



L.Dis.No:134883/TS/2024

Dated:13/01/2024 Valid until:11/01/2025

GOOD MANUFACTURING PRACTICES CERTIFICATE

This is to certify that M/s GLS PHARMA LIMITED situated at address PLOT-10, PHASE-I, IDA JEEDIMETLA, HYDERABAD-500055, JEEDIMETLA - PHASE I&II VILLAGE, QUTHBULLAPUR MANDAL, MEDCHAL - MALKAJGIRI DISTRICT, PINCODE 500055, TELANGANA STATE, INDIA is holding Drug Manufacturing Licence in Form 25&28 bearing No. 22/RR/TS/2015/F/G Date.13/01/2015 Valid upto 12/01/2025 for manufacture for sale or distribution of drugs approved by this Department. The firm is subjected to periodical inspection by this Department.

The firm is following **GOOD MANUFACTURING PRACTICES** as stipulated under the provisions of Schedule "M" of the Drugs and Cosmetics Rules, 1945. The firm should however carry out self inspection from time to time to ensure that the requirements of Good Manufacturing Practices are complied with.

This certificate is valid for one year from the date of issue, unless the firm's manufacturing license is suspended or cancelled by the Licenseing Authority/the firm failed to pay the required the license retention fee.



Digitally Signed By RAMDHAN GUGULOTH Deputy Director and Certifying Authority DRUGS CONTROL ADMINISTRATION TELANGANA STATE Date:13-01-2024 21:38:42 PM

This Document is Digitally Signed. Signature is not required





No of Certificate : 4190037/TS/2024	Valid UpTo	o: 19/02/2027
1.Name and Dosage form of Product:	Exporting (Certifying)Country:	INDIA
2.Bleomycin Injection USP 15 Units		
3.Active Ingredients(s)^2 and amount(s) per unit dose^3:	Importing (Requesting)country:	AFGHANISTAN
Each lyophilized Vial contains Bleomycin Sulfate USP, Equivalent to Bleomycin 15u	nits	
For complete qualitative composition including excipients see above^4		
3.1 Is this Product licensed to be placed on the market for use in Exporting country	·?^5	Yes
3.2 Is this product actually on the marketing in the Exporting Country?		Yes
If the answer to 1.2 is Yes, continue with section 2A and omit section 2B.If the answ	wer to 1.2 is No, omit section 2A co	ontinue with section
2B^6		
	2B.1 Applicant for Certificate(N	Jame and Address)
2A.1 Number of Product Licence^7: 22/RR/TS/2015/F/G, Dt: 12/01/2020.	NOVE ENVE E	
	2B.2 Status of Applicant^8	
2A.2 Product License Holder(Name and address): GLS PHARMA LIMITED, PLOT - 10, IDA JEEDIMETLA, HYDERABAD - 500055, TELANGANA STATE, INDIA.		AX N D
2A.3 Status of License Holders^8 : a	2B2.1 For Categories (b) and (c address of the manufacturer pro	
2A.3.1 For Category b and c the name and address of the manufacturer	form is^9	
producing the dosage form is ^9 NOT APPLICABLE		
2A.4 Is Summary basis of approval appended ? ^10 No	2B.3 Why is marketing authoris	sation lacking?
	2B.4 Remarks^13 :	
2A.5 Is the Attached, officially approved production information	2B.4 Remarks^13 :	
complete and consonant with the license?^11: Not Provided		
2A.6 Applicant for Certificate, if different from licence holder		
(name and address) NO		
3 Does the certifying authority arrange for periodic spection of the manufacturing	plant in which the dosage	
form is produced?^14		Yes
3.1 Periodicity of routine inspection(years)		Once in a Year
3.2 Has the Manufacture of this type of dosage from been inspected?		Yes
3.3 Do the facilities and operations conform to GMP as recommended by World H	ealth Organization?^15	Yes
4.0 Does the information Submitted by the applicant satisfy the certifying authorit	y on all aspects of the	
manufacture of the product?^16		Yes
Address of Certifying Authority.	Name of the authorize	
Drugs Control Administration, Vengalraonagar, Hyderabad 500038, India Telephone No : 91-040-23814119 Fax No : 91-040-23814360		Digitally Signed By RAMDHAN GUGULOTH
		nd Certifying Authority
	DRUGS CON	
	Da	TELANGANA STATE te:02/01/2024 1:16 PM
This certificate conforms to the format recommended by the	World Health Organization	
(General instructions and explanatory r	iotes overleaf)	

