THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR D50 (GLUCOSE 50% W/V) SOLUTION FOR INTRAVENOUS INFUSION

Version number 1.0
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1. Introduction

D50 is a is for use in admixtures to provide temporary relief from the symptoms of increased intracranial pressure and hypoglycaemic coma and is also indicated for the supplementation of energy in parenteral nutrition. D50 is approved in Tanzania for use in adults and pediatric population.

1.1 Product details

Registration number	TAN 22 H 0198
Brand name	D50
Generic name, strength, and form	Glucose 50% w/v
ATC classification	B05ba03 – Carbohydrates solutions for parenteral nutrition
Distribution category	POM
Country of origin	India
Associated product	N/A
Marketing Authorization Holder	Kairuki Pharmaceutics Industry Limited 192 Zegereni Industrial Area Tanzania
Local Technical Representative	N/A

1.2 Assessment procedure

The application for registration of D50 was submitted on 08/04/2022. The product underwent full assessment. Assessment was completed in 3 (three) rounds of evaluation and the product was registered on 01 June 2023.

1.3 Information for users

Visual description of the finished product	Clear colourless solution
Primary packing material	Polypropylene bottle of 100 ml with Euro cap
Secondary packing materials	A printed carton box
Shelf-life and storage condition	24 months, Store below 30°C, Protect from light.
Route of administration	Intravenous Infusion
Therapeutic indications	Provide temporary relief from the symptoms of increased intracranial pressure and hypoglycaemic coma and is also indicated for the supplementation of energy in parenteral nutrition

2. Labelling and product information

Summary of product characteristics
The SmPC included all the relevant information to ensure correct and safe use of the medicine by healthcare providers. The complete SmPC can be accessed here.

Package insert/leaflet
The package insert is confirmed to be derived from the SmPC and contains sufficient data for the end user. Since the product is POM, the package insert contains full prescribing information as per SmPC.

Container labels
The product label information is presented in English. Details in the secondary pack label include:
Brand name: D50

Composition: each 100 ml contain anhydrous Glucose 50 g

Pack size: 1 bottle

Manufacturing details: batch number, manufacturing date, and expiry date

Storage conditions: Store below 30°C. Protect from light.

Manufacturer address: physical address of release site

Unique identifier: Not applicable

Special warnings/precautions or instructions for use: See enclosed leaflet

The details of the primary pack include:

Brand name and strength: D50

Manufacturing details: batch number, manufacturing date and expiry date

Name of manufacturer: Kairuki Pharmaceutics Industry Limited

The content of the primary and secondary labels was aligned to the requirements of the Part V of the Compendium: Guidelines on Format and Content of Product Labels for Medicinal products. The label contains sufficient information for proper identification of the medicine and post marketing follow up of the product.

Mock labels are appended as annex I.

3. Scientific discussion

Quality of Active Pharmaceutical Ingredient

Information on the quality of the API was submitted in form of DMF.

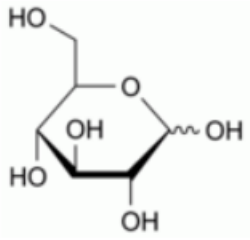
Glucose/Dextrose anhydrous

General Information

Glucose API is compendia in USP, Ph.Eur., and BP.

Molecular formula: $C_6H_{12}O_6$
Chemical name:

D- (+)-glucopyranose anhydrous
Structure:



General properties

The active substance is a white or almost white, crystalline powder that is free soluble in water, and sparingly soluble in ethanol (96 percent). Four (4) asymmetric carbons are present in the molecule. The substance shows stereoisomerism. Stereo chemical purity is controlled routinely by specific optical rotation (+52.6°~+53.2° in line with BP).

The active substance displays polymorphism. Nonetheless, this is not considered important as the active substance is present in solution in the finished product. The active is present in the drug product dissolved in water, hence the polymorphic form and particle size distribution are not considered as critical quality aspects.

Manufacture

Glucose anhydrous API manufacturer is Weifang Shengtai Pharmaceutical Co., Limited, The East of Changda Road, Changle County, Weifang City, Shandong Province, P.R. China. The manufacturing complies with GMP requirements as evidenced by the GMP certificate issued by the Shandong Food and Drug Administration. Glucose anhydrous is derived from starch. Sufficient controls of quality of materials and in-process checks were employed throughout the manufacturing process.

Specifications

The API specifications were set as per BP standards and ICHQ3A. The parameters monitored during quality control are: Description, solubility, appearance of solution, identification, content,

conductivity, related substances, dextrin, soluble starch, sulfite, microbiological quality. Compliance to these specifications were established via batch analysis data and stability studies.

Stability and container closure system

The re-test period of Glucose anhydrous API is 12 months when packed in an inner low density polyethylene (LDPE) bag, that is heat-sealed and appropriately labelled. The secondary packaging is polypropylene woven bag that is also heat-sealed and appropriately labelled with storage condition 'Should be stored Below 30ºC'.

Quality of the Finished Pharmaceutical Product

Formulation

D50 is a clear, colorless solution.

D50 contains the Glucose anhydrous, and other ingredients listed here after: Water for Injection. The quantities of all ingredients are confirmed to be in line with the recommendations of Handbook of Pharmaceutical Excipients, 8th Edition in terms of function and quantities.

