

**भारतीय मानक**  
**Indian Standard**

**IS 5383 : 2021**

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**दंत मंजन — विशिष्टि**  
( तीसरा पुनरीक्षण )

**Tooth Powder — Specification**  
( *Third Revision* )

ICS 71.100.70

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## FOREWORD

This Indian Standard (Third Revision) was adopted by the Bureau of Indian Standards after the draft finalized by the Cosmetics Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

This standard was originally published in 1966 and first revised in 1978 when changes were made in the requirements of fineness. In place of the requirement of abrasion, the requirement of freedom from hard and sharp edged particles and method of test was prescribed. Relaxation was given for the determination of heavy metals and arsenic, if these were tested in the raw materials.

In the second revision, the requirement for microbial purity was included. Important marking requirements on containers and ECO-Mark certification were also retained in this revision. The fineness requirement with an appropriate test method was included to incorporate technologies such as use of soft agglomerates/capsules, which are internationally considered as safe ingredients. Important marking requirements for best use before, list of key ingredients on containers and ECO-mark certification were also incorporated in this revision. Limit for fineness and pH was revised keeping in mind various types of products currently marketed in India.

Tooth powder formulations may be designed to have optimal abrasivity to effect cleaning action without hurting soft tissues or tooth enamel by way of excessive abrasivity. Relative dentine abrasivity (RDA) is recognized in most of the International Standards as the measure to determine this parameter. RDA is therefore recommended as a type test in this standard.

The abrasivity of the tooth powder shall not exceed the limits specified when tested as per procedure given in Annex H. The abrasivity measurement methodology has been based on ISO 11609 : 2017. As RDA measurement facility is currently not available in India, a simpler abrasion test using a photographic paper is being developed. This procedure may be adopted in future after completing the studies and establishing validation with RDA.

A good tooth powder when used in normal manner assists in the removal of usual daily accumulation of debris and deposits from the exposed surface of the teeth, without causing injury to the teeth and mucous membrane of the mouth. In addition it may remove stains and odour. The use of tooth powder may improve the oral hygiene. To prevent/reduce the incidence of oral/dental problems like caries, gingivitis and periodontitis the essential active ingredients may be incorporated in tooth powder.

In this third revision, tooth powder classification has been revised into fluoridated and non-fluoridated types based on similar classification for toothpaste. Keeping in line with the Indian standard on tooth paste IS 6356 : 2001, a requirement for fluoride has been introduced. The test method for determination of fluoride is provided in Annex J.

While no changes have been made on the maximum limit on heavy metal content expressed as lead in tooth powder, a requirement of mercury has been added. While a method for estimation of heavy metals expressed as lead has been provided in Annex F of this standard, alternate, validated methods, such as Atomic Absorption Spectrophotometry (AAS), Inductively Coupled Plasma Mass Spectrometry (ICP-MS) and Inductively Coupled Plasma Optical Emission Spectrometry (ICP-OES) may also be used. However, in case of dispute, the method described in Annex F of this standard will be the referee method.

No stipulations have been made regarding the composition of tooth powder, however, it is essential that the tooth powder formulations do not contain any ingredient in sufficient concentration to cause a toxic or irritating reaction when used in the mouth. Nor shall it be harmful in normal use, keeping in mind that small amounts may be ingested inadvertently.

A scheme for labelling environment friendly products to be known as ECO Mark has been introduced at the instance of the Ministry of Environment, Forests and Climate Change (MoEF & CC). The ECO Mark shall be administered by the Bureau of Indian Standards (BIS) under the *Bureau of Indian Standards Act, 2016* as per the Resolution No. 71 dated 20 February 1991 and No. 768 dated 24 August 1992 published in the Gazette of the Government of India. For a product to be eligible for ECO Mark it shall also carry Standard Mark of BIS for quality, besides meeting additional environment friendly (EF) requirements. For this purpose, the Standard Mark of BIS would be a single mark being a combination of the ISI Mark and the ECO logo. The requirements for the ECO friendliness will be additional, manufacturing units will be free to opt for Standard Mark alone also.

