of the Manufacturer produci	ng the dosage form is 9?
	Yes	No 🗌	Not applicable
2.A.4	Is summary basis for approval ap	ppended 10? (enclosed at the time of pro	duct approval)
	Yes 🛛	No 🗆	Not applicable
2.A.5	Is the attached, officially approve (key as appropriate)	ed product information complete and con	nsonant with the license?11
2. A.6	Yes ⊠ Applicant for certificate, if differ	No ☐ rent from license holder (Name & Addre	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: 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 que	estion 4.				
	Periodic	ity of routine inspections (year	rs): NOT LESS THA	N ONCE A YEAR			
	Has the	manufacturer of this type of de	osage form been inspected Yes/No (Ke	y in as appropriate)			
	Yes	$\boxtimes$	No 🗌	Not applicable			
	Do the f	acilities and operations confor	m to GMP as recommended by the Wo	orld Health Organisation <sup>15</sup> ?			
	Yes	$\boxtimes$	No 🗌	Not applicable			
4.		e information submitted by the turer of the product ? <sup>16</sup>	applicant satisfy the certifying authori	ty on all aspects of the			
	Yes	$\boxtimes$	No 🗌	Not applicable			
	Address	of certifying authority	: Drug Control A Deputy Director (FAC) Licens Nizamabad , Hyderabad 500	sing & Controlling Authority			
	Telepho	ne and Fax numbers	: TEL: +91 40 23814119	FAX: +91 40 23814360			
	Name of	f Authorized Person		HAGYA LAXMI			
	Signatur	e		RECTOR (FAC) ROLLING AUTHORITY			
	Stamp a	nd Date	R. Swho	-pyaley 02/2			
	Ocputy Director	Nizamabad Region	Deputy I Licensing & C Drugs Contr Government	HAGYA LAXMI Director (FAC) Controlling Authority rol Administration ent of Telangana id-500 038, T.S.			

## 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: 30.03.2024

No. of Certificate: 4537/A3/2022

Exporting	g (certifyi	ng) country:	INDIA					
Importing	g (requesti	ing) country:	CAMBO	DIA				
1. Name	e and dosa	ge form of the	product:	DOXORU DOXOGE	BICIN HYDROCHLORIDE T 50	INJECTION USP 50 mg		
1.1 Activ		ent (S) <sup>2</sup> and an rophilized vial	307-1762	per unit dose	3:			
	Doxorul	oicin Hydroch	lloride	USP	50 mg			
	Lactose	Monohydrate	e	USP	250 mg			
1.2	Is this product licensed to be placed on the market for use in the exporting country? <sup>5</sup> (Key in as appropriate)					ntry? 5		
	Yes	$\boxtimes$			No 🔲			
1.3	Is this product actually on the market in the exporting country?							
	Yes	$\boxtimes$			No 🗌	Unknown		
	If the ans	swer to 1.2 is y	es, continu	e with section	on 2A and omit section 2B.			
	If the answer to 1.2 is no, omit section 2A and continue with section 2B6							
S	ECTION	2A						
2.A.1	Number	of product Lic	ence <sup>7</sup> and o	late of issue	: 22/RR/TS/2015/F/G, Dated	: 13.01.2015		
2.A.2	Plot. Jeedi			address):	GLS PHARMA LIMITED Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, IND	ot.No. 10,IDA, Phase-I		
2.A.3	Status of product – license holder <sup>8</sup> (Key is appropriate category as defined in note (8)				note (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?				e dosage form is 9?			
	Yes 🗌			No		Not applicable		
2.A.4	Is summa	ary basis for a	pproval app	pended 10 ?	(enclosed at the time of product a	approval)		
	Yes 🛛			No		Not applicable		
2.A.5	Is the atta (key as	ached, official appropriate)	ly approved	d product inf	formation complete and consona	nt with the license? <sup>11</sup>		
2. A.6	Yes 🛭 Applican	t for certificat	e, if differe		nse 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: 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 que	estion 4.			
	Periodicity of routine inspections (years): NOT LESS THAN ONCE A YEAR					
	Has the	manufacturer of this type of do	osage form been inspected Yes/No (Key	in as appropriate)		
	Yes		No 🗌	Not applicable		
	Do the f	acilities and operations confor	m to GMP as recommended by the Wor	rld Health Organication 159		
			₹D	52004		
	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 $?^{16}$					
	Yes	$\boxtimes$	No 🗌	Not applicable		
	Address	of certifying authority	: Drug Control A Deputy Director (FAC) Licensi Nizamabad , Hyderabad 500	ing & Controlling Authority		
	Telepho	ne and Fax numbers	: TEL: +91 40 23814119	FAX: +91 40 23814360		
	Name of	f Authorized Person		HAGYA LAXMI		
	Signatur	e		ECTOR (FAC) ROLLING AUTHORITY		
	Stamp a	nd Date	R. Swhie	pyr len 02/2		
	Ocputy Director	Nizamabad Region	Deputy D Licensing & Co Drugs Contr Governme	AGYA LAXMI Director (FAC) ontrolling Authority of Administration nt of Telangana d-500 038, T.S.		

