KENYA STANDARD

DKS 2943S/2022 ICS
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First Edition

Dentistry — Tooth Powder — Specification

TECHNICAL COMMITTEE REPRESENTATION

The following organizations were represented on the Technical Committee:

Kenya Bureau of Standards — Secretariat

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DKS 2943:2022
ICS ……..

First Edition

Dentistry —Tooth Powder — Specification

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Foreword

This Kenya Publicly Available Specification was prepared by the Hospital devices, tools and equipment Technical Committee under the guidance of the Standards Projects Committee, and it is in accordance with the procedures of the Kenya Bureau of Standards

A good tooth powder when used in normal manner assists in the removal of the usual daily accumulation of debris and deposits.

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

IS 5383 — *Indian Standard — Specification for Tooth Powder*

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

Dentistry —Tooth Powder — Specification

1 Scope

This Draft Kenya Standard prescribes requirements and the methods of sampling and test for tooth powders.

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.

KS 87: Specification for hydrochloric acid
ISO 3696:1987: Water for analytical laboratory use - Specification and test methods
ISO 11969:1996 - Water quality — Determination of arsenic
KS 1668: 2001: Kenya Standard — Methods of sampling cosmetics
KS 2937: 2021: Cosmetics — General requirements for Safety of Cosmetic Products — Specification
KS 1474- 7: 2010, Classification of cosmetic raw materials and adjuncts

3 Terms and definitions

For the purpose of this document, the terms and definitions given in KS ISO 4007 and the following apply.

3.1 Tooth powder
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4 Requirements

4.1 Description

Tooth powder shall be smooth, uniform, or sluggishly flowing fine powder dentifrice formulation, free from any foreign matter. It shall be free from hard abrasive material which could damage the dentine enamel.

4.1.1 The tooth powders shall be classified into the following types:

- Type 1 – Non-fluoridated and
- Type 2 – Fluoridated.

4.1.2 *Description* – Tooth powder shall be smooth, uniform, free-flowing fine powder, free from foreign matter. It shall be free from hard abrasive material.

4.1.3 Ingredients

The principal ingredient(s) shall be one or more of the conventionally used materials in the manufacture of tooth powders (see Annex A) and shall conform to the requirements of respective Kenya Standards.
Tooth powder shall not contain readily fermentable carbohydrates, such as mono- or disaccharides, e.g. glucose or sucrose.

4.1.4 Dyes, colours and pigment
These ingredients, if used, shall conform to the requirements of EAS 377-3:2013.

4.1.5 Additional ingredients, such as flavours and sweating agents may be added to improve the appearance, taste and flavour of the powder. These ingredients shall conform to the provision of KS EAS 377-2:2013.

4.1.7 The tooth powder shall also meet the requirements given in Table 1 when tested in accordance with the methods given in Annex A.

Packing and Marking

4.1 The material shall be packed in suitable well-closed containers.

	Table 1. Requirements for Tooth Powder			
SN	**Characters**	**Type 1**	**Type 2**	**Method of Test (Ref to Cl No. of Annex A)**
i)	Fineness: a) Particles retained on 150-micron, % by Wt., *Max* b) Particles retained on 75-micron, % by Wt., *Max*	 0.1 2	 0.1 5	A-2
ii)	Moisture and volatile matter, % by Wt., *Max*	5	5	A-3
iii)	pH of per cent aqueous suspension	8-10.5	6-9	A-4
iv)	Foaming powder, mL, *Min*	50	-	A-5
v)	Lead (as Pb), ppm, *Max.*	20	20	A-6
vi)	Arsenic (as AS_2O_3), ppm, *Max.*	2	2	A-7
vii)	Abrasion	To pass test	To pass test	A-8

4.2 The container shall be legibly and indelibly marked with the following information:

a) Name and physical address of the manufacturer;
b) Recognized Trade name, if any;
c) The name and type of the material;
d) Net weight;
e) Batch number, in code or otherwise, to enable the lot of manufacture to be traced from records.
f) Number of pieces in the secondary package;

Annex A
(Informative)
Ingredients

a) Calcium carbonate, precipitated;
b) Magnesium carbonate;
c) Dicalcium phosphate;
d) Tricalcium phosphate;
e) Insoluble sodium metaphosphate;
f) Hydrated alumina;
g) Amorphous precipitated silica, and
h) Charcoal.

Annex B
(normative)
Methods of Test for Tooth Powder

B-1 Quality of the Reagents

B-1.1 Unless specified otherwise, pure chemicals and distilled water meeting the requirements of KS EAS 123 shall be employed in test.

