DRUGS CONTROL ADMINISTRATION
Government of Telangana

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

DRUGS CONTROL ADMINISTRATION
Government of Telangana

CERTIFICATE OF A PHARMACEUTICAL PRODUCT^1

No of Certificate : 4190037/TS/2024 Valid UpTo : **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 15units

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 answer to 1.2 is No, omit section 2A continue with section 2B^6

2A.1 Number of Product Licence^7: **22/RR/TS/2015/F/G, Dt: 12/01/2020.**

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

2A.3.1 For Category b and c the name and address of the manufacturer producing the dosage form is ^9 NOT APPLICABLE

2A.4 Is Summary basis of approval appended ? ^10 No

2A.5 Is 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

2B.1 Applicant for Certificate(Name and Address)

2B.2 Status of Applicant^8

2B2.1 For Categories (b) and (c) the name and address of the manufacturer producing the dosage form is^9

2B.3 Why is marketing authorisation lacking?

2B.4 Remarks^13 :

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 Health Organization?^15 Yes

4.0 Does the information Submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?^16 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:02/01/2024 1:16 PM

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

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;

(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.

DRUGS CONTROL ADMINISTRATION
Government of Telangana

CERTIFICATE OF A PHARMACEUTICAL PRODUCT^1

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 answer to 1.2 is No, omit section 2A continue with section 2B^6

2A.1 Number of Product Licence^7: **22/RR/TS/2015/F/G, Dt: 12/01/2020.**

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

2A.3.1 For Category b and c the name and address of the manufacturer producing the dosage form is ^9 NOT APPLICABLE

2A.4 Is Summary basis of approval appended ? ^10 No

2A.5 Is 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

2B.1 Applicant for Certificate(Name and Address)

2B.2 Status of Applicant^8

2B2.1 For Categories (b) and (c) the name and address of the manufacturer producing the dosage form is^9

2B.3 Why is marketing authorisation lacking?

2B.4 Remarks^13 :

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 Health Organization?^15 Yes

4.0 Does the information Submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?^16 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 World Health Organization
(General instructions and explanatory notes overleaf)

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;
(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.

DRUGS CONTROL ADMINISTRATION
Government of Telangana

CERTIFICATE OF A PHARMACEUTICAL PRODUCT^1

No of Certificate : 4283738/TS/2024 Valid UpTo: **24/04/2027**

1.Name and Dosage form of Product: Exporting(Certifying)Country: **INDIA**

Cyclophosphamide Injection USP 200mg CTX-GLS 200

1.1 Active Ingredients(s)^2 and amount(s) per unit dose^3: Importing(Requesting) country **MEXICO**

Each sterile vial contains Cyclophosphamide monohydrate USP Equivalent to Cyclophosphamide anhydraous 200mg

For complete qualitative composition including excipients see above^4

1.2 Is this Product licensed to be placed on the market for use in Exporting country?^5 **Yes**

1.3 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 answer to 1.2 is No, omit section 2A continue with section 2B^6

2A.1 Number of Product Licence^7: **22/RR/TS/2015/F/G Dt:12/01/2020.**

2A.2 Product License Holder(Name and address): GLS Pharma Limited,Plot.No:10,Phase-1,IDA,Jeedimetla,Hyderabad-500055,Telangana State,India.

2A.3 Status of License Holders^8 : a

2A.3.1 For Category b and c the name and address of the manufacturer producing the dosage form is ^9 Not Applicable

2A.4 Is Summary basis of approval appended ? ^10 No

2A.5 Is 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

2B.1 Applicant for Certificate(Name and Address)

2B.2 Status of Applicant^8

2B2.1 For Categories (b) and (c) the name and address of the manufacturer producing the dosage form is^9

2B.3 Why is marketing authorisation lacking?

2B.4 Remarks^13 :

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 Health Organization?^15 Yes

4.0 Does the information Submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?^16 Yes

Address of Certifying Authority.
Drugs Control Administration, Vengalraonagar, Hyderabad500038, 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:03-05-2024 15:35:25 PM

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

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;
(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.

DRUGS CONTROL ADMINISTRATION
Government of Telangana

CERTIFICATE OF A PHARMACEUTICAL PRODUCT^1

No of Certificate : 4232100/TS/2023 Valid UpTo : **23/07/2026**

1.Name and Dosage form of Product: Exporting(Certifying)Country: **INDIA**

Leuprolide Acetate Depot for Injection 3.75mg

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 answer to 1.2 is No, omit section 2A continue with section 2B^6

2A.1 Number of Product Licence^7: **22/RR/TS/2015/F/G, Dt: 12/01/2020.**

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

2A.3.1 For Category b and c the name and address of the manufacturer producing the dosage form is ^9 NOT APPLICABLE

2A.4 Is Summary basis of approval appended ? ^10 No

2A.5 Is 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

2B.1 Applicant for Certificate(Name and Address)

2B.2 Status of Applicant^8

2B2.1 For Categories (b) and (c) the name and address of the manufacturer producing the dosage form is^9

2B.3 Why is marketing authorisation lacking?

2B.4 Remarks^13 :

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 Health Organization?^15 Yes

4.0 Does the information Submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?^16 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 World Health Organization
(General instructions and explanatory notes overleaf)

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;
(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.
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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.

DRUGS CONTROL ADMINISTRATION
Government of Telangana

CERTIFICATE OF A PHARMACEUTICAL PRODUCT^1

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 Alcohol 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 answer to 1.2 is No, omit section 2A continue with section 2B^6

2A.1 Number of Product Licence^7: **22/RR/TS/2015/F/G, Dt: 12/01/2020.**

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

2A.3.1 For Category b and c the name and address of the manufacturer producing the dosage form is ^9 NOT APPLICABLE

2A.4 Is Summary basis of approval appended ? ^10 No

2A.5 Is 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

2B.1 Applicant for Certificate(Name and Address)

2B.2 Status of Applicant^8

2B2.1 For Categories (b) and (c) the name and address of the manufacturer producing the dosage form is^9

2B.3 Why is marketing authorisation lacking?

2B.4 Remarks^13 :

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 Health Organization?^15 Yes

4.0 Does the information Submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?^16 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:10-01-2023 2:33 PM

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

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;

(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.