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DISPOSABLE SANITARY TOWELS - SPECIFICATION

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Textiles — Disposable sanitary towels — Specification



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Foreword

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This African Standard was prepared by the ARSO Technical Harmonization Committee Number 7 on *Leather and Textile Products* (ARSO/THC 07).

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Introduction

The functions of sanitary napkins are to absorb and retain menstrual fluid, and isolate menstrual fluids from the body. A sanitary napkin, sanitary towel, sanitary pad, menstrual pad, or pad is an absorbent item worn in the underwear by females who are menstruating, bleeding after giving birth, recovering from gynaecologic surgery, experiencing a miscarriage or abortion, or in any other situation where it is necessary to absorb a flow of blood from the vagina. Important and desired properties are: (i) high absorbency/no leakage, especially no side leakage; (ii) no chafing (not abrasive, soft to the touch, to be friendly to skin); (iii) comfortable to wear (thin body shape); (iv) good fit to the body contour, stay in place; (v) no unaesthetic appearance or colour; (vi) no odour; (vii) no noise; (viii) no humidity that leads to skin rash; (ix) a high level of hygiene; and (x) to be easy to use and to dispose (Osada *et al.*, 2001; Ajmeri *et al.*, 2010; Kellie, 2016). Disposable menstrual pads are usually individually wrapped so they are easier and more discreet to carry in a purse or bag. This wrapper may be used to wrap the soiled pads before disposing of them in appropriate receptacles.

There are several different types of disposable menstrual pads:

- **Panty liner:** Designed to absorb daily vaginal discharge, light menstrual flow, "spotting", slight urinary incontinence, or as a backup for tampon or menstrual cup use.
- **Ultra-thin:** A very compact (thin) pad, which may be as absorbent as a Regular or Maxi/Super pad but with less bulk.
- **Regular:** A middle range absorbency pad.
- **Maxi/Super:** A larger absorbency pad, useful for the start of the menstrual cycle when menstruation is often heaviest.
- **Overnight:** A longer pad to allow for more protection while the wearer is lying down, with an absorbency suitable for overnight use.
- **Maternity:** These are usually slightly longer than a maxi/Super pad and are designed to be worn to absorb lochia (bleeding that occurs after childbirth) and also can absorb urine.

The shape, absorbency and lengths may vary depending on the type of application, but usually range from the short slender panty liner to the larger and longer overnight. Long pads are offered for extra protection or for larger people whose undergarments might not be completely protected by regular length pads, and also for overnight use.

Other options are often offered in a manufacturer's line of pads, such as wings or tabs that wrap around the sides of underwear to add additional leak protection and help secure the pad in place. Deodorant is also added to some pads, which is designed to cover menstrual odour with a light fragrance.

This African Standard provides uniform requirements for disposable sanitary towels/napkins aimed at ensuring that the products are fit for use by the target population and offer the desirable characteristics outlined above.

This standard is revision of ARS 653:1990(E), *Textiles — Sanitary towels — General requirements*.

ARS 653:1990 is hereby superseded.

ENQUÊTE PUBLIQUE N° 19

Textiles — Disposable sanitary towels — Specification

1 Scope

This African Standard specifies requirements and test methods for four types of disposable sanitary towels for external use.

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.

ISO 139, *Textiles — Standard atmospheres for conditioning and testing*

ISO 3071, *Textiles -- Determination of pH of aqueous extract*

ISO 4833-2, *Microbiology of food and animal feeding stuffs — Horizontal method for the enumeration of microorganisms — Colony-count technique at 30 °C.*

ISO 6887, *Microbiology — General guidance for the preparation of dilutions for microbiological examination*

ISO 6888-2, *Microbiology of food and animal feeding stuffs — Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) — Part 2: Technique using rabbit plasma fibrinogen agar medium*

ISO 7218, *Microbiology of food and animal feeding stuffs — General requirements and guidance for microbiological examinations*

ISO 9073-12, *Textiles — Test methods for nonwovens — Part 12: Demand absorbency*

ISO 14184-1, *Textiles — Determination of formaldehyde — Part 1: Free and hydrolysed formaldehyde (water extraction method)*

ISO 14184-2, *Textiles — Determination of formaldehyde — Part 2: Released formaldehyde (vapour absorption method)*

ISO 20158, *Textiles — Determination of water absorption time and water absorption capacity of textile fabrics*

ISO 22198, *Textiles — Fabrics — Determination of width and length*

United States Pharmacopoeia (USP)

International Agency for Research on Cancer (IARC)

