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Medical ultrasound gel — Specification

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In order to match with technological development and to keep continuous progress in industries, standards are subject to periodic review. Users shall ascertain that they are in possession of the latest edition

Rwanda Standards Board

P.O Box 7099 Kigali-Rwanda

KK 15 Rd, 49

Tel. +250 788303492

Toll Free: 3250

E-mail: info@rsb.gov.rw

Website: www.rsb.gov.rw

ePortal: www.portal.rsb.gov.rw

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Foreword

Rwanda Standards are prepared by Technical Committees and approved by Rwanda Standards Board (RSB) Board of Directors in accordance with the procedures of RSB, in compliance with Annex 3 of the WTO/TBT agreement on the preparation, adoption and application of standards.

The main task of technical committees is to prepare national standards. Final Draft Rwanda Standards adopted by Technical committees are ratified by members of RSB Board of Directors for publication and gazettment as Rwanda Standards.

DRS 478 was prepared by Technical Committee RSB/TC 015, *Pharmaceutical Products*

In the preparation of this standard, reference was made to the following standard:

US 2129: Medical Ultrasound gel — Specification

The assistance derived from the above source is hereby acknowledged with thanks.

Committee membership

The following organizations were represented on the Technical Committee on *Pharmaceutical Products* (RSB/TC 015) in the preparation of this standard.

Healthcare Pharmacy

HORIZON/SOPYRWA

IKIREZI Products

National Pharmacy Council (NPC)

Rwanda Food and Drugs Authority (FDA)

Rwanda Forensic Laboratory (RFL)

Rwanda Inspectorate, Competition and Consumer Protection Authority (RICA)

Rwanda Medical Supply Ltd

Rwanda Social Security Agency (RSSB)

University of Rwanda/College of Medicine and Pharmacy Sciences (UR/CMPS)

University of Rwanda/College of Sciences and Technology (UR/CST)

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Introduction

Ultrasound gel or a coupling agent utilizes a basic physics principle where sound waves tend to carry very well through an aqueous or watery medium. When applied to the surface of the patient's skin, the ultrasound gel acts as a coupling medium and enhances the transmission of ultrasonic sound waves from the skins surface to the head of the ultrasound transducer. Ultrasound gel serves as a lubricant and improves the acoustic transmission of sound waves to the create the image for the sonographer to examine on the monitor.

Medical ultrasound gel — Specification

1 Scope

This Draft Rwanda Standard specifies requirements, sampling and test methods for medical ultrasound gels.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

RS EAS 847-17: 2017, *Cosmetic industry — Analytical methods —Part 17: Determination of pH*

ISO 21149, *Enumeration and detection of aerobic mesophilic bacteria*

ISO 21150, *Cosmetics -- Microbiology -- Detection of Escherichia coli*

US 1847:2017, Standard Test Methods for Specific Gravity, Apparent, of Liquid Industrial Chemicals

ISO 3104:1994, *Petroleum products - Transparent and opaque liquids - Determination of kinematic viscosity and calculation of dynamic viscosity*

ISO 22718, *Cosmetics -- Microbiology -- Detection of Staphylococcus aureus*

ISO 22717, *Cosmetics -- Microbiology -- Detection of Pseudomonas aeruginosa*

ISO 10993-1:2003, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

3 Terms and definitions

For the purposes of this standard, the following terms and definitions apply.

3.1

medical ultrasound gel

conductive medium that enables air free bond between the skin/mucus linings of cavities and the probe or transducer, letting the waves transmit directly to the tissues beneath and to the parts that need to be imaged.

3.2

bacteriostatic

capable of inhibiting the growth or reproduction of bacteria.

3.3

transducer

a device that converts energy from one form to another.

4 Requirements

4.1 General requirements

4.1.1 The medical ultrasound gel shall be a clear viscous gel, free from any foreign matter, sediments and air bubbles.

4.1.2 The medical ultrasound gel shall be odourless, bacteriostatic and non-irritating when tested in accordance ISO 10993-1.

4.1.3 The medical ultrasound gel shall be free from formaldehyde, soluble in water, non-staining and shall not damage transducers.

4.1.4 The sterile medical ultrasound gel shall be tested in accordance with Annex A.

4.2 Specific requirements

4.2.1 The medical ultrasound gel shall conform to the requirements specified in table 1 when tested in accordance with the test methods prescribed therein.