(Continued to third cover)

# *Indian Standard*

## TOOTH POWDER — SPECIFICATION

( *Third Revision* )

### 1 SCOPE

This standard prescribes the requirements and the methods of sampling and test for tooth powder.

### 2 REFERENCES

The following standards contain provisions, which through reference in this text, constitute provisions of this standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standard indicated below:

<i>IS No.</i>	<i>Title</i>
265 : 1993	Hydrochloric acid ( <i>fourth revision</i> )
1070 : 1992	Water reagent grade ( <i>third revision</i> )
2088 : 1983	Methods for determination of arsenic ( <i>second revision</i> )
3958 : 1984	Methods of sampling cosmetics ( <i>first revision</i> )
4011 : 2018	Methods of test for safety evaluation of cosmetics ( <i>third revision</i> )
4707	Classification of cosmetic raw materials and adjuncts:
(Part 1) : 2020	Dyes colours and pigments ( <i>fourth revision</i> )
(Part 2) : 2017	List of raw materials generally not recognized as safe for use in cosmetics ( <i>fourth revision</i> )
14648 : 2011	Methods of test for microbiological examinations of cosmetics and cosmetic raw material ( <i>second revision</i> )
16913 : 2018	Methods of test for cosmetics and determination of heavy metals (Arsenic, Cadmium, Lead and Mercury) by atomic absorption spectrometry (AAS)

### 3 TYPES

Tooth powder shall be classified into the following two types:

- a) *Type 1* — Non-fluoridated; and
- b) *Type 2* — Fluoridated.

### 4 REQUIREMENTS

#### 4.1 Description

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

#### 4.2 Ingredients

The ingredient(s) shall be one or more of the conventionally used materials in the manufacture of tooth powders. A list of ingredients conventionally used in the manufacture of tooth powder is given in Annex A for information only. All the raw materials used shall conform to respective Indian Standards wherever they exist. Tooth powder shall not contain mono or disaccharide for example, glucose, sucrose or other readily fermentable carbohydrates.

**4.3** The dyes, colours and pigments used in the manufacture of tooth powder shall comply with the provisions of IS 4707 (Part 1). Additional ingredients, such as flavours, sweetening agents, active ingredients etc. may be added to improve the appearance, performance, taste and flavour. These ingredients shall conform to the provisions of IS 4707 (Part 2).

**4.4** For safety evaluation of novel ingredients used in the formulation of a tooth powder, the tooth powder shall comply to IS 4011. It shall be the responsibility of the manufacturers of tooth powder to satisfy themselves of the dermatological safety of their formulation before releasing the product for sale.

**4.5** The tooth powder shall also meet the requirements given in Table 1 when tested according to methods given in col 5 and 6 of Table 1.

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**Table 1 Requirement for Tooth Powder**  
( Clause 4.5 )

SI No.	Characteristic	Requirement for		Method of Test, Ref to	
		Type 1 (Non-fluoridated)	Type 2 (Fluoridated)	Annex No.	IS
(1)	(2)	(3)	(4)	(5)	(6)
i)	Fineness:				
	a) Particles retained on 75-micron IS sieve, percent by mass, <i>Max</i>	2.5	2.5	B	
	b) Particles retained on 150-micron IS sieve, percent by mass, <i>Max</i>	1.0	1.0		
ii)	Moisture and volatile matter, by mass, <i>Max</i>	5	5	C	
iii)	pH of 50 percent aqueous suspension	5.5-10.5	5.5-10.5	D	
iv)	Foaming power, ml, <i>Min</i> <sup>1)</sup>	50	50	E	
v)	Heavy metals as lead (Pb), parts per million, <i>Max</i>	20	20	F	
vi)	Arsenic (as As <sub>2</sub> O <sub>3</sub> ), parts per million, <i>Max</i>	2	2	G or IS 16913	
vii)	Available fluoride ion, parts per million, <i>Max</i>	50	1000	J	
viii)	Mercury (as Hg), parts per million, <i>Max</i>	1	1	IS 16913	
ix)	Microbial count:				
	a) Total viable count, cfu/g, <i>Max</i>	1000	1000	14648	
	b) Gram negative pathogens/g	Absent	Absent	14648	

<sup>1)</sup> Applicable to foaming tooth powder only.

