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Tampon — Specification

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The Executive Director
Uganda National Bureau of Standards
P.O. Box 6329
Kampala
Uganda
Tel: +256 417 333 250/1/2
Fax: +256 414 286 123
E-mail: info@unbs.go.ug
Web: www.unbs.go.ug

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Foreword

Uganda National Bureau of Standards (UNBS) is a parastatal under the Ministry of Trade, Industry and Cooperatives established under Cap 327, of the Laws of Uganda, as amended. UNBS is mandated to co-ordinate the elaboration of standards and is

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

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(c) the National Enquiry Point on TBT Agreement of the World Trade Organisation (WTO).

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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 315, *Textiles and related products.*

Tampon — Specification

1 Scope

This Draft Uganda Standard specifies requirements, sampling and test methods for tampons

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.

ISO 4074, *Natural rubber latex male condoms — Requirements and test methods*

ISO 18416, *Cosmetics — Microbiology — Detection of candida albicans*

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

ISO 22717, *Cosmetics — Microbiology — Detection of pseudomonas aeruginosa*

ISO 22718, *Cosmetics — Microbiology — Detection of staphylococcus aureus*

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

tampon
absorbing plug made of absorbent materials such as cotton, viscose rayon or a blend of the two or equivalent materials that is inserted into the vagina and used to absorb menstrual or other vaginal discharge

4 Construction of tampons

Tampons may be constructed in any of the following shapes:

4.1 Rectangle

The absorbent material is in the form of a rectanguar or square pad which is compressed in both length and width directions. This tampon expands in both length and width, but predominantly in the lengthways direction.

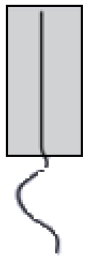

Figure 1 — Rectangular shaped tampon

4.2 Chevron:

The absorbent material is in the form of a chevron shaped pad which is compressed primarily in the width direction. The tampon expands in both length and width, but predominantly widthways, mostly in one laterla plane.

Figure 2 — Chevron shaped tampon

4.3 Swiss roll

The absorbent material is rolled up like a Swiss roll and then compressed to produce a tampon which predominantly expands radially in the widthways direction

Figure 3 — Swiss roll shaped tampon

4.4 Swiss cross

The absorbent material is in the form of two rectangular pads placed on top of each other at a 90-degree angle. A cord is centrally placed between the pads and the tampon is folded from the centre and compressed radially. Upon expansion the tampon opens in a similar way to that of a flower opening.

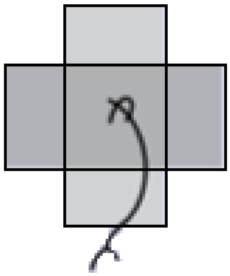

Figure 4 — Swiss cross shaped tampon

5 Types of tampons

5.1 Digital or non-applicator

These tampons are inserted into the vagina by using a finger. The finished tampon is usually packaged in a wrapper

5.2 Applicator tampons

These tampons are inserted into the vagina by using an applicator. The applicators are made from an outer and inner tube with the latter fitting inside the outer tube.

6 Requirements

6.1 General requirements

6.1.1 The absorbent material in a tampon shall be formed from cotton fibres or viscose rayon or a blend of the two.

6.1.2 Fibres used for making tampons shall not be chlorine bleached.

6.1.3 Tampons shall be free from 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), 2,3,7,9-tetrachlorofuran dioxin (TCDF) and any pesticide and herbicide residues.

6.1.4 Tampons should include a provision for withdrawal with a suitably attached withdrawal cord to ensure safe and complete tampon removal.

6.1.5 Tampons may have an additional nonwoven layer or perforated film covering the tampon, which can aid insertion and removal.

6.1.6 Tampons may contain a lubricant or fragrance/scent. Where this is the case, it shall be stated on the pack.

6.1.7 The applicator, if provided shall be residue-chlorine free and shall be non-irritant and non-sensitizing.

6.1.8 There shall be no premature expulsion of the applicator (if provided) and it shall not cause any damage to the vagina during the insertion process.