DRUGS CONTROL ADMINISTRATION TELANGANA

DRUGS CONTROL ADMINISTRATION Government of Telangana



Explanatory notes

Explanatory notes	
1. This certificate, which is in the format recommended by WHO, establishes the status of the pharm	naceutical product and of the
applicant for the certificate in the exporting country. It is for a single product only since manufac	turing arrangements and approved
information for different dosage forms and different strengths can vary.	
2. Use whenever possible, International Non-proprietary Names (INNs) or national non-proprietary	names.
3. The formula (complete composition) of dosage form should be given on the certificate or be appe	ended.
4. Details of quantitative composition are preferred, but their provision is subject to the agreement of	of the product licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administratio	
specified in the product license.	
6.Sections 2A and 2B are mutually exclusive.	
7. Indicate when applicable, if the license is provisional, or the product has not yet been approved.	
8. Specify whether the person responsible for placing the product on the market:	
(a) manufactures the dosage form;	
(b) packages and/or labels a dosage form manufactured by an independent company; or	
(c) is involved in non of the above	
9. This information can be provided only with the consent of the product license holder or, in the cas	e of non registered
products, the applicant. Non-completion of this section indicates that the party concerned has no	
information. It should be noted that information concerning the site of production is part of the production is part of th	
site is changed, the license Must be updated or it will cease to be valid.	
10. This refers to the document, prepared by some national regulatory authorities, that summarizes	the technical basis on which the
product has been licensed.	
11. This refers to the product information approved by the competent national regulatory authority, s	uch as a Summary of Product
Characteristics (SmPC).	den as a ourninary of 1 roddet
12.In this circumstance, permission for issuing the certificate is required from the product license ho	der. This permission must be provided to
the authority by the applicant.	nder. This permission must be provided to
13.Please indicate the reason that the applicant has provided for not requesting registration:	
(a) the product has been developed exclusively for the treatment of conditions - particularly tro	prical diseases - not endemic in the country
of export;	pical diseases - not endernic in the country
(b) the product has been reformulated with a view to improving its stability under P tropical conc	litions
(c) the product has been reformulated to exclude excipients not approved for used in pharmace	
(d) the product has been reformulated to excite exciptents not approved for used in phaimace (d) the product has been reformulated to meet a different maximum dosage limit for an active in	
	igrealent,
(e) any reason, please specify. 14.Not applicable means that the manufacture is taking place in a country other than that issuing th	a product cartificate and inspection is
	e product certificate and inspection is
conducted under the aegis of the country of manufacture.	n the cortificate are these included in the
15. The requirements for good practices in the manufacture and quality control of drugs referred to in	In the certificate are those included in the
thirty-	D Taskairal Depart Carico No. 000, 4000
second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHC	
Annex 1). Recommendations specifically applicable to biological products have been formulated	by the WHO Expert Committee on
Biological Standardization (WHO Technical Report Series, No. 822, 1992 Annex 1)	(h) en (e) es described in note 0 about
16. This section is to be completed when the product license holder or applicant conforms to status	
It is of Particular importance when foreign contractors are involved in the manufacture of the	
applicant should supply the certifying authority with information to identify the contracting partie	
manufacture of the finished dosage form, and the extent and nature of any controls exercised	over each of these parties.





