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 : **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 dose[3] :

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 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

B. Sowbhagya Laxmi 21/02/22

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

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

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No.7775/A2/2018. Dated 15-02-2020

To

M/s. GLS Pharma Limited,
Plot.No.10, Phase – I,
IDA., Jeedimetla,
Medchal-Malkajgiri District – 500 055,
Telangana, INDIA.

Sirs,

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Issue of World Health Organization Good Manufacturing Practice Certificate – Regarding.

Ref:
1. Your application dated 05.11.2018.
2. Joint Inspection Report dated 20.02.2019 & 21.02.2019.
3. Compliance Verification Report dated 05.12.2019.
4. Lr.No. 5-6(490 A1)/2018/7492, dated 13.02.2020 of Deputy Drugs Controller(India), CDSCO, Hyderabad

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I forward herewith **WORLD HEALTH ORGANIZATION GOOD MANUFACTURING PRACTICE CERTIFICATE** for the products recommended by the Joint Inspection Team consisting of officers of Central Drugs Standard Control Organization and officer from Drugs Control Administration, Telangana for **Export** Purpose.

This Certificate is valid for a period of **Three** years from the date of issue.

DRUGS CONTROL ADMINISTRATION HYDERABAD JD(FAC) GOVERNMENT OF TELANGANA

Yours faithfully,

15/02/20

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

THE SEAL OF NOTARY ★ R.D. MAURYA ★ Appd. by Govt. of India Reg.No. 7688/09

PHD Chamber of Commerce and Industry ★ New Delhi-110016 ★ 09 SEP 2020

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ATTESTED
Gur Singh Dharwal
Executive Assistant
PHD Chamber of Commerce and Industry
New Delhi (INDIA)

ATTESTED
09-09-2020
NOTARY PUBLIC
DELHI (India)