DRAFT TANZANIA STANDARD

CDC16(5436) P3

Hospital based Intravenous Fluids-Sterilized compound sodium lactate (Ringer-lactate solution for 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.

Ringer's lactate(RL) solution, also known as sodium lactate solution and Hartmann's solution, is a mixture of sodium chloride, sodium lactate, potassium chloride, and calcium chloride in water. It is used for replacing fluids and electrolytes in those who have low blood volume or low blood pressure.

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 597:2014- Sterilized compound sodium lactate intravenous infusion (Ringer-lactate solution for injection)

1 Scope

This standard covers chemical and biological requirements for a solution of sodium chloride, potassium chloride, calcium chloride and sodium lactate in water for injections that have been dispensed into suitable containers, sealed and sterilized.

2 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 59:2010 Water for analytical laboratory use – Specification and test methods.

TZS 773:2016(2nd Edition) Labelling and marking of pharmaceutical products - Specification

2.2 Other publications

British Pharmacopoeia (BP).
United States Pharmacopoeia (USP).

3 Definitions

For the purposes of this document, the following 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
that quantity of the product that is homogenous, filled and sealed into containers, and sterilized in the same cycle of operations

3.3
certified
reagent for which a certificate of analysis stating the percentage purity is available

3.4
Product

compound sodium lactate intravenous infusion (Ringer-lactate solution for injection) 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 colourless, without odour or taste, and shall not contain any antimicrobial agent nor any other added substances.

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 shall not exceed:
a) 115 % for containers with a nominal volume of < 50 mL; and
b) 110 % for containers with a nominal volume of ≥ 50 mL.

4.3 pH value

When determined in accordance with 5.4, the pH value of a product that complies with the USP requirements for "Lactated Ringer's injection" shall be between 6.0 and 7.5 and a product that complies with the BP requirements for "Ringer-lactate solution for injection" shall be between 5.0 and 7.0

4.4 Particulate matter (sub-visible particles)

When tested in accordance with 5.5, 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 given in the USP, as relevant.

4.5 Sterility

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

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, 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.
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 Determine the pH value in accordance with the relevant procedure described in the current USP or BP.
5.4.2 Check for compliance with 4.3.

5.5 Particulate matter (sub-visible particles)

5.5.1 Use the method "Light obscuration particle count test" under particulate matter in injections given in the pharmacopoeia.
5.5.2 Check for compliance with 4.4.

5.6 Sterility

5.6.1 Use the method under "Sterility tests" given in the pharmacopoeia.
5.6.2 Check for compliance with 4.5.

6 Packing, marking and labeling

6.1 Packing

6.1.1 Containers

6.1.1.1 The product shall be dispensed in acceptable, clean, single-dose, colourless 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 pharmacopoeia.
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 packages of suitable design that is sufficiently robust to protect the contents during normal handling, transportation and storage.

6.1.3 Bulk packs

An acceptable number of packages of the same batch identification shall be packed in a bulk pack that is sufficiently robust to protect the contents during normal handling, transportation and storage.

6.2 Marking and labeling

Marking and labeling of the product shall be in accordance with TZS 773.

Annex A
(normative)

Notes to purchasers

Each order or contract shall specify whether the Ringer-lactate (Hartmann's) intravenous solution ordered shall comply with the requirements of the USP or the BP (see 4.5).