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SPECIFICATION FOR
TOOTH POWDER
(FIRST REVISION)

BUREAU OF CEYLON STANDARDS

Gr.6

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FOREWORD

This Sri Lanka Standard specification was authorized for adoption and publication by the Council of the Bureau of Ceylon Standards on 1981-07-27, after the draft, finalized by the Drafting Committee on Tooth Powder, had been approved by the Chemicals Divisional Committee.

This revision was undertaken in the light of experience gained during the implementation of the specification. A substantial change has been made in the requirements for fineness of tooth powder. The range of pH and maximum content of heavy metals and arsenic were also changed.

A good tooth powder would exhibit minimum abrasive quality, consistent with maximum cleaning efficiency and effective polishing action. Highly polished teeth resist retention of dental debris, and remain cleaner longer.

Tooth powders contain polishing agents, surface active agents or detergents, colours, flavours and sweetening agents. Additives for special action may be present.

This specification is subject to the restrictions imposed under the Sri Lanka Cosmetics, Devices and Drugs Act No. 27 of 1980 and the regulations framed thereunder wherever applicable.

Dimensions and other characteristics in this specification are given in SI units.

For the purpose of deciding whether a particular requirement of this specification is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with **CS 102**. The number of figures to be retained in the rounded off values shall be the same as that of the specified value in this specification.

In the preparation of this specification, the considerable assistance derived from publications of the Indian Standards Institution and the United States Federal Supplies Service, General Services Administration is gratefully acknowledged.

1 SCOPE

This specification prescribes the minimum requirements and methods of sampling and test methods for both foaming and non-foaming tooth powder for general use.

2 REFERENCES

ISO/R 468	Surface roughness
CS 102	Presentation of numerical values
CS 124	Test sieves
SLS 242	Methods for the destruction of organic matter
SLS 311	Determination of lead
SLS 312	Determination of arsenic
SLS 428	Random sampling methods

3 REQUIREMENTS

3.1 Composition

The tooth powder shall be made from a combination of polishing agents with one or more of the ingredients given in **B.3**. One or more of the ingredients given in **B.2** may also be used. The polishing agents which may be used are listed in **B.1**.

3.2 Flavour

The flavour of the tooth powder shall be distinct and pleasant.

3.3 Consistency

The tooth powder shall be a homogeneous mixture and when examined as prescribed in **7.1** shall be a smooth, free-flowing, fine powder free of lumps. It shall not contain any hard abrasive materials.

3.4 Irritation

The tooth powder shall not irritate the mucous membrane of the mouth.

3.5 Safety

When used in the normal manner, the tooth powder shall not cause injury to the teeth, gums, mucous membrane of the mouth or the body in general.

3.6 Specification

The tooth powder shall also comply with the specifications given in Table 1 when tested according to the relevant methods given in Column 4 of the table.

TABLE 1 - Specifications for tooth powder

Serial No. (1)	Characteristic (2)	Specification (3)	Method of test; reference (4)
i	Moisture and volatile matter, per cent by mass, max.	5.0	7.2
ii	pH of 10 per cent aqueous suspension	6 to 10	7.3
iii	Heavy metals (as Pb), mg/kg, max.	2	7.4
iv	Arsenic (as As), mg/kg, max.	1	7.5
v	Fineness		
	a) Particles retained on 150-µm sieve, per cent by mass, max.	5	7.6
	b) Particles retained on 75-µm sieve, per cent by mass, max.	20	7.6
vi	Abrasion	To satisfy test	Appendix C

4 PACKAGING

The tooth powder shall be packed in suitable containers which shall be securely closed and sealed to prevent leakage and contamination of the product.

A number of these containers may form a pack.

5 MARKING

Each container shall be labelled with the following information:

a) The name and address of the manufacturer, and/or registered trade mark;

b) Net mass, in g;

c) Batch number in code to enable the lot of manufacture to be traced back from records; and

d) Information of the contents, if specific claims are made.

NOTE - Any therapeutic or prophylactic functions of the tooth powder shall not be stated unless it has been clinically established.

6 SAMPLING

Representative samples of tooth powder for carrying out tests shall be drawn as specified in Appendix A.

7 METHODS OF TEST

Tests shall be carried out as specified in **7.1** to **7.6** and in accordance with Appendix C.

7.1 Determination of consistency

Examine visually about 50 g of the material, weighed to the nearest g, for lumps or particles.

7.2 Determination of moisture and volatile matter

7.2.1 *Procedure*

Weigh to the nearest 0.1 mg, about 2.0 g of powder in a tared petri dish. Dry it at 105 ± 2 °C in an oven to constant mass. Cool in a desiccator and weigh.

7.2.2 *Calculation*

$$\text{Moisture and volatile matter, per cent by mass} = \frac{m_1 - m_2}{m_1} \times 100$$

where,

m_1 = mass, in g, of the powder taken for test;

m_2 = mass, in g, of the material after drying.

7.3 Determination of pH value

7.3.1 *Procedure*

Take about 5 g of the material, weighed to the nearest g, 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 calomel electrodes.