## 4.6 Additional Requirements for ECO-Mark (Optional)

### 4.6.1 General Requirements

**4.6.1.1** The product shall confirm to be requirements for quality, safety and performance prescribed under 4.5.1 to 4.5.5.

**4.6.1.2** All the ingredients that go into formulation shall comply with the provisions of IS 4707 (Part 1) and IS 4707 (Part 2). The product shall also meet specific requirements as given in the above standard.

**4.6.2** The product package shall display a list of key ingredients in descending order of quantity present.

**4.6.3** The product shall not be manufactured from any carcinogenic ingredients.

**4.6.4.** The manufacturer shall produce to BIS environmental consent clearance from the concerned State Pollution Control Board as per the provisions of the *Water (Prevention and Control of Pollution) Cess Act, 1977* and the *Air (Prevention and Control Pollution) Act, 1981* along with the authorization, if required under the *Environment (Protection) Act, 1986* and the Rules made there under, while applying for ECO-Mark. Additionally, provisions of the *Drugs and Cosmetics Act, 1940* and the Rules there under shall also be complied with.

### 4.6.5 Specific Requirements

**4.6.5.1** Heavy metals calculated as lead (Pb), Arsenic (as As<sub>2</sub>O<sub>3</sub>), and mercury shall not exceed 20 ppm, 2 ppm, and 1 ppm respectively when tested by the respective method prescribed in Indian Standards.

**4.6.5.2** Product shall be dermatologically safe when tested as prescribed in IS 4011.

## 5 ABRASIVITY (TYPE TEST)

The tooth powder shall not exceed the limits of dentin abrasivity that of 2.5 times when tested as per the procedure given in Annex H.

It may be noted that type test is recommended to be done on the formulation only once to pass the above criterion. This test need not be done for each and every batch. However, the type test is a must again, if the abrasive system is changed in the formulation. It is not required for the new formulation as long as abrasive components are not changed.

## 6 PACKING AND MARKING

### 6.1 Packing

Tooth Powder shall be packed in suitable containers like plastic bottles, sachets or other suitable dispensing systems. When packed in containers, the containers shall be properly sealed and have a leak-proof cap

or closure. The containers, if necessary, may further be packed in cartons or any other suitable packaging material.

**6.1.1** The material for product packaging shall meet the parameters evolved under the scheme of labelling environment friendly packaging/package materials.

## 6.2 Marking

**6.2.1** The labelling and marking of tooth powder shall comply with the requirements of the *Drugs and Cosmetic Act and Rules*, Legal Metrology and any other relevant statutory requirement. In addition, the tooth powder containers and the cartons shall be legibly marked with the following information:

- a) Name and type of tooth powder;
- b) Indication of the source of manufacture;
- c) Net mass or volume of the material in the container;
- d) Batch number, in code or otherwise;
- e) Month and year of manufacture;
- f) Fluoride ion content for Type 2 tooth powder in ppm;
- g) “Best use before... ..” (Month and year to be declared by the manufacturer).
- h) Foaming/non-foaming; and
- j) List of key ingredients.

NOTE — This is exempted in case of pack sizes of 30 g or less.

## 6.2.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

**6.2.3** If the product is covered under ECO-Mark (optional), it shall be suitably marked with ECO-Mark logo besides Standard Mark. The label may clearly specify that ECO-Mark is applicable to the contents or the package or both, as case may be. If the product package is not separately covered under ECO-Mark scheme, it shall be clearly mentioned on the product that ECO-Mark label is applicable to contents only.

## 7 SAMPLING

**7.1** Representative samples of the material shall be drawn as prescribed in IS 3958.

**7.2** The lot shall be declared as conforming to requirements of the specification, if all the test results on each individual samples meet the requirements prescribed in 4.1 to 4.5.

## 8 QUALITY OF REAGENTS

Unless specified otherwise, pure chemicals and distilled water (*see* IS 1070) shall be employed in tests.

NOTE — ‘Pure chemicals’ shall mean chemicals that do not contain impurities which affect the results of analysis.

