

Disposable Maternity Pads — Specification

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Disposable Maternity Pads — Specification

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Foreword

This standard has been prepared by the Technical Committee on Towels, Medical and Hygienic Textile Products under guidance of the Textile Industry Standards Committee, and it is in accordance with the procedures of the Kenya Bureau of Standards.

A Maternity pad is an absorbent product used to absorb and retain vaginal discharge after giving birth. The standard is therefore meant to guide the manufacturers of the maternity pads on the expected quality requirements and enhance consumer satisfaction.

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

KS EAS 96:2018

Acknowledgement is hereby made for the assistance derived from these sources.

Scope

1. This Draft Kenya Standard specifies the minimum requirements for disposable maternity pads.

2 Normative references

2. The following referenced documents are indispensable for the application of this standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies

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

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

ISO 8784, Microbiological examination — Part 1: Enumeration of bacteria and bacterial spores based on disintegration

KS ISO 22717, Cosmetics — Microbiology — Detection of *Pseudomonas aeruginosa*

KS ISO 22718, Cosmetics — Microbiology — Detection of *Staphylococcus aureus*

KS ISO 18416, Cosmetics -- Microbiology -- Detection of *Candida albicans*

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

3 Definitions

For the purposes of this Kenyan Standard, the following definitions shall apply:

3.1

package

the smallest unit of maternity pads as declared by a manufacturer that can be purchased by a consumer

3.2

absorbent filler material

the material at the core of the maternity pad that absorbs fluids

3.3

Leakage

The test solution which penetrates the maternity pad under specific pressure.

4 Requirements

4.1 General

All components used in the manufacture of Maternity Pads shall not cause any harm to the skin.

4.2 Materials

4.1.1 Absorbent filler

When visually examined, the absorbent filler shall be white in colour and shall be free from any water soluble colouring matter when tested in accordance with Annex C. It shall not contain extraneous materials, which are not designed to enhance performance.

4.1.2 Covering

The absorbent filler covering shall be made of fabric with sufficient porosity to permit the assembled towel to meet absorbency requirement.

Note: If harsh absorbent fillers or cover fabrics are used in the manufacture of Maternity Pads, they may cause discomfort and body rashes on the delicate skin due to undesired friction

4.1.3 Protective barrier

The protective barrier shall be water resistant (no wetting of outer surface and no water penetration) when tested in accordance with Annex E. It shall be clearly identifiable with a mark, colour or some other means.

4.2 Workmanship and finish

4.2.1 Absorbent filler

The absorbent filler shall be continuous and neatly cut to the required size. It shall be free from hard lumps. It shall be completely covered and free from wrinkles that are not a design feature.

4.2.2 Securing mechanism

Any of the following may be used:

- a) Loops or tabs which shall extend beyond the length of the filler material;
- b) Adhesive strip or patch;
- c) Wings with adhesive which shall be of sufficient length in such a manner as to form folds around the panty/brief for securing the Maternity Pad when in use.

4.2.3 Freedom from defects

The Maternity Pad when visually examined shall be free from defects, which affect the appearance and utility such as oil stains, dirt, soil particles and hard lumps.

4.2.4 Odour

The Maternity Pad shall have no unpleasant odour either in dry state immediately after sampling from the packages or after wetting the sample with distilled water.

4.3 Performance requirements

The Maternity Pad shall comply with the performance requirements given in Table 1.

Table 1 — Performance requirements for Disposable Maternity Pads

| Characteristics | Requirement | | | Test method |
|--|----------------------------|-------------------|------------------|--------------------------------------|
| Absorbency capacity | No leakage | | | Annex A |
| Absorbency rate, s, max. | 6 | | | Annex A |
| Rate of absorption per gush, s, (max) | 1st Gush 15ml | 2nd Gush 15 ml | 3rd Gush 10ml | Annex A |
| | 5 | 15 | 15 | |
| Rewet under load,g (max) | 6 | | | Annex A |
| Moisture content of filler material, % m/m, max. | 8 | | | Annex B |
| Water soluble extract of filler material, (%), m/m, max. | 1.0 | | | Annex C |
| Fluorescence of filler material | None | | | Annex D |
| Size (mm) min. | Width 65 Length 240 | | | Measure with a calibrated steel rule |
| pH of aqueous extract” | 5.5 - 8 | | | KS ISO 3071, Method B1 |
| 1 In case a jelly forms, dilute with more distilled water before determining the pH. | | | | |

4.5 Microbiological requirements

4.5.1 When packed in sterile conditions as declared by the manufacturer (see 6.1 c)) maternity pad shall pass tests for sterility when tested in accordance with ISO 11737-1:2018.

