DUS 2229-2

DRAFT UGANDA STANDARD

First Edition
2020-mm-dd

Surgical gauze — Specification — Part 2: Petrolatum

Reference number
DUS 2229-2:2020

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The Executive Director
Uganda National Bureau of Standards
P.O. Box 6329
Kampala
Uganda
Tel: +256 414 333 250/1/2/3
Fax: +256 414 286 123
E-mail: info@unbs.go.ug
Web: www.unbs.go.ug

Foreword

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(a) a member of International Organisation for Standardisation (ISO) and

(b) a contact point for the WHO/FAO Codex Alimentarius Commission on Food Standards, and

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Draft Uganda Standards adopted by the Technical Committee are widely circulated to stakeholders and the general public for comments. The committee reviews the comments before recommending the draft standards for approval and declaration as Uganda Standards by the National Standards Council.

The committee responsible for this document is Technical Committee UNBS/TC 14, *Medical devices*

US 2229 consists of the following parts, under the general title *surgical gauze — Specification*:

- — *Part 1: Absorbent*
- — *Part 2: Petrolatum*

Surgical gauze — Specification — Part 2: Petrolatum

1 Scope

This Draft Uganda standard specifies the requirements, methods of test and sampling of petrolatum gauze (also known as paraffin gauze or vaseline gauze).

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.

FDUS 2229-1, *Surgical gauze — Specification — be Part 1: Absorbent*

US ISO 2137, *Petroleum products and lubricants — Determination of cone penetration of lubricating greases and petrolatum*

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

petrolatum gauze
gauze saturated with white petrolatum

4 Requirements

4.1 General requirements

4.1.1 Petrolatum gauze shall consist of absorbent gauze saturated with white petrolatum

4.1.2 Petrolatum gauze shall be free from any foreign matter.

4.2 Specific requirements

4.2.1 Petrolatum gauze 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 petrolatum gauze

Characteristic	Requirement	Test method
Assay, %	70 – 80	Annex A

4.2.2 The conditioned absorbent gauze obtained in the assay shall meet the requirements for fibre content, thread count, length, width, and weight under FDUS 2229-1.

4.2.3 The petrolatum recovered by draining in the assay shall meet the following requirements given in Table 2

Table 2 — Requirements of petrolatum

Characteristic	Requirement	Test method
Consistency at 25°C, (0.1 mm)	60 – 300	US ISO 2137
Sulphated ash, %, max	0.05	Annex B
Polycyclic aromatic hydrocarbons	At no wavelength in the range 260 nm to 420 nm does the absorbance of the test solution exceed that of the reference solution at 278 nm.	Annex C

5 Sterility

Petrolatum gauze shall be sterile when tested in accordance with Annex D

6 Biocompatibility

When tested in accordance with the relevant parts of ISO 10993, the petrolatum gauze shall not cause any harmful effect on the user.

7 Packaging

Each petrolatum gauze unit shall be packaged individually that the sterility of the unit is maintained until the package is opened for use.

8 Labelling

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

a) Name of product as “petrolatum gauze”; or “paraffin gauze” or “Vaseline gauze”

b) name and physical address of manufacturer;

c) thread count/ type;

d) length and width;

e) date of manufacture,

f) date of expiry;

g) batch/lot number;

h) storage conditions;

i) precaution “don’t use if damaged” or has been opened previously; and

j) sterile

9 Sampling

Sampling shall be done in accordance with US ISO 2859-1.

Annex A
(normative)

Assay

A.1 Procedure

A.1.1 Weigh not less than 20 units of petrolatum gauze, place them in a heated glass funnel, maintaining the temperature at approximately 75°C, and allow the petrolatum to melt and drain from the funnel. Draining may be facilitated by pressing the gauze with a glass rod or porcelain spatula

A.1.2 Wash the gauze on the funnel with successive portions of warm methyl chloroform until it is free from petrolatum, allow the residual methyl chloroform to evaporate spontaneously, condition the gauze in a standard atmosphere of 65 %± 2% relative humidity at 21 °C± 1.1°C for not less than 4 hours, and weigh.