B- 2 Determination of fineness

B-2.1 Procedure – Place about 50 g of the material, accurately weighed, in a 75-micron sieve and shake till no more material passes through the sieve. Transfer the residue with the help of a brush to a tared sheet of glazed paper and weigh. Calculate the weight of the material retained on the sieve and express it as percentage by weight of the material taken for the test.

B-2.2 Place the residue obtained in A-2.1 in a 150-micron Sieve and proceed as A-2.1. Transfer the residue left on the sieve to a glazed paper and weigh. Calculate the weight of the residue as percentage by weight of the material taken for the test in A-2.1.

B-3 Determination of moisture and volatile matter

B-3.1 Procedure – In previously dried and weighed petri-dish, take about 2 g of the material, accurately weighed. Dry it at 105 ºC ± 2 ºC in an oven for 4 hours or till constant weight. Cool in a desiccator and weigh.

B-3.2 Calculation

Moisture and volatile matter, % by Wt., = $\frac{100\,(W-w)}{W}$

Where,

W = weight in g of the material taken for test, and

w = weight in g of the material after drying.

B-4 Determination of pH

B-4.1 Procedure – Take 5 g of the material in a 100-mL beaker. Add 45 mL of freshly boiled and cooled water and mix well. Determine the pH with a pH-meter using glass and Calomel electrodes.

B-5 Determination of foaming power

B-5.1 General – Strict attention shall be paid to all details of the procedure in order to ensure concordant results. Particular care shall be taken to shake the cylinder exactly as described.

B-5.2 Overview of the method

A suspension of the material in water is taken in a graduated cylinder and given 12 shakes under prescribed conditions. The volume of the foam formed is observed after keeping the cylinder for 5 minutes.

B-5.3 Apparatus

B-5.3.1 *Graduated cylinder* – Glass stoppered, with graduations from 0 to 250 mL, with 2 mL divisions, overall height about 35 cm and the height of the graduated portion about 20 cm.

B-5.3.2 *Graduated cylinder* - with graduation from 0 to 100 mL, with 1 mL divisions.

B-5.3.3 *Thermometer* – of range 0 ºC to 110 ºC.

B-5.3.4 Procedure

B-5.3.4.1 Weigh about 5 g of the tooth powder accurately in a 100-mL glass beaker, add 15 mL water, cover the beaker with a watch-glass and allow to stand for 30 minutes. This operation is carried out to make the tooth powder easily dispersible.

Note – Ensure that the detergent is completely dissolved, warming the aqueous suspension, if necessary.

B-5.3.4.2 Stir the contents of the beaker with a glass rod and transfer the slurry to the graduated cylinder, ensuring that no foam (more than 2 mL) is produced and no lumpy paste goes into the cylinder. Repeat the transfer of the residue left in the beaker with further portions of 5 to 6 mL of water ensuring that all the matter in the beaker is transferred to the cylinder.

B-5.3.4.3 Adjust the contents in the cylinder to 50 mL by adding sufficient water and bring the contents of the cylinder to 30 ºC. Stir the contents of the cylinder with a glass rod or thermometer to ensure a uniform suspension.

B-5.3.4.4 As soon as the temperature of the contents of the cylinder reaches 30 ºC, stopper the cylinder and give it 12 complete shakes, each shake comprising movements shown in Figure 1 in a vertical plane, upside down and vice versa. After 12 shakes have been given, allow the cylinder to stand still for 5 minutes and read the volume of:

a) Foam plus water (V1 mL), and
b) Water only (V2 mL) as shown in Figure 2.

