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: 2499/DI/	MLK/TST/COPP/1	5022020	Valid up to: 14/02/2022					
Exporti	ng (certifying) country:	INDIA							
Importi	ng (requesting) country:	CHILE							
1. Nan	ne and dosage form of the	e product: METHO?	TREXATE INJECTION USP	500 mg 5 mL/Vial					
1.1 Act	ive Ingredient (S) ² and a	mounts (S) per unit do	ose ³ :						
	Each mL contains: Methorexate Sodium Chloride Benzoyl Alcohol Water for injection Sodium hydroxide		ng 49 mg 90 mg						
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 c	exporting country?						
	Yes		No 🗆	Unknown					
	If the answer to 1.2 is yes, continue with section 2A and omit section 2B.								
	If the answer to 1.2 is no, omit section 2A and continue with section 2B6								
	SECTION 2A								
2.A.1	Number of product Lic	cence ⁷ and date of issu	ue: 22/RR/TS/2015/F/G, Dated	1: 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	ense 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 the dosage form is 9?								
	Yes	No	o 🗆	Not applicable					
2.A.4	Is summary basis for a	approval appended 10 ? (enclosed at the time of product approval)							
	Yes 🛛	No	o 🗆	Not applicable					
2.A.5	Is the attached, official (key as appropriate)	lly approved product in	nformation complete and consona	nt with the license? ¹¹					
2. A.6	Yes Applicant for certificat		ense holder (Name & Address) ¹²	Not applicable					
	Yes 🗌	No	o 🛛	Not applicable					

SECTION 2B IS TO BE OMITTED

2. B.1	Applicant for certificate (Name & address)								
2. B.2	Status of applicant: (Key in the appropriate category as defined in note 8)								
2. B.2.1	1 For categories b and c the name and address of the manufacturer producing the dosage from is 9:								
2. B.3	Why is marketing authorization lacking? Not required / Not requested / under consideration / Refused (Key in as appropriate)								
2. B.4	Remarks: ¹³								
3.	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 qu	uestion 4.						
	Periodicity of routine inspections (years):			NOT LESS THAN ONCE A YEAR					
	Has the	Has the manufacturer of this type of dosage form been inspected Yes/No (Key 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 ¹⁵ ?				
	Yes	\boxtimes		No 🗆	Not applicable				
 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacturer of the product?¹⁶ 					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	:	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. VENKATESHWARLU JOINT DIRECTOR(FAC)					
		ROLADAM		JOIN! DIKE	JIUK(FAC)				



DRUGS CONTROL ADMINISTRATION

GOVERNMENT OF TELANGANA DRUGS CONTROL ADMINISTRATION Vengalarao Nagar, Hyderabad 500 038

CERTIFICATE OF PHARMACEUTICAL PRODUCT

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

No. of C	ertificate	: 3902/A3/2	2021				Valid up to: 10.11.2023	3
Exportin	g (certifyi	ng) country:	INDIA					
Importin	g (requesti	ng) country:	EGYPT					
1. Name	e and dosa	ge form of the	e product: VINC	RELBI	NE I	NJECTION USP 50 1	mg/5mL Vial	
1.1 Activ	e Ingredie	ent (S) ² and an	nounts (S) per uni	it dose ³ :				
	Each mL	Contains						
		ne Tartrate						
	-	nt to Vinorelbi		JSP		50 mg		
	Water for	Injection		JSP		q.s		
1.2		oduct licensed as appropriate		he marke	et for	use in the exporting cou	ntry? 5	
	Yes	\boxtimes			No			
1.3	Is this pro	oduct actually	on the market in	the expo	rting	country?		
	Yes	\boxtimes			No		Unknown	
	If the ans	wer to 1.2 is y	es, continue with	section 2	2A ar	nd omit section 2B.		
	If the ans	wer to 1.2 is 1	no, omit section 2	A and co	ntinu	e with section 2B6		
S	ECTION	2A						
2.A.1	Number	of product Lic	ence ⁷ and date of	issue:	22/R	R/TS/2015/F/G, Dated	: 13.01.2015	
2.A.2	Product l	icense holder	(Name and addre	ss):	Plot. Jeed	S PHARMA LIMITED No. 10,IDA, Phase-I imetla, R.R.Dist, erabad, Telangana, IND		
2.A.3	Status of	product – lice	ense holder8 (Key	is appro	priate	category as defined in	note (8)	
	a) 🛛			b) 🗌			c) 🔲	
2A.3.1	For categ	gories b and c	the name and add	ress of th	ne Ma	nufacturer producing the	e dosage form is 9?	
	Yes 🗌			No []		Not applicable	
2.A.4	Is summa	ary basis for a	pproval appended	l ¹⁰ ? (end	close	d at the time of product a	approval)	
	Yes 🛛			No []		Not applicable	
2.A.5		ached, official appropriate)	ly approved prod	uct inforr	natio	n complete and consona	nt with the license? ¹¹	
2. A.6	Yes 🛭 Applican	t for certificat	e, if different from	No [n license] hold	er (Name & Address) ¹²	Not applicable	
	Yes 🗌			No 🗵	₫		Not applicable	