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## ANNEX A

( Clause 4.2 )

### A-1 INGREDIENTS CONVENTIONALLY USED IN THE MANUFACTURE OF TOOTH POWDER

the material used falls into the following categories:

- a) Polishing agents,
- b) Foaming agents, and
- c) Others as per IS 4707 (Part 1) and (Part 2).

### A-2 POLISHING AGENTS

The principal polishing agents generally used are one or more of those given below:

1. Calcium carbonate
2. Magnesium carbonate
3. Di-calcium phosphate
4. Tri-calcium phosphate
5. Insoluble sodium meta-phosphate
6. Hydrated alumina
7. Amorphous precipitated silica
8. Aluminium hydroxide
9. Aluminium/Alumino silicate
10. Alumina
11. Alumina fumed
12. Calcium phosphate
13. Calcium pyrophosphate
14. Dicalcium phosphate dehydrate
15. Kaolin
16. Magnesium silicate
17. Potassium meta-phosphate
18. Silica fumed
19. Silica hydrated
20. Sodium aluminium silicate
21. Sodium bicarbonate
22. Sodium meta-phosphate
23. Hydroxyapatite
24. Zirconium silicate
25. Sodium polymeta-phosphate
26. Tungsten carbide
27. Pumice
28. Silicon carbide
29. Magnesium silicate
30. Charcoal

31. Agglomerates (mainly consisting of one or more of the polishing agents)
32. Rice husk
33. Mica/coated mica
34. Red ochre
35. Others as per IS 4707 (Part 1) and (Part 2)

### A-3 FOAMING AGENTS

The foaming agent(s) generally used are one or more of those given below:

1. Soap
2. Sodium ricinoleate
3. Sodium sulphoricinoleate
4. Sodium lauryl sulphate
5. Sodium alkyl sulfoacetate
6. Sodium salt of sulphated monoglyceride
7. Sodium lauryl sarcosinate
8. Sodium alpha olefin sulphonate
9. Coco-amido-propyl-betaine
10. Sodium dodecyl benzene sulphonate
11. Sodium lauryl sulfoacetate
12. Coconut monoglyceride sulphonates
13. Dioctylsodium-sulphosuccinate
14. Magnesium lauryl sulphate
15. Sodium alkyl benzene sulphonate
16. Sodium alkyl sulphate
17. Sodium lauryl ether sulphate
18. Coco – betaine
19. Others as per IS 4707 (Part 1) and (Part 2)

### A-4 OTHER SUBSTANCES

1. Fluorides of sodium and stannous
2. Monofluoro phosphate of ammonium, potassium and sodium
3. Sweeteners, saccharine, aspartame
4. Petroleum jelly – silicon defoaming compounds and mineral oil
5. Colouring agents
6. Essential oils
7. Flavouring agents
8. Astringents
9. Preservatives

- |                          |   |
|--------------------------|---|
| 10. Antibacterial agents | 15. Calcium glycerophosphate                    |
| 11. Antiplaque agents    | 16. Granules / Agglomerates                     |
| 12. Antitartar agents    | 17. Anti-gingival agents                        |
| 13. Whitening agents     | 18. Sodium chloride                             |
| 14. Anticaries agents    | 19. Others as per IS 4707 (Part 1) and (Part 2) |

## ANNEX B

[ Table 1, SI No. (i) ]

### DETERMINATION OF FINENESS

#### B-1 METHOD BASED ON ULTRASONIFICATION

##### B-1.1 Outline of the Method

Subject the tooth powder suspension to an ultrasonic treatment and pass through fineness test. Ultrasonification loosens out the soft agglomerates into the constituent materials.

##### B-1.2 Apparatus

**B-1.2.1 Ultrasonic Bath** — Trans-o-sonic compact model or equivalent (60±10 watts power with 35±5 kHz Ultrasonic frequency, 1-2 watts/inch 2 power density, L × B × h : 225 × 125 × 60 mm – Tank).

