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Zinc oxide surgical adhesive plaster — Specification

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Foreword

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

Zinc oxide surgical adhesive plaster (tape) — Specification

1 Scope

This Draft Uganda standard specifies the requirements, methods of test and sampling of zinc oxide surgical adhesive plaster.

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 ISO 10993, *Biological evaluation of medical devices*

ISO 1833*, Textiles — Quantitative chemical analysis — Part 5: Mixtures of viscose, cupro or modal and cotton fibres (method using sodium zincate)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

3.1
surgical adhesive plaster(surgical adhesive tape)
medical device in the form of pressure-sensitive adhesive tape used in medicine and first aid as a bandage to hold dressing onto a wound

3.2
zinc oxide surgical adhesive plaster
surgical adhesive plaster consisting of a strip of fabric material or plastic coated on one side with an adhesive material containing zinc oxide as a mild antiseptic

4 Requirements

4.1 General requirements

4.1.1 The zinc oxide surgical adhesive plaster shall be made of a fabric coated with zinc oxide adhesive mass and shall not set when unrolled.

4.1.2 The fabric shall be plain-woven consisting of cotton or rayon/viscose or combined cotton and rayon/viscose. The composition of rayon/viscose in the blends shall not exceed 25% when tested in accordance with ISO 1833-5.

4.1.3 The zinc oxide surgical adhesive plaster shall be free from any spinning, weaving, or processing defects.

4.1.4 The zinc oxide surgical adhesive plaster shall be non-toxic, hypoallergenic and non-irritating when tested in accordance with US ISO 10993.

4.1.5 The adhesive surface shall be free from any foreign matter.

4.1.6 Each roll selected for test under annex C and D shall be conditioned for minimum period of 24hours at 27°C ± 2°C and 65% ± 5% relative humidity prior to testing and testing shall be conducted under the same atmosphere. Where the testing cannot be carried out in the same atmosphere, the testing shall be commenced within 2minutes of withdrawal of the sample from the conditioning atmosphere.

4.2 Specific requirements

The zinc oxide surgical adhesive plaster shall also conform to the requirements specified in Table 1 when tested in accordance with the test methods prescribed therein.

Table 1 — Specific requirements for zinc oxide surgical adhesive plaster

Characteristic	Requirement	Test method
Zinc oxide content	≥ 10%	Annex A
Weight of adhesive mass, g/m^2	≥ 115	Annex B
Tensile strength, kgf/cm	≥ 8	Annex C
Adhesion property	Adhesive strength, kgf/cm ≥7	Annex D
	Adhesion to metal ,gf/cm ≥ 200	Annex E

5 sterility

The sterile zinc oxide surgical adhesive plaster shall be when tested in accordance with annex F

6 Packaging

6.1 The zinc oxide surgical adhesive plaster shall be uniformly wound on suitable spools or cores

6.2 The wound zinc oxide surgical adhesive plaster shall be packaged in suitable packaging materials, which shall protect the product from contamination and damage during transportation, handling and storage.

7 Labelling

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

a) Name of plaster as " "Zinc oxide surgical adhesive plaster" manufacturer's name;

b) dimensions of the plaster;

   1. width in Centimetres

   2. length in metres / yards;

c) batch (lot) number;

d) month and year of manufacture and expiry,

e) direction for storage and use;

f) sterile or non-sterile

g) caution : discard after use, for single use, don’t expose to direct sunlight

h) and other information required by the regulatory body.

8 Sampling

Sampling shall be done in accordance with annex G.

Annex A
(normative)

Determination of zinc oxide content

A.1 Reagents

A.1.1 Nitric acid

A.1.2 Dilute ammonium hydroxide (6N)

A.1.3 pH 10 buffer — Dissolve 68g of ammonium chloride in 200ml of water, add 570ml of concentrated ammonia and dilute to one litre.

A.1.4 Eriochrome black T indicator — Dissolve 0.2g of eriochrome black T and add 2g of hydroxylamine hydrochloride in 50 ml of methanol.

A.1.5 Standard EDTA solution 0.01M

A.2 Procedure

A.2.1 Cut from the sample under test 1 g of specimen weighing taking as much care as possible to cut parallel to the warp and weft threads.

A.2.2 Heat it in 10ml of nitric acid in a round bottomed flask until the plaster disintegrates and boil it for 10 - 15minutes on a low flame.

A.2.3 Cool and dilute with 10 to 15 ml of water and one or two drops of methyl red indicator. Neutralise using dilute ammonia solution.

A.2.4 Add 20ml of pH 10 buffer and 2 drops of eriochrome black T indicator to obtain a clear visible red colouration in the solution.

A.2.5 Titrate it with EDTA solution until the colour changes from red to blue.