No of Certificate : 7902190/TS/2023	Valid UpTo: 23/07/2026
1.Name and Dosage form of Product:	Exporting(Certifying) Country: INDIA
2. Dacarbazine For Injection USP 200mg	
3.Active Ingredients(s) ² and amount(s) per unit dose ³ :	Importing(Requesting) Country: YEMEN
Each Sterile Lyophilized Vial contains Dacarbazine USP 200mg, Excipients q.s	
For complete qualitative composition including excipients see above^4	
3.1 Is this Product licensed to be placed on the market for use in Exporting country	/?^5 Yes
3.2 Is this product actually on the marketing in the Exporting Country?	Yes
If the answer to 1.2 is Yes, continue with section 2A and omit section 2B.If the ans 2B^6	wer to 1.2 is No, omit section 2A continue with section
2A.1 Number of Product Licence^7: 22/RR/TS/2015/F/G, Dt: 12/01/2020.	2B.1 Applicant for Certificate(Name and Address)
2A.2 Product License Holder(Name and address): GLS PHARMA LIMITED, PLOT - 10, IDA JEEDIMETLA, HYDERABAD - 500055, TELANGANA STATE, INDIA.	2B.2 Status of Applicant ⁸
2A.3 Status of License Holders^8 : a	2B2.1 For Categories (b) and (c) the name and address of the manufacturer producing the dosage form is^9
2A.3.1 For Category b and c the name and address of the manufacturer producing the dosage form is ^9 NOT APPLICABLE	2B.3 Why is marketing authorisation lacking?
2A.4 Is Summary basis of approval appended ? ^10 No	2B.4 Remarks^13 :
2A. <mark>5 Is the Attached, officially approved production information complete and consonant with the license?^11: Not Provided</mark>	
2A.6 Applicant for Certificate, if different from licence holder (name a <mark>nd a</mark> ddress) NO	
3 Does the certifying authority arrange for periodic spection of the manufacturing	
form is produced?^14	Yes
3.1 Periodicity of routine inspection(years)	Once in a Year
3.2 Has the Manufacture of this type of dosage from been inspected?	Yes
3.3 Do the facilities and operations conform to GMP as recommended by World H	
4.0 Does the information Submitted by the applicant satisfy the certifying authorit manufacture of the product?^16	y on all aspects of the Yes
Address of Certifying Authority. Drugs Control Administration, Vengalraonagar, Hyderabad 500038, India Telephone No : 91-040-23814119 Fax No : 91-040-23814360	Name of the authorized person: Digitally Signed By RAMDHAN GUGULOTH Deputy Director and Certifying Authority DRUGS CONTROL ADMINISTRATION TELANGANA STATE
	Date:16-08-2023 12:15:17 PM
This certificate conforms to the format recommended by the (General instructions and explanatory)	





<u>Explanatory notes</u>
1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the
applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved
information for different dosage forms and different strengths can vary.
2. Use whenever possible, International Non-proprietary Names (INNs) or national non-proprietary names.
3. The formula (complete composition) of dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is
specified in the product license.
6.Sections 2A and 2B are mutually exclusive.
7. Indicate when applicable, if the license is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:
(a) manufactures the dosage form;
(b) packages and/or labels a dosage form manufactured by an independent company; or
(c) is involved in non of the above
9. This information can be provided only with the consent of the product license holder or, in the case of non registered
products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this
information. It should be noted that information concerning the site of production is part of the product license. If the production
site is changed, the license Must be updated or it will cease to be valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the
product has been licensed.
11. This refers to the product information approved by the competent national regulatory authority, such as a Summary of Product
Characteristics (SmPC).
12.In this circumstance, permission for issuing the certificate is required from the product license holder. This permission must be provided to
the authority by the applicant.
13.Please indicate the reason that the applicant has provided for not requesting registration:
(a) the product has been developed exclusively for the treatment of conditions - particularly tropical diseases - not endemic in the country
of export;
(b) the product has been reformulated with a view to improving its stability underP tropical conditions;
(c) the product has been reformulated to exclude excipients not approved for used in pharmaceutical products in the country of import;
(d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
(e) any reason, please specify.
14.Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is
conducted under the aegis of the country of manufacture.
15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the
thirty-
second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series No. 823, 1992
Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on
Biological Standardization (WHO Technical Report Series, No. 822, 1992 Annex 1)
16. This section is to be completed when the product license holder or applicant conforms to status (b) or (c) as described in note 8 above.
It is of Particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the
applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of
manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.
sall sall
Sall sall