Table 1 – Specific requirements for medical ultrasound gel

S/N	Parameters	Requirements	Test methods
1	pH (neat)	6.5 – 7.5	RS EAS 847-17
2	Density at 23°C, g/cm^3	0.683 – 1.283	US 1847
3	Viscosity, Centipoise, min.	10,000	ISO 3104

4.2.2 The medical ultrasound gel shall comply with the heavy metal limits given in Table 2 when tested in accordance with the test methods specified therein.

Table 2 – Heavy metal limits for medical ultrasound gel

S/N	Parameters	Maximum limits[a]	Test methods
1	Lead as Pb, mg/kg.	10.0	EAS 847-16
2	Arsenic as As, mg/kg.	2.0	
3	Mercury as Hg, mg/kg.	2.0	
a The total amount of heavy metals as lead, arsenic and mercury, in combination in the finished product shall not exceed 10 mg/kg			

4.2.3 The medical ultrasound gel shall comply with the microbiological limits given in table 3 when tested in accordance with the test methods specified therein.

Table 3 – Microbiological limits for medical ultrasound gel

S/N	Parameters	Requirements	Test methods
1	Total viable count for aerobic mesophilic microorganisms, CFU/g or CFU/ml, max.	1 000	ISO 21149
2	*Pseudomonas aeruginosa*	Not detectable in 1 ml or 1 g of the product	ISO 22717
3	*Staphylococcus aureus*		ISO 22718
4	*Candida albicans*		ISO 18416

5 Packaging and labelling

5.1 Packaging

The medical ultrasound gel shall be packaged in suitable containers to ensure stability and prevent contamination of the product during of transportation, handling and storage.

5.2 Labelling

The package shall be legibly and indelibly marked with the following information in any of the three languages officially accepted in the Republic of Rwanda namely: Kinyarwanda, French and English:

a) Manufacturer's name and physical address;

b) Product name as "Medical ultrasound gel";

c) Batch/lot number;

d) List of ingredients;

e) Net content;

f) Manufacture and expiry dates;

g) Country of origin;

h) Storage instructions;

i) Warning/precautions.

j) For the sterile, indicate the word "sterile"

6 Sampling

Sampling shall be done in accordance with annex B.

Annex A
(normative)

Sterility test

A.1 Introduction

The following culture media have been found to be suitable for the test for sterility. Fluid thioglycollate medium is primarily intended for the culture of anaerobic bacteria; however, it will also detect aerobic bacteria. Soya-bean casein digest medium is suitable for the culture of both fungi and aerobic bacteria.

A.2 Fluid thioglycollate medium

L-Cystine	0.5 g
Agar	0.75 g
Sodium chloride	2.5 g
Glucose monohydrate/anhydrous	5.5 g/5.0 g
Yeast extract (water-soluble)	5.0 g
Pancreatic digest of casein	15.0 g
Sodium thioglycollate, or	0.5 g
Thioglycollic acid	0.3 mL
Resazurin sodium solution (1g/L of resazurin sodium) freshly prepared	1.0 mL
Water	1000 mL
pH after sterilization	7.1 ± 0.2

A.2.1 Mix the L-cystine, agar, sodium chloride, glucose, water-soluble yeast extract and pancreatic digest of casein with the water R and heat until solution is effected.

A.2.2 Dissolve the sodium thioglycollate or thioglycollic acid in the solution and, if necessary, add 1 M sodium hydroxide so that, after sterilisation, the solution will have a pH of 7.1 ± 0.2. If filtration is necessary, heat the solution again without boiling and filter while hot through moistened filter paper.

A.2.3 Add the resazurin sodium solution, mix and place the medium in suitable vessels which provide a ratio of surface to depth of medium such that not more than the upper half of the medium has undergone a

colour change indicative of oxygen uptake at the end of the incubation period. Sterilise using a validated process. If the medium is stored, store at a temperature between 2 °C and 25 °C in a sterile, airtight container.

A.2.4 If more than the upper one-third of the medium has acquired a pink colour, the medium may be restored once by heating the containers in a water-bath or in free- flowing steam until the pink colour disappears and cooling quickly, taking care to prevent the introduction of non-sterile air into the container. Do not use the medium for a longer storage period than has been validated. Fluid thioglycollate medium is to be incubated at 30-35 °C.

