



DRAFT TANZANIA STANDARD

Textiles — Zinc oxide adhesive plaster — Specification

Draft for Stakeholders' Comments Only

TANZANIA BUREAU OF STANDARDS

Foreword

This Draft Tanzania Standard is being developed by the Hospital Textiles Technical Committee under the supervision of Textile and Leather Divisional Standards Committee and it is in accordance with the procedures of the Bureau.

In the preparation of this standard assistance has been obtained from the following standard:

IS 4717: 2020 Medical Textiles — Zinc Oxide Adhesive Plaster — Specification

In reporting the result of a test or analysis made in accordance with this standard if the final value, calculated or observed is to be rounded off, it shall be done in accordance with TZS 4 *Rounding off numerical values*.

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1. Scope

This Draft Tanzania Standard specifies test methods, sampling and requirements pertaining to material, construction and performance of zinc oxide adhesive plaster.

2. Normative reference

For the purpose of this Draft Tanzania Standard, the following references shall apply. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies:

TZS 3, *Atmospheric conditions for testing.*

TZS 4, *Rounding off numerical values.*

TZS 20/ISO 7211-2:1984, *Textiles – Woven fabrics – Determination of the number of threads per unit length*

TZS 21, *Textiles – Woven or knitted fabrics – Determination of mass per unit length and per unit area.*

TZS 326, *Textiles – Ternary fibre mixtures – Quantitative analysis*

TDC 9 (1666) CD2, *Surgical dressings — Methods of test.*

3. Terms and definitions

For the purpose of this Draft Tanzania Standard, the following term shall apply:

3.1 adhesive plaster

medical device in the form of a pressure sensitive strip used in medicine as a bandage to hold dressing on to the wound.

3.2 zinc oxide adhesive plaster

adhesive plaster consisting of a strip of fabric material coated on one side with zinc oxide as a mild antiseptic.

4. Material

4.1 Cloth

The cloth shall be plain woven made of either cotton, rayon, a blend of cotton and rayon or white/dyed cotton and polyester fabric evenly coated on one side with a pressure sensitive adhesive mixture.

- 4.1.1 The cloth shall be reasonably free from spinning, weaving and processing defects. It shall be finished to a good white colour or dyed to flesh colour with a suitable non-toxic dye. The basic cloth shall conform to the requirements given in Table 1.

Table 1: Manufacturing requirements of basic cloth

S/N	Characteristics	Requirements	Test Method
1.	Weight, g/m ² , min	100	TZS 21
2.	Ends per dm, min	230	TZS 20
3.	Picks per dm, min	205	
4.	Fibre Identification	Cotton, rayon or a blend of cotton and rayon or a blend of cotton and polyester	TZS 326

4.2 Adhesive material

Adhesive mass shall contain zinc oxide of pharmacopeia grade.

5. Dimensions and weight

5.1 The dimensions of the plaster shall be agreed to between the buyer and the seller. Recommended sizes are as follows:

Width (mm)	Length (m)
12.5	1, 5, 8, 9
25	1, 5, 8, 9, 10
50	5, 8, 9, 10
75	5, 8, 9, 10
100	5, 8, 9, 10
150	8, 9
180	8, 9

5.1.1 The length shall be not less than 98 percent of the declared length and width shall not be less than 95 percent of the declared width.

5.2 Weight of adhesive mass

Weight of adhesive mass shall be not less than 45 g/m² when determined according to TDC 9 (1666) CD2.

5.3 Zinc Oxide Content

Zinc oxide content of the adhesive mass shall be not less than 10 percent when tested according to TDC 9 (1666) CD2.

6. Workmanship and finish

- 6.1** The zinc oxide adhesive plaster shall be clean and free from substances liable to cause tendering during storage.
- 6.2** The manufacture and preparation of the zinc oxide adhesive plaster shall be conducted under proper hygienic conditions.