DRUGS CONTROL ADMINISTRATION TELANGANA	DRUGS CONTROL ADMIN Government of Te		State
CERT	TIFICATE OF A PHARMACEUTICA	AL PRODUCT^1	
No of Certificate : 4283738/TS/2024		Valid UpTo	o: 24/04/2027
1.Name and Dosage form of Product: Cyclophosphamide Injection USP 200mg	CTX-GLS 200	Exporting(Certifying)Country:	INDIA
1.1 Active Ingredients(s)^2 and amount(s) per Each sterile vial contains Cyclophospham Cyclophosphamide anhydraous 200mg		Importing(Requesting) country	MEXICO
For complete qualitative composition including excipients se	e above^4		
1.2 Is this Product licensed to be placed on th	ne market for use in Exporting country	?^5	Yes
1.3 Is this product actually on the marketing	in the Exporting Country?		Yes
If the an <mark>swer</mark> to 1.2 is Yes, continue with see	ction 2A and omit section 2B.If the ans 2B^6	wer to 1.2 is No, omit section 2A c	ontinue wi <mark>th se</mark> ction
2A.1 Number of Product Licence^7: 22/RR/1	rs/2015/F/G Dt:12/01/2020.	2B.1 Applicant for Certificate(N	lame and Addr <mark>ess)</mark>
2A.2 Product License Holder(Name and addr Limited,Plot.No:10,Phase-1,IDA,Jeedimetla,Hy Stat <mark>e,In</mark> dia.		2B.2 Status of Applicant ⁸	
2A.3 Status of License Holders^8 : a	THE OFFEEE	2B2.1 For Categories (b) and (c address of the manufacturer pro form is^9	
2A.3.1 For Category b and c the name and a producing the dosage form is ^9 Not App		2B.3 Why is marketing authoris	sation lacking?
2A.4 Is Summary basis of approval appended	? ^10 No	2B.4 Remarks^13 :	
2A.5 Is the Attached, officially approved proc complete and consonant with the license?^11	Little Comments of the second se	目目八	
2A.6 Applicant for Certificate, if different fro (name and address) NO	om licence holder	10a1 10a1	
3 Does the certifying authority arrange for pe form is produced?^14	eriodic spection of the manufacturing	plant in which the dosage	Yes
3.1 Periodicity of routine inspection(years)			Once in a Year
3.2 Has the Manufacture of this type of dosa	ge from been inspected?		Yes
3.3 Do the facilities and operations conform	to GMP as recommended by World H	ealth Organization?^15	Yes
4.0 Does the information Submitted by the a manufacture of the product?^16	pplicant satisfy the certifying authority	on all aspects of the	Yes
Address of Certifying Au Drugs Control Administration, Vengalraonag Telephone No : 91-040-23814119 Fax No :91	ar, Hyderabad500038, India	Name of the authorized Digitally Sign RAMDHAN GUGU Deputy Director and Certif DRUGS CONTROL ADMII TELANGANA ST. Date:03-05-2024 15:3	person: ed By LOTH ying Authority NISTRATION ATE

This certificate conforms to the format recommended by the World Health Organization (General instructions and explanatory notes overleaf)

