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

CERTIFICATE OF PHARMACEUTICAL PRODUCT

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

No. of Certificate : **2499/DI/MLK/TST/COPP/15022020** Valid up to: **14/02/2022**

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **CHILE**

1. Name and dosage form of the product: **METHOTREXATE INJECTION USP 500 mg 5 mL/Vial**

1.1 Active Ingredient (S)[2] and amounts (S) per unit dose[3] :

Each mL contains:		
Methorexate	USP	25 mg
Sodium Chloride	USP	0.0049 mg
Benzoyl Alcohol	USP	0.0090 mg
Water for injection	USP	q.s
Sodium hydroxide	USP	q.s

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

Yes ☒ No ☐

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

Yes ☒ No ☐ 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 Licence[7] and date of issue : **22/RR/TS/2015/F/G, Dated: 13.01.2015**

2.A.2 Product license holder (Name and address) : **GLS PHARMA LIMITED**
Plot.No. 10,IDA, Phase-I
Jeedimetla, R.R.Dist,
Hyderabad, Telangana, INDIA

2.A.3 Status of product – license holder[8] (Key is appropriate category as defined in note (8)

a) ☒ b) ☐ c) ☐

2A.3.1 For categories b and c the name and address of the Manufacturer producing the dosage form is [9] ?

Yes ☐ No ☐ Not applicable ☒

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

Yes ☒ No ☐ Not applicable ☐

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

Yes ☒ 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 from is[9] :

2. B.3 Why is marketing authorization lacking?
Not required / Not requested / under consideration / Refused (Key in as appropriate)

2. B.4 Remarks: [13]

3. Dose the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

Yes ☒ No ☐ Not applicable[14] ☐

If not or not applicable, proceed to 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 Organisation[15]?

Yes ☒ No ☐ Not applicable ☐

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacturer of the product ?[16]

Yes ☒ No ☐ Not applicable ☐

Address of certifying authority : **Office of the Deputy Director**
Drugs Control Administration, Vengalarao 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 & CERTIFITING AUTHORITY

Signature :

Stamp and Date

15/02/20

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

DRUGS CONTROL ADMINISTRATION * GOVERNMENT OF TELANGANA * HYDERABAD JD(FAC)

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

CERTIFICATE OF PHARMACEUTICAL PRODUCT

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

No. of Certificate : **3902/A3/2021** Valid up to: **10.11.2023**

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **EGYPT**

1. Name and dosage form of the product: **VINORELBINE INJECTION USP 50 mg/5mL Vial**

1.1 Active Ingredient (S)[2] and amounts (S) per unit dose[3] :

Each mL Contains		
Vinorelbine Tartrate		
Equivalent to Vinorelbine	USP	50 mg
Water for Injection	USP	q.s

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

Yes ☒ No ☐

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

Yes ☒ No ☐ 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 Licence[7] and date of issue : **22/RR/TS/2015/F/G, Dated: 13.01.2015**

2.A.2 Product license holder (Name and address) : **GLS PHARMA LIMITED**
Plot.No. 10,IDA, Phase-I
Jeedimetla, R.R.Dist,
Hyderabad, Telangana, INDIA

2.A.3 Status of product – license holder[8] (Key is appropriate category as defined in note (8)

a) ☒ b) ☐ c) ☐

2A.3.1 For categories b and c the name and address of the Manufacturer producing the dosage form is [9] ?

Yes ☐ No ☐ Not applicable ☒

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

Yes ☒ No ☐ Not applicable ☐

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

Yes ☒ 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 from is[9] :

2. B.3 Why is marketing authorization lacking?
Not required / Not requested / under consideration / Refused (Key in as appropriate)

2. B.4 Remarks: [13]

3. Dose the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

Yes ☒ No ☐ Not applicable[14] ☐

If not or not applicable, proceed to 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 Organisation[15]?

Yes ☒ No ☐ Not applicable ☐

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacturer of the product ?[16]

Yes ☒ 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)
LICENSING & CONTROLLING AUTHORITY

Signature :

Stamp and Date

Deputy Director (FAC), Drugs Control Administration
Government of Telangana
Nizamabad Region

B. Sowbhagya Laxmi 11/11/21

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
Vengalarao Nagar, Hyderabad 500 038

CERTIFICATE OF PHARMACEUTICAL PRODUCT

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

No. of Certificate : **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 50 MG**

1.1 Active Ingredient (S)[2] and amounts (S) per unit dose[3] :

Each film coated tablets contains

Bicalutamide	USP	50 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 Licence[7] and date of issue : **22/RR/TS/2015/F/G, Dated: 13.01.2015**

2.A.2 Product license holder (Name and address) : **GLS PHARMA LIMITED**
Plot.No. 10,IDA, Phase-I
Jeedimetla, R.R.Dist,
Hyderabad, Telangana, INDIA

2.A.3 Status of product – license holder[8] (Key is appropriate category as defined in note (8)

a) ☒ b) ☐ c) ☐

2A.3.1 For categories b and c the name and address of the Manufacturer producing the dosage form is [9] ?

Yes ☐ No ☐ Not applicable ☒

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

Yes ☒ No ☐ Not applicable ☐

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

Yes ☒ 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 from is[9] :

2. B.3 Why is marketing authorization lacking?
Not required / Not requested / under consideration / Refused (Key in as appropriate)

2. B.4 Remarks: [13]

3. Dose the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

Yes ☒ No ☐ Not applicable[14] ☐

If not or not applicable, proceed to 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 Organisation[15]?

Yes ☒ No ☐ Not applicable ☐

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacturer of the product ?[16]

Yes ☒ No ☐ Not applicable ☐

Address of certifying authority : **Office of the Deputy Director**
Drugs Control Administration, Vengalarao 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 & CERTIFITING AUTHORITY

Signature :

Stamp and Date

15/02/20

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

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