6.2 Specific requirements

6.2.1 Absorbency

6.2.1.2 Tampons shall be classified in accordance with the range of absorbencies given in Table 1.

Table 1 — Absorbency classification of tampons

Droplet	Corresponding term of absorbency	Absorbency, g
	Very light to light flow	< 6
	Light to medium flow	6 - 9
	Medium to heavy flow	9 - 12
	Heavy flow	12 - 15
	Very heavy flow	15 - 18
	Extremely heavy flow	18 - 21
NOTE Each set of droplet symbol represents a range of 3 g of Syngina absorbency		

6.2.1.2 When tested in accordance with the “Syngina testing” method in Annex A, the tampon shall comply with the absorbency range declared on the label.

6.2.2 Microbiological requirements

Tampons shall comply with the microbiological requirements given in Table 2 when tested in accordance with the test methods specified therein.

Table 2 — Microbiological requirements of tampons

Parameter	Requirement cfu/g	Test method
Escherichia coli	Not detected	ISO 21150
Candida albicans	Not detected	ISO 18416
Staphylococcus aureus	Not detected	ISO 22718
Pseudomonas aeruginosa	Not detected	ISO 22717

6.2.3 Requirements of the removal string

6.2.3.1 The removal string shall be strong enough to withstand the withdrawal force applied by the user.

6.2.3.2 When the string is hanging free from the tampon the length of the string should be no less than 80mm long when measured with the aid of a steel rule.

6.2.3.3 The withdrawal cord shall not sink completely beneath the surface of the water when tested in accordance with Annex B.

6.2.3.4 The pull strength of the removal string and its attachment point shall be such that the mean force required to break or detach the cord shall not be less than 28 N when tested in accordance with Annex C. No value for an individual string shall be less than 22.4 N when tested at a constant rate of 200 ± 25 mm/min using a tensile tester or equivalent.

7 Instruction leaflet

Each tampon pack shall be enclosed with an instruction leaflet which gives legible and clear advice and guidance on the use of tampons. The leaflet shall include the following:

a) information about Toxic Shock Syndrome (TSS) such as:

   i) statement that “TSS can be fatal”;

   ii) full description of the symptoms of TSS i.e., a sudden high fever usually over 39°C, vomiting, diarrhoea, muscle aches, a sun burn like rash, sore throat, dizziness and/or fainting;

   iii) statement that not all the symptoms of TSS may occur simultaneously;

   iv) instruction that if symptoms of TSS occur, the user should remove the tampon, consult a doctor urgently and inform him or her that a tampon has been used

   v) a web web link for further information on TSS such as www. tssis.com;

b) frequency of use statement such as:

   i) in the case of night time use, insert a fresh tampon before going to sleep replace the tampon first thing in the morning.

   ii) regardless of when used, day or night, change the tampon every 4 to 8 hours or more often if needed.

c) Instruction to the user to use the lowest absorbency for their flow as it changes throughout their period. In this instruction, include the following:

   i) a full description of absorbencies available within a brand’s product range (or sub range), including Syngina absorbency in grams e.g. 6 – 9g, 9-12g etc. and linking to menstrual flow via the primary and secondary descriptors and droplets.

   ii) advice to the user to alternate between tampons and towels/pads, liners from time to time during their period.

d) Emphasis on the importance of personal hygiene, particularly the washing of hands before and after inserting a tampon.

e) Information to the user to only use tampons during menstruation, use only one tampon at any time, and to ensure the removal of the last tampon once menstruation has finished.

f) instruct the user on the method for insertion and withdrawal.

g) storage instructions

h) include brief details of the type of absorbent materials in the product.

i) advise the user to correctly dispose of tampons, applicator tubes and wrappers in a waste bin. Additionally, advise the user not to flush tampons, applicator tubes or wrappers.

8 Packaging

Tampons shall be individually wrapped in suitable packaging to ensure that the hygienic quality and physical integrity of the products are maintained.

9 Labelling

Each tampon pack shall be legibly and indellibly labelled with the following information:

a) name and address of the manufacturer'

b) product name, i.e. tampon

c) clear wording to notify the consumer that tampons are associated with Toxic Shock Syndrome (TSS) and advise the user to read and retain the instruction leaflet within the pack; The potentially fatal disease causes women to experience fever, shock, low blood pressure, skin rashes, liver and kidney abnormalities.")

d) Wear time

e) pictogram, absorbency term and corresponding numerical value in grams for absorbency;

f) construction (i.e. shape of the tampon and applicator (if present));

g) chemical composition of the component materials;

h) additives and finishing agents used;

i) for scented or scented-deodorized tampons, include a warning statement about allergic reactions and irritations, for example "If an allergic reaction or irritation occurs from using tampons, you should discontinue use and consult a medical professional."