S CONTROL ADMINISTRATION TEI ANGANA

DRUGS CONTROL ADMINISTRATION Government of Telangana



Explanatory notes

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary. 2. Use whenever possible, International Non-proprietary Names (INNs) or national non-proprietary names. 3. The formula (complete composition) of dosage form should be given on the certificate or be appended. 4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product licence holder. 5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product license. 6.Sections 2A and 2B are mutually exclusive. 7. Indicate when applicable, if the license is provisional, or the product has not yet been approved. 8. Specify whether the person responsible for placing the product on the market: (a) manufactures the dosage form; packages and/or labels a dosage form manufactured by an independent company; or (b) is involved in non of the above (c) 9. This information can be provided only with the consent of the product license holder or, in the case of non registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license Must be updated or it will cease to be valid. 10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed. 11. This refers to the product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SmPC). 12. In this circumstance, permission for issuing the certificate is required from the product license holder. This permission must be provided to the authority by the applicant. 13.Please indicate the reason that the applicant has provided for not requesting registration: (a) the product has been developed exclusively for the treatment of conditions - particularly tropical diseases - not endemic in the country export: of (b) the product has been reformulated with a view to improving its stability underP tropical conditions; (c) the product has been reformulated to exclude excipients not approved for used in pharmaceutical products in the country of import; (d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient; (e) any reason, please specify. 14.Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture. 15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirtysecond report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series No. 823, 1992) Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Standardization (WHO Technical Report Series, No. 822, 1992 Annex 1) Biological 16. This section is to be completed when the product license holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of Particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of dosage form, and the extent and nature of any controls exercised over each of these parties. manufacture of the finished



08/05/2023

DRUGS CONTROL ADMINISTRATION Government of Telangana



No of Certificate : 4232100/TS/2023	Valid UpTo: 23/07/2026
1.Name and Dosage form of Product: Leuprolide Acetate Depot for Injection 3.75mg	Exporting(Certifying)Country: INDIA
2.Active Ingredients(s)^2 and amount(s) per unit dose^3:	Importing(Requesting)country UZBEKISTAN
Each Lyophilized vial contains Leuprolide Acetate USP 3.75mg, Excipients q.s	
For complete qualitative composition including excipients see above^4	
2.1 Is this Product licensed to be placed on the market for use in Exporting country	?^5 Yes
2.2 Is this product actually on the marketing in the Exporting Country?	Yes
If the answer to 1.2 is Yes, continue with section 2A and omit section 2B.If the answ 2B^6	wer to 1.2 is No, omit section 2A continue with section
2A.1 Number of Product Licence^7: 22/RR/TS/2015/F/G, Dt: 12/01/2020.	2B.1 Applicant for Certificate(Name and Address)
2A.2 Product License Holder(Name and address): GLS PHARMA LIMITED, PLOT - 10, IDA JEEDIMETLA, HYDERABAD - 500055, TELANGANA STATE, INDIA.	2B.2 Status of Applicant^8
2A.3 Status of License Holders^8 : a	2B2.1 For Categories (b) and (c) the name and address of the manufacturer producing the dosage form is^9
2A.3.1 For Category b and c the name and address of the manufacturer producing the dosage form is ^9 NOT APPLICABLE	2B.3 Why is marketing authorisation lacking?
2A.4 Is Summary basis of approval appended ? ^10 No	2B.4 Remarks^13 :
2A. <mark>5 Is</mark> the Attached, officially approved production information complete and consonant with the license?^11: Not Provided	
2A.6 Applicant for Certificate, if different from licence holder (name and address) NO	
3 Does the certifying authority arrange for periodic spection of the manufacturing	
form is produced?^14	Yes
S.1 Periodicity of routine inspection(years)	Once in a real
3.2 Has the Manufacture of this type of dosage from been inspected?	Yes
3.3 Do the facilities and operations conform to GMP as recommended by World H	ealth Organization?^15 Yes
4.0 Does the information Submitted by the applicant satisfy the certifying authority manufacture of the product?^16	y on all aspects of the Yes
Address of Certifying Authority. Drugs Control Administration, Vengalraonagar, Hyderabad 500038, India Telephone No : 91-040-23814119 Fax No : 91-040-23814360	Name of the authorized person: Digitally Signed By RAMDHAN GUGULOTH Deputy Director and Certifying Authority DRUGS CONTROL ADMINISTRATION TELANGANA STATE
	Date:08-05-2023 10:19 AM
This certificate conforms to the format recommended by the (General instructions and explanatory n	





