

**GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION
Vengal Rao 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 : **3802/A3/2021**

Valid up to: **01.01.2024**

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **JORDAN**

1. Name and dosage form of the product: **BLEOMYCIN INJECTION USP 15 UNITS
BLEOGET 15**

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

Each Lyophilized vial contains

Bleomycin sulfate	USP	15 IU
Equivalent to Bleomycin free base		15 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 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 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 holder⁸ (Key is appropriate category as defined in note (8))

a) ☒

b) ☐

c) ☐

2.A.3.1 For categories b and c the name and address of the Manufacturer producing the dosage form is⁹?

Yes ☐

No ☐

Not applicable ☒

2.A.4 Is summary basis for approval appended¹⁰? (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 ☒

No ☐

Not applicable ☐

2. A.6 Applicant for certificate, if different from license holder (Name & Address)¹²

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 form is⁹ :
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 applicable¹⁴ ☐

If not or not applicable, proceed to question 4.

Periodicity of routine inspections (years) : **NOT LESS THAN ONCE A YEAR**

Has the manufacturer of this type of dosage form been inspected Yes/No (Key in as appropriate)

Yes ☒ No ☐ Not applicable ☐

Do the facilities and operations conform to GMP as recommended by the World Health Organisation¹⁵?

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 ☒ No ☐ Not applicable ☐

Address of certifying authority : **Office of the Deputy Director
Drugs Control Administration, Vengal Rao Nagar,
Hyderabad 500 038, Telangana, INDIA.**

Telephone and Fax numbers : **TEL: +91 40 23814119 FAX: +91 40 23814360**

Name of Authorized Person :

**Dr. Y. NAVEEN KUMAR.
JOINT DIRECTOR(FAC)
LICENSING & CONTROLLING AUTHORITY**



Dr. Y. NAVEEN KUMAR
M.Pharm., Ph.D
Joint Director (Enforcement)
Licensing & Controlling Authority (FAC)
Drugs Control Administration
Government of Telangana
Hyderabad-500 038, T.S.

**GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION
Vengal Rao 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 : **1012/DI/MLK/TST/COPP/15022020**

Valid up to: **14/02/2022**

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **CROATIA**

1. Name and dosage form of the product: **BICALUTAMIDE TABLETS USP 150 MG**

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

Each film coated tablets contains

Bicalutamide USP 150 mg

Excipients q.s

Colour: Titanium Dioxide USP

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 ☐ 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 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 holder⁸ (Key is appropriate category as defined in note (8))

a) ☒ b) ☐ c) ☐

2.A.3.1 For categories b and c the name and address of the Manufacturer producing the dosage form is⁹?

Yes ☐ No ☐ Not applicable ☒

2.A.4 Is summary basis for approval appended¹⁰? (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 ☒ No ☐ Not applicable ☐

2. A.6 Applicant for certificate, if different from license holder (Name & Address)¹²

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 form is⁹ :
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 applicable¹⁴ ☐

If not or not applicable, proceed to question 4.

Periodicity of routine inspections (years) : **NOT LESS THAN ONCE A YEAR**

Has the manufacturer of this type of dosage form been inspected Yes/No (Key in as appropriate)

Yes ☒ No ☐ Not applicable ☐

Do the facilities and operations conform to GMP as recommended by the World Health Organisation¹⁵?

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 ☒ No ☐ Not applicable ☐

Address of certifying authority : **Office of the Deputy Director
Drugs Control Administration, Vengal Rao Nagar,
Hyderabad 500 038, Telangana, INDIA.**

Telephone and Fax numbers : **TEL: +91 40 23814119 FAX: +91 40 23814360**

Name of Authorized Person : **Dr. B. VENKATESHWARLU
JOINT DIRECTOR & CERTIFYING AUTHORITY**

Signature :

Stamp and Date



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

**GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION
Vengal Rao 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 : 4511/A3/2022

Valid up to: 20.03.2024

Exporting (certifying) country: INDIA

Importing (requesting) country: EGYPT

1. Name and dosage form of the product: **CHLORAMBUCIL TABLETS USP 2 mg**
CHLORAMAX 2

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

Each film coated tablets contains
Chlorambucil USP 2 mg
Excipients q.s
Color: Iron Oxide of Yellow & Titanium Dioxide USP

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 ☐ 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 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 holder⁸ (Key is appropriate category as defined in note (8))

a) ☒ b) ☐ c) ☐

2.A.3.1 For categories b and c the name and address of the Manufacturer producing the dosage form is⁹?

