CERTIFICATE OF PHARMACEUTICAL PRODUCT

No. of C	ertificate : 1096/DI/N	ILK/TST/COPP/0912	22019	Valid up to: 08/12/2021
Exportin	g (certifying) country:	INDIA		
Importin	g (requesting) country:	TAJIKISTAN		
1. Nam	e and dosage form of the p	roduct: LEUCOVO	RIN CALCIUM INJECTI	ON USP 30 mg 3 mL/Vial
1.1 Activ	ve Ingredient (S) ² and amo Each mL contains Leucovorin (as Leucovorin Calcium Excipients	10 mg		
1.2	Is this product licensed to (Key in as appropriate)	be placed on the mark	et for use in the exporting cou	intry? ⁵
	Yes 🛛		No 🗌	
1.3	Is this product actually o	n the market in the expo	orting country?	
	Yes 🖂		No 🗌	Unknown
	If the answer to 1.2 is ye	s, continue with section	2A and omit section 2B.	
	If the answer to 1.2 is no	, omit section 2A and co	ontinue with section 2B6	
5	SECTION 2A			
2.A.1	Number of product Licer	nce ⁷ and date of issue :	22/RR/TS/2015/F/G, Dated	1: 13.01.2015
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.3	Status of product - licen	se holder ⁸ (Key is appr	opriate category as defined in	note (8)
	a) 🔀	b) [c)
2A.3.1	For categories b and c th	e name and address of t	he Manufacturer producing th	ne dosage form is ⁹ ?
	Yes	No [Not applicable 🛛
2.A.4	Is summary basis for app	proval appended ¹⁰ ? (er	nclosed at the time of product	approval)
	Yes 🛛	No [Not applicable
2.A.5	Is the attached, officially (key as appropriate)	approved product info	rmation complete and conson	ant with the license? ¹¹
2. A.6	Yes 🛛 Applicant for certificate,	No [e holder (Name & Address) ¹²	Not applicable
	Yes 🗌	No I	MEDEFERENT GRUP» S.R.L.	Not applicable

2. B.1	Applicar	nt for certificate (Name & addr	ess)		
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	s: ¹³			
3.		e certifying authority arrange fo produced?	or periodic	inspection of the manufactu	ring plant in which the dosage
	Yes	\boxtimes		No 🗌	Not applicable ¹⁴
	If not or	not applicable, proceed to que	stion 4.		
	Periodic	ity of routine inspections (year	s):	NOT LESS THA	N ONCE A YEAR
	Has the	manufacturer of this type of do	sage form	been inspected Yes/No (Ke	y in as appropriate)
	Yes	\boxtimes		No 🗌	Not applicable
	Do the f	acilities and operations conform	n to GMP	as recommended by the Wo	rld Health Organisation ¹⁵ ?
	Yes	\boxtimes		No 🗌	Not applicable
4.	Does the manufac	e information submitted by the turer of the product ? ¹⁶	applicant	satisfy the certifying authori	ty on all aspects of the
	Yes	\boxtimes		No 🗌	Not applicable
	Address	of certifying authority	:	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	:	Dr. B. VENKA	TESHWARLU
	C		DEI	PUTY DIRECTOR & C	ERTIFYING AUTHORITY
	Signatu	e			
	Stamp a	nd Date		<u> パ</u> Dr. B. VEN	KATESHWARLU
		Director Annual Control Activity of the control Activity of the control of the co	DEP	UTY DIRECTOR &	CERTIFYING AUTHORITY





CERTIFICATE OF PHARMACEUTICAL PRODUCT

No. of C	ertificate : 3824/A3	3/2021			Valid up to: 11.01.2023
Exportin	g (certifying) country:	INDIA			
Importin	g (requesting) country:	CROATIA			
1. Name	e and dosage form of t		CYTARABIN CYTARAMA	E INJECTION BP 1g X 1000	10 mL/Vial
1.1 Activ	e Ingredient (S) ² and a	imounts (S) p	er unit dose ³ :		
	Each mL Contains: Cytarabine	BP	100 r	200	
	Water for injection	BP	q.s	np	
1.2	Is this product license (Key in as appropria		d on the marke	et for use in the exporting	country? ⁵
	Yes 🛛			No 🗌	
1.3	Is this product actual	ly on the mark	ket in the expo	rting country?	
	Yes 🛛			No 🗌	Unknown
	If the answer to 1.2 is	s yes, continue	e with section	2A and omit section 2B.	
	If the answer to 1.2 is	s no, omit sec	tion 2A and co	ntinue with section 2B6	
S	ECTION 2A				
2.A.1	Number of product L	icence ⁷ and d	ate of issue :	22/RR/TS/2015/F/G, D	ated: 13.01.2015
2.A.2	Product license holde	r (Name and	address) :	GLS PHARMA LIMI Plot.No. 10,IDA, Phase- Jeedimetla, R.R.Dist, Hyderabad, Telangana,	-1
2.A.3	Status of product - lie	cense holder ⁸	(Key is appro	priate category as defined	d in note (8)
	a) 🔀		b)	1	c)
2A.3.1	For categories b and	c the name an	d address of th	ne Manufacturer producin	ig the dosage form is ⁹ ?
	Yes		No [3	Not applicable
2.A.4	Is summary basis for	approval app	ended ¹⁰ ? (en	closed at the time of prod	luct approval)
	Yes 🛛		No []	Not applicable
2.A.5	Is the attached, official (key as appropriate		product inform	mation complete and con	sonant with the license?11
2. A.6	Yes 🛛 Applicant for certific	ate, if differer	No [nt from license	holder (Name & Addres	Not applicable
	Yes 🗌		No 🛛	MEDEFERE GRUP» S.R.L. S.R.L. S.R.L. S.R.L. S.R.L. S.R.L. S.R.L. S.R.L.	Not applicable

