**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 : **3911/A3/2021** Valid up to: **22.11.2023**

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **CROATIA**

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

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

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 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 23/11/21

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