3 Terms and definitions

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

3.1

extraneous dust

atmospheric particulate matter that is produced from a source or sources other than any of the components used in the manufacture of sanitary towels

3.2

absorption

tendency of a textile fabric to swallow and keep a liquid in the voids and pores of the materials

3.3

water absorption time

time required for textile fabric to become saturated with water under specified conditions

3.4

demand absorbency capacity

DAC

maximum absorbed mass of liquid, A_f , divided by the mass of the test piece, m , expressed in grams per gram

3.5

mechanical pulp

papermaking pulp made entirely by mechanical means from various raw materials but usually from wood

3.6

sanitary towels

disposable feminine hygienic product made of fabric intended to absorb menstrual flow; a feminine hygienic product made of fabric intended to absorb menstrual flow, vaginal discharge and post delivery flow

4 Requirements

4.1 General

4.1.1 Sanitary towels shall have been made so as to meet the requirements of this standard. The sanitary towel shall be of an acceptable uniform shape and finish.

4.1.2 All sanitary towels shall be free from lumps, oil spots, streaks of dirt, and similar foreign matter that might affect their appearance or impair their serviceability (or both).

4.1.3 Sanitary towels shall be delivered in a clean and commercially dry condition and shall, when so required, be capable of withstanding sterilization in an autoclave, or shall be individually sterile packed.

4.1.4 Sanitary towels shall not contain carcinogens or potentially oncogenic substances outside the permitted concentration limits as specified in IARC.

4.2 Construction

4.2.1 Sanitary towels shall consist of a filler that is completely encased in a cover. The general construction of a sanitary pad is depicted in Figure 1.

4.2.2 The cover in all sanitary towels shall be so sealed or secured that it cannot unwrap from the filler during normal handling and use.

4.2.3 The absorbent face shall be clearly indicated.

4.2.4 Sanitary towels shall be with or without loops, or shall have adhesive backing strips on the cover to hold it in place.

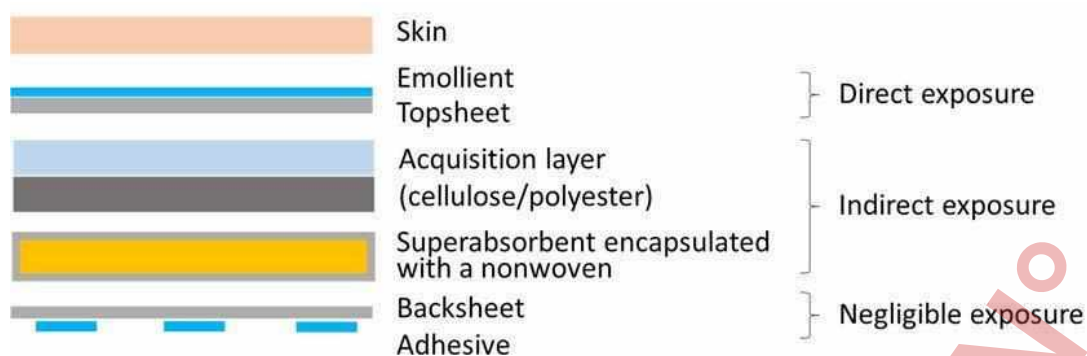


Figure 1 — Cross-sectional view of a sanitary napkin (Osada *et al.*, 2001)

4.3 Materials

Materials specified in 4.3.1 to 4.3.3 shall not contain any harmful substances.

4.3.1 Absorbent filler

The absorbent filler material shall be free from lumps, oil spots, dirt or foreign materials.

4.3.2 Covering

The covering of the absorbent filler shall be of woven gauze or of non-woven material or of tubular knitted fabric (with or without a seam) or other suitable fabrics with sufficient porosity to permit the assembled pad to meet the absorbency requirements.

4.3.3 Protective barrier

The protective barrier shall be water resistant, biodegradable or non-biodegradable with at least 60 microns.

4.4 Dimensions of filler components

The average length and width of the filler components, determined in accordance with 5.3, shall fall within the range of values given in Table 1, appropriate to the size designation of disposable sanitary towels.

Table 1 — Dimensions of filler components

1	2	3	4	5
Dimensions in millimetres	Size designation			
	"Thins"	Regular	Maternity	Delivery
Length ^a	180 to 260	180 to 270	230 to 300	270 to 330
Width (of filler)	60 to 80	60 to 90	60 to 100	90 to 110
^a The length of the absorbent component intended to be nearest to the body and excluding any non-absorbent or tissue wrappings.				