2. B.1	Applicar	nt for certificate (Name & add	ress)		
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	s: ¹³			
3.		e certifying authority arrange produced?	or periodic	inspection of the manufactu	ring plant in which the dosage
	Yes	\boxtimes		No 🗌	Not applicable ¹⁴
	If not or	not applicable, proceed to que	estion 4.		
	Periodic	ity of routine inspections (yea	rs) :	NOT LESS THA	N ONCE A YEAR
	Has the	manufacturer of this type of d	osage form	been inspected Yes/No (Key	/ in as appropriate)
	Yes	\boxtimes		No 🗌	Not applicable
	Do the fa	acilities and operations confo	m to GMP	as recommended by the Wo	rld Health Organisation ¹⁵ ?
	Yes	\boxtimes		No 🗌	Not applicable
4.	Does the manufac	e information submitted by the turer of the product ? ¹⁶	e applicant	satisfy the certifying authorit	y on all aspects of the
	Yes	\boxtimes		No 🗌	Not applicable
	Address	of certifying authority	:	Office of the Dep Drugs Control Administra Hyderabad 500 038, 1	tion, Vengalarao Nagar,
		of certifying authority ne and Fax numbers	:	Drugs Control Administra	tion, Vengalarao Nagar,
	Telepho			Drugs Control Administra Hyderabad 500 038, 7	ation, Vengalarao Nagar, Felangana, INDIA.
	Telepho	ne and Fax numbers	:	Drugs Control Administra Hyderabad 500 038, 7 TEL: +91 40 23814119 Dr. Y. NAV JOINT DI	ation, Vengalarao Nagar, Felangana, INDIA.
	Telepho	ne and Fax numbers	:	Drugs Control Administra Hyderabad 500 038, 7 TEL: +91 40 23814119 Dr. Y. NAV JOINT DI LICENSING & CO	ation, Vengalarao Nagar, Felangana, INDIA. FAX: +91 40 23814360 /EEN KUMAR. RECTOR(FAC) /NTROLING AUTHORITY ////////////////////////////////////

CERTIFICATE OF PHARMACEUTICAL PRODUCT

		(General Instruc	tions and	expl	anatory notes a	ittached.)		
No. of C	ertificate	: 4912/DI/N	ILK/TST/CO	PP/051	2202	0		Valid up to: 0	6/01/2022
Exportin	g (certify	ing) country:	INDIA						
Importin	g (reques	ting) country:	KAZAKHST	TAN					
1. Nam	e and dos	sage form of the	product: F	PIRUB	ICIN	HYDROCH	LORID	E INJECTION	USP 10 mg 10 mL/Vial
1.1 Acti	ve Ingred	ient (S) ² and am	ounts (S) per un	it dose ³	:				
	Each m	L contains :							
		in Hydrochlori	de ph.Eur			5 mg			
	Sodium Excipier	Chloride		USP		9 mg q.s			
		or Injection		USP		q.s			
1.2		oduct licensed t as appropriate)	o be placed on t	he marke	et for	use in the expo	orting cou	ntry? ⁵	
	Yes	\boxtimes			No				
1.3	Is this pr	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	section	2A ai	nd omit section	2B.		
	If the an	swer to 1.2 is no	o, omit section 2	A and co	ontinu	e with section	2B6		
	SECTIO	ON 2A							
2.A.I	Number	of product Lice	nce ⁷ and date of	issue :	22/F	RR/TS/2015/F/	G, Dated	l: 13.01.2015	
2.A.2	Product	license holder ()	Name and addre	ss):	Plot Jeec	S PHARMA I .No. 10,IDA, F limetla, R.R.Di lerabad, Telang	Phase-I ist,		
2.A.3	Status o	f product – licen	se holder ⁸ (Key	is appro	opriate	e category as d	efined in	note (8)	
	a) 🖾			b) 🗌]			c)	
2A.3.1	For cate	gories b and c th	e name and add	ress of th	he Ma	anufacturer pro	ducing th	e dosage form is	?
	Yes 🗌			No [Not applicable	\boxtimes
2.A.4	Is summ	ary basis for ap	proval appended	l ¹⁰ ? (en	close	d at the time of	f product	approval)	
	Yes 🛛			No [Not applicable	
2.A.5	Is the att (key as	tached, officially appropriate)	approved prod	uct infor	matio	on complete and	d consona	ant with the licens	e?11
2. A.6	Yes 🛛 Applica	ht for certificate	, if different from	No [m license		ler (Name & A	ddress) ¹²	Not applicable	HOI WEDEFERENT CRUS C.C.
	Yes 🗌			No [\triangleleft			Not applicable	MEDEFERENT
								Als	S.R.L S.R.L Contraction of the second