Explanatory notes
1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the
applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved
information for different dosage forms and different strengths can vary.
2. Use whenever possible, International Non-proprietary Names (INNs) or national non-proprietary names.
3. The formula (complete composition) of dosage form should be given on the certificate or be appended.
3. The following composition of the profession is due to the centrate of the appendent.
4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is
specified in the product license.
6.Sections 2A and 2B are mutually exclusive.
7. Indicate when applicable, if the license is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:
(a) manufactures the dosage form;
(b) packages and/or labels a dosage form manufactured by an independent company; or
(c) is involved in non of the above
9. This information can be provided only with the consent of the product license holder or, in the case of non registered
products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this
information. It should be noted that information concerning the site of production is part of the product license. If the production
site is ch <mark>ange</mark> d, the license Must be updated or it will cease to be valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the
product has been licensed.
11. This refers to the product information approved by the competent national regulatory authority, such as a Summary of Product
Characteristics (SmPC).
12.In this circumstance, permission for issuing the certificate is required from the product license holder. This permission must be provided to
the authority by the applicant.
13.Please indicate the reason that the applicant has provided for not requesting registration:
(a) the product has been developed exclusively for the treatment of conditions - particularly tropical diseases - not endemic in the countr
of export;
(b) the product has been reformulated with a view to improving its stability underP tropical conditions;
(c) the product has been reformulated to exclude excipients not approved for used in pharmaceutical products in the country of import;
(d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
(e) any reason, please specify.
14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is
conducted under the aegis of the country of manufacture.
15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the
thirty-
second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series No. 823, 1992
Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on
Biological Standardization (WHO Technical Report Series, No. 822, 1992 Annex 1)
16. This section is to be completed when the product license holder or applicant conforms to status (b) or (c) as described in note 8 above.
It is of Particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the
applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of
manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.





No of Certificate : 4230511/TS/2023	Valid UpTo: 10/02/2026
1.Name and Dosage form of Product:	Exporting (Certifying)Country: INDIA
Mesna Injection 400mg 4mL/Ampoule	
2.3.Active Ingredients(s) ² and amount(s) per unit dose ³ :	Importing (Requesting)country: AFGHANISTAN
Each mL contains Mesna Ph.Eur 100mg, Disodium Edetate USP 0.25mg, Benzyl Alo	cohol USP 10.4mg, Water for Injection USP q.s.
For complete qualitative composition including excipients see above^4	
3.1 Is this Product licensed to be placed on the market for use in Exporting country	/?^5 Yes
3.2 Is this product actually on the marketing in the Exporting Country?	Yes
If the answer to 1.2 is Yes, continue with section 2A and omit section 2B.If the ans	wer to 1.2 is No, omit section 2A continue with section
2B^6	
A statement and the statement of the sta	2B.1 Applicant for Certificate(Name and Address)
2A.1 Number of Product Licence^7: 22/RR/TS/2015/F/G, Dt: 12/01/2020.	「「の提手」に出る。
	2B.2 Status of Applicant^8
2A.2 Product License Holder(Name and address): GLS PHARMA LIMITED, PLOT - 10, IDA JEEDIMETLA, HYDERABAD - 500055, TELANGANA STATE, INDIA.	
2A.3 Status of License Holders^8 : a	2B2.1 For Categories (b) and (c) the name and address of the manufacturer producing the dosage
2A.3.1 For Category b and c the name and address of the manufacturer	form is^9
producing the dosage form is ^9 NOT APPLICABLE	
2A <mark>.4 Is</mark> Summary basis of approval appended ? ^10 No	2B.3 Why is marketing authorisation lacking?
	2B.4 Remarks^13 :
2A. <mark>5 Is</mark> the Attached, officially approved production information complete and consonant with the license?^11: Not Provided	
2A.6 Applicant for Certificate, if different from licence holder	
(name and address) NO	
3 Does the certifying authority arrange for periodic spection of the manufacturing	plant in which the dosage
form is produced?^14	Yes
3.1 Periodicity of routine inspection(years)	Once in a Year
3.2 Has the Manufacture of this type of dosage from been inspected?	Yes
3.3 Do the faciliti <mark>es an</mark> d operations conform to GMP as recommended by World H	lealth Organization?^15 Yes
4.0 Does the information Submitted by the applicant satisfy the certifying authorit manufacture of the product?^16	y on all aspects of the Yes
Address of Certifying Authority.	Name of the authorized person:
Drugs Control Administration, Vengalraonagar, Hyderabad 500038, India	Digitally Signed By
Telephone No : 91-040-23814119 Fax No : 91-040-23814360	RAMDHAN GUGULOTH Deputy Director and Certifying Authority
	Drugs Control Administration
	TELANGANA STATE
	Date:10-01-2023 2:33 PM
This certificate conforms to the format recommended by the (General instructions and explanatory	