4.5.2 When packed in non-sterile condition The Maternity Pad shall comply with the microbiological requirements given in Table 2.

Table 2 : Microbiological Requirements

| | Parameter | Limits | Method |
|---------------------|-------------------------------|-----------------------------------|-------------------|
| Hygiene monitoring | Total aerobic bacterial count | 100 cfu/g | ISO 8784-1:2014 |
| Potential pathogens | <i>Pseudomonas aeruginosa</i> | Not detectable per gram of sample | KS ISO 22717:2015 |
| | <i>Staphylococcus aureus</i> | Not detectable per gram of sample | KS ISO 22718:2015 |
| | <i>Candida albicans</i> | Not detectable per gram of sample | KS ISO 18416:2015 |
| | <i>E.coli</i> | Not detectable per gram of sample | KS ISO 21150:2015 |

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5 Packaging

5.1 Package

Disposable Maternity Pads shall be supplied in packages made of suitable materials, which are sealed so as to protect them from moisture, soiling and contamination during storage and transportation.

5.2 Bulk packaging

5.2.1 When supplied in bulk, the bulk package shall be made of materials, which are strong enough to hold the number of declared packages.

5.2.1.2 The Package shall protect the quality of the product during handling, transportation and storage.

5.2.1.3 The Bulk Package shall be properly sealed to prevent the packages from spilling.

5.2.1.4 Only packages with the same batch number and containing the same size shall be packed together in a bulk package.

6 Labelling

6.1 Packages

3. The following information shall appear legibly and indelibly on the outside of each package:

- a) the manufacturer's name and/or registered trade mark;
- b) the words "Maternity pads";
- c) words 'Sterile' if applicable (4.5.1);
- d) securing mechanism (as per 4.2.2.);
- e) number of maternity pads in a package;
- f) batch identification number;
- g) country or region of manufacture;
- h) disposal instructions;
- i) storage instructions
- j) date of manufacture.
- k) expiry date
- l) size of the maternity Pad

6.2 Bulk packages

The following information shall appear legibly and indelibly on the outside of each bulk package:

- a) the manufacturer's name and/or registered trade mark;
- b) the words "Maternity pads".
- c) Number of packages in a bulk package
- d) Manufacture date
- e) expiry date

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7 Sampling

7.1 Lot

In any consignment all packages of the maternity pads of the same size and type belonging to one batch of manufacture or supply shall constitute a lot.

7.2 Scale of sampling

7.2.1 Samples shall be tested from each lot ascertaining its conformity to the requirements of this specification.

7.2.2 The number of packages to be selected from a lot shall be in accordance with Table 3.

Table 3 –scale of sampling

| Number of packages in a lot | Number of packages to be selected |
|-----------------------------|-----------------------------------|
| Up to 250 | 6 |
| 251-500 | 8 |
| 501-1000 | 11 |
| 1001-2500 | 15 |
| 2501-5000 | 20 |
| 5001 and above | 30 |

7.2.3 The bulk packages and packages shall be selected at random.

7.3 Number of tests

7.3.1 Each package selected as per table 3 shall be inspected for packaging and marking requirements

7.3.3 Maternity pads selected as per table 3 shall be examined for requirements stipulated in clause 4

Annex A (normative)

Determination of rate of absorption, absorptive capacity and rewet under load

A.1 Principle

The intention of this method is to test the minimum fluid handling performance requirement of maternity pads.

This test simulates the introduction of vaginal discharge into a maternity pad under the following conditions;

- a) The maternity pad is tested under pressure to simulate real wearing conditions i.e. to mimic the pressure that the mother applies onto the maternity pad when wearing it.
- b) Specific loading volumes are used for each maternity pad

A.2 Apparatus and materials

A.2.1 A rigid cover plate with a weight as shown

Dimensions of the plate (200 mm \pm 2 mm) x (70 mm \pm 2 mm). Inner diameter of cylinder 40 mm \pm 2 mm, total Weight: 6300 g \pm 10 g representing a pressure of 4.41 kPa \pm 0.05 kPa (0.64 psi \pm 0.007 psi) for all sizes

A.2.2 Tray

A.2.3 Filter paper, having a diameter of 110 mm and conditioned together with the test samples.