A.2.5 For products containing a mercurial preservative that cannot be tested by the membrane-filtration method, fluid thioglycollate medium incubated at 20-25 °C may be used instead of soya-bean casein digest medium provided that it has been validated as described in growth promotion test.

A.3 Alternative

Where prescribed or justified and authorized, the following alternative thioglycollate medium may be used. Prepare a mixture having the same composition as that of the fluid thioglycollate medium, but omitting the agar and the resazurin sodium solution, sterilise as directed above. The pH after sterilisation is 7.1 ± 0.2. Heat in a water-bath prior to use and incubate at 30-35 °C under anaerobic conditions.

A.4 Soya-bean casein digest medium

Pancreatic digest of casein	17.0 g
Papaic digest of soya-bean meal	3.0 g
Sodium chloride	5.0 g
Dipotassium hydrogen phosphate	2.5 g
Glucose monohydrate/anhydrous	2.5 g/2.3 g
Water R	1000 mL
pH after sterilization	7.3 ± 0.2

A.4.1 Dissolve the solids in water R, warming slightly to effect solution. Cool the solution to room temperature. Add 1 M sodium hydroxide, if necessary, so that after sterilisation the solution will have a pH of 7.3 ± 0.2.

A.4.2 Filter, if necessary, to clarify, distribute into suitable vessels and sterilise using a validated process. Store at a temperature between 2 °C and 25 °C in a sterile well-closed container, unless it is intended for immediate use. Do not use the medium for a longer storage period than has been validated. Soya-bean casein digest medium is to be incubated at 20-25 °C. The media used comply with the following tests, carried out before or in parallel with the test on the product to be examined.

A.5 Sterility

Incubate portions of the media for 14 days. No growth of micro-organisms occurs.

Annex B
(normative)

Sampling

B.1 General requirements of sampling

B.1.1 In drawing, preparing, storing and handling samples, the following precautions and directions shall be observed.

B.1.2 Samples shall be taken in a protected place not exposed to damp air, dust or Soot.

B.1.3 The sampling instrument shall be clean and dry.

B.1.4 The samples, the material being sampled, the sampling instrument and the containers for samples shall be protected from adventitious contamination.

B.1.5 The samples shall be placed in clean and dry glass containers. The sample containers shall be of a size such that they are almost completely filled by the sample.

B.1.6 Each container shall be sealed air-tight after filling and marked with full details of sampling, batch or code number, name of manufacturer, and other important particulars of the consignment.

B.1.7 The samples shall be stored in such a. manner that the temperature of the material does not vary unduly from the normal temperature and they are protected from light.

B.1.8 Sampling shall be done by a person agreed to between the purchaser and the supplier, and in the presence of the purchaser or his representative and the supplier or his representatives.

B.2 Sampling of packages

B.2.1 General – The sampling procedure for packages shall consist essentially in selecting and drawing, a sufficient number of unit packs.

Lot – In a single consignment, all the packages containing medical ultrasound gel of the same type and form, representing the same batch of manufacture, shall constitute a lot. If the consignment consists of packages containing medical ultrasound gel of different types or forms or batches of manufacture, then the packages containing products of the same type, form and batch of manufacture shall be grouped together; each group shall constitute a separate lot.

Scale of sampling – For ascertaining the conformity of a lot to the requirements prescribed in the specifications for individual medical ultrasound gel and toilet goods, tests shall be carried out on each lot separately. The number (n) of packages to be selected for drawing the samples shall depend on the size (N) of the lot in accordance with Table B.1.

Table B.1 – Scale of sampling for packages

Number of packages in the lot (N)	Number of packages to be selected (n)
Up to 3	Each container
4 to 50	3
51 to 150	4
151 to 300	5
301 to 500	6
501 and above	7

The packages shall be selected at random and to ensure random and to ensure randomness of selection, random number tables shall be used. In case such tables are not available, the following procedure may be adopted: 'Starting from any package, count all the packages in one order as 1,2,3 . . . . . up to r and so on, where r is the integral part of N/n. Every r^{th} package thus counted shall be withdrawn to give a sample for purposes of test.

Bibliography

[1]

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