Yes ☐ No ☐ Not applicable ☒

2.A.4 Is summary basis for approval appended¹⁰? (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 ☒ No ☐ Not applicable ☐

2. A.6 Applicant for certificate, if different from license holder (Name & Address)¹²

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 form is⁹ :
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 applicable¹⁴ ☐

If not or not applicable, proceed to question 4.

Periodicity of routine inspections (years) : **NOT LESS THAN ONCE A YEAR**

Has the manufacturer of this type of dosage form been inspected Yes/No (Key in as appropriate)

Yes ☒ No ☐ Not applicable ☐

Do the facilities and operations conform to GMP as recommended by the World Health Organisation¹⁵?

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 ☒ No ☐ Not applicable ☐

Address of certifying authority : **Drug Control Administration
Deputy Director (FAC) Licensing & Controlling Authority
Nizamabad , Hyderabad 500 038, Telanagana, INDIA**

Telephone and Fax numbers : **TEL: +91 40 23814119 FAX: +91 40 23814360**

Name of Authorized Person : **Smt. B. SOWBHAGYA LAXMI
DEPUTY DIRECTOR (FAC)**

Signature : **LICENSING & CONTROLLING AUTHORITY**

Stamp and Date



B. Sowbhagya Laxmi
21/02/22

**B. SOWBHAGYA LAXMI
Deputy Director (FAC)
Licensing & Controlling Authority
Drugs Control Administration
Government of Telangana
Hyderabad-500 038, T.S.**

**GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION
Vengal Rao 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 : **3824/A3/2021**

Valid up to: **11.01.2023**

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **CROATIA**

1. Name and dosage form of the product: **CYTARABINE INJECTION BP 1g 10 mL/Vial
CYTARAMAX 1000**

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

Each mL Contains:

Cytarabine	BP	100 mg
Water for injection	BP	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 ☐

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 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 holder⁸ (Key is appropriate category as defined in note (8))

a) ☒

b) ☐

c) ☐

2.A.3.1 For categories b and c the name and address of the Manufacturer producing the dosage form is⁹?

Yes ☐

No ☐

Not applicable ☒

2.A.4 Is summary basis for approval appended¹⁰? (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 ☒

No ☐

Not applicable ☐

2. A.6 Applicant for certificate, if different from license holder (Name & Address)¹²

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 form is⁹ :
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 applicable¹⁴ ☐

If not or not applicable, proceed to question 4.

Periodicity of routine inspections (years) : **NOT LESS THAN ONCE A YEAR**

Has the manufacturer of this type of dosage form been inspected Yes/No (Key in as appropriate)

Yes ☒ No ☐ Not applicable ☐

Do the facilities and operations conform to GMP as recommended by the World Health Organisation¹⁵?

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 ☒ No ☐ Not applicable ☐

Address of certifying authority : **Office of the Deputy Director
Drugs Control Administration, Vengal Rao Nagar,
Hyderabad 500 038, Telangana, INDIA.**

Telephone and Fax numbers : **TEL: +91 40 23814119 FAX: +91 40 23814360**

Name of Authorized Person :

**Dr. Y. NAVEEN KUMAR.
JOINT DIRECTOR(FAC)
LICENSING & CONTROLLING AUTHORITY**



Dr. Y. NAVEEN KUMAR
M.Pharm., Ph.D
Joint Director (Enforcement)
Licensing & Controlling Authority (FAC)
Drugs Control Administration
Government of Telangana
Hyderabad-500 038, T.S.

**GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION
Vengal Rao 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 : 3935/A3/2021

Valid up to: 12.09.2023

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **ALGERIA**

1. Name and dosage form of the product: **DACARBAZINE FOR INJECTION USP 100 mg
CARBANOVA 100 mg**

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

Each sterile lyophilized vial contains

Dacarbazine	USP	100 mg
Excipients		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 ☐ 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 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 holder⁸ (Key is appropriate category as defined in note (8))

a) ☒ b) ☐ c) ☐

2.A.3.1 For categories b and c the name and address of the Manufacturer producing the dosage form is⁹?

Yes ☐ No ☐ Not applicable ☒

2.A.4 Is summary basis for approval appended¹⁰? (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 ☒ No ☐ Not applicable ☐

2. A.6 Applicant for certificate, if different from license holder (Name & Address)¹²

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 form is⁹ :
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 applicable¹⁴ ☐

If not or not applicable, proceed to question 4.

Periodicity of routine inspections (years) : **NOT LESS THAN ONCE A YEAR**

Has the manufacturer of this type of dosage form been inspected Yes/No (Key in as appropriate)

Yes ☒ No ☐ Not applicable ☐

Do the facilities and operations conform to GMP as recommended by the World Health Organisation¹⁵?

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 ☒ No ☐ Not applicable ☐

Address of certifying authority : **Drug Control Administration
Deputy Director (FAC) Licensing & Controlling Authority
Nizamabad , Hyderabad 500 038, Telanagana, INDIA**

Telephone and Fax numbers : **TEL: +91 40 23814119 FAX: +91 40 23814360**

Name of Authorized Person : **Smt. B. SOWBHAGYA LAXMI
DEPUTY DIRECTOR (FAC)**

Signature : **LICENSING & CONTROLLING AUTHORITY**

Stamp and Date



B. Sowbhagya Laxmi
12/09/21

**B. SOWBHAGYA LAXMI
Deputy Director (FAC)
Licensing & Controlling Authority
Drugs Control Administration
Government of Telangana
Hyderabad-500 038, T.S.**

**GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION
Vengal Rao 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 : **4516/A3/2022**

Valid up to: 20.03.2024

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **TURKEY**

1. Name and dosage form of the product: **DECITABINE FOR INJECTION 50mg**

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

Each Lyophilized vial contains

Decitabine	50 mg
Excipients	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 ☐ 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 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 holder⁸ (Key is appropriate category as defined in note (8))

a) ☒ b) ☐ c) ☐

2.A.3.1 For categories b and c the name and address of the Manufacturer producing the dosage form is⁹?

Yes ☐ No ☐ Not applicable ☒

2.A.4 Is summary basis for approval appended¹⁰? (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 ☒ No ☐ Not applicable ☐

2. A.6 Applicant for certificate, if different from license holder (Name & Address)¹²

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 form is⁹ :
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 applicable¹⁴ ☐

If not or not applicable, proceed to question 4.

Periodicity of routine inspections (years) : **NOT LESS THAN ONCE A YEAR**

Has the manufacturer of this type of dosage form been inspected Yes/No (Key in as appropriate)

Yes ☒ No ☐ Not applicable ☐

Do the facilities and operations conform to GMP as recommended by the World Health Organisation¹⁵?

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 ☒ No ☐ Not applicable ☐

Address of certifying authority : **Drug Control Administration
Deputy Director (FAC) Licensing & Controlling Authority
Nizamabad , Hyderabad 500 038, Telanagana, INDIA**

Telephone and Fax numbers : **TEL: +91 40 23814119 FAX: +91 40 23814360**

Name of Authorized Person : **Smt. B. SOWBHAGYA LAXMI
DEPUTY DIRECTOR (FAC)**

Signature : **LICENSING & CONTROLLING AUTHORITY**

Stamp and Date



B. Sowbhagya Laxmi
21/02/22

**B. SOWBHAGYA LAXMI
Deputy Director (FAC)
Licensing & Controlling Authority
Drugs Control Administration
Government of Telangana
Hyderabad-500 038, T.S.**

**GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION
Vengal Rao 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 : **4537/A3/2022**

Valid up to: **30.03.2024**

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **CAMBODIA**

1. Name and dosage form of the product: **DOXORUBICIN HYDROCHLORIDE INJECTION USP 50 mg
DOXOGET 50**

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

Each Lyophilized vial contains

Doxorubicin Hydrochloride USP 50 mg

Lactose Monohydrate USP 250 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 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 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 holder⁸ (Key is appropriate category as defined in note (8))

a) ☒

b) ☐

c) ☐

2.A.3.1 For categories b and c the name and address of the Manufacturer producing the dosage form is⁹?