7.4 Determination of lead

7.4.1 *Principle of method*

The material is brought into solution as specified in **7.4.3.1** and after removal of interfering substances, lead is extracted with dithizone at pH 9 to 9.5 and determined absorptiometrically as prescribed in **SLS 311**.

7.4.2 *Reagents*

The following reagents shall be used in addition to those specified in **SLS 311:**

a) Nitric acid, concentrated 65 per cent (m/m) (or *perchloric acid,* 60 per cent (m/m))

b) Hydrofluoric acid, 40 per cent (m/m)

c) Bromophenol blue indicator, dissolve 0.1 g of bromophenol blue in 100 ml of rectified spirit.

7.4.3 *Procedure*

7.4.3.1 Place about 2 g of the material, weighed to the nearest mg, in a platinum dish and incinerate for about 2 hours at 525 °C to 550 °C. Cool, add 10 ml of concentrated nitric acid (or 5 ml of perchloric acid) and heat on a steam bath for 2 hours. Evaporate off the nitric acid (or perchloric acid) as far as possible, then add 5 ml of water and again evaporate to dryness. To the residue, add 5 ml of hydrofluoric acid, warm on a hot plate till fumes cease. Repeat twice. Cool and dilute with water. Filter the solution, if necessary, with suction through a fine fritted glass filter and dilute the filtrate and washings to 50 ml in a graduated flask.

NOTE - Exercise caution with perchloric acid.

7.4.3.2 Extract the lead with dithizone at pH 9 to 9.5 and determine the lead content absorptiometrically as specified in **SLS 311.**

7.5 Determination of arsenic

7.5.1 *Procedure*

Take about 2 g of the material weighed to the nearest mg, in a Kjeldahl digestion flask and wet, oxidise according to the method specified in **SLS 242.** Determine the arsenic content by the modified Gutzeit method specified in **SLS 312.**

7.6 Determination of fineness

7.6.1 *Procedure*

Place about 50 g of the material, weighed to the nearest 0.1 g, in a 75-μm sieve conforming to **CS 124** 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. Express the mass of the material retained on the sieve as a percentage by mass of the material taken for the test.

7.6.2 Place the residue obtained in **7.6.1**, in a 150-µm sieve conforming to **CS 124** and proceed as in **7.6.1**. Transfer the residue left on the sieve to a glazed paper and weigh. Express the mass of the residue as a percentage by mass of the material taken for the test in **7.6.1**.

8 CRITERIA FOR CONFORMITY

A lot shall be considered as conforming to the requirements of this specification if the following conditions are satisfied:

8.1 Test results of each individual sample shall satisfy the relevant requirements.

8.2 Test results of the composite sample shall satisfy the relevant requirements.

APPENDIX A

SAMPLING

A.1 LOT

In a single consignment all the packs (See 4) containing tooth powder of the same type and form, representing the same batch of manufacture, shall constitute a lot.

A.2 SCALE OF SAMPLING

A.2.1 The number of packs to be selected from a lot shall be in accordance with Table 2.

TABLE 2 - Scale of sampling

Number of packs in a lot	Number of packs to be selected
Up to 50	03
51 to 200	04
201 to 400	05
401 to 650	06
651 and above	07

A.2.2 These packs shall be selected at random. To ensure randomness of selection, random number tables as given in **SLS 428** shall be used.

A.3 PREPARATION OF SAMPLE

A.3.1 Gross sample

From each of the packs selected as in **A.2.1** draw at random one or more containers. The material in the containers as chosen from each pack shall be about three times the quantity required for carrying out a complete series of tests for all the requirements of the specification. The material taken out of the containers from each pack shall be separately mixed thoroughly to give a gross sample.

A.3.2 Individual sample

Each gross sample shall be divided into four equal parts. Three of these four parts shall constitute individual samples to represent a particular pack. Individual samples shall be transferred to separate clean, dry, glass containers. These containers shall be sealed air-tight with stoppers and labelled with full particulars for identification.

An individual sample from each gross sample in the lot shall be taken to constitute a set of individual samples. One set of individual samples shall be for the purchaser, another for the supplier and the third shall serve as the referee sample to be used in case of dispute between purchaser and the supplier.

A.3.3 Composite sample

The remaining part of the material of each gross sample shall be mixed together to form a composite sample. The composite sample shall be divided into three equal parts, and each part shall be transferred to separate clean, dry, glass containers. These containers shall be sealed air-tight with stoppers and labelled with full particulars for identification. One part shall be for the purchaser, another for the supplier and the third shall serve as the referee sample.

A.4 NUMBER OF TESTS

A.4.1 Tests for requirements 5 (fineness) and 6 (abrasion) of Table 1 shall be done on each of the individual samples.

A.4.2 Tests for all requirements other than fineness and abrasion shall be done on the composite sample.