4.5 Disposable sanitary towel types and filler composition

4.5.1 Sanitary towels shall be of one of the types given in Table 1.

4.5.2 When determined in accordance with 5.3.2, the filler composition shall comply with the appropriate requirements given in Table 2.

4.5.3 No component of the filler shall contain unprocessed waste paper or mechanical pulp.

NOTE The filler may contain absorbent gelling agents.

Table 2 — Type designation and filler composition

1	2
Type designation	Filler composition
COM	A combination of cellulose pulp and cellulose tissue, cotton wool or cotton (or similar material(s))
CP	Cellulose pulp
AGM	Absorbent Gelling Material (Super absorbent material)

4.6 Performance requirements

Sanitary towels shall comply with the requirements given in Table 3.

Table 3 — Performance requirements

1	2	3
Parameter	Requirement	Test method subclause
Absorbency volume (ml), min.		5.4
"Thins"	5	
Regular	10	
Maternity	15	
Delivery	20	
Absorbency rate (s)		5.5
All sizes, max.	10	
pH Value	6 - 8	ISO 3071
Formaldehyde, mg/kg.	Less than 16	ISO 14184-1

4.7 Microbiological requirements

Sanitary towels that have not been sterile-packed (see 4.1.3) shall be such that

- the total viable bacterial count, determined in accordance with 5.6.4.1, does not exceed 1 000 per gram of sanitary towel, and
- when tested in accordance with 5.6.4.2, 5.6.4.3 and 5.6.4.4, they shall be free from *Enterobacteriaceae*, *Staphylococcus aureus* and *Pseudomonas aeruginosa*, respectively.

4.8 Sterility

When sterile-packed sanitary towels are required, they shall pass the test for sterility given in 5.7.

4.9 Autoclavability

When so required, and when tested in accordance with 5.8, sanitary towels shall be able to withstand steam sterilization without showing any appreciable deterioration in handle or appearance.

5 Inspection and methods of test

5.1 Inspection

After checking each package in the sample for compliance with the relevant requirements of Clause 6, retain enough unopened packages for the microbiological tests, and then visually examine the contents of the remaining packages for compliance with the requirements given in 4.1 and 4.2.

5.2 Test specimens

5.2.1 Physical tests

Condition the test samples in accordance with ISO 139 and then take, at random, sufficient sanitary towels for each of the tests given in 5.3 to 5.5 (inclusive) and, when relevant, 5.8.

5.2.2 Microbiological tests

From the packages retained in terms of 5.1, aseptically draw, at random, sufficient sanitary towels for the tests given in 5.6 and, when relevant, 5.7.

5.3 Filler

5.3.1 Dimensions of filler components

5.3.1.1 Remove the cover from the sanitary towel under test.

5.3.1.2 Measure the width of the filler and the length of the appropriate absorbent component in accordance with ISO 22198, but take only one measurement in each direction (see Table 1).

5.3.1.3 Record as the average length and average width the arithmetic mean of the corresponding results on at least 10 sanitary towels.

5.3.1.4 Check for compliance with 4.4.

5.3.2 Filler composition

5.3.2.1 Determine the composition of the filler by microscopical examination and chemical analysis.

5.3.2.2 Check for compliance with 4.5.

5.4 Absorbency volume

5.4.1 Test solution

Dissolve 2 g of Masson's light green stain in 1 L of water at ambient temperature.

5.4.2 Apparatus

5.4.2.1 Electrodes

The following electrodes made from woven copper wire gauze of aperture size approximately (2 × 2) mm, with each electrode having all cut edges so soldered as to cover the ends of the wires and with, soldered to an edge or corner, an insulated single-core conductor that has a jack plug connection at the free end:

- a) **electrode A**, of size (60 × 50) mm and with, cut from the centre, a square aperture with sides of length approximately 25 mm;
- b) **electrodes B1 and B2**, each of size (90 × 30) mm;
- c) **electrode C**, of size (100 × 50) mm; and

- d) **electrodes D1 and D2**, each of the shape and dimensions given in Figure 2 and with, at the centre of the upper edge, a tag of size (20 × 15) mm that is perpendicular to the 20 mm wide surface of the electrode.

5.4.2.2 Cylinder

5.4.2.2.1 A hollow open-ended cylinder of a clear plastics material, with a nominal external diameter of 100 mm, a length of at least 120 mm, and two diametrically opposite holes, each of diameter approximately 20 mm, at the midpoint of the length of the cylinder.

5.4.2.2.2 Electrode A is so attached to the cylinder that the square aperture is centred over one of the holes and the longer sides are parallel to the circumference of the cylinder.