2. B.1	Applica	nt for certificate (Name & add	ress)		
2. B.2	Status o	f applicant: (Key in the approp	oriate categ	gory as defined in note 8)	
2. B.2.1	For cate	gories b and c the name and a	ldress of t	he manufacturer producing the	e dosage from is ⁹ :
2. B.3		marketing authorization lackin uired / Not requested / under c		on / Refused (Key in as appro	priate)
2. B.4	Remark	s: ¹³			
3.		e certifying authority arrange f produced?	or periodi	c inspection of the manufactu	ring plant in which the dosage
	Yes	\boxtimes		No 🗌	Not applicable ¹⁴
	If not o	r not applicable, proceed to qu	estion 4.		
	Periodi	city of routine inspections (yea	rs):	NOT LESS THA	N ONCE A YEAR
	Has the	manufacturer of this type of d	osage forn	n been inspected Yes/No (Key	y in as appropriate)
	Yes	\boxtimes		No 🗌	Not applicable
	Do the	facilities and operations confo	m to GMI	P as recommended by the Wo	rld Health Organisation ¹⁵ ?
	Yes	\boxtimes		No 🗌	Not applicable
4.	Does th manufa	ne information submitted by the acturer of the product ? ¹⁶	e applicant	satisfy the certifying authorit	ty on all aspects of the
	Yes	\boxtimes		No 🗌	Not applicable
	Addres	s of certifying authority	:	Office of the Dep Drugs Control Administra Hyderabad 500 038, 7	ation, Vengalarao Nagar,
	Teleph	one and Fax numbers	:	TEL: +91 40 23814119	FAX: +91 40 23814360
	Name o	of Authorized Person	:	Dr. B. VENKAT	FESHWARLU
	Signatu	ire	JO]	INT DIRECTOR & CI	ERTIFITING AUTHORITY
	Stamp	and Date		B. hye	5101120



Dr. B. VENKATESHWARLU JOINT DIRECTOR(FAC) DRUGS CONTROL ADMINISTRATION



CERTIFICATE OF PHARMACEUTICAL PRODUCT

No. of C	ertificate : 1512/D	I/MLK/TST/COPP/09	1219	Valid up to: 08/12/2021
Exportin	ng (certifying) country	INDIA		
Importin	ng (requesting) country	: TAJIKISTAN		
1. Nam	e and dosage form of	the product: FLUORO	URACIL INJECTION USP	250 mg 5 mL/Ampoule
1.1 Acti	ve Ingredient (S) ² and	amounts (S) per unit dos	se^3 :	
	Each mL contains :			
	Fluorouracil Water for Injection	USP USP	50 mg q.s	
1.2	Is this product licen (Key in as appropr		narket for use in the exporting cou	untry? ⁵
	Yes 🛛		No 🗌	
1.3	Is this product actua	lly on the market in the e	exporting country?	
	Yes 🛛		No 🗌	Unknown
	If the answer to 1.2	is yes, continue with sect	tion 2A and omit section 2B.	
	If the answer to 1.2	is no, omit section 2A an	d continue with section 2B6	
5	SECTION 2A			
2.A.1	Number of product	Licence ⁷ and date of issu	ue: 22/RR/TS/2015/F/G, Dated	d: 13.01.2015
2.A.2	Product license holo	ler (Name and address) :	GLS PHARMA LIMITEI Plot.No. 10,IDA, Phase-I Jeedimetla, R.R.Dist, Hyderabad, Telangana, INE	
2.A.3	Status of product -	icense holder ⁸ (Key is a	ppropriate 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 th	ne dosage form is ⁹ ?
	Yes	N	0	Not applicable
2.A.4	Is summary basis fo	r approval appended 10 ?	(enclosed at the time of product	approval)
	Yes 🛛	N	0	Not applicable
2.A.5	Is the attached, offic (key as appropria		nformation complete and consona	ant with the license? ¹¹
2. A.6	Yes 🛛 Applicant for certifi		o conse holder (Name & Address)	Not applicable
	Yes 🗌	N	■ Market Contraction (MEDEFEREN GRUP) S.R.L. S.R.L. S.R.L. S.R.L. S.R.L. S.R.L. S.R.L. S.R.L. S.R.L. S.R.L. S.R.L.	Not applicable

2. B.1	Applica	nt for certificate (Name & add	ress)			
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	Remark	s: ¹³				
3.		e certifying authority arrange f produced?	`or periodi	c inspection of the manufactur	ring plant in which the dosage	
	Yes	\boxtimes		No 🗌	Not applicable ¹⁴	
	If not or	r 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 d	osage forr	n been inspected Yes/No (Key	/ in as appropriate)	
	Yes	\boxtimes		No 🗌	Not applicable	
	Do the	facilities and operations confor	m to GMI	P as recommended by the Wo	rld Health Organisation ¹⁵ ?	
	Yes	\boxtimes		No 🗌	Not applicable	
4.		e information submitted by the cturer of the product ? ¹⁶	e applicant	t satisfy the certifying authorit	y on all aspects of the	
	Yes	\boxtimes		No 🗌	Not applicable	
	Address	s of certifying authority	:	Office of the Dep Drugs Control Administra Hyderabad 500 038, T	ition, Vengalarao Nagar,	
	Telepho	one and Fax numbers	:	TEL: +91 40 23814119	FAX: +91 40 23814360	
	Name o	of Authorized Person	: DE	Dr. B. VENKAT	TESHWARLU ERTIFYING AUTHORITY	
	Signatu	re	:			
	Stamp a	and Date		戊. Dr. B. VEN	KATESHWARLU	