A.3 Calculation

Zinc oxide (as ZnO) percent by weight = $8.138 \times \frac{V \times M}{W}$

Where

V Volume in ml of EDTA solution used for titration

W Weight in grams of adhesive mass

M molarity of EDTA solution used for titration

Annex B
normative

Determination of weight of adhesive mass

B.1 Test specimen

Cut about 1g of plaster from the sample and weigh accurately. Take care to cut parallel to the edges of the plaster

B.2 procedure

B.2.1 Measure the area of the specimen accurately and extract with chloroform in a soxhlet extractor until the adhesive mas completely disintegrates. Take out the fabric, dry to remove residual chloroform and immerse in dilute acetic acid for 3hours.

B.2.2 Remove the sample in a suitable vessel and wash 12 times with boiling water using 1000 ml for each washing. Pass the wash waters through 150-micron sieve to collect any loose fibre or yarn. Dry the residue to constant weight at 100°C ± 2°C and correct the weight for moisture regain.

B.3 Calculation

Calculate the weight of the adhesive mass in grams per square metre

Weight of adhesive mass = $\frac{W - w}{A}$ g/m²

Where

W weight in grams of the sample taken,

w weight in grams of residual fabric corrected for moisture regain

A Area in square metres of sample taken

Annex C
(normative)

Determination of tensile strength

C.1 Apparatus

Tensile testing machine

C.2 Procedure

C.2.1 Take test sample of sufficient length to accommodate in the jaw separation of 12 cm and measure its width.

C.2.2 Clamp the strip of the plaster squarely in the jaw of the tensile testing machine. Note the load at break.

C.2.3 Reject the pieces breaking within 5mm of the edge of the jaws. Repeat the test for two-test specimen taken from the sample roll.

C.2.3 Determine the mean of the three determinations as the breaking strength in kilograms per centimetre width.

Annex D
(normative)

Determination of adhesive strength

D.1 Apparatus

D.1.1 Tensile testing machine

D.1.2 Plastic or glass plates

D.1.3 Roller- Rubber roller which applies 850g pressure to the specimen. It shall be constructed that the weight of the handle is not added to the weight of the roller during use.

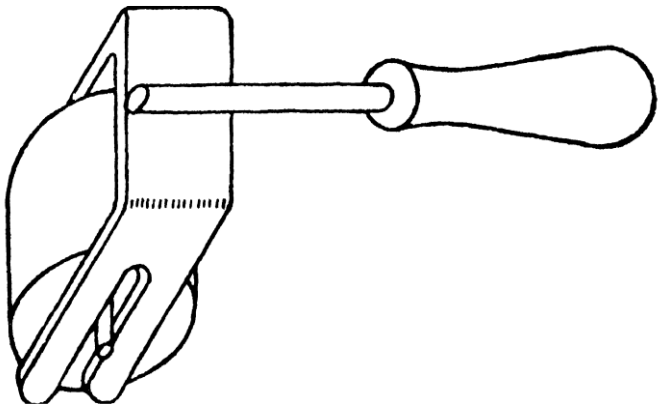

Figure 1 — Roller

D.2 Procedure

D.2.1 Clean the surface of the glass or plastic plate thoroughly with toluene. When all the solvent has evaporated ,Wipe the surface with a piece of clean dry tissue paper or cotton wool.

D.2.2 Apply 2.5 cm by 5cm of one end of the test specimen to the plastic /glass plate without stretching, keeping adhesive side down to the centre of the plate and leaving the reminder of the test specimen extending beyond the plate. Precautions should be taken not to entrap any air bubble between the tape.

D.2.3 Place the roller centrally across the test specimen and draw the roller once in each direction at constant speed of about 30cm/min.

D.2.4 Adjust the temperature of the plastic or glass plate surface and the tape to 37°C and conduct the test within two minutes.

D.2.5 Clamp the specimen in the jaws of the tensile strength machine. The jaws are about 10cm apart at the beginning of the test. Start the machine. Read the load at break or maximum load in case of the peel off on the sealer. Discard the specimen breaking near the edge of the jaws. Repeat the test for four-test specimen taken from the sample roll.

D.3 Calculation

Calculate the load require6d to cause break or pull off of the tape in terms of 9cm of width. The mean of the five values obtained shall be reported as adhesive strength.

Annex E
(normative)

Determination of adhesion to metal

E.1 Apparatus

E.1.1 Tensile testing machine

E.1.2 Stainless steel plates —Rectangular 10 x 30 cm polished stainless steel plates. The stainless steel shall be have a standard abrasive satin finish(180grit) with the direction of gritting lying parallel to the longer side of the plate. It shall be marked boldly at intervals of 2cm along both longitudinal edges.