SECTION 2B IS TO BE OMITTED

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 o	r not applicable, proceed to q	uestior	14.					
	Periodi	city of routine inspections (ye	ears):	NOT LESS T	THAN ONCE A YEAR				
	Has the	manufacturer of this type of	dosage	e form been inspected Yes/No	(Key in as appropriate)				
	Yes	\boxtimes		No 🗆	Not applicable				
	Do the	Do the facilities and operations conform to GMP as recommended by the World Health Organisation 15?							
	Yes			No 🗌	Not applicable				
4.	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacturer of the product ? ¹⁶								
	Yes	\boxtimes		No 🗌	Not applicable				
	Addres	s of certifying authority	2	Deputy Director (FAC) Lic	ol Administration ensing & Controlling Authority 500 038, Telanagana, INDIA				
	Telepho	one and Fax numbers	:	TEL: +91 40 23814119	9 FAX: +91 40 23814360				
	Name of Authorized Person		:		BHAGYA LAXMI				
	Signature		:		DIRECTOR (FAC) NTROLLING AUTHORITY				
	Stamp and Date			R. Swh	reppley 11/21				
	Ocputy Director	Nizamabad Region		Deputy Licensing & Drugs Co Govern	BHAGYA LAXMI y Director (FAC) Controlling Authority ntrol Administration ment of Telangana bad-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: 14/02/2022

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

Exportin	g (certifyi	ng) country:	INDIA							
Importin	g (request	ing) country:	CROATIA							
1. Name	e and dosa	ige form of the	product: BICAL	UTAN	MIDE TABLETS USP 50 N	MG				
1.1 Activ	-	ent (S) ² and ame	ounts (S) per unit	dose ³						
	Bicalutar Excipien Colour:		USP de USP	50 q.s	mg					
1.2		oduct licensed (as appropriate)		e mark	et for use in the exporting cour	ntry? 5				
	Yes	\boxtimes			No 🗌					
1.3	Is this pr	oduct actually o	on the market in the	ne expo	orting country?					
	Yes				No 🗆	Unknown				
	If the ans	swer to 1.2 is ye	es, continue with	section	2A and omit section 2B.					
	If the ans	If the answer to 1.2 is no, omit section 2A and continue with section 2B6								
	SECTIO	ON 2A								
2.A.1	Number	of product Lice	nce 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 appre	opriate category as defined in r	note (8)				
	a) 🛛			b) []	c) 🔲				
2A.3.1	For categ	gories b and c th	ne name and addre	ess of t	he Manufacturer producing the	dosage form is 9?				
	Yes 🗌			No []	Not applicable				
2.A.4	Is summa	ary basis for ap	proval appended	⁰ ? (er	nclosed at the time of product a	approval)				
	Yes 🛛			No [Not applicable				
2.A.5	Is the atta (key as	ached, officially appropriate)	y approved produc	et infor	rmation complete and consonar	nt with the license? ¹¹				
2. A.6	Yes 🛭 Applican	t for certificate	, if different from	No [license	e holder (Name & Address) ¹²	Not applicable				
	Yes 🗌			No [\boxtimes	Not applicable				

SECTION 2B IS TO BE OMITTED

2. B.1	Applicant for certificate (Name & address)								
2. B.2	Status of applicant: (Key in the appropriate category as defined in note 8)								
2. B.2.1	1 For categories b and c the name and address of the manufacturer producing the dosage from is 9:								
2. B.3	Why is marketing authorization lacking? Not required / Not requested / under consideration / Refused (Key in as appropriate)								
2. B.4	Remarks: ¹³								
3.	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 qu	uestion 4.						
	Periodicity of routine inspections (years):			NOT LESS THAN ONCE A YEAR					
	Has the	Has the manufacturer of this type of dosage form been inspected Yes/No (Key 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 ¹⁵ ?				
	Yes	\boxtimes		No 🗆	Not applicable				
 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacturer of the product?¹⁶ 					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	:	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. VENKATESHWARLU JOINT DIRECTOR(FAC)					
		ROLADAM		JOIN! DIKE	JIUK(FAC)				



DRUGS CONTROL ADMINISTRATION