DEPUTY DIRECTOR & CERTIFYING AUTHORITY

CERTIFICATE OF PHARMACEUTICAL PRODUCT

No. of C	ertificate	: 3825/A3/20	21					Valid up to: 1	1.01.2023
Exportin	g (certifyi	ng) country: IN	DIA						
Importin	g (request	ing) country: M	OLDOVA						
1. Nam	e and dosa	age form of the p	oroduct: IFOSF IPOG		DE FO	R INJECTION U	ISP 1g		
1.1 Activ	ve Ingredie	ent (S) ² and amo	unts (S) per uni	dose ³	:				
	Each Vial Ifosfamic	l Contains: le	USP	1000	mg				
1.2		oduct licensed to as appropriate)) be placed on th	e marl	ket for	use in the exporti	ng cou	ntry? ⁵	
	Yes	\boxtimes			No				
1.3	Is this pro	oduct actually or	n the market in t	he exp	orting	country?			
	Yes	\boxtimes			No			Unknown	
	If the ans	swer to 1.2 is yes	s, continue with	section	12A ai	nd omit section 21	Β.		
	If the ans	wer to 1.2 is no.	, omit section 24	and c	ontinu	e with section 2B	6		
S	ECTION	2A							
2.A.1	Number	of product Licen	ce ⁷ and date of	issue :	22/R	R/TS/2015/F/G,	Dated	: 13.01.2015	
2.A.2	Product 1	icense holder (N	ame and addres	s) :	Plot Jeed	S PHARMA LIM No. 10,IDA, Pha imetla, R.R.Dist, erabad, Telangan	se-I		
2.A.3	Status of	product - licens	e holder ⁸ (Key	is appr	ropriate	e category as defin	ned in	note (8)	
	a) 🖾			b) [c)	
2A.3.1	For categ	ories b and c the	e name and addr	ess of	the Ma	nufacturer produc	cing the	e dosage form is	⁹ ?
	Yes 🗌			No				Not applicable	\boxtimes
2.A.4	Is summa	ary basis for app	roval appended	¹⁰ ? (e	nclose	d at the time of pr	oduct a	approval)	
	Yes 🛛			No				Not applicable	
2.A.5	Is the atta (key as	ached, officially appropriate)	approved produ	ct info	rmatio	n complete and co	onsona	nt with the licens	æ? ¹¹
2. A.6	Yes 🛛 Applican	t for certificate,	if different from	No licens		er (Name & Addr		Not applicable	
	Yes 🗌			No		And GRI GRI	FERE UP»	Nor applicable	Bary

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	Remark	s: ¹³				
3.		e certifying authority arran produced?	ge for periodi	c inspection of the manufact	uring plant in which the dosage	
	Yes	\boxtimes		No 🗌	Not applicable ¹⁴	
	If not or	r not applicable, proceed to	question 4.			
	Periodic	city of routine inspections (years) :	NOT LESS THA	AN ONCE A YEAR	
	Has the	manufacturer of this type of	of dosage form	n been inspected Yes/No (Ke	ey in as appropriate)	
	Yes	\boxtimes		No 🗌	Not applicable	
	Do the f	facilities and operations co	nform to GMI	P as recommended by the Wo	orld Health Organisation ¹⁵ ?	
	Yes	\boxtimes		No 🗌	Not applicable	
4.		e information submitted by cturer of the product ? ¹⁶	the applicant	t satisfy the certifying author	ity on all aspects of the	
	Yes	\boxtimes		No 🗌	Not applicable	
	Address	s 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 o	f Authorized Person	:			
				JOINT D	VEEN KUMAR. IRECTOR(FAC) ONTROLING AUTHORITY	
		Signature -YDERABAD DIFAC Stamp and Date	:	Dr. Y. NAVEEN M.I Joint Director (En Licensing & Controlling Drugs Control Ad Government of Hyderabad-500	ministration	
					RUSENI, SOCIA	



CERTIFICATE OF PHARMACEUTICAL PRODUCT

No. of C	ertificate : 3826/A3/2021			Valid up to: 11.01.2023
Exporting	g (certifying) country: INDIA			
Importin	g (requesting) country: MOLDO	OVA		
1. Name	e and dosage form of the product:	LEUPROLIDE A PROLEMAX 3.7		INJECTION 3.75 mg
1.1 Activ	e Ingredient (S) ² and amounts (S)	per unit dose ³ :		
	Each Lyophilized vial contains			
	Leuprolide Acetate Excipients	USP 3.75 1 q.s	ng	
	1 mL Ampoule of Solvent contai			
	Each Sterile ampoule contains: Sodium Carboxymethyl Cellulose	USP 5 mg		
	Mannitol Polysorbate 80	USP 50 mg USP 1 mg		
	Water for Injection	USP q.s.		
1.2	Is this product licensed to be plac (Key in as appropriate)	ed on the market f	or use in the exporting cou	intry? ⁵
	Yes 🛛	N	0	
1.3	Is this product actually on the ma	rket in the exporti	ng country?	
	Yes 🛛	N	o 🗌	Unknown
	If the answer to 1.2 is yes, contin	ue with section 2A	and omit section 2B.	
	If the answer to 1.2 is no, omit se	ction 2A and conti	nue with section 2B6	
S	ECTION 2A			
2.A.I	Number of product Licence ⁷ and	date of issue : 2	2/RR/TS/2015/F/R, Dated	: 19.04.2018
2.A.2	Product license holder (Name an	P Jo	LS PHARMA LIMITEI lot.No. 10,IDA, Phase-I cedimetla, R.R.Dist, yderabad, Telangana, IND	
2.A.3	Status of product - license holde	⁸ (Key is appropri	ate 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 th	e dosage form is ⁹ ?
	Yes	No 🗌		Not applicable 🛛
2.A.4	Is summary basis for approval ap	pended ¹⁰ ? (enclo	osed at the time of product	approval)
	Yes 🖂	No 🗌		Not applicable
2.A.5	Is the attached, officially approve (key as appropriate)	ed product informa	tion complete and consona	int with the license? ¹¹
2. A.6	Yes 🛛 Applicant for certificate, if differ	No 🔲 ent from license ho	x	Not applicable
	Yes 🗌	No 🖂	GRUP GRUP	Not applicable
			S.R.L. S.R.L. S.R.L. S.R.L. S.R.L. S.R.L. S.R.L. S.R.L. S.R.L. S.R.L. S.R.L.	ARSON 4