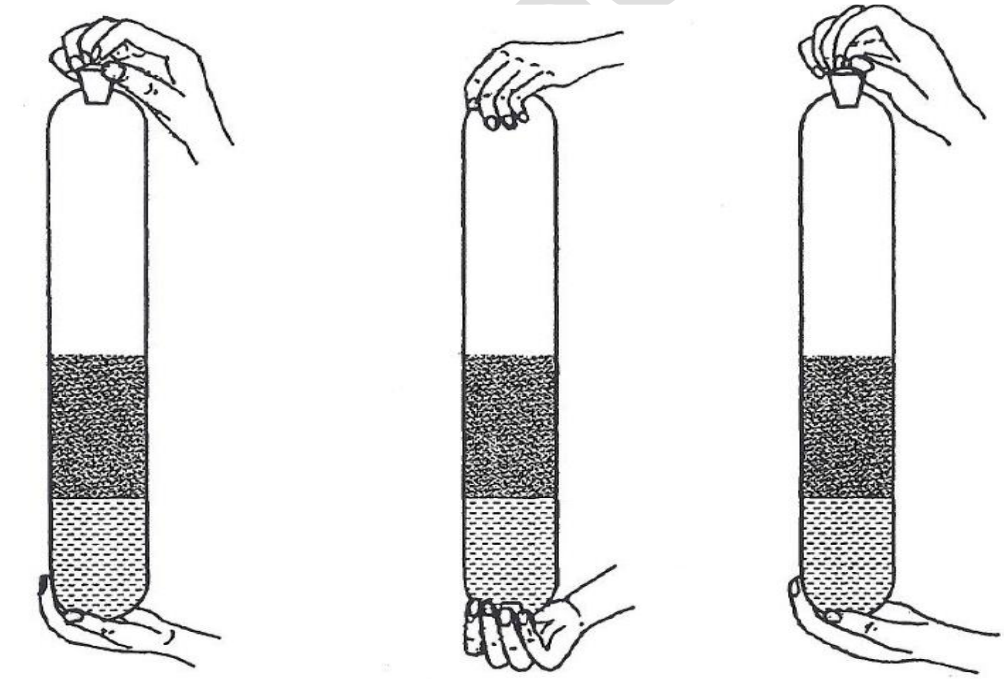

FIG. 1 ONE COMPLETE SHAKE OF CYLINDER

A-5.3.4.5 Calculation

Foaming power, mL = $V_1 - V_2$

Where

V_1 = volume in mL of foam plus water, and

V_2 = volume in mL of water only.

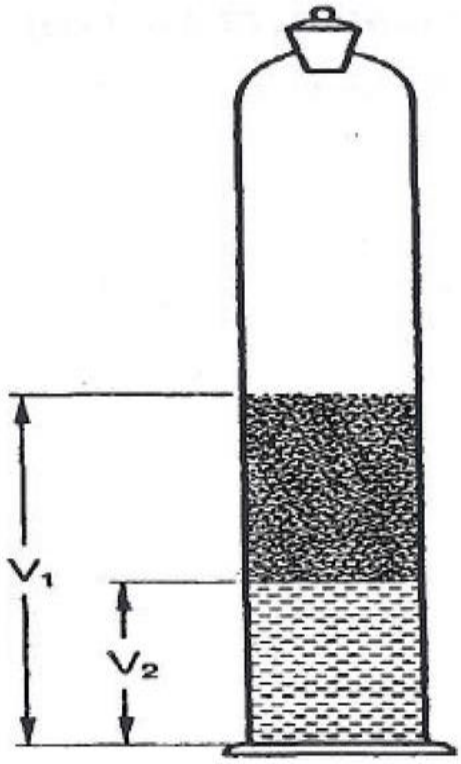

FIG. 2 MEASUREMENT OF FOAM

B-7 Test for Lead

B-7.1 Test method outline

The material is brought into solution. The brown colour produced with aqueous hydrogen sulphide solution is matched with that produced with a standard lead solution.

B-7.2 Apparatus

B-7.2.1 *Nessler Tubes* – 100 mL capacity

B-7.3 Reagents

B-7.3.1 *Concentrated Nitric Acid*

B-7.3.2 *Hydrofluoric Acid* – 40 per cent (w/w)

B-7.3.3 *Citric Acid*

B-7.3.4 *Bromophenol Blue Indicator* – Dissolve 0.1 g of bromophenol blue in 100-mL of rectified spirit.

B-7.3.5 *Copper Sulphate*

B-7.3.6 *Hydrogen Sulphide* – gas, from Kipp's apparatus

B-7.3.7 *Dilute Nitric Acid* – approximately 1 per cent

B-7.3.8 *Ammonium Hydroxide* – Dilute one volume of liquor ammonia (20 percent by weight) with 10 volumes of water

B-7.3.9 *Thymol Blue Indicator* – Dissolve 0.1 g of thymol blue in 100 mL of rectified spirit

B-7.3.10 *Potassium Cyanide Solution* – 10 percent (w/v)

B-7.3.11 *Hydrogen Sulphide Solution* – Freshly prepared, saturated solution

B-7.3.12 *Standard Lead Solution* – Dissolve 1.6 g of lead nitrate in water and make up the solution to exactly 1000 mL. Pipette out 10 mL of the solution and dilute it again with water to 1000 mL. One millilitre of final solution contains 0.01 mg of lead (Pb). The solution should be freshly prepared.

B-7.4 Procedure