A.2.4 Graduated cylinder (1 ml graduation)

A.2.5 Stopwatch

A.2.6 Ruler (at least 2 cm longer as absorbent core of the sample, 1mm graduation)

A.2.7 Pen

A.2.8 Weighing scale

A.2.9 0.9% Saline solution (22 – 24 °C): 9 g sodium chloride, and 1 g of blue dye added into 200 mL distilled water at ambient temperature after which the solution is made up to 1 L. The pH shall be between 6.2 – 6.7. When not within this range adjust by using 0.1 mol/L sodium hydroxide solution or acetic acid as required.

Depending on the size of the maternity pad, the following amount of saline solution shall be used

A.2.10: Volume of saline solution poured per maternity pad is 15ml 15ml and 10 ml at intervals of 2 min to make a total of 45 ml

A.3 Sample preparation and set-up

A.3.1 Condition the test samples in accordance with ISO 139 before taking the test specimens required for the tests

A.3.2 Take 5 test specimens randomly from the test samples

Determination of absorption capacity

A.3.3 Mark the loading point in the middle of the absorbent core. Note that the absorbent core does not cover the full length of the maternity pad but it is more concentrated in the front of the maternity pad. Therefore, the middle of the absorbent core will not be the same as the middle of the maternity pad : Measure the length and width of the absorbent core. Mark the midpoint, which will be the loading point.

A.3.4 Place core with top sheet facing upward on the tray

A.3.5 Place the rigid cover plate onto the maternity pad ensuring that the plate is centered towards the width of the maternity pad core and the cylinder opening is placed over marked loading point. The maternity pad should be flat

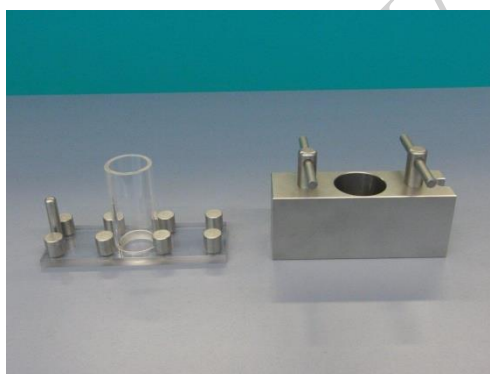


Fig A.1: apparatus and set up

A.3.6 Gently place weights on the plate (ideally use weight in a ring form to allow for equally applied pressure)

A.3.7 Fill the measuring cylinder with respective amount of saline solution

A.3.8 Set the stopwatch to 2 minutes

A.3.9 Gently pour the saline solution onto the maternity pad via cylinder and immediately start the stopwatch.

A.3.10 If the saline solution is absorbed after 2 minutes (i.e. no more liquid observed in the cylinder and no liquid on the tray outside the maternity pad), then proceed to the next step.

A.3.11 Leave the maternity pad undisturbed for 5 min

A.3.12 Repeat step A.3.7 to A.3.11 twice more on the same di (i.e. a total of 3 loads of saline solution with 2-minute intervals between successive loads) and observe for any liquid leaking out of the absorbent core.

Note your observations after a total of 3 loads of the specified amount of fluid and score the maternity pad based on the minimum volumes specified in A.2.10

A.3.13 Acceptance criteria

Pass: No fluid observed leaking out of the maternity pad.

Report the time it takes for the fluid to be completely absorbed.

Determination of rewet under load

A.3.14 Weigh a stack of 5 dry filter papers and record as weight "W1".

A.3.15 Lift the weight and cover plate and place the filter paper stack on the absorption point of the maternity pad.

A.3.16 Place the cover plate and weight on top of the stack of filter paper and leave undisturbed for 2 min.

A.3.17 After 2 min, remove the weight and cover plate and immediately determine and record the weight of the wet filter paper stack as "W2".

A.3.18 Repeat A.3.13 to A.3.16 on the remaining 4 test specimens and record each result separately.

A.3.19 Calculation of results

A.3.18.1 $\text{Rewet (g)} = W2 \text{ (Weight of stack of wet filter paper)} - W1 \text{ (Weight of stack of dry filter paper)}$.

Record the average rewet of the 5 samples tested and score the samples as follows:

Pass: Average rewet weight is less than or equal to the maximum limit specified in Table 1.

Fail: Average rewet weight exceeds the maximum limit specified in Table 1.

Annex B
(normative)

Determination of moisture content

1 Principle

A specimen of specified mass of filler material of maternity pad is dried in an oven at specified temperature and the moisture content is determined.