2. B.1	Applicar	nt for certificate (Name & ad	dress)		
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		narketing authorization lacki iired / Not requested / under o		n / Refused (Key in as approp	priate)
2. B.4	Remarks	s: ¹³			
3.		e certifying authority arrange produced?	for periodic	inspection of the manufactu	ring plant in which the dosage
	Yes	\boxtimes		No 🗌	Not applicable ¹⁴
	If not or	not applicable, proceed to qu	uestion 4.		
	Periodic	ity of routine inspections (ye	ars):	NOT LESS THA	N 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 f	acilities and operations confo	orm to GMP	as recommended by the Wor	rld Health Organisation ¹⁵ ?
	Yes	\boxtimes		No 🗌	Not applicable
4.		e information submitted by th turer of the product ? ¹⁶	ne applicant	satisfy the certifying authorit	y on all aspects of the
	Yes	\boxtimes		No 🗌	Not applicable
	Address	of certifying authority	:	Office of the Dep Drugs Control Administra Hyderabad 500 038, 7	tion, Vengalarao Nagar,
	Telepho	ne and Fax numbers	:	TEL: +91 40 23814119	FAX: +91 40 23814360
	Name of	f Authorized Person	:		
				JOINT DI	'EEN KUMAR. RECTOR(FAC) 'NTROLING AUTHORITY
		Signature	:	Dr. Y. NAVEEN M.P Joint Director (Enfl Licensing & Controlling Drugs Control Adm Government of T Hyderabad-500	harmPh.D orcement) Authority (FAC) ninistration
					EDEFERENT GRUP, s.R.L

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CERTIFICATE OF PHARMACEUTICAL PRODUCT

No. of C	ertificate	: 3827/A3/	2021				Valid up to: 11.01.2023
Exportin	ıg (certifyi	ng) country:	INDIA				
Importin	g (request	ing) country:	VENEZUE	LA [°]			
1. Nam	e and dosa	nge form of the		OMUSTIN	TE CAPSULE 0	S 40 mg	
1.1 Activ			nounts (S) po	er unit dose ³ : 40 mg q.s	:		
1.2		oduct licensed is appropriate		l on the mark	et for use in the	e exporting cou	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 s	ection 2B.	
	If the ans	swer to 1.2 is r	o, omit sect	ion 2A and co	ontinue with se	ction 2B6	
s	ECTION	2A					
2.A.1	Number	of product Lie	ence ⁷ and da	te of issue :	22/RR/TS/20	15/F/G, Dated	: 13.01.2015
2.A.2	Product l	icense holder	(Name and a	ddress) :	Plot.No. 10,II Jeedimetla, R		Α
2.A.3	Status of	product - lice	nse holder ⁸	(Key is appro	opriate category	y as defined in r	note (8)
	a) 🛛			b) []		c)
2A.3.1	For categ	gories b and c t	he name and	l address of t	he Manufacture	er producing the	dosage form is ⁹ ?
	Yes 🗌			No [Not applicable
2.A.4	Is summa	ary basis for ap	proval appe	nded 10? (en	closed at the ti	me of product a	pproval)
	Yes 🛛			No [Not applicable
2.A.5	Is the atta (key as	ached, officiall appropriate)	y approved	product infor	mation comple	te and consonar	it with the license?11
2. A.6	Yes 🛛 Applican	t for certificate	e, if different	No [t from license	holder (Name		Not applicable
	Yes 🗌			No [AN	AEDEFEREN GRUP»	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	Remark	s: 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 of	r not applicable, proceed to question 4.						
	Periodic	city of routine inspections (years) :	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	\boxtimes	No 🗌	Not applicable				
	Do the	facilities and operations conform to GMI	⁹ as recommended by the Wo	rld Health Organisation ¹⁵ ?				
	Yes		No 🗌	Not applicable				
4.	Does th manufa	e information submitted by the applicant cturer of the product ? ¹⁶	satisfy the certifying authori	ty on all aspects of the				
	Yes	\boxtimes	No 🗌	Not applicable				
	Address	s 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	f Authorized Person :						
		Dr. Y. NAVEEN KUMAR. JOINT DIRECTOR(FAC) LICENSING & CONTROLING AUTHORITY						
			1					

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 : 3828/A3/2021

Valid up to: 11.01.2023

Exporting (certifying) country: INDIA

Importing (requesting) country: MOLDOVA

1. Name and dosage form of the product: MESNA INJECTION 400 mg 4 mL/ Ampoule MESNA 400

1.1 Active Ingredient (S)² and amounts (S) per unit dose³ :

Each mL Contains Mesna

Mesna	Ph.Eur	100 mg
Disodium Editate	USP	0.25 mg
Benzyl Aclohol	USP	10.4 mg
Water for Injection	USP	q.s

1.2 Is this product licensed to be placed on the market for use in the exporting country? ⁵ (Key in as appropriate)

Yes 🛛 No 🗌

1.3 Is this product actually on the market in the exporting country?

Yes 🛛 No 🗌

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

SECTION 2A

Yes 🗌

- 2.A.1 Number of product Licence⁷ 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	(Key is appropriate category as defined in note (8)				
	a) 🔀	b)	c)			
2A.3.1	For categories b and c the name an	d address of the Manufac	turer producing the dosage form is 9?			