j) country of origin/manufacture;

k) Disposal instructions of the tampon, and the applicator (if provided) including the "Do Not Flush" symbol;

10 Sampling

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

Annex A
(normative)

Absorbency test (Syngina test)

In the absorbency test, an unlubricated condom, with tensile strength between 17 Mega Pascals (MPa) and 30 MPa, as measured according to the procedure in the ISO 4074 is attached to the large end of a glass chamber (or a chamber made from hard transparent plastic) with a rubber band (see Figure A.1) and pushed through the small end of the chamber using a smooth, finished rod.

The condom is pulled through until all slack is removed. The tip of the condom is cut off and the remaining end of the condom is stretched over the end of the tube and secured with a rubber band.

A pre-weighed (to the nearest 0.01 gram) tampon is placed within the condom membrane so that the center of gravity of the tampon is at the center of the chamber.

An infusion needle (14 gauge) is inserted through the septum created by the condom tip until it contacts the end of the tampon. The outer chamber is filled with water pumped from a temperature-controlled waterbath to maintain the average temperature at 27 ^{0}C ± 1 ^{0}C. The water returns to the waterbath as shown in figure 2.

Syngyna fluid (10 grams sodium chloride, 0.5 gram Certified Reagent Acid Fushsin, 1,000 milliliters distilled water) is then pumped through the infusion needle at a rate of 50 milliliters per hour. The test shall be terminated when the tampon is saturated and the first drop of fluid exits the apparatus. (The test result shall be discarded if fluid is detected in the folds of the condom before the tampon is saturated).

The water is then drained and the tampon is removed and immediately weighed to the nearest 0.01 gram. The absorbency of the tampon is determined by subtracting its dry weight from this value. The condom shall be replaced after 10 tests or at the end of the day during which the condom is used in testing, whichever occurs first.