5.4.2.2.3 Electrodes B1 and B2 are also attached to the cylinder, each one 10 mm away from each end of the electrode A and with the longer sides parallel to the longitudinal axis of the cylinder.

5.4.2.2.4 The cylinder is permanently mounted (see Figure 3) in a suitable frame (see 5.4.2.5) with the holes in vertical alignment and the hole that is surrounded by electrode A at the bottom.

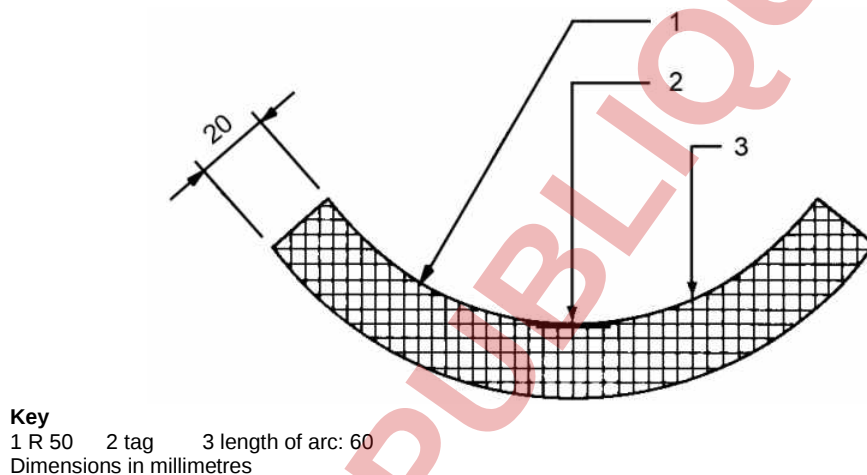


Figure 2 — Electrodes D1 and D2

5.4.2.3 Funnel

A small glass funnel with a stem of length at least 100 mm and an internal bore of approximately 4 mm, and so suspended through the upper hole in the cylinder that the end of the stem just reaches the lower hole.

5.4.2.4 Reservoir

A suitable reservoir (preferably of the constant-head type) mounted above the funnel, containing the test solution (see 5.4.1), and equipped with a tap or other suitable means for controlling the outflow of the solution into the funnel at a rate of (10 ± 0.1) mL/min.

5.4.2.5 Supporting frame

The frame is equipped with

- a) a means for wrapping the sanitary towel under test around the underside of the cylinder (with the sanitary towel centred below the lower hole) by attaching one end of the sanitary towel to a suitable anchor that is fixed to the side of the frame at a level not below the upper surface of the cylinder, and the other end of the sanitary towel to a cord that passes over a pulley that is secured to the other side of the frame (at the same level as the anchor), and that carries a mass piece of approximately 250 g to apply tension to the sanitary towel;

- b) a means, similar to that described in 5.4.2.5(a), for holding the ends of electrode C so that its midpoint is in vertical alignment with the lower hole in the cylinder, its upper surface is in full contact with the lower surface of the sanitary towel under test, and that it is under the same tension as the sanitary towel;
- c) a means for holding each of electrodes D1 and D2 against each edge of the sanitary towel under test and centred on its transverse centre-line; and
- d) a mirror, so positioned and fixed to the base of the frame below the lower hole of the cylinder as to reflect the lower surface of the sanitary towel under test.