Yes 🗌 No 🗌 Not applicable 🛛

2.A.4 Is summary basis for approval appended ¹⁰? (enclosed at the time of product approval)

Yes 🛛 No 🗌 Not applicable 🗌

2.A.5 Is the attached, officially approved product information complete and consonant with the license?¹¹ (key as appropriate)

	Yes 🛛 Applicant for certificate, i	No		The show	Not applicable	
2. A.6	Applicant for certificate, i	f different from licer	ise hold	er (Name & A	ddress) ¹²	
				IT	- CCPENII 25	

No 🖾

Unknown

Not applicable

GRUP»

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 dos form is produced?							
	Yes	\boxtimes		No 🗌	Not applicable ¹⁴			
	If not or	not applicable, proceed to q	uestion 4.					
	Periodic	rity of routine inspections (ye	ears):	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 f	acilities and operations confe	orm to GMI	P as recommended by the Wo	rld Health Organisation ¹⁵ ?			
	Yes			No 🗌	Not applicable			
4.	Does the manufact	e information submitted by th cturer of the product ? ¹⁶	ne applicant	t satisfy the certifying authori	y on all aspects of the			
	Yes	\boxtimes		No 🗌	Not applicable			
	Address	of certifying authority	:	Office of the Dep Drugs Control Administra Hyderabad 500 038, 7	ition, Vengalarao Nagar,			
	Telepho	ne and Fax numbers	:	TEL: +91 40 23814119	FAX: +91 40 23814360			
	Name o	f Authorized Person	:					
				JOINT DI	'EEN KUMAR. RECTOR(FAC) NTROLING AUTHORITY			
		Signature -YDERABAD DFAC Stamp and Date Stamp and Date	:	Dr. Y. NAVEEN M.P Joint Director (Enf Licensing & Controlling Drugs Control Adm Government of T Hyderabad-500	ainistration			



CERTIFICATE OF PHARMACEUTICAL PRODUCT

No. of (Certificate : 2564/DL	MLK/TST/COPP/1	00520	Valid up to: 09/05/2022				
Exporti	Exporting (certifying) country: INDIA							
Importi	ng (requesting) country:	KENYA						
1. Nan	ne and dosage form of th	e product: SORAFE	NIB TABLETS 200 mg					
1.1 Acti	ve Ingredient (S) ² and a		se ³ :					
	Each film coated table Sorafenib Tosylate	et contains:						
	Equivalent to Sorafeni	ib 2	00 mg					
	Excipients		.S					
	Colour: Iron Oxide of							
1.2	Is this product licensec (Key in as appropriate		arket for use in the exporting cou	ntry? ⁵				
	Yes 🛛		No 🗌					
1.3	Is this product actually	on the market in the e	xporting country?					
	Yes 🛛		No 🗌	Unknown				
	If the answer to 1.2 is y	es, continue with secti	on 2A and omit section 2B.					
	If the answer to 1.2 is a	no, omit section 2A and	l continue with section 2B6					
S	ECTION 2A							
2.A.1	Number of product Lic	ence ⁷ and date of issue	e: 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 - lice	nse holder ⁸ (Key is ap	propriate category as defined in a	note (8)				
	a) 🔀	b)		c)				
2A.3.1	For categories b and c	the name and address o	of the Manufacturer producing the	e dosage form is 9?				
	Yes	No		Not applicable 🛛				
2.A.4	Is summary basis for a	pproval appended ¹⁰ ?	(enclosed at the time of product a	(pproval)				
	Yes 🖂	No		Not applicable				
2.A.5	Is the attached, official (key as appropriate)	ly approved product in	formation complete and consonar	it with the license?11				
2. A.6	Yes 🛛 Applicant for certificate	No e, if different from lice	nse holder Name & Address)	Not applicable				
	Yes 🗌	No	MEDEFEREN GRUP»	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	\boxtimes		No 🗌	Not applicable ¹⁴				
	If not or	not applicable, proceed to qu	estion 4.						
	Periodic	ity of routine inspections (yea	urs):	NOT LESS THAI	N ONCE A YEAR				
	Has the	manufacturer of this type of d	losage forn	h been inspected Yes/No (Key	in as appropriate)				
	Yes	\boxtimes		No 🗌	Not applicable				
	Do the f	acilities and operations confo	rm to GMP	as recommended by the Wor	ld Health Organisation ¹⁵ ?				
	Yes	\boxtimes		No 🗌	Not applicable				
4.	Does the manufac	e information submitted by the cturer of the product ? ¹⁶	e applicant	satisfy the certifying authorit	y on all aspects of the				
	Yes	\boxtimes		No 🗌	Not applicable				
	Address of certifying authority :			Office of the Deputy Director Drugs Control Administration, Vengalarao Nagar, Hyderabad 500 038, Telangana, INDIA.					
	Telepho	ne and Fax numbers	:	TEL: +91 40 23814119	FAX: +91 40 23814360				
	Name of	f Authorized Person	:	Dr. B. VENKAT	ESHWARLU				
	Signatur	e .	JOI	NT DIRECTOR & CE	RTIFITING AUTHORITY				
				10 A					