B.2 Apparatus

B.2.1 Balance, with an accuracy of 0.05 % of the weighed mass

B.2.2 Sample container

Waterproof when sealed, will be used for transfer of analyzed material and during weighing.

B.2.3 Oven, well ventilated with a temperature of 102 °C to 105 °C

B.3 Sample preparation

B.3.1 Take a sufficient number of dry sample containers, number them and take their masses after they are held open for a short period of time so that they will have the same air pressure as the surrounding atmosphere. Then leave them open until you take the test piece.

B.3.2 Take 5 random pieces from the absorbent filler material of maternity pad . The test pieces shall weigh 5 g.

B.3.3 If the surrounding atmosphere is hot and humid, prevent water condensation on the internal and external surfaces of the container.

B.3.4 Handle the test pieces gently to prevent dirt or changes in water content. Don't touch the test pieces with your bare hands. Put the test pieces in a container just after taking them and close the container immediately.

B.4 Procedure

B.4.1 Dry the test pieces in an oven with a temperature of 102 °C to 105 °C. Open the containers lid and dry the specimen inside the container. Open the container for a moment, to balance the air pressure inside the container with the surrounding pressure, weigh the container that holds the specimen again and calculate the weight of the specimen.

B.4.2 First cycle of drying will last at least 30 minutes. Return the container with the test pieces to the oven, for at least half the first cycles drying time. Take the container out and take the mass with the test pieces inside. Repeat the drying and weighing cycles. When the drying time on every cycle is at least half of the total previous drying cycle times. Continue the process until the difference between two consecutive masses does not exceed 0.1 % of the original mass of the specimen.

B.5 Calculations

Calculate the moisture content using the following formula and round the results up to the nearest 0.1 %.

$$V = 100 \frac{a - b}{b - c}$$

Where,

- a is weight of the container with the specimen before drying (in grams);
- b is weight of the container with the specimen after drying (in grams);
- c is weight of the container (in grams); and
- V is water content (in weight %).

Annex C
(normative)

Determination of water soluble colouring matter

C.1 Principle

Absorbent filler material is extracted in ethanol and then viewed for any colouring matter.

C.2 Apparatus

C.2.1 Weighing balance

C.2.2 Narrow percolator

C.2.3 Cylindrical glass tube

C.3 Procedure

Extract 10 g of absorbent filler material in 100 mL ethanol in a narrow percolator until 50 mL of the extract are obtained. Pour the liquid into a clean cylindrical glass tube at least 20 cm wide and view the layer on a white background.

C.4 Test report

Bluish or greenish shade indicates the presence of colouring substance

Annex D (normative)

Determination of fluorescence in Maternity Pads

D.1 Principle

A layer of absorbent filler material is examined under ultra violet radiation for the presence of fluorescent brightening agents

D.2 Apparatus

D.2.1. Ultra-violet source

D.2.2 Graduated Scale, in mm

D.3 Procedure

Examine a layer of absorbent filler material of approximately 5 mm thick under ultra violet radiation of wave length 365 nm.

D.4 Test report

Bright fluorescence indicates the presence of fluorescent brightening agents.

Annex E
(normative)

Determination of water-resistance of protective barrier (cone test method)

E.1 Apparatus

E.1.1 Funnel, metallic, glass or plastic of sufficient size for holding the test piece with water.

E.1.2 Glass, container for collecting water under the glass funnel.

E.1.3 Burette, for introducing water into the test piece

E.2 Test piece preparation

Cut a square test piece of approximately 6.5 mm in length (length is short proposals to be given) by members from the protective barrier and fold into a cone without creasing the folds (see Figure B.1).