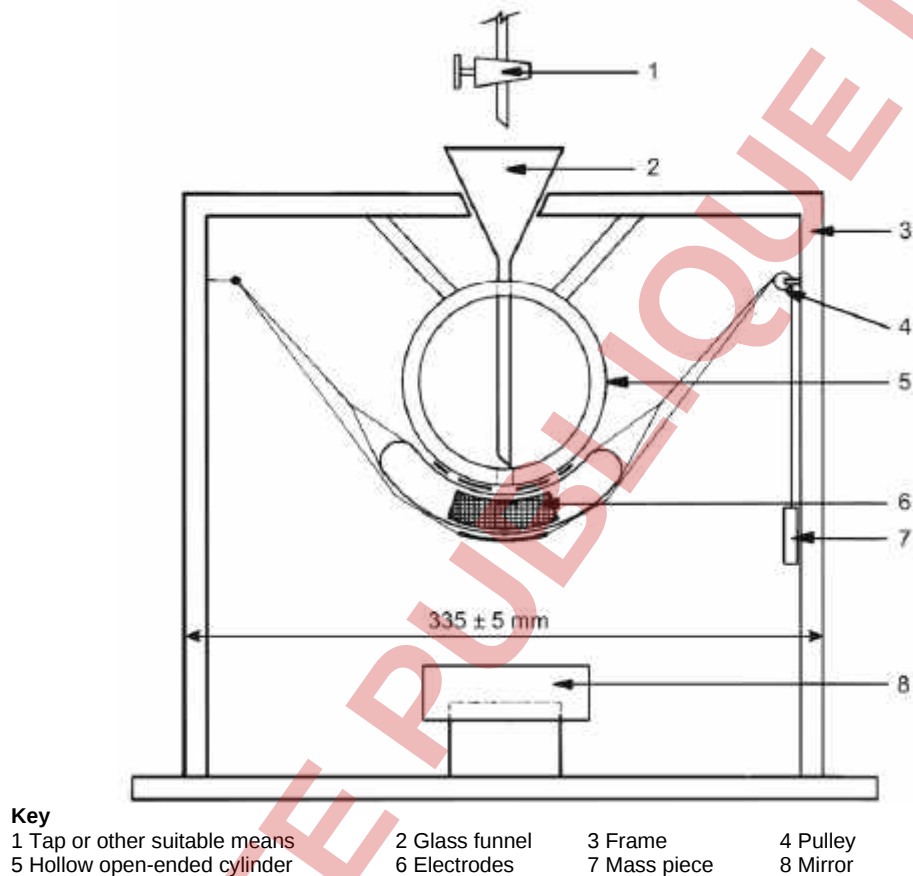


Figure 3 — Test rig

5.4.2.6 Relay box

A suitable electrical relay box with a built-in transformer and rectifier (for reducing voltage to 1 mV DC), that is connected to a mains supply, and that has six interconnected jack plug sockets to accommodate the connections from the electrodes, and is such that an electrical circuit made between any two of the electrodes by means of electrical conductance through the test solution, is registered by a suitable signal lamp connected to each socket.

5.4.2.7 Balance

A balance with a sensitivity of at least 0.1 g.

5.4.3 Procedure

5.4.3.1 Fill the reservoir with the test solution, weigh the sanitary towel under test to the nearest 0.1 g, and secure and tension it as described in 5.4.2.5(a).

5.4.3.2 Secure and tension electrode C as described in 5.4.2.5(b), and position electrodes D1 and D2 (with the horizontal tags away from the sanitary towel) as described in 5.4.2.5(c).

5.4.3.3 Connect the jack plug from each electrode to the corresponding socket of the relay box and switch on the mains supply.

5.4.3.4 Run the test solution through the funnel at a rate of (10 ± 0.1) mL/min until a signal lamp indicates that an electrical circuit has been made between two of the electrodes.

5.4.3.5 Close the tap from the reservoir, disconnect the mains supply to the electrodes, remove the sanitary towel and, using the dye in the test solution as an indicator, check the correct functioning of the electrode.

5.4.3.6 Reweigh the sanitary towel.

5.4.3.7 Repeat the test on at least a further nine sanitary towels.

NOTE It is essential to ensure that all electrodes are always kept free from non-conductive matter.

5.4.4 Calculation

5.4.4.1 Calculate the mean gain in grams (demand absorbency capacity) of the sanitary towels tested and report this as the absorbency volume, in millilitres, of the sanitary towels.

5.4.4.2 Check for compliance with 4.6.

5.5 Absorbency rate

5.5.1 Apparatus

5.5.1.1 Waterbath, of depth at least 100 mm and maintained at a temperature of (30 ± 1) °C.

5.5.1.2 Stopwatch

5.5.1.3 Forceps

5.5.2 Preparation of test specimens

5.5.2.1 From each of at least 10 sanitary towels, carefully remove and discard the cover on the side of the sanitary towel that is not intended to be in contact with the body, the loops (when relevant) and any non-absorbent layer(s) or layer(s) that do not contribute to the absorbency of the sanitary towel.

5.5.2.2 Cut a test specimen of area 42 cm² from across the full width of the remaining filler in each sanitary towel and staple or tack the specimen at each corner.

5.5.3 Procedure

5.5.3.1 By means of the forceps, place a specimen lightly on the surface of the water, ensuring that the side of the sanitary towel that is intended to be in contact with the body is in full contact with the water surface and start the stopwatch simultaneously.

5.5.3.2 As soon as the specimen sinks below the surface of the water, stop the stopwatch and record the absorption period to the nearest 0.1 s.

5.5.3.3 Repeat the test on each of the remaining test specimens.

5.5.4 Calculation

5.5.4.1 Calculate the arithmetic mean of the absorbency rate of the fillers tested.

5.5.4.2 Check for compliance with 4.6.

5.6 Microbiological examination

5.6.1 Apparatus and equipment

Use apparatus and equipment that comply designated for microbiological examinations in accordance with ISO 7218.