7. Performance requirements

7.1 Tensile Strength of Plaster

The plaster shall have a tensile strength of not less than 20.41 kgf/2.54 cm width along the warp when determined by the method given in *Annex A*.

7.2 Adhesion Property

7.2.1 Adhesion to Metal

The adhesion strength of plaster to metal shall not be less than 500 gf/2.54 cm width when tested according to the method given in *Annex B*.

7.2.2 Adhesive Strength

The adhesive strength shall not be less than 18.0 kgf/2.54 cm width when tested according to the method given in *Annex C*.

8. Conditioning

- 8.1** Each roll selected for testing shall be conditioned for a minimum period of 24 h at 27 ± 2 °C and 65 ± 5 percent relative humidity (see TDS 3) prior to testing; and the testing shall be conducted in the same atmosphere. Where the tests cannot be carried out in the same atmosphere, the testing shall be commenced within 2 min of withdrawal of the specimen from the conditioning atmosphere.

- 8.2** Three outer layers of each roll shall be discarded before taking specimen for test.

- 8.3** All specimens shall be removed from the roll at an approximate speed of 30 cm/min.

- 8.4** The adhesive surface shall not be permitted to come in contact with the fingers, to be contaminated with dust, or to come in contact with any other foreign matter.

9. Packaging and marking

9.1 Packaging

The adhesive plaster shall be uniformly and evenly wound on suitable spools. These spools shall be packed in suitable containers so that it is adequately protected from dust, damage in transportation and from deterioration due to climatic conditions. Details of the packing shall be as agreed to between the buyer and the seller. Packaging of the product shall be such as to maintain the integrity of the product throughout its shelf life.

9.2 Marking

Each spool and container or both of the adhesive plaster shall be legibly marked with the following information:

- a) Name and type of the plaster;
- b) Product composition,
- c) Manufacturer's name and site;
- d) Dimensions of the plaster;
- e) Manufacturing and expiry date;
- f) Batch and lot number;
- g) Directions for storage and use.

10. Sampling and criteria for conformity

10.1 Lot

All the zinc oxide adhesive plasters of the same material and produced under similar conditions of manufacture shall constitute a lot.

10.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

10.1.2 The number of zinc oxide adhesive plaster to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, 3 and 5 of Table 2.

10.1.3 These plasters shall be selected at random from the lot.

10.2 Number of tests and criteria for conformity

10.2.1 All plasters selected as per column 3 of Table 2 shall be examined for workmanship and finish (see 6.1).

10.2.1.1 Any plaster failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 4 of Table 2. Otherwise, the lot shall be rejected.

10.2.2 Out of the sample already found satisfactory according to **10.2.1.1**, a sub-sample as per column 5 of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.

10.2.3 The lot shall be considered as conforming to the requirements of the specification, if the total number of defective plasters found in the sample (see **10.2.2**) is less than or equal to the acceptance number as given in column 6 of Table 2.

Table 2: Number of zinc oxide adhesive plaster to be selected

S/N (1)	Lot size (2)	Non-destructive testing		Destructive testing	
		Number of plasters to be selected (3)	Acceptance number (4)	Number of plasters to be selected (5)	Acceptance number (6)
1.	Up to 280	13 ¹⁾	1	8	0
2.	281 to 500	20	2	8	0
3.	501 to 1200	32	3	13	0
4.	1201 to 3200	50	5	13	0
5.	3201 to 10000	80	7	20	1
¹⁾ or lot size when less than 13.					

Annex A

METHOD FOR DETERMINATION OF TENSILE STRENGTH

A-1 OUTLINE OF THE METHOD

Breaking strength is determined by finding the load at which the tape breaks, when tested on a tensile strength testing machine.

A-2 NUMBER OF TESTS

Carry out the determinations on three test specimens taken from the same roll.

A-3 APPARATUS

A-3.1 Tensile Testing Machine

A suitable tensile testing machine.

A-4 CONDITIONING

Condition the rolls as specified in 8.1 and take all the precautions as specified in 8.2 to 8.4 for taking the test specimen.