DRUGS CONTROL ADMINISTRATION TELANGANA

DRUGS CONTROL ADMINISTRATION Government of Telangana



Explanatory notes

Explanatory notes	
1. This certificate, which is in the format recommended by WHO, establishes the status of the pharm	naceutical product and of the
applicant for the certificate in the exporting country. It is for a single product only since manufac	turing arrangements and approved
information for different dosage forms and different strengths can vary.	
2. Use whenever possible, International Non-proprietary Names (INNs) or national non-proprietary	names.
3. The formula (complete composition) of dosage form should be given on the certificate or be appe	ended.
4. Details of quantitative composition are preferred, but their provision is subject to the agreement of	of the product licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administratio	
specified in the product license.	
6.Sections 2A and 2B are mutually exclusive.	
7. Indicate when applicable, if the license is provisional, or the product has not yet been approved.	
8. Specify whether the person responsible for placing the product on the market:	
(a) manufactures the dosage form;	
(b) packages and/or labels a dosage form manufactured by an independent company; or	
(c) is involved in non of the above	
9. This information can be provided only with the consent of the product license holder or, in the cas	e of non registered
products, the applicant. Non-completion of this section indicates that the party concerned has no	
information. It should be noted that information concerning the site of production is part of the production is part of th	
site is changed, the license Must be updated or it will cease to be valid.	
10. This refers to the document, prepared by some national regulatory authorities, that summarizes	the technical basis on which the
product has been licensed.	
11. This refers to the product information approved by the competent national regulatory authority, s	uch as a Summary of Product
Characteristics (SmPC).	den as a ourninary of 1 roddet
12.In this circumstance, permission for issuing the certificate is required from the product license ho	der. This permission must be provided to
the authority by the applicant.	nder. This permission must be provided to
13.Please indicate the reason that the applicant has provided for not requesting registration:	
(a) the product has been developed exclusively for the treatment of conditions - particularly tro	prical diseases - not endemic in the country
of export;	pical diseases - not endernic in the country
(b) the product has been reformulated with a view to improving its stability under P tropical conc	litions
(c) the product has been reformulated to exclude excipients not approved for used in pharmace	
(d) the product has been reformulated to excite exciptents not approved for used in phaimace (d) the product has been reformulated to meet a different maximum dosage limit for an active in	
	igrealent,
(e) any reason, please specify. 14.Not applicable means that the manufacture is taking place in a country other than that issuing th	a product cartificate and inspection is
	e product certificate and inspection is
conducted under the aegis of the country of manufacture.	n the cortificate are these included in the
15. The requirements for good practices in the manufacture and quality control of drugs referred to in	In the certificate are those included in the
thirty-	D Taskairal Depart Carico No. 000, 4000
second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHC	
Annex 1). Recommendations specifically applicable to biological products have been formulated	by the WHO Expert Committee on
Biological Standardization (WHO Technical Report Series, No. 822, 1992 Annex 1)	(h) en (e) es described in note 0 about
16. This section is to be completed when the product license holder or applicant conforms to status	
It is of Particular importance when foreign contractors are involved in the manufacture of the	
applicant should supply the certifying authority with information to identify the contracting partie	
manufacture of the finished dosage form, and the extent and nature of any controls exercised	over each of these parties.