5.6.2 Media and reagents

5.6.2.1 General

Ensure compliance with the general requirements for the ingredients and for the preparation of media and reagents given in ISO 6887.

5.6.2.2 Bacteriological peptone

5.6.2.2.1 Ingredients

Peptone:	10 g
Disodium hydrogen phosphate dodecahydrate ($\text{Na}_2\text{HPO}_4 \cdot 12\text{H}_2\text{O}$):	9 g
Sodium chloride	5 g
Monobasic potassium phosphate (KH_2PO_4):	1.5 g

5.6.2.2.2 Preparation

Prepare the bacteriological peptone medium as follows:

- Dissolve the ingredients in distilled water and make up to 1 L with water.
- Adjust the pH value so that it will be 7.0 ± 0.1 after sterilization.
- Dispense 300 mL volumes into flasks of 500 mL capacity and sterilize by autoclaving at $(121 \pm 2)^\circ\text{C}$ for 20 min.

5.6.2.3 Plate count agar

5.6.2.3.1 Ingredients

Agar:	15 g
Glucose:	1 g
Tryptone:	5 g
Yeast extract:	2.5 g

5.6.2.3.2 Preparation

Prepare the plate count agar medium as follows:

- Dissolve the ingredients in distilled water and make up to 1 L with water.
- Adjust the pH value to 7.2.
- Dispense 15 mL volumes into bottles and sterilize by autoclaving at $(121 \pm 2)^\circ\text{C}$ for 20 min.

5.6.2.4 Neutral red-bile salt peptone glucose medium

5.6.2.4.1 Ingredients

Peptone:	20 g
Glucose:	10 g
Bile salts No. 3:	1.5 g

Sodium chloride:	5 g
Neutral red:	0.03 g
Crystal violet:	0.002 g

5.6.2.4.2 Preparation

Prepare the neutral red-bile salt peptone glucose medium as follows:

- Dissolve the ingredients in 400 mL of distilled water and make up to 500 mL with water, boiling to aid solution.
- Adjust the pH value to 7.4, and filter to obtain a clear solution.
- Dispense 10 mL volumes into bottles each containing a Durham tube and sterilize by autoclaving at $(121 \pm 2) ^\circ\text{C}$ for 20 min.

5.6.2.5 Fluid soybean-casein digest medium

5.6.2.5.1 Ingredients

Pancreatic digest of casein:	17 g
Papaic digest of soybean meal:	3 g
Sodium chloride:	5 g
Dibasic potassium phosphate (K_2HPO_4):	2.5 g
Dextrose:	2.5 g

5.6.2.5.2 Preparation

Prepare the fluid soybean-casein digest medium as follows:

- Dissolve the ingredients in distilled water, warming slightly to aid solution, and make up to 1 L with water.
- Cool the solution to room temperature.
- Adjust the pH value so that it will be 7.3 ± 0.2 after sterilization, and filter to obtain a clear solution, if necessary.
- Dispense into suitable containers and sterilize by autoclaving at $(121 \pm 2) ^\circ\text{C}$ for 20 min.

5.6.2.6 Cetrimide agar medium

5.6.2.6.1 Ingredients

Pancreatic digest of gelatin:	20 g
Magnesium chloride:	1.4 g
Potassium sulfate (K_2SO_4):	10 g
Agar:	13.6 g
Cetyl trimethylammonium bromide (Cetrimide):	0.3 g
Glycerin:	10 mL

5.6.2.6.2 Preparation

Prepare the Cetrimide agar medium as follows:

- Dissolve all the solid ingredients in distilled water, make up to 1 L with water, and then add the glycerin.
- Heat, agitating frequently, and boil for 1 min.
- Adjust the pH value so that it will be 7.2 ± 0.2 after sterilization.

- d) Dispense into suitable containers and sterilize by autoclaving at $(121 \pm 2) ^\circ\text{C}$ for 20 min.

5.6.2.7 Pseudomonas agar medium for the detection of fluorescein

5.6.2.7.1 Ingredients

Pancreatic digest of casein:	10 g
Peptic digest of animal tissue:	10 g
Dibasic potassium phosphate (K_2HPO_4):	1.5 g
Magnesium sulfate ($\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$):	1.5 g
Glycerin:	10 mL
Agar:	15 g

5.6.2.7.2 Preparation

Prepare the Pseudomonas agar medium for the detection of fluorescein as follows:

- Dissolve all the solid ingredients in distilled water, make up to 1 L with water, and then add the glycerin.
- Heat, agitating frequently, and boil for 1 min.
- Adjust the pH value so that it will be 7.2 ± 0.2 after sterilization.
- Dispense into suitable containers and sterilize by autoclaving at $(121 \pm 2) ^\circ\text{C}$ for 20 min.