A-5 PROCEDURE

Take test specimen of sufficient length to accommodate in a jaw separation of 12 cm and measure its width. Clamp the strip of plaster squarely in the jaws of the tensile testing machine. Note the load at break. Reject the pieces breaking within 5 mm of the edge of the jaws. Repeat the test.

A-6 CALCULATION AND REPORTING

The mean of the three determinations shall be taken as the breaking strength in kgf per 2.54 cm width.

Annex B

METHOD FOR DETERMINATION OF ADHESION TO METAL

B-1 OUTLINE OF THE METHOD

Adhesion to metal is determined by finding the force required to peel a strip of tape from a standard test panel at a specified angle and speed.

B-2 NUMBER OF TESTS

Carry out the determination of 5 test specimens taken from the same roll.

B-3 APPARATUS

B-3.1 Tensile Testing Machine

A suitable tensile testing machine.

B-3.2 Stainless Steel Plates

Rectangular, 10 × 30 cm polished stainless steel plates.

B-3.2.1 The stainless steel plates shall have a standard abrasive satin finish (180 grit) with the direction of gritting lying parallel to the longer side of the plate.

B-3.2.2 The stainless steel plates shall also be marked boldly or etched at intervals of 2 cm along both the longitudinal edges.

B-3.3 Roller — A steel roller of minimum 80 mm diameter and 45 ± 1 mm in width covered with rubber approximately 6 mm thick having a hardness of 80 ± 5 IRHD. The weight of the roller which applies pressure to the specimen shall be 2.05 ± 0.05 kg. It shall be so constructed that the weight of the handle is not added to the weight of the roller during use (see Fig. 1).

B-4 PREPARATION OF TEST SPECIMEN

Condition the rolls as specified in 8.1 and take all precautions as specified in 8.2 to 8.4 for taking the test specimen. The test specimen shall be 2.54 cm in width and not less than 50 cm in length. If the width of the tape is greater than 2.54 cm, then reduce it to 2.54 cm by cutting it with a sharp blade.

B-5 PROCEDURE

B-5.1 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 a piece of clean dry tissue paper or cotton wool, taking precautions not to touch the steel plate with the fingers. Apply at least 25 cm of test specimen without stretching, keeping adhesive side down, to the centre of surface of the steel plate and parallel to the longer side, leaving the remainder of the test specimen extending beyond the steel plate sufficient to be accommodated in the testing equipment. Precaution shall be taken so that no air bubbles are trapped between the tape and the plate.

NOTE: In the case of tapes less than 2.54 cm width, cut other strips from the same sample roll and apply them parallel and adjacent to the test specimen to provide a total width of 2.54 cm for rolling purposes only.

B-5.2 Place the roller centrally across the test specimen at one end of the plate and pass the roller once in each direction at a constant speed of approximately 30 cm/min, ensuring that no additional pressure of the weight of the roller is applied during the process. Allow the steel plate with the test specimen to remain undisturbed for 10 ± 0.5 min at a temperature of 27 ± 2 °C and 65 ± 5 percent relative humidity.

B-5.3 Fold the free end of the test specimen at an angle of 180° and peel off 3 cm from the steel plate at the separation speed of 305 ± 13 mm per minute leaving at least 22 cm in contact with the steel plate. Clamp this exposed end of the plate in the lower jaw (if using a vertical pendulum or spring balance type machine), or attach the whole plate to the moving carriage (if the testing machine is of the horizontal type). Attach the free end of the tape to the head of the tension measuring device and disengage the pawls, if any. Start the tensile testing machine and take readings at 2 cm intervals when the tape is pulled from the steel plate, disregarding the pulling of the first 5 cm and last 3 cm. The mean of 5 readings shall give the load required to cause the separation of the tape from the steel plate. If the specimen breaks during the test, repeat the test on another specimen cut from the same roll.