E.1.3 Roller- A steel roller of 80 ± 2mm diameter and 45 ± 1mm in width covered with rubber approximately 6mm thick having a hardness of 80 ± 5 IRHD. The weight of the roller which applies pressure to the test sample shall be 205 ± 0.05kg.It shall be so constructed that the weight of the handle is not added to the weight of the roller during use.(see figure 1)

E.2 Procedure

E.2.1 Clean thoroughly the surface of the stainless steel plate with redistilled toluene using a fresh piece of untreated paper tissue or cotton wool for each cleaning. When all the solvent has evaporated, wipe the surface with apiece of clean dry tissue paper or cotton wool taking precautions not to touch the steel plate with fingers

E.2.2 Apply atleast 25 cm of test sample without stretching, keeping adhesive side down. To the centre of surface of the steel plate and parallel to the longer side, leaving the reminder of the test sample extending beyond the steel plate sufficient to be accommodated in the testing equipment. Precaution shall be taken that no air bubbles are trapped between the tape and the plate.

Note – In the case of the tapes less than 3cm width, cut the other strips from the sample roll and apply them parallel and adjacent to the test sample to provide a total width of 3cm for rolling purposes.

E.2.3 Place the roller centrally across the test sample at one end of the plate and pass the roller once in each direction at constant speed of approximately 30cm /min, ensuring that no additional pressure of the weight of the roller s applied during the process.

E.2.4 Allow the steel plate with the test sample to remain undisturbed for 10 ± 0.5 minutes at the temperature of 27°C ± 2°C and 65% ± 5% relative humidity.

E.2.5 Fold the free end of the test sample at an angle of 180° and peel off 3cm from the steel plate leaving atleast 22 cm in contact with the steel plate.

E.2.6 Clamp this exposed end of the plate in the lower jaw (if using a vertical pendulum or spring balance machine) or attach the whole plate to the moving carriage (if the testing machine is of horizontal type).attach the free end of the tape to the head of the tension measuring device and disengage the pawls if any.

E.2.7 Start the tensile machine and take readings at 2cm intervals when the tape is pulled from the steel plate, disregarding the pulling of the first 5 cm and the last 3cm.The mean of 5 readings shall give the load required to cause the separation of tape from the steel plate. If the specimen breaks during the test, repeat the test on another specimen cut from the same roll.

E3 Calculation

Calculate the load required to cause the separation of the tape from the steel plate (or from a piece of tape itself as the case may be) in terms of grams per centimetre of width. The mean of five values obtained shall be reported as adhesion strength.

Annex F
(normative)

Sterility test

F.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.

F.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 (1g/L of resazurin sodium), freshly prepared	1.0 mL
Water R	1000 mL
pH after sterilisation	7.1 ± 0.2

F.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.

F.2.2 Dissolve the sodium thioglycollate or thioglycollic acid in the solution and, if necessary, add 1 M sodium hydroxide so that, after sterilisation, 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.

F.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. Sterilise using a validated process. If the medium is stored, store at a temperature between 2 °C and 25 °C in a sterile, airtight container.

F.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 30-35 °C.

F.2.5 For products containing a mercurial preservative that cannot be tested by the membrane-filtration method, fluid thioglycollate medium incubated at 20-25 °C may be used instead of soya-bean casein digest medium provided that it has been validated as described in growth promotion test.

F.3 Alternative thioglycollate medium

Where prescribed or justified and authorised, 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, sterilise as directed above. The pH after sterilisation is 7.1 ± 0.2. Heat in a water-bath prior to use and incubate at 30-35 °C under anaerobic conditions.

F.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 g	2.5 g/2.3
Water R	1000 mL
pH after sterilization	7.3 ± 0.2

F.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 sterilisation the solution will have a pH of 7.3 ± 0.2.

F.4.2 Filter, if necessary, to clarify, distribute into suitable vessels and sterilise 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 20-25 °C.

The media used comply with the following tests, carried out before or in parallel with the test on the product to be examined.

F.5 Sterility

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

Annex G
(normative)

Sampling

G.1 The number of sample to be selected from each lot shall depend upon the size of the lot and shall be in accordance with table G1

Table G1 — sample size and criteria for conformity

Lot size	Sample size	Acceptance number
Upto 300	13	1
300 to 500	13	1
5001 to 1000	20	2
1001 to 3000	32	3
3001 to 10000	32	3
10001 to 35000	50	5
35001 and above	80	7

G.2 The lot shall be considered as conforming to the requirements if the number of defectives found in the sample is less than or equal to the corresponding acceptance number of defectives as given in table G1

Bibliography

[1] IS 4717 (1980): Zinc Oxide Self-adhesive Plaster

[2] USP42-NF37 - 4181

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