Yes ☐

No ☐

Not applicable ☒

2.A.4 Is summary basis for approval appended¹⁰? (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 ☒

No ☐

Not applicable ☐

2. A.6 Applicant for certificate, if different from license holder (Name & Address)¹²

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 form is⁹ :
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. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

Yes ☒ No ☐ Not applicable¹⁴ ☐

If not or not applicable, proceed to question 4.

Periodicity of routine inspections (years) : **NOT LESS THAN ONCE A YEAR**

Has the manufacturer of this type of dosage form been inspected Yes/No (Key in as appropriate)

Yes ☒ No ☐ Not applicable ☐

Do the facilities and operations conform to GMP as recommended by the World Health Organisation¹⁵?

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 ☒ No ☐ Not applicable ☐

Address of certifying authority : **Drug Control Administration
Deputy Director (FAC) Licensing & Controlling Authority
Nizamabad , Hyderabad 500 038, Telanagana, INDIA**

Telephone and Fax numbers : **TEL: +91 40 23814119 FAX: +91 40 23814360**

Name of Authorized Person : **Smt. B. SOWBHAGYA LAXMI
DEPUTY DIRECTOR (FAC)**

Signature : **LICENSING & CONTROLLING AUTHORITY**

Stamp and Date



B. Sowbhagya Laxmi
21/02/22

**B. SOWBHAGYA LAXMI
Deputy Director (FAC)
Licensing & Controlling Authority
Drugs Control Administration
Government of Telangana
Hyderabad-500 038, T.S.**

**GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION
Vengal Rao 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 : **1032/DI/MLK/TST/COPP/091219**

Valid up to: **08/12/2021**

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **TAJIKISTAN**

1. Name and dosage form of the product: **DOXORUBICIN HYDROCHLORIDE INJECTION USP 10 mg**

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

Each Lyophilized vial contains

Doxorubicin Hydrochloride USP 10 mg

Lactose Monohydrate USP 50 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 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 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 holder⁸ (Key is appropriate category as defined in note (8))

a) ☒

b) ☐

c) ☐

2.A.3.1 For categories b and c the name and address of the Manufacturer producing the dosage form is⁹?

Yes ☐

No ☐

Not applicable ☒

2.A.4 Is summary basis for approval appended¹⁰? (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 ☒

No ☐

Not applicable ☐

2. A.6 Applicant for certificate, if different from license holder (Name & Address)¹²

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 form is⁹ :
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 applicable¹⁴ ☐

If not or not applicable, proceed to question 4.

Periodicity of routine inspections (years) : **NOT LESS THAN ONCE A YEAR**

Has the manufacturer of this type of dosage form been inspected Yes/No (Key in as appropriate)

Yes ☒ No ☐ Not applicable ☐

Do the facilities and operations conform to GMP as recommended by the World Health Organisation¹⁵?

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 ☒ No ☐ Not applicable ☐

Address of certifying authority : **Office of the Deputy Director
Drugs Control Administration, Vengal Rao Nagar,
Hyderabad 500 038, Telangana, INDIA.**

Telephone and Fax numbers : **TEL: +91 40 23814119 FAX: +91 40 23814360**

Name of Authorized Person : **Dr. B. VENKATESHWARLU
DEPUTY DIRECTOR & CERTIFYING AUTHORITY**

Signature :

Stamp and Date



B. Venkateshwarlu
**Dr. B. VENKATESHWARLU
DEPUTY DIRECTOR & CERTIFYING AUTHORITY**