B-6 CALCULATION AND REPORTING

Calculate the load required to cause the separation of the tape from the steel plate (or from a piece of the tape itself as the case may be), in terms of grams per 2.54 cm of width. The mean of 5 values obtained shall be reported as adhesion strength.

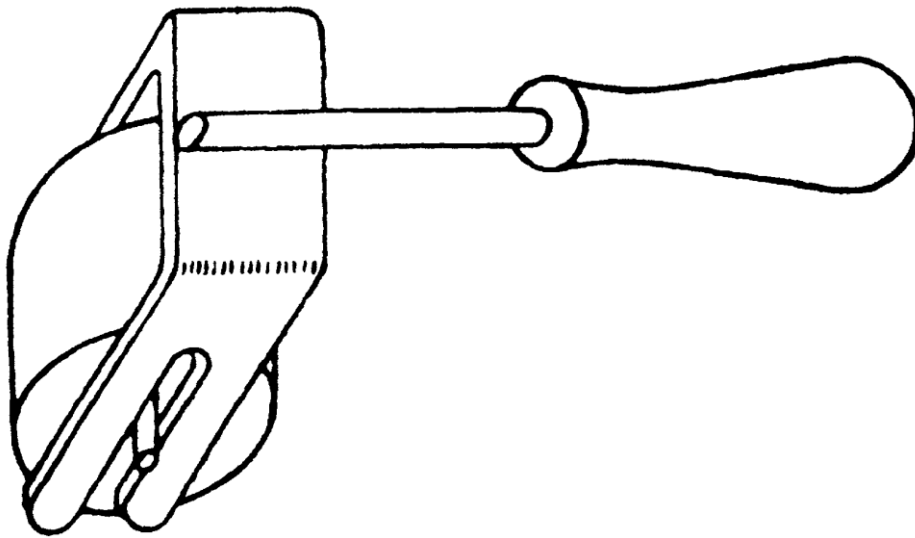


Figure 1: Roller

Annex C

METHOD FOR DETERMINATION OF ADHESIVE STRENGTH

C-1 OUTLINE OF THE METHOD

Adhesive strength is determined by finding the force required to peel or break a strip of tape from a standard test panel at a specified angle and speed.

C-2 NUMBER OF TESTS

Carry out the determination of 5 test specimens taken from the sample roll.

C-3 APPARATUS

C-3.1 Tensile Testing Machine is the same as the one described in **B-3.1**.

C-3.2 Plastic or Glass Plates

C-3.3 Roller

A rubber roller that applies 850 g pressure to the specimen. It shall be so constructed that the weight of the handle is not added to the weight of the roller during use (see Fig. 1).

C-4 PREPARATION OF TEST SPECIMEN

Condition the rolls as specified in **8.1** and Take all precautions as specified in **8.2** to **8.4** for taking the test sample. The test specimen shall be 2.5 cm in width and 15 cm in length. If the width of the tape is greater than 2.5 cm, reduce it to 2.5 cm by cutting it with a sharp blade.

C-5 PROCEDURE

C-5.1 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.

C-5.2 Apply 2.5 cm by 5 cm of one end of the test specimen to the plastic/glass plate without stretching, keeping the adhesive side down, to the centre of the plate, and leaving the remainder of the test specimen extending beyond the plate. Precautions should be taken not to entrap any air bubbles between the tape.

C-5.3 Place the roller centrally across the test specimen and draw the roller once in each direction at a constant speed of about 30 cm/min.

C-5.4 Adjust the temperature of the plastic or glass plate surface and the tape to 37 °C and conduct the test within two minutes.

C-5.5 Clamp the specimen in the jaws of the tensile strength machine. The jaws are about 10 cm apart at the beginning of the test. Start the machine. Read the load at break or maximum load in case of peel off on the sealer. Discard the specimen breaking near the edge of the jaws and repeat the test.

C-6 CALCULATION AND REPORTING

Calculate the breaking load required. The mean of the five values obtained shall be reported as adhesive strength.