Manufacture

The finished product manufacturers are Kairuki Pharmaceutical Industry Limited, 192 Zegereni Industrial Area. The compliance of the sites to TMDA GMP standards was confirmed through site inspection on 17 – 18 March, 2022.

Specifications

The FPP is compendia. The manufacturer controls the quality of the finished product as per BP and ICH requirements. The parameters monitored during quality control are: visual description, identification of API, visible particles, particulate contamination, osmolality, 5-hydroxymethylfurfural and related substances, assay, sterility. Compliance to the standard was established using batch analysis data and stability data.

Stability and container closure system

Stability studies were conducted on three (3) batches of the finished product stored at 30 ± 2°C & RH: 75 ± 5% RH for 24 months and 40± 2°C & RH: 75% ± 5% RH for 6 months. Based on the stability data presented, the approved shelf-life is 24 months when stored in polypropylene infusion bottle with storage condition 'Store below 30°C. Protect from light'.

Safety and efficacy information

D50 solution for intravenous infusion is a parenteral formulation and therefore fulfils the exemption mentioned in the part III: guidelines on therapeutic equivalence requirements, which states that a bioequivalence study is not required if the solutions for injection that contain the same active ingredients and excipients in the same concentrations as currently registered products and which are administered by the same route(s). The quantitative composition of D50 solution for

intravenous infusion is entirely the same as the reference products in the market. Therefore, it may be considered as therapeutic equivalent, with the same efficacy/safety profile as known for the active substance of the reference medicinal product. The current product can be used instead of its reference product

4. Benefit-Risk Assessment and Conclusion

On basis of the data submitted, the current state of knowledge and compliance to Good Manufacturing Practice, the benefit of the product outweighs the risks associated with its use when used in accordance to the summary of product characteristics. D50 solution for intravenous infusion is recommended for registration.

5. Post-approval updates

Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date

Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response

Re-registration applications

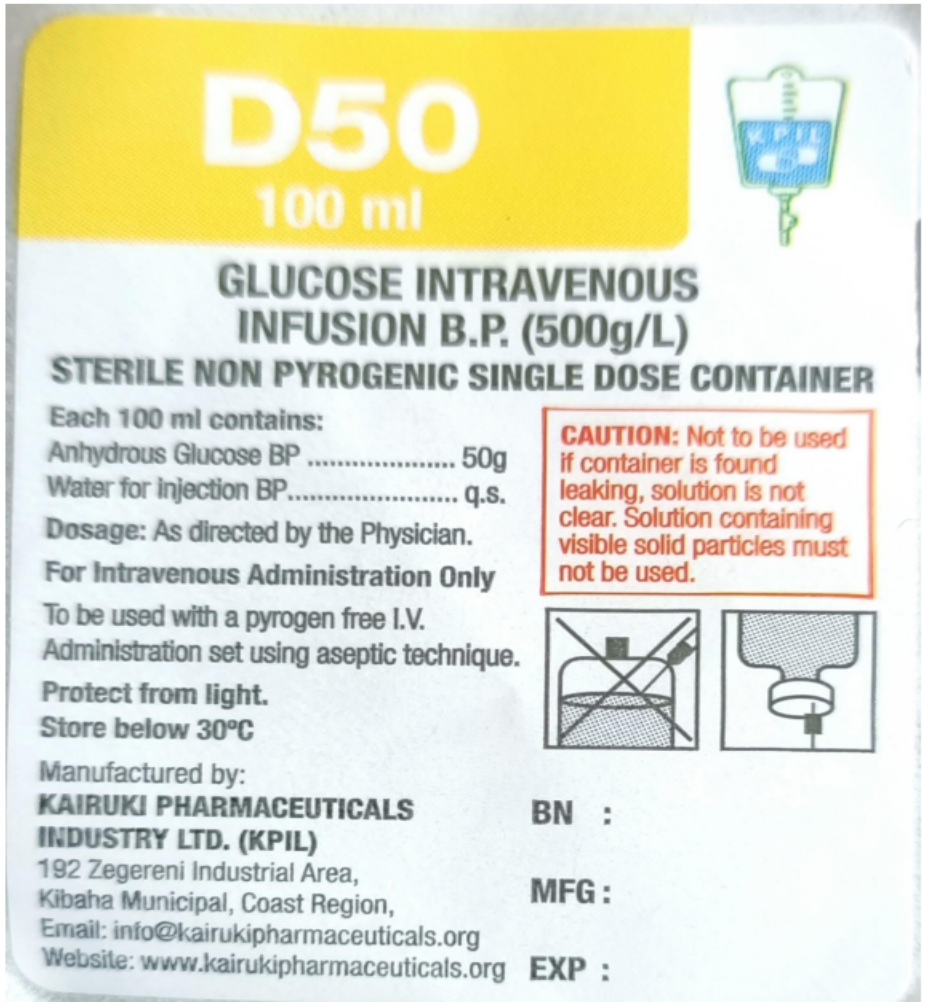
Application for renewal of registration was submitted on <DDMMYYYY>. The application was finalized in <number> rounds of evaluation. The product was confirmed to still be compliant to the standards of quality, safety and efficacy, hence registration was renewed on <DDMMYYYY>.

PART 5: CHANGE HISTORY

Version number	Date	Description of update	Section(s) Modified	Approval date

Annex I: Mock up labels;

Primary pack label;



Secondary pack label;