Stamp and Date



B. WENKATESHWARLU JOINT DIRECTOR(FAC) DRUGS CONTROL ADMINISTRATION



CERTIFICATE OF PHARMACEUTICAL PRODUCT

No. of C	ertificate	: 3929/A3/2	2021					Valid up to: 11.01.2023
Exportin	g (certifyi	ng) country:	INDIA					
Importin	g (requesti	ng) country:	MOLDOVA					
1. Nam	e and dosa	ge form of the	product: THAI THAI	LIDOMI LIMAX		CAPSULES US	SP 100 i	mg
1.1 Activ		ent (S) ² and an psules contain	nounts (S) per uni ns:	t dose ³ :				
	Thalidon	nide	USP	100 m	ig			
	Excipien	its		q.s				
1.2		oduct licensed s appropriate	to be placed on t)	he marke	t for u	ise in the exporti	ing count	ry? ⁵
	Yes	\boxtimes			No			
1.3	Is this pro	duct actually	on the market in	the expor	rting c	country?		
	Yes	\boxtimes			No [Unknown
	If the ans	wer to 1.2 is y	es, continue with	section 2	2A an	d omit section 21	B.	
	If the ans	wer to 1.2 is n	o, omit section 2.	A and cor	ntinue	with section 2B	36	
S	ECTION	2A						
2.A.1	Number o	of product Lice	ence ⁷ and date of	issue :	22/R	R/TS/2015/F/G,	, Dated:	13.01.2015
2.A.2	Product li	cense holder (Name and addres		Plot.] Jeedi	PHARMA LIN No. 10,IDA, Pha metla, R.R.Dist, rabad, Telangan	ise-I	Δ.
2.A.3	Status of	product – licer	nse holder ⁸ (Key	is approp	priate	category as defi	ned in no	ote (8)
	a) 🖾			b) 🗌				c)
2A.3.1	For catego	ories b and c t	he name and addi	ess of the	e Mai	nufacturer produc	cing the	dosage form is ⁹ ?
	Yes 🗌			No 🗌]			Not applicable 🛛
2.A.4	Is summa	ry basis for ap	proval appended	¹⁰ ? (enc	losed	at the time of pr	roduct ap	proval)
	Yes 🛛			No 🗌]		i	Not applicable
2.A.5		ched, officiall appropriate)	y approved produ	ict inform	nation	complete and co	onsonant	with the license? ¹¹
2. A.6	Yes 🖾 Applicant	for certificate	, if different fron	No 🔲 1 license 1] holde	r (Name & Addr		Not applicable
	Yes 🗌			No 🛛]	10 mm 5		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	\boxtimes	No 🗌	Not applicable ¹⁴				
	If not or	not applicable, proceed to question 4.						
	Periodic	ity of routine inspections (years) :	NOT LESS THAT	N ONCE A YEAR				
	Has the	manufacturer of this type of dosage form	n been inspected Yes/No (Key	/ in as appropriate)				
	Yes		No 🗌	Not applicable				
	Do the f	acilities and operations conform to GMF	as recommended by the Wo	rld Health Organisation ¹⁵ ?				
	Yes		No 🔲	Not applicable				
4.	Does the manufac	e information submitted by the applicant turer of the product ? ¹⁶	satisfy the certifying authorit	y on all aspects of the				
	Yes	\boxtimes	No 🗌	Not applicable				
	Address	of certifying authority :	Office of the Dep Drugs Control Administra Hyderabad 500 038, T	tion, Vengalarao Nagar,				
	Telepho	ne and Fax numbers :	TEL: +91 40 23814119	FAX: +91 40 23814360				
	Name of	f Authorized Person :						
			JOINT DI	'EEN KUMAR. RECTOR(FAC) NTROLING AUTHORITY				
		Signature : YDEPABAD DIFAC Stamp and Date Stamp and Date	Dr. Y. NAVEEN M.P Joint Director (Enfe Licensing & Controlling - Drugs Control Adm Government of T Hyderabad-500	inistration				
			and the second se	NO 1002600053 47				



CERTIFICATE OF PHARMACEUTICAL PRODUCT

No. of C	ertificate	: 3930/A3/20	21				Valid up to: 11.01.2023		
Exportin	g (certifyin	ng) country:	INDIA						
Importin	g (requestin	ng) country:	ZAMBL	4					
1. Name	1. Name and dosage form of the product: VINBLASTINE SULFATE FOR INJECTION USP 10 mg								
				<i>6</i> m					
1.1 Activ		nt (S) ² and amou hilized vial contai		unit dose	· :				
	Vinblastin Mannitol Water for			USP USP USP	10 mg q.s q.s				
1.2		oduct licensed to s appropriate)	be placed	on the mar	ket for use	in the exportin	g country? ⁵		
	Yes	\boxtimes			No 🗌				
1.3	Is this pro	duct actually on	the marke	t in the exp	porting cou	intry?			
	Yes	\boxtimes			No 🗌		Unknown		
	If the answ	wer to 1.2 is yes	, continue	with sectio	n 2A and c	mit section 2B			
	If the answ	wer to 1.2 is no,	omit sectio	on 2A and	continue w	ith section 2B6)		
S	ECTION	2A							
2.A.1	Number o	of product Licen	ce ⁷ and dat	e of issue	: 22/RR/	FS/2015/F/G, I	Dated: 13.01.2015		
2.A.2	Product li	cense holder (N	ame and ac	ldress) :	Plot.No Jeedime	HARMA LIM . 10,IDA, Phas etla, R.R.Dist, bad, Telangana	e-I		
2.A.3	Status of J	product – license	e holder ⁸ (Key is app	ropriate ca	tegory as defin	ed in note (8)		
	a) 🔀			b) [c)		
2A.3.1	For catego	ories b and c the	name and	address of	the Manuf	acturer produci	ng the dosage form is 9?		
	Yes 🗌			No			Not applicable		
2.A.4	Is summa	ry basis for appr	oval appen	ded ¹⁰ ? (e	enclosed at	the time of pro	duct approval)		
	Yes 🛛			No			Not applicable		
2.A.5		ched, officially a appropriate)	pproved p	roduct info	ormation co	omplete and con	nsonant with the license?11		
2. A.6	Yes 🛛 Applicant	for certificate, i	f different	No from licen	□ se holder (Name & Addre	Not applicable		
	Yes 🗌			No		MEDEL Manuel Manuel Manuel Manuel Manuel Manuel Manuel Manuel Manuel Medel GRI Sul Sul Sul	A LIDO	14	