### 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	: 1032/DI/ML	K/TST/COP	P/0912	19	Valid up to: 08/12/2	2021
Exportin	g (certifyi	ng) country:	INDIA				
Importin	g (requesti	ing) country:	TAJIKIST	AN			
1. Nam	e and dosa	ge form of the pr	roduct: DOX	ORUB	ICIN HYDROCHLORIDE	INJECTION USP	10 mg
1.1 Activ	-	ent (S) <sup>2</sup> and amou rophilized vial co		it dose <sup>3</sup>			
	Doxorul	oicin Hydrochlor	ride USF	)	10 mg		
	Lactose	Monohydrate	USF	•	50 mg		
1.2	.2 Is this product licensed to be placed on the market for use in the exporting country? <sup>5</sup> (Key in as appropriate)					ntry? 5	
	Yes	$\boxtimes$			No 🔲		
1.3	Is this pr	oduct actually on	the market in	the expe	orting country?		
	Yes	$\boxtimes$			No 🗌	Unknown	
	If the ans	swer to 1.2 is yes	, continue with	n section	2A and omit section 2B.		
	If the ans	swer to 1.2 is no,	omit section 2	2A and co	ontinue with section 2B6		
S	ECTION	2A					
2.A.1	Number of product Licence <sup>7</sup> and date of issue: 22/RR/TS/2015/F/G, Dated: 13.01.2015						
2.A.2	Product l	icense holder (N	ame and addre	ess):	GLS PHARMA LIMITED Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, IND		
2.A.3	Status of	product – license	e holder <sup>8</sup> (Ke	y is appr	opriate category as defined in a	note (8)	
	a) 🛛			b) [	]	c) 🗌	
2A.3.1	For categ	gories b and c the	name and add	lress of t	he Manufacturer producing the	e dosage form is <sup>9</sup> ?	
	Yes 🗌			No [		Not applicable	
2.A.4	Is summa	ary basis for appr	oval appended	i <sup>10</sup> ? (er	nclosed at the time of product a	approval)	
	Yes 🛛			No [		Not applicable	
2.A.5	Is the atta (key as	ached, officially appropriate)	approved prod	luct infor	rmation complete and consonar	nt with the license?11	
2. A.6	Yes 🛭 Applican	t for certificate, i	if different fro	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 cate	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 or not applicable, proceed to question 4.						
	Periodicity of routine inspections (years): NOT LESS THAN ONCE A YEAR						
	Has the manufacturer of this type of dosage form been inspected Yes/No (Key in as appropriate)						
	Yes	$\boxtimes$	No 🗆	Not applicable			
	Do the facilities and operations conform to GMP as recommended by the World Health Organisation 15?						
	Yes	$\boxtimes$	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			
	outy Director ation, Vengalarao Nagar, Felangana, INDIA.						
	Telepho	ne and Fax numbers :	TEL: +91 40 23814119	FAX: +91 40 23814360			
	Name of	Authorized Person :		B. VENKATESHWARLU ECTOR & CERTIFYING AUTHORITY			
	Signature :						
	Stamp a		KATESHWARLU CERTIFYING AUTHORITY				

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