

DRAFT UGANDA STANDARD

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Alcohol swabs — Specification



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Foreword

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- (a) a member of International Organisation for Standardisation (ISO) and
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The committee responsible for this document is Technical Committee UNBS/TC 14, *Medical devices*

Alcohol swabs — Specification

1 Scope

This Draft Uganda Standard specifies requirements, sampling and methods of test for alcohol swabs (also known as alcohol prep pad or alcohol pad or alcohol disinfection wipe).

2 Normative references

The following referenced documents 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.

US 1692, *Determination of bactericidal efficacy of disinfectants/sanitizers*

US ISO 2859-1, *Sampling procedures for inspection by attributes —Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

US ISO 10993 (all parts), *Biological evaluation of medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply. ISO and IEC maintain terminological databases for use in standardization at the following addresses: — ISO Online browsing platform: available at <http://www.iso.org/obp>

alcohol swab

soft absorbent pad saturated with alcohol

4 Requirements

4.1 General requirements

4.1.1 Alcohol swab shall consist of soft absorbent pad saturated with alcohol. Isopropyl alcohol is the commonly used alcohol. Soft absorbent pad may include linen, cotton and any other suitable material

4.1.2 Alcohol swab shall be free from any foreign matter.

4.1.3 Alcohol swab shall be sterile when tested in accordance with Annex A.

4.2 Specific requirements

Alcohol swab shall also conform to the requirements specified in Table 1 when tested in accordance with the test methods prescribed therein.

Table 1 — Specific requirements of alcohol swab

S.No	Characteristic	Requirement	Test method
i	Alcohol content, %, v/v,	70 - 80	US EAS 104
ii	Efficacy	To pass test	US 1692

5 Biocompatibility

When tested in accordance with the relevant parts of ISO 10993, the alcohol swabs shall not cause any harmful effect to the skin

6 Packaging

6.1 Each alcohol swab shall be individually wrapped in suitable containers, which guarantee product safety, sterility, and integrity until the container is opened.

6.2 Individually wrapped alcohol swabs shall be packaged in secondary packages.

7 Labelling

Each package shall be legibly and indelibly marked with the following information:

- a) name and physical address of manufacturer;
- b) name of the product; “alcohol swabs” or “alcohol prep pads” or “alcohol pads” or “alcohol disinfection wipes”;
- c) instructions for use;
- d) swab size in mm
- e) % alcohol content;
- f) precaution, “for external use only” “for single use”; and “don’t use when package is damaged”,
- g) lot/batch number;
- h) country of origin;
- i) date of manufacture; and
- j) expiry date

8 Sampling

Sampling shall be done in accordance with US ISO 2859-1. Acceptance criteria: None shall fail

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 (1 g/L of resazurin sodium), freshly prepared	1.0 mL
Water R	1 000 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. Dissolve the sodium thioglycollate or thioglycollic acid in the solution and, if necessary, add 1 M sodium hydroxide so that, after sterilization, 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. Sterilize 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 °C -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 °C -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 thioglycollate medium

Where prescribed, 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, sterilize as directed above. The pH after sterilization is 7.1 ± 0.2 . Heat in a water-bath prior to use and incubate at 30 °C -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	1 000 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 sterilization the solution will have a pH of 7.3 ± 0.2 .

A.4.2 Filter, if necessary, to clarify, distribute into suitable vessels and sterilize 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 °C -25 °C.

A.4.3 The media used shall comply with the following tests given in D.6, carried out before or in parallel with the test on the product to be examined.

D.5 Sterility

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

A.6 Growth promotion test of aerobes, anaerobes, and fungi

A.6.1 Test each lot of ready-prepared medium and each batch of medium prepared either from dehydrated medium or from ingredients. Suitable strains of microorganisms are indicated in Table D1.

A.6.2 Inoculate portions of Fluid Thioglycollate Medium with a small number (not more than 100 cfu) of the following microorganisms, using a separate portion of medium for each of the following species of microorganism, *Clostridium sporogenes*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus*. Inoculate portions of alternative thioglycollate medium with a small number (not more than 100 cfu) of *Clostridium sporogenes*. F Inoculate portions of Soybean–Casein.

A.6.3 Digest medium with a small number (not more than 100 cfu) of the following microorganisms, using a separate portion of medium for each of the following species of microorganism, *Aspergillus brasiliensis*, *Bacillus subtilis*, and *Candida albicans*. Incubate for not more than 3 days in the case of bacteria and not more than 5 days in the case of fungi.

A.6.4 Seed lot culture maintenance techniques (seed-lot systems) are used so that the viable microorganisms used for inoculation are not more than five passages removed from the original master seed lot. The media are suitable if a clearly visible growth of the microorganisms occurs.

Table A.1 —Strains of the test microorganisms suitable for use in the growth promotion test

Test microorganisms		
Aerobic bacteria	Fungi	Anaerobic bacterium
<i>Staphylococcus aureus</i> ATCC 6538, CIP 4.83, NCTC10788, NCIMB 9518, NBRC 13276 <i>Bacillus subtilis</i> ATCC 6633, CIP 52.62, NCIMB 8054, NBRC 3134 <i>Pseudomonas aeruginosa</i> ATCC 9027, NCIMB 8626, CIP 82.118, NBRC 13275	<i>Candida albicans</i> ATCC 10231, IP 48.72, NCPF 3179, NBRC 1594	<i>Clostridium sporogenes</i> ATCC 19404, CIP 79.3, NCTC 532 or ATCC 11437, NBRC 14293

Bibliography

- [1] Dulong, C., Brett, K., & Argáez, C. (2020). Skin Preparation for Injections: A Review of Clinical Effectiveness, Cost-Effectiveness and Guidelines.
- [2] KS 2556: 2018, Impregnated Cotton swabs—Specification
- [3] US EAS 789: 2013, Instant hand sanitizers — Specification

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