DRAFT TANZANIA STANDARD

CDC16(5435) P3

Hospital based intravenous fluids-Sterilized Dextrose Injection-Specification

TANZANIA BUREAU OF STANDARDS

0 Foreword

This draft Tanzania Standard is being prepared by the Pharmaceuticals Technical Committee, under the supervision of Chemicals Divisional Standards Committee and it is in accordance with the procedures of the Bureau. It lays down requirements for Dextrose injection manufactured in Hospital infusion units.

Dextrose is a form of glucose (sugar). Dextrose (%) in water is injected into a vein to replace lost fluids and provide carbohydrates to the body.

For the purpose of deciding whether a particular requirement of this draft Tanzania Standard is complied with, the final value observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with TZS 4.

In the preparation of this draft Tanzania Standard assistance was drawn from South African National Standard SANS 598- Sterilized dextrose intravenous infusion

1 Scope

This standard covers chemical and biological requirements for a solution of dextrose in water for injections that has been dispensed into suitable containers, sealed and sterilized.

Field of application

This draft Tanzania standard apply to Dextrose injection 5%.

2.0 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

2.1 Standards

TZS 4 Rounding off numerical values.

TZS 59 Water for analytical laboratory use – Specification and test methods**.**

TZS 773 Labelling and marking of pharmaceutical products – Specification.

2.2 Other publications used

British Pharmacopoeia (BP).

United States Pharmacopeia (USP).

3.0 Terms and definitions

For the purposes of this draft Tanzania standard, the following terms and definitions apply;

3.1 acceptable

acceptable to the authority administering this standard, or to the parties concluding the purchase contract, as relevant

3.2 batch

quantity of the product that is homogenous, filled and sealed in containers, and sterilized in the same cycle of operations

3.3 product

dextrose intravenous infusion that is filled, sealed and sterilized in the final container

4. Requirements

4.1 Freedom from visible suspended matter and sediment

When examined in accordance with 5.2, the product shall be clear and colorless and shall not contain any antimicrobial agents nor any other added substances. Solutions containing 200 g or more of dextrose per litre shall not be more than faintly straw-colored.

4.2 Fill volume

4.2.1 The maximum nominal fill volume of a container shall not exceed 1 L.
4.2.2 When determined in accordance with 5.3, the volume of the contents of each container shall not be less than the nominal volume and not more than 110 % of the nominal volume.

4.3 pH Value

When determined in accordance with 5.4, the pH value of the product shall be between 3.5 and 6.5.

4.4 Dextrose content

The dextrose ($C_6H_{12}O_6$) content of the product shall be determined in accordance with BP and/or USP requirements.

4.5 5-Hydroxymethylfurfural and related substances

5-Hydroxymethylfurfural and related substances shall be determined in accordance with BP and/or USP requirements.

4.6 Particulate matter (sub-visible particles)

The number of particles with a diameter ≥ 10 µm and ≥ 25 µm, respectively, shall comply with the limits for small volume injections and large volume injections, as relevant to clause 2.2

4.7 Sterility

When tested in accordance with 5.6, there shall be no signs of microbial growth.

4.8 Bacterial endotoxins

Dextrose 5% injection shall contain not more than 10.0 USP Endotoxin Units per gram, and this is in accordance with USP requirements.

5 Inspection and methods of test

5.1 General

Unless otherwise specified, only use water that complies with the requirements for grade 3 water as given in TZS 59:2010, and reagents of analytical reagent grade or of the purest grade available.

5.2 Inspection

5.2.1 Gently invert the container and examine, without magnification, for any visible signs of suspended matter or sediment (see A.3).
5.2.2 Check for compliance with 4.1.

5.3 Fill volume

5.3.1 Transfer, as completely as possible, the contents of a container into a graduated measuring cylinder of a size able to contain at least 110 % of the nominal volume of the container.
5.3.2 Record the volume of liquid in the measuring cylinder.
5.3.3 Determine the average fill volume of at least three containers.
5.3.4 Check for compliance with 4.2.

5.4 pH value

5.4.1 Dilute the product with water for injections or grade 3 water that complies with TZS 59:2010, if necessary, to contain not more than 5 g of dextrose per 100 mL.
5.4.2 Determine the pH value in accordance with the relevant procedure described in the current BP.
5.4.3 Check for compliance with 4.3.

5.5 5-Hydroxymethylfurfural and related substances

5.5.1 Perform the test in accordance with BP and/or USP.
5.6.2 Check for compliance with 4.5.

5.6 Sterility

5.6.1 Use the method under "Sterility tests" given in the USP.
5.6.2 Check for compliance with 4.8

5.7 Bacterial endotoxins

5.7.1 Use the method under "Bacterial endotoxins test" given in the USP.
5.7.2 Check for compliance with 4.8.

6 Packing and labelling

6.1 Packing

6.1.1 Containers

6.1.1.1 The product shall be dispensed in acceptable, clean, single-dose, colorless containers that shall not affect or be affected by the contents.
6.1.1.2 Glass containers shall be transparent and shall be of type I glass as described under "Glass containers for pharmaceutical use" in the BP.
6.1.1.3 Containers shall be hermetically closed by means of suitable closures that shall not affect or be affected by the contents of the container.

6.1.2 Packages

An acceptable number of containers of the same batch identification shall be packed together in a package of suitable design that is sufficiently robust to protect the contents during normal handling, transportation and storage.

6.2 Labelling

Labeling shall be done according to TZS 773

Annex A
(normative)

Sampling and compliance with this standard

A.1 Sampling

A.1.1 General

The following sampling procedure shall be applied in determining whether a batch submitted for inspection and testing complies with the relevant requirements of this standard. The sample so drawn shall be deemed to represent the batch.

A.1.2 Definitions

A.1.2.1 defective
sample that fails in one or more respects to comply with the relevant requirements of this standard

A.1.2.2 batch

applicable number of containers of the same type and nominal volume, bearing the same batch identification, from one manufacturer, and submitted at any one time for inspection and testing

A.2 Sample for testing

A.2.1 Chemical tests

From the batch take, at random, applicable containers to obtain a volume of at least 200 mL.

A.2.2 Sterility test

From the batch take, at random, applicable containers.

A.2.3 Bacterial endotoxin test

From the batch take, at random, applicable containers to obtain a volume of at least 100 mL.

A.3 Compliance with this standard

The batch shall be deemed to comply with the requirements of this standard if, after inspection (see 5.2) and testing of the samples taken in accordance with A.2, no defective is found.