5.6.2.8 Pseudomonas agar medium for the detection of pyocyanin

5.6.2.8.1 Ingredients

Pancreatic digest of gelatin:	20 g
Anhydrous magnesium chloride:	1.4 g
Potassium sulfate (K_2SO_4):	10 g
Agar:	15 g
Glycerin:	10 mL

5.6.2.8.2 Preparation

Prepare the Pseudomonas agar medium for the detection of pyocyanin as follows:

- Dissolve all the solid ingredients in distilled water, make up to 1 L with water, and then add the glycerin.
- Heat, agitating frequently, and boil for 1 min.
- Adjust the pH value so that it will be 7.2 ± 0.2 after sterilization.
- Dispense into suitable containers and sterilize by autoclaving at $(121 \pm 2) ^\circ\text{C}$ for 20 min.

5.6.3 Preparation of test suspension

5.6.3.1 Transfer 300 mL of the sterile solution of bacteriological peptone (see 5.6.2.2) to a sterile wide-mouthed jar of capacity not less than 1 L and not more than 2 L, with a mouth of diameter not less than 150 mm and not more than 250 mm, and that is fitted with a hermetically closing glass or metal-and-glass lid.

5.6.3.2 Aseptically determine the mass of the sanitary towel under test to the nearest 0.1 g, place the sanitary towel in the solution in the jar, fit the lid, agitate the contents of the jar for 2 min and then allow the jar to stand for 10 min.

5.6.3.3 Repeat this agitating and standing procedure twice more.

5.6.3.4 Aseptically remove about 100 mL of the test suspension for testing in accordance with 5.6.4.

5.6.4 Procedure

5.6.4.1 Total viable bacterial count

5.6.4.1.1 Aseptically pipette a 1 mL portion of the test suspension into each of three sterile Petri dishes.

5.6.4.1.2 Add 15 mL of freshly melted plate count agar (see 5.6.2.3) that has been cooled to 45 °C to each dish, and mix well.

5.6.4.1.3 Incubate, count and calculate the total count as described in ISO 4833-2.

5.6.4.1.4 From the total viable bacterial count and the mass of the sanitary towel (see 5.6.3.2), calculate the total viable bacterial count per gram of sanitary towel.

5.6.4.1.5 Check for compliance with 4.7(a).

5.6.4.2 Examination for the presence of *Enterobacteriaceae*

5.6.4.2.1 Aseptically add 10 mL of the test suspension to a bottle that contains neutral red-bile salt peptone glucose medium (see 5.6.2.4).

5.6.4.2.2 Incubate the bottle for (24 to 36) h at $(37 \pm 0.5) ^\circ\text{C}$ and examine for the presence of *Enterobacteriaceae* as evidenced by the formation of acid and gas.

5.6.4.2.3 Check for compliance with 4.7(b).

5.6.4.3 Examination for the presence of *Staphylococcus aureus*

5.6.4.3.1 Use the media, reagents and procedure in accordance with ISO 6888-2 to examine the test suspension (see 5.6.3).

5.6.4.3.2 Pipette 0.1 mL of a 1:1 000 dilution of an (18 to 24) h culture of *Staphylococcus aureus* medium as a control, and proceed as with the test suspension.

5.6.4.3.3 Check for compliance with 4.7(b).

5.6.4.4 Examination for the presence of *Pseudomonas aeruginosa*

5.6.4.4.1 Aseptically pipette 10 mL of the test suspension into 90 mL of fluid soybean-casein digest medium (see 5.6.2.5) and mix well.

5.6.4.4.2 Incubate for 24 h at (30 to 35) °C.

5.6.4.4.3 By means of an inoculating loop, transfer a portion from the 24 h incubated sample tube of fluid soybean-casein digest medium to the dry surface of Petri dishes each containing approximately 20 mL of Cetrimide agar medium (see 5.6.2.6).

5.6.4.4.4 Incubate at (30 to 35) °C and examine, after 24 h and again after 48 h incubation, for suspect colonies, bearing in mind that in general, greenish fluorescent colonies are typical of *Pseudomonas aeruginosa* and that, in its presence, a gram stain examined microscopically will reveal gram-negative slender rod-shaped cells.