**B-1.2.2 75 and 150 Microns Sieves**, conforming .to IS 460 (Part 1).

**B-1.2.3 Glass beakers** (250 ml, 500 ml) and stirring rods.

**B-1.3 Determination of particle size on 150-Micron IS Sieve.**

##### B-1.3.1 Procedure

Place about 5 g of the tooth powder, accurately weighed, in a 250 ml beaker. Add 200 ml of water and allow standing for about 5 min with occasional stirring until the tooth powder is completely dispersed. Transfer the beaker in an ultrasonic bath.

Fill the ultrasonic bath (2 litre capacity) to about three-fourth height with water. Clamp the above beaker in the centre of the bath keeping about 1 cm clearance from

the bottom of the bath and subject ultrasonification for 10 min to completely loosen out the constituents.

Transfer this suspension quantitatively to a 150 micron IS Sieve and wash by means of a slow stream of running tap water and finally with a fine stream from a wash bottle until all the matter that can pass through the sieve has passed. Let the water drain out and then dry the sieve containing the residue in an oven. If there is any residue on the sieve, carefully transfer it to a tarred watch glass and dry it to constant mass in an oven at 105±2 °C.

##### B-1.4 Calculation

Material retained on 150 – micron IS Sieve, percent by

$$\text{mass} = \frac{M_1 \times 100}{M}$$

where

$M_1$  = mass of residue retained on the sieve, in g; and

$M$  = mass of the material taken for the test, in g.

#### B-2 DETERMINATION OF PARTICLE SIZE ON 75- MICRON IS SIEVE

##### B-2.1 Procedure

Weigh accurately about 5 g of the tooth powder and proceed as in **B-1.3.1**, using a 75-micron IS Sieve. If there is any residues on the sieve carefully transfers it to a tarred watch glass and dry it to constant mass in an oven at 105±2 °C.

##### B-2.2 Calculation

Calculate as in **B-1.4**



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## ANNEX C

[ Table 1 *Sl No.* (ii) ]

### DETERMINATION OF MOISTURE AND VOLATILE MATTER

#### C-1 PROCEDURE

In a previously dried and weighed petri dish, take about 2 g of the material, accurately weighed. Dry it at  $105 \pm 2$  °C in an oven for 4 h or till constant mass. Cool in a desiccators and weigh.

#### C-2 CALCULATION

Moisture and volatile matter percent by mass =

$$\frac{100(M - M_1)}{M}$$

where

$M$  = mass of the material taken for the test, in g; and

$M_1$  = mass of the material after drying, in g.

## ANNEX D

[ Table 1, *Sl No.* (iii) ]

### DETERMINATION OF pH

#### D-1 PROCEDURE

Dispense 10 g of the tooth powder from the container in a 50 ml beaker and add 10 ml of freshly boiled and

cooled water (at 27 °C) to make 50 percent aqueous suspension. Stir well to make a thorough suspension. Determine the pH of the suspension within 5 min, using a pH meter.

## ANNEX E

[ Table 1, *Sl No.* (iv) ]

### DETERMINATION OF FOAMING POWER

#### E-1 GENERAL

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

##### E-1.1 Outline 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 min.

#### E-2 APPARATUS

**E-2.1 Graduated Cylinder (250 ml)** — 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.

**E-2.2 Graduated Cylinder (100 ml)** — with graduations from 0 to 100 ml, with 1 ml divisions.

**E-2.3 Thermometer**, of range 0 to 110 °C.

#### E-3 PROCEDURE

**E-3.1** Weigh about 5 g of the tooth powder accurately in a 100 ml glass beaker, add 15 ml of water, cover the beaker with watch glass and allow to stand for 30 min. 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.

**E-3.2** Stir the contents of the beaker with the glass rod and transfer the slurry to the 250 ml 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 water ensuring that all the matter in the beaker is transferred to the cylinder.