A.2 Calculation

The assay expressed as percent, shall be calculated by the formula below:

$$\frac{W_1 - W_2}{W_1} \times 100$$

where

W_1 is the weight in grams of petrolatum gauze

W_2 is the weight in grams of the gauze

Annex B
(normative)

Determination of sulphated ash

B.1 Procedure

B.1.1 Ignite a suitable crucible (for example, silica, platinum, porcelain or quartz) at 600 °C ± 50 °C for 30 min, allow to cool in a desiccator over silica gel or other suitable desiccant and weigh.

B.1.2 Place the 2 g of the substance to be examined in the crucible and weigh.

B.1.3 Moisten the substance to be examined with a small amount of *sulfuric acid R* (usually 1 mL) and heat gently at as low a temperature as practicable until the sample is thoroughly charred.

B.1.4 After cooling, moisten the residue with a small amount of *sulfuric acid R* (usually 1 mL), heat gently until white fumes are no longer evolved and ignite at 600 ± 50 °C until the residue is completely incinerated. Ensure that flames are not produced at any time during the procedure.

B.1.5 Allow the crucible to cool in a desiccator over silica gel or other suitable desiccant, weigh it again and calculate the percentage of residue. If the amount of the residue so obtained exceeds the prescribed limit, repeat the moistening with *sulfuric acid R* and ignition, as previously, for 30 min periods until 2 consecutive weighings do not differ by more than 0.5 mg or until the percentage of residue complies with the prescribed limit.

B.2 Calculation

The Loss on drying, expressed as percent by mass, shall be calculated by the formula below.

$$\frac{W_2 - W_3}{W_2 - W_1} \times 100$$

Where

W_1 is the weight in grams of a crucible

W_2 is the weight in grams of sample and crucible before drying

W_3 is the weight in grams of sample and crucible after drying

Annex C
(normative)

Polycyclic aromatic hydrocarbons

C.1 Procedure

C.1.1 Use reagents for ultraviolet spectrophotometry.

C.1.2 Dissolve 1.0 g in 50 mL of hexane R which has been previously shaken twice with 10 mL of dimethyl sulfoxide R and transfer the solution to a 125 mL separating funnel with unlubricated ground-glass parts (stopper, stopcock, add 20 mL of dimethyl sulfoxide R and shake vigorously for 1 min and allow to stand until 2 clear layers are formed.

C.1.3 Transfer the lower layer to a second separating funnel. Repeat the extraction with a further 20 mL of dimethyl sulfoxide R, shake vigorously the combined lower layers with 20 mL of hexane R for 1 min and allow to stand until 2 clear layers are formed.

C.1.4 Separate the lower layer and dilute to 50.0 mL with dimethyl sulfoxide R. Measure the absorbance (2.2.25) over the range 260 nm to 420 nm using a path length of 4 cm and as compensation liquid the clear lower layer obtained by vigorously shaking 10 mL of dimethyl sulfoxide R with 25 mL of hexane R for 1 min. Prepare a reference solution in dimethyl sulfoxide R containing 6.0 mg of naphthalene R per litre and measure the absorbance of the solution at the maximum at 278 nm using a path length of 4 cm and dimethyl sulfoxide R as compensation liquid.

C.2 Result

At no wavelength in the range 260 nm to 420 nm does the absorbance of the test solution exceed that of the reference solution at 278 nm.

Annex D
(normative)

Sterility test

D.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.

D.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

D.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.

D.2.2 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.

D.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.

D.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.

D.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.

D.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.

D.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

D.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.

D.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.

D.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.

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

D.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.

D.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.

D.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.

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

Test microorganisms		
Aerobic bacteria	**Fungi**	**Anaerobic bacterium**
Staphylococcus aureus ATCC 6538, CIP 4.83,NCTC 10788, NCIMB 9518, NBRC 13276 *Bacillus subtilis* ATCC 6633, CIP 52.62, NCIMB 8054, NBRC 3134 *Pseudomonas aeruginosa* ATCC 9027, NCIMB 8626, CIP 82.118, NBRC 13275	*Candida albicans* ATCC 10231, IP 48.72, NCPF 3179, NBRC 1594	*Clostridium sporogenes* ATCC 19404, CIP 79.3, NCTC 532 or ATCC 11437, NBRC 14293

Bibliography

[1] British Pharmacopeia 2015

[2] USP43-NF38 - 2092

[3] USP42-NF37 - 2045

[4] USP41-NF36 - 1929

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ICS 11.040.30

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