FOOD AND DRUGS AUTHORITY GHANA

Public Assessment Report

HYDROXYUREA CAPSULES 500mg

Hydroxyurea

AFF0071/24

Add Pharma Ghana Limited - P.O. Box AN 17045 Accra-North, Ghana

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Administrative info

Dosage Form	Capsules
Strength	500mg
Applicant's Name & Postal A,ddress	Add Pharma Ghana Limited - P.O. Box AN 17045 Accra-North, Ghana
Manufacturer's Name & Address	BRUCK PHARMA PRIVATE LIMITED - Survey Number: 188/1 to 6, 189/1, 190/2 to 4, Atiyawad, Dabhel, Daman-396210, Daman & Diu, India
Local Agent	Add Pharma Ghana Limited - P.O Box AN 1705, Accra North Ghana

1. Part 1

1.1 Abstract

Based on the review of the data on quality, safety and efficacy, the application for Hydroxyurea Capsules 500mg, for the treatment of chronic myeloid leukemia is approved.

1.2 Executive Summary

1.2.1 About the product

A comprehensive description of the indications and posology is given in the SmPC. This registration application concerns a generic application claiming essential similarity with the reference products, Hydrea Capsules 500mg.

The marketing authorization has been granted pursuant to section 118 of the Public Health Act, Act 857.

2. Part 2: All accepted presentations (Description of all accepted presentations and dosages, as given in the product dossier)

FDA Registration Number	Product Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package Size
FDA/GD.243-090245	Hydroxyurea Capsule USP 500 mg	500mg	Hard gelatin capsules	Oral	Alu- Pvc Blister Pack	10x10 capsules

Part 2b: Appearance of Product (Photograph of formulation (solid forms) or other product characteristics (liquid forms)

3. Part 3: Product information for the user (Patient Information Leaflet - PIL) – annex 1

Hydroxyurea-500mg-capsules-PIL.pdf

4. Part 4: Information for the health care provider (Summary of Product Characteristics– SmPC) – annex 2

HYDROXYUREA-500mg-Capsules-Smpc.pdf

5. Part 5: Labelling

5.1 Particulars to appear on the Outer Packaging (Secondary Package)

- **Name of the medicinal product**

Hydroxyurea Capsules USP 500 mg

- **Statement of active substance**

Each hard gelatin capsule contains Hydroxyurea 500mg

- **List of excipients (excipient of safety concern)**

N/A

- **Pharmaceutical form and contents**

Each hard gelatin capsule contains Hydroxyurea 500mg

- **Method and route of administration**

Oral use
Read the patient information leaflet before use

- **Special warning that the medicinal product must be stored out of the reach and sight of children**

Keep this medicine out of the sight and reach of children

- **Other special warning(s), if necessary**

N/A

- **Expiry date**

EXP {MM/YYYY}

- **Special storage conditions**

Store below 30°C

- **Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate.**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

- **Name and address of the manufacturer**

Bruck Pharma Private Limited Survey Number: 188/1 to 6, 189/1, 190/2 to 4, Atiyawad, Dabhel, Daman-396210, Daman & Diu, INDIA.

- **Manufacturer's batch number**

Batch {number}

- **(Advice on) General classification for supply**
  POM

- **Instructions on use**

5.2 MINIMUM PARTICULARS TO APPEAR ON PRIMARY PACKAGE

Blister strips

- **Name of the medicinal product**

Hydroxyurea Capsules USP 500 mg

- **Name of the manufacturer**

Bruck Pharma Private Limited

- **Expiry date**

EXP {MM/YYYY}

- **Manufacturer's batch number**

Batch {number}

- **Other**

6. Part 5 Scientific Overview and Discussion

6.1 Introduction

Hydroxyurea capsules is a hard gelatin capsule size '0' with scarlet cap & scarlet body containing white colour fine powder. Each capsule contains Hydroxyurea 500mg. The capsules are packed in Alu-PVC (Clear) blister pack..

The excipients are: Lactose anhydrous, Disodium hydrogen phosphate, Polyvinyl pyrrolidone k-30, Isopropyl Alcohol, citric acid monohydrate, Disodium hydrogen phosphate, Colloidal silicon dioxide, Magnesium Stearate, EHG Capsule Size “0” (Scarlet / Scarlet).

6.2 Active Pharmaceutical Ingredient(s) (API)

The active pharmaceutical ingredient(s) is USP. Hydroxyurea is The API is a white to off-white powder which is freely soluble in water and hot alcohol. Available literature shows that, it is BCS class I, hence it has high solubility and high permeability, hence, polymorphism will not have any effect on efficacy and absorption of hydroxyurea.

Manufacturing process

The manufacturing process was presented with sufficient details. The active pharmaceutical ingredient has been adequately characterized and acceptable specifications have been adopted for the relevant materials and products (starting materials, intermediate products, solvents).

Quality control of active pharmaceutical ingredients

The pharmaceutical ingredient specification is considered adequate to control the quality. Batch analytical data demonstrating compliance with this specification have been provided.

Stability of active pharmaceutical ingredients

Stability data are provided on the active substance of three stored at 20°C to 25°C. The currently acceptable retest period is 36 months when stored 20°C to 25°C

6.3 Finished Pharmaceutical Product.

Manufacturing process

The manufacturing process consists of raw material dispensing followed by sifting of material, dry mixing, wet granulation, drying, dry screening, blending and lubrication of granules, capsule filling, capsules are sampled by QA for testing and finally packing.

The manufacturing process has been validated according to relevant FDA/ICH guidelines. Process validation data on the product have been presented for at least three production scale batches in accordance with the relevant FDA guidelines.

Control of excipients
The excipients are controlled with acceptable specifications. Certificates of analysis were submitted and reviewed and found compliant with the respective specifications.

Quality control of finished pharmaceutical products.
The finished product specifications (release and shelf-life) are adequate to control the relevant parameters for the dosage form. The test parameters include; Description, Identification (by Infra-red absorption), average weight of capsule, uniformity of dosage unit, disintegration time, dissolution, assay, microbial limit test.. The proposed acceptance criteria at release and shelf -life has been justified and are considered appropriate for the quality control of the product. Batch analytical data from production scale batches manufactured at the proposed finished product manufacturing site have been reviewed. The data demonstrate compliance with the specification and also shows batch to batch consistent.

Stability of finished pharmaceutical products.
Stability data on the product have been provided on three production scale batches stored at Store below 30°C and keep container tightly closed. The conditions used in the stability studies are according to the FDA/ICH stability guideline. The batches were stored in the proposed unit dose containers. All parameters remain with the specified limits. The proposed shelf-life of The proposed shelf life of the drug product is 36 months and storage conditions are justified.

Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies.
There are no substances of ruminant animal origin present in the product nor have any been used in the manufacturing of this product, so a theoretical risk of transmitting TSE can be excluded.

6.4 Summary of product safety and efficacy

No bioequivalence study has been performed. The finished product contains active ingredients eligible for a BCS-based biowaiver. Accordingly, a request for a biowaiver was submitted with the required supporting data in line with the FDA guidance and criteria for biowaivers.

7. Part 7: Steps taken for registration.

The application was submitted as a Full Review application procedure. Initial date of submission was Friday, 5 July 2024 It was first approved by the FDA Ghana on Thursday, 5 September 2024.

8. Part 8: Steps taken following registration.

This is a first registration. The report will be updated at the next renewal date.