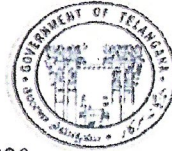




L.Dis.No.7775/A2/2018.

DRUGS CONTROL ADMINISTRATION
Government of Telangana



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.

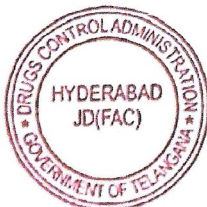
- Ref: 1. Your application dated 05.11.2018.
2. Joint Inspection Report dated 20.02.2019 & 21.02.2019.
3. Compliance Verification Report dated 05.12.2019.
4. Lr.No. 5-6(490 A1)/2018/7492, dated 13.02.2020 of Deputy Drugs Controller(India), CDSCO, Hyderabad

@ @ @

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**.

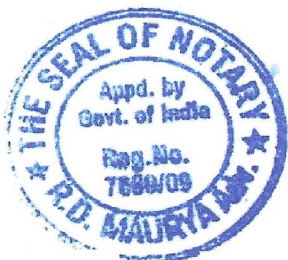
This Certificate is valid for a period of **Three** years from the date of issue.

Yours faithfully,



B. Venkateshwarlu
15/02/20

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



ATTESTED

A
09-09-2020

NOTARY PUBLIC
DELHI (India)



00290
ATTESTED
Gur Singh Dharwal
Executive Assistant
PHD Chamber of Commerce and Industry
New Delhi (INDIA)

**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 : 1096/DI/MLK/TST/COPP/09122019

Valid up to: 08/12/2021

Exporting (certifying) country: INDIA

Importing (requesting) country: TAJIKISTAN

1. Name and dosage form of the product: LEUCOVORIN CALCIUM INJECTION USP 30 mg 3 mL/Vial

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

Each mL contains

Leucovorin 10 mg
(as Leucovorin Calcium USP)

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 : **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**