APPENDIX B

INGREDIENTS GENERALLY USED IN THE MANUFACTURE OF TOOTH POWDER

B.1 POLISHING AGENTS

One or more of the following polishing agents may be used:

a) Precipitated calcium carbonate;

b) Magnesium carbonate;

c) Dicalcium phosphate;

d) Tricalcium phosphate;

e) Tetracalcium phosphate;

f) Sodium metaphosphate;

g) Sodium orthophosphate;

h) Hydrated alumina;

j) Amorphous precipitated silica; and

k) Charcoal.

B.2 SURFACE ACTIVE AGENTS OR DETERGENTS

The above ingredients shall be of pharmaceutical grade and quality.

B.3 PRESERVATIVES, FLAVOURS, COLOURING MATTER

The above ingredients shall satisfy the requirements of the Sri Lanka Food Act No. 26 of 1980 and the regulations framed thereunder.

APPENDIX C

DETERMINATION OF ABRASION

C.1 PRINCIPLE OF METHOD

A paste made of the material with water, placed on a glass slide is subjected to reciprocating strokes from a metal disc. The glass slide is then examined for any scratching.

C.2 APPARATUS

An apparatus similar to that shown in Fig. 1 shall be used. It consists essentially of the following components:

a) *Glass slide,* soda lime microscope slide.

b) *Metal disc,* a copper nickel alloy disc 20 mm diameter, 2 mm width, surface finish of 10 μm R_a (See ISO/R 468), (the surface finish shall not be obtained with abrasives). Inspect the rim carefully by means of a hand lens to ensure the absence of projections capable of scratching glass.

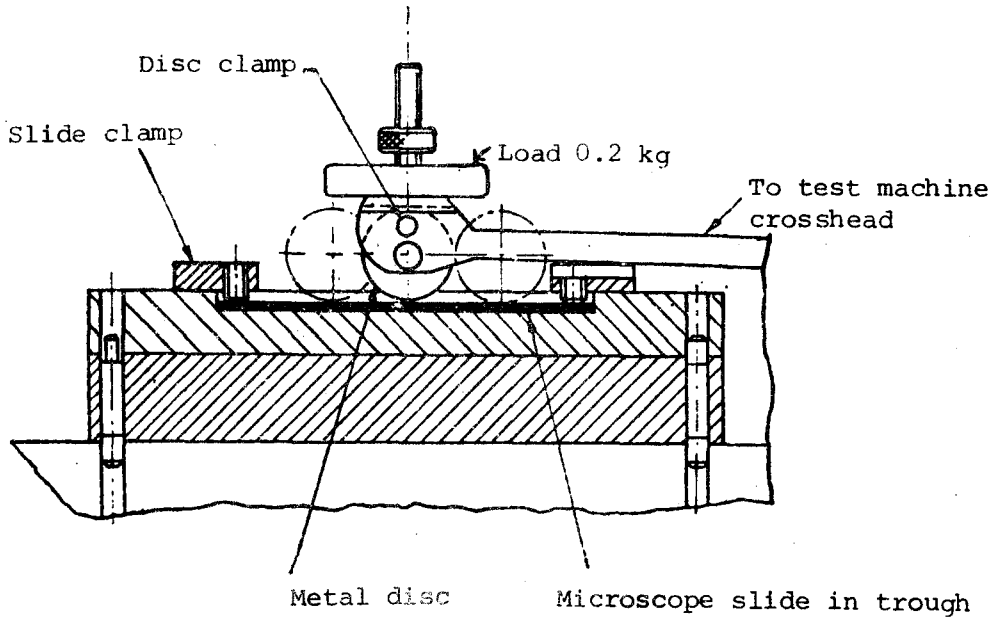

FIGURE 1 - Glass slide disc test apparatus

C.3 PROCEDURE

C.3.1 Clean the glass slide with chromic acid, rinse in water and dry. Make a paste of the material with water. Place approximately 1 g of the paste on the slide and operate the apparatus shown in Figure 1 for 100 double strokes using a load of 200 g on the disc. Run a control test alongside of the previous track using glycerine as the control medium. Rotate the disc to provide a fresh surface for each test. After completion of both tests, wash the glass slide and dip into dilute nitric acid to remove any particles of metal alloy adhering to the slide. Wash the slide in water and after drying, view in reflected light.

C.3.2 If the track produced by the paste shows visible scratches, then it shall be considered to have failed in the test. Ignore any smooth polished grooves. An example of this type of grooving will be exhibited by the glycerol test track. If the glycerol test track shows signs of scratching, then the test shall be repeated using a fresh glass slide in a different position on the rim of the disc.

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The Sri Lanka Standards Institution is the owner of the registered certification mark shown below. Beneath the mark, the number of the Sri Lanka Standard relevant to the product is indicated. This mark may be used only by those who have obtained permits under the SLS certification marks scheme. The presence of this mark on or in relation to a product conveys the assurance that they have been produced to comply with the requirements of the relevant Sri Lanka Standard under a well designed system of quality control inspection and testing operated by the manufacturer and supervised by the SLSI *which includes surveillance inspection of the factory, testing of both factory and market samples.*

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