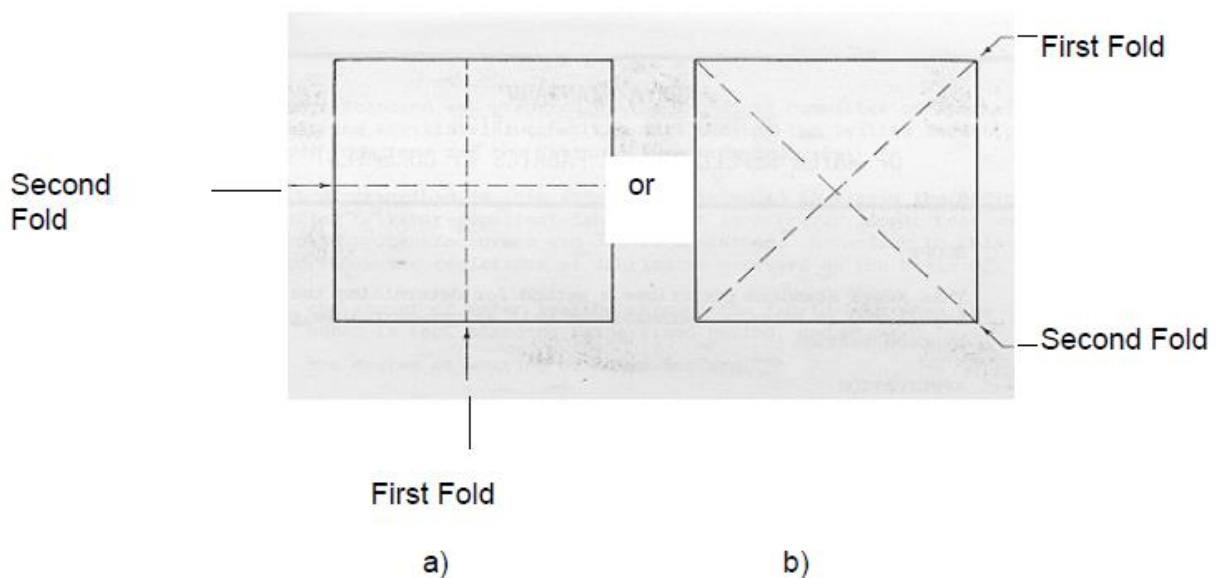


Figure B.1 — Folding of specimens

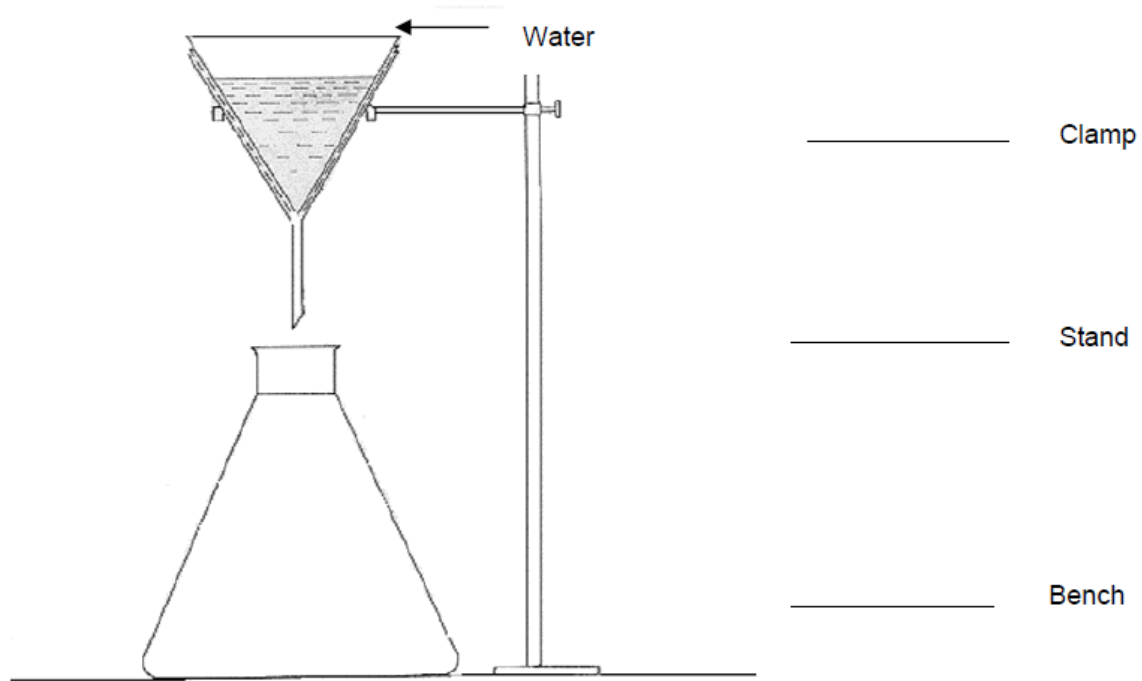


Figure B.2 — Test apparatus

E.3 Procedure

Assemble the apparatus as shown in Figure B.2. Pour slowly approximately 5 mL of distilled water into the cone assembly. Let it stand for 24 h

E.4 Test report

Observe for water in the glass container and wetness of the outer surface of the cone

Bibliography

1. SLS 111:1989, Specification for sanitary towels
2. KS EAS 96:2018 – Sanitary Towels – Specification
3. Chinese Standard: GB/T 28004-2001

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