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 **4526/A3/2022** Valid up to: **30.03.2024**

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **CAMBODIA**

1. Name and dosage form of the product: **HYDROXY UREA CAPSULES USP 500 mg**
DROXIGET 500

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

Each Capsules contains		
Hydroxy Urea	USP	500 mg
Excipients		q.s
Colour: Approved colors used in capsule shell		

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 21/02/22

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

General instructions:
Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.
The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.
Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

2. Use whenever possible, International Non-proprietary Names (INNs) or national non-proprietary names.

3. The formula (complete composition) of dosage form should be given on the certificate or be appended.

4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product licence holder.

5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product license.

6. Sections 2A and 2B are mutually exclusive.

7. Indicate when applicable, if the license is provisional, or the product has not yet been approved.

8. Specify whether the person responsible for placing the product on the market:
   (a) manufactures the dosage form;
   (b) packages and/or labels a dosage form manufactured by an independent company; or
   (c) is involved in non of the above

9. This information can be provided only with the consent of the product license holder or, in the case of non registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information.
   It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license must be updated or it will cease to be valid.

10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

11. This refers to the product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SmPC).

12. In this circumstance, permission for issuing the certificate is required from the product license holder. This permission must be provided to the authority by the applicant.

13. Please indicate the reason that the applicant has provided for not requesting registration:
   (a) the product has been developed exclusively for the treatment of conditions – particularly tropical diseases – not endemic in the country of export;
   (b) the product has been reformulated with a view to improving its stability under tropical conditions;
   (c) the product has been reformulated to exclude excipients not approved for used in pharmaceutical products in the country of import;
   (d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
   (e) any reason, please specify.

14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series No. 823, 1992 Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992 Annex 1)

16. This section is to be completed when the product license holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.