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		ting authorization lacking? Not requested / under consideration	on / Refused (Key in as appro-	priate)				
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 ap	pplicable, proceed to question 4.						
	Periodicity of	routine inspections (years) :	NOT LESS THAN	N ONCE A YEAR				
	Has the manuf	acturer of this type of dosage form	been inspected Yes/No (Key	in as appropriate)				
	Yes 🛛		No 🗌	Not applicable				
	Do the facilitie	es and operations conform to GMP	as recommended by the Wor	ld Health Organisation ¹⁵ ?				
	Yes 🛛		No 🗌	Not applicable				
4.	Does the information manufacturer of	mation submitted by the applicant of the product ? ¹⁶	satisfy the certifying authority	y on all aspects of the				
	Yes 🛛		No 🗌	Not applicable				
	Address of cer	tifying authority :	Office of the Dep Drugs Control Administra Hyderabad 500 038, 1	tion, Vengalarao Nagar,				
	Telephone and	Fax numbers :	TEL: +91 40 23814119	FAX: +91 40 23814360				
	Name of Authoria	orized Person :						
			JOINT DI	EEN KUMAR. RECTOR(FAC) NTROLING AUTHORITY				
	Signa * Stamp	ture MCEPABAD DIFAC and Date SWTOP	Joint Director (Enfo Licensing & Controlling A Drugs Control Adm Government of T Hyderabad-500	harmPh.D preement) suthority (FAC) sinistration				

CERTIFICATE OF PHARMACEUTICAL PRODUCT

No. of C	ertificate	: 3931/A3/	2021				Valid up to: 11	.01.2023		
Exporting (certifying) country: INDIA										
Importing (requesting) country: JAMAICA										
1. Name and dosage form of the product: VINCRISTINE SULFATE INJECTION USP 1mg 1mL/ Vial										
1.1 Active Ingredient (S) ² and amounts (S) per unit dose ³ : Each mL contains:										
	Mannito	ine Sulfate I or Injection	USP USP USP	1 mg 100 i q.s						
1.2	Is this product licensed to be placed on the market for use in the exporting country? ⁵ (Key in as appropriate)									
	Yes	\boxtimes		No						
1.3	Is this product actually on the market in the exporting country?									
	Yes	\boxtimes		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									
S	SECTION 2A									
2.A.1	Number of product Licence ⁷ 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 ⁸ (Key	is appropria	te category as de	efined in n	ote (8)			
	a) 🛛			b) 🗌			c) 🔲			
2A.3.1	For categ	gories b and c th	nd c the name and address of the Manufacturer producing the dosage form is 9?							
	Yes 🗌			No 🗌			Not applicable	\boxtimes		
2.A.4	Is summary basis for approval appended ¹⁰ ? (enclosed at the time of product approval)									
	Yes 🛛			No 🗌			Not applicable			
2.A.5	Is the attached, officially approved product information complete and consonant with the license? ¹¹ (key as appropriate)									
2. A.6	Yes 🖾 Applican	t for certificate.	if different from	No 🔲 license hol	der (Name & Ag	MI. SOCIETA	Not applicable			
	Yes 🗌			No 🛛		S.R.L.	Not applicable	□ કે∕\ પ્		

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	\boxtimes		No 🗌	Not applicable ¹⁴					
	If not or									
	Periodic	ity of routine inspections (yea	rs) :	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			Νο	Not applicable					
4.	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacturer of the product 2 ¹⁶									
	Yes	\boxtimes		No 🗌	Not applicable					
	Address	of certifying authority	:	Office of the Deputy Director Drugs Control Administration, Vengalarao Nagar, Hyderabad 500 038, Telangana, INDIA.						
	Telepho	ne and Fax numbers	:	TEL: +91 40 23814119	FAX: +91 40 23814360					
	Name of	Authorized Person	:							
				Dr. Y. NAVEEN KUMAR. JOINT DIRECTOR(FAC) LICENSING & CONTROLING AUTHORITY						
		Signature -YDERABAD JDIFAC Stamp and Date Stamp and Date	:	Dr. Y. NAVEEN M.F Joint Director (End Licensing & Controlling Drugs Control Adr Government of T Hyderabad-500	PharmPh.D orcement) Authonty (FAC) ninistration					
				DODOVA, ANG	MEDEFERENT GRUP»					

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DRUGS CONTROL ADMINISTRATION Government of Telangana



Dated 15-02-2020

То

M/s. GLS Pharma Limited, Plot.No.10, Phase – I, IDA., Jeedimetla, Medchal-Malkajgiri District – 500 055, Telangana, INDIA.

Sirs,

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Issue of World Health Organization Good Manufacturing Practice Certificate – Regarding.

- Ref: 1. Your application dated 05.11.2018.
 - 2. Joint Inspection Report dated 20.02.2019 & 21.02.2019.
 - 3. Compliance Verification Report dated 05.12.2019.
 - 4. Lr.No. 5-6(490 A1)/2018/7492, dated 13.02.2020 of Deputy Drugs Controller(India), CDSCO, Hyderabad

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I forward herewith WORLD HEALTH ORGANIZATION GOOD MANUFACTURING PRACTICE CERTIFICATE for the products recommended by the Joint Inspection Team consisting of officers of Central Drugs Standard Control Organization and officer from Drugs Control Administration, Telangana for Export Purpose.

This Certificate is valid for a period of Three years from the date of issue.



Yours faithfully,

Dr. B. VENKATESHWARLU JOINT DIRECTOR(FAC) DRUGS CONTROL ADMINISTRATION