5.6.4.4.5 Add 0.1 mL of a 1:1 000 dilution of an (18 to 24) h culture of *Pseudomonas aeruginosa* to 100 mL of fluid soybean-casein digest medium (see 5.6.2.5) as a control, and proceed as with the test suspension.

5.6.4.4.6 If none of the colonies obtained from the test suspension conform to the description given in 5.6.4.4.4 and the control culture has been satisfactorily recovered, deem the test sample to be free from *Pseudomonas aeruginosa*.

5.6.4.4.7 If colonies conforming to the description given in 5.6.4.4.4 are found, so streak representative suspect colonies from the Cetrimide agar onto the surfaces of *Pseudomonas* agar medium for the detection of fluorescein (see 5.6.2.7) and *Pseudomonas* agar medium for the detection of pyocyanin (see 5.6.2.8) to obtain isolated colonies.

5.6.4.4.8 Cover and invert the Petri dishes and incubate at (30 to 35) °C for at least 3 d.

5.6.4.4.9 Examine the streaked surfaces under ultraviolet light for suspect colonies in accordance with table 4.

5.6.4.4.10 If any further doubt exists as to the identity of the colonies, obtain final confirmation by inoculating the suspect colonies to the wells on commercially available diagnostic kits in accordance with the manufacturer's instructions.

5.6.4.4.11 Check for compliance with 4.7(b).

Table 4 — Description of colonies

1	2
Medium	Description of colonies
<i>Pseudomonas</i> agar for the detection of fluorescein	Generally colourless to yellowish. Yellowish fluorescence in ultra-violet light.
<i>Pseudomonas</i> agar for the detection of pyocyanin	Generally greenish. Blue fluorescence in ultraviolet light.

5.7 Sterility

5.7.1 Use the method "Sterility tests" given in the USP.

5.7.2 Check for compliance with 4.8.

5.8 Autoclavability

5.8.1 Steam sterilize at least three test specimens at a temperature of 134 °C for a period of 3 min.

5.8.2 Condition the test specimens in accordance with ISO 139, then visually and physically examine the specimens for signs of deterioration and compare with untreated specimens.

5.8.3 Examples of deterioration include:

- harshness of handle;
- lumpiness;
- linting of cover;
- shrinkage;
- melting of adhesive backing strips;
- brittleness or hardness of strike-through barrier; and
- tackiness of any adhesive.

5.8.4 When there is appreciable deterioration in handle or appearance, reject the test specimen.

5.8.5 If there is any doubt as to the degree of deterioration (for example, slight deterioration), conduct performance tests in accordance with 5.3, 5.4 and 5.5. Accept the test specimens if they pass, but reject the specimens if they fail any of the performance tests.

6 Packing and marking

6.1 Packing

6.1.1 Sanitary towels shall be supplied in suitable packages each containing 10 or 12 sanitary towels (or multiples thereof) or, when so required, shall be individually sterile-packed.

6.1.2 The packages shall be packed in bulk containers that will protect the contents from damage and contamination during normal handling, transportation and storage.

6.1.3 Only packages bearing the same date of manufacture (or other batch identification) and containing sanitary towels of the same construction, size designation, and type shall be packed together in a bulk container.

6.2 Marking

6.2.1 Packages

The following information shall appear in legible and indelible marking on the outside of each package:

- a) the trade name or trademark of the manufacturer (or both);
- b) the words "Disposable sanitary towels";
- c) the size designation and type, and whether with loops, without loops or with adhesive backing strips;
- d) the number of disposable sanitary towels in the package;
- e) the date of manufacture or other suitable batch identification;
- f) the net weight and gross weight;
- g) the country of origin and location address;

6.2.2 Bulk containers

The following information shall appear in legible and indelible marking on the outside of each bulk container:

- a) the information required in 6.2.1(a) to 6.2.1(e) (inclusive);
- b) the words "Individually sterile-packed", if relevant; and
- c) the quantity of packages.

6.2.3 Additional marking

When so required, packages or bulk containers (or both) shall bear information additional to that specified in 6.2.1 and 6.2.2.

Annex A
(informative)

Notes to purchasers

The following requirements may be specified in tender invitations and in each order or contract:

- a) When relevant, disposable sanitary towels shall be capable of withstanding autoclaving (see 4.1.3).
- b) When relevant, disposable sanitary towels shall be with wings or without wings, with loops or without loops, or with adhesive backing strips (see 4.2).
- c) The size designation (see 4.4).
- d) The type (see 4.5).
- e) When relevant, that sanitary towels shall be individually sterile-packed (see 6.1.1).
- f) Additional marking, if required (see 6.2.3).

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