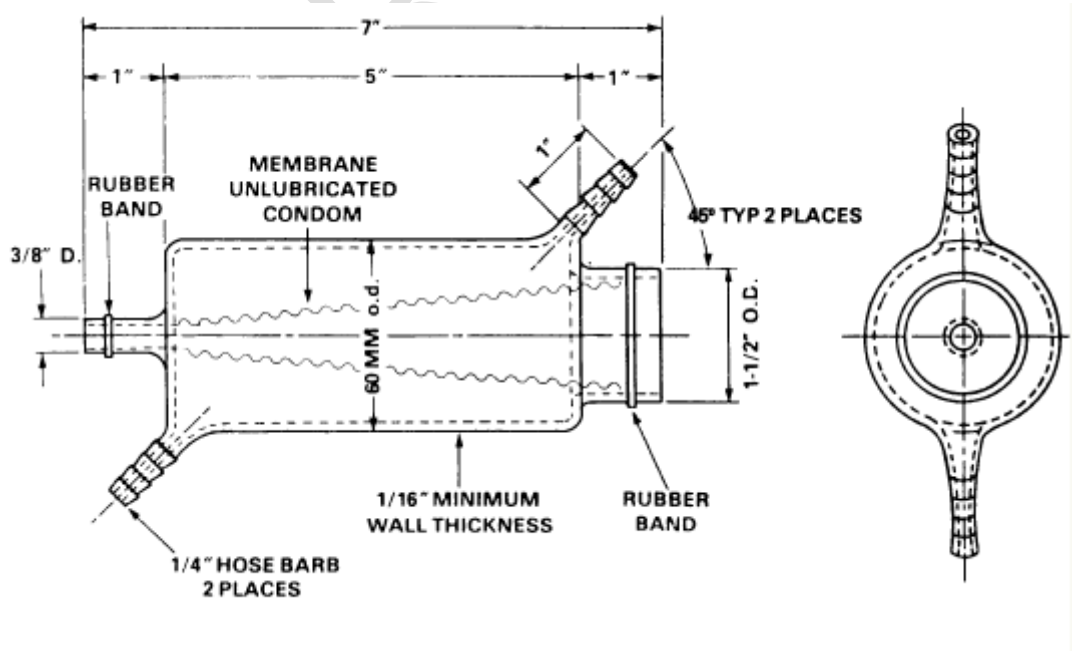

Figure A.1 — Syngina test chamber

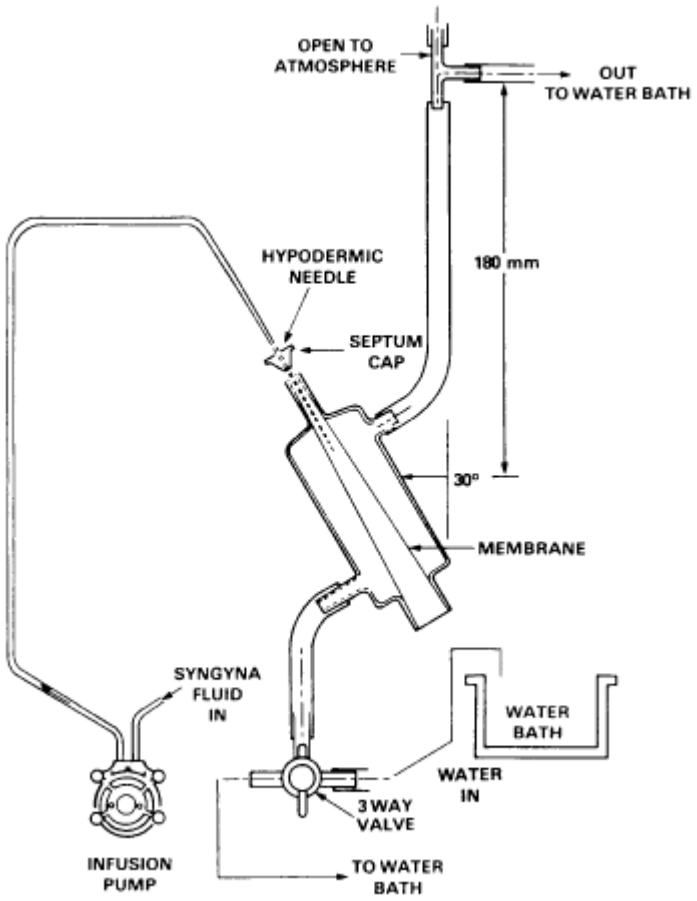

Figure A.2 — Syngina test set-up

Annex B
(normative)

Determination of water repellency of the withdrawal cord

Procedure

B.1 Cut a section of the cord approximately 75 mm long and gently place them on the top of a beaker containing 500ml water.

B.2 Observe at the end of 5h to see if the cord samples are floating on the water surface or have sunk completely beneath the surface.

B.3 If the repellency of the cord is such that it does not sink in a prescribed time, the cord is determined to have satisfactory water repellency.

B.4 Do five samples parallel.

Annex C
(normative)

Determination of the pull strength of the withdrawal cord

C.1 Apparatus

Tensile testing machine, capable of testing at a constant rate of 200 ± 25 mm/min.

C.2 Procedure

C.2.1 Condition the wrapped tampons for not less than 12 h at 20 °C ± 2 °C and 65 % ± 5% relative humidity.

C.2.2 The tampon is placed in a holder having internal diameters of 26 ± 1 mm and the cord is pulled through the base of the hole in the holder and then attached to the lower jaw of the tensile machine.

C.2.3 Place the flange on the holder into the upper jaw of the tensile testing machine making sure to extend the cord so that there are no kinks in it.

C.2.4 Start the test at a constant rate of extension of 200 ± 25 mm/min and record the force required to either break the cord or detach it from the body of the tampon. Repeat and note the average of 6-9 readings.

C.2.5 Repeat the test in the wet state which is as follows. Place the tampon in the 1000 mL beaker in an excess of the water and leave the tampon in the water for at least 5 min. Remove the tampon with the tongs and gently squeeze to remove excess water and repeat the test as above.

C.2.6 Record the average of 6-9 readings as the mean pull strength (force) of the cord.

Bibliography

[1] *UK Code of Practice for Tampon Manufacturers and Distributors Version No.8 dated May 2019.*

[2] Edana guidelines for testing feminine hygiene products Version 13th December 2018

[3] 21CFR801.430, Code of Federal Regulations Title 21

[4] *Technical Specifications for Tampons" available at https://www.unicef.org/supply/media/12541/file/technical-specification-tampons-2022.pdf*

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ICS 11.020

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