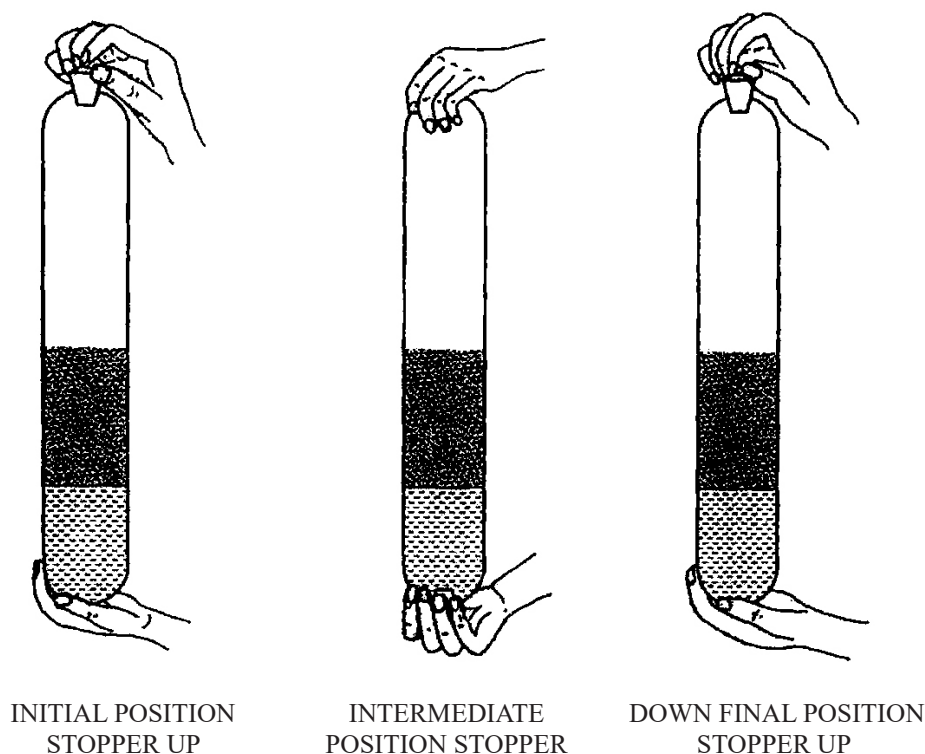


FIG. 1 ONE COMPLETE SHAKE OF CYLINDER

**E-3.3** Adjust the contents in the cylinder to 50 ml by adding sufficient water and bring the contents of the cylinder to 30 °C. Stir the contents of the cylinder with a glass rod or thermometer to ensure a uniform suspension.

**E-3.4** As soon as the temperature of the contents of the cylinder reaches 30 °C, stopper the cylinder and give it 12 complete shakes, each shake comprising movements show in Fig. 1 in a vertical plane, upside down and vice versa. After the 12 shakes have been given, allow the cylinder to stand still for 5 min and read the volumes of:

- a) Foam plus water ( $V_1$  ml), and
- b) Water only ( $V_2$  ml) as shown in Fig. 2.

#### E-4 CALCULATION

Foaming power, ml =  $V_1 - V_2$ .

where

$V_1$  = volume of foam plus water, in ml; and

$V_2$  = volume of water only, in ml.

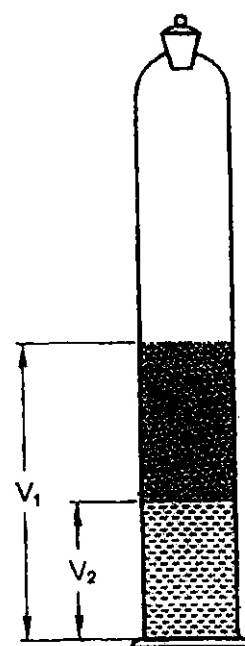


FIG. 2 MEASUREMENT OF FOAM

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## ANNEX F

[ Table 1, Sl No. (v) ]

### TEST FOR LEAD

#### F-1 OUTLINE OF THE METHOD

The colour produced with hydrogen sulphide solution is matched against that obtained with standard lead solution.

#### F-2 APPARATUS

**F-2.1 Nessler Cylinders** — 50 ml capacity.

#### F-3 REAGENTS

**F-3.1 Dilute Hydrochloric Acid** — Approximately 5 N.

**F-3.2 Dilute Acetic Acid** — Approximately 1 N.

**F-3.3 Dilute Ammonium Hydroxide** — Approximately 5 N.

**F-3.4 Hydrogen Sulphide Solution** — Standard.

**F-3.5 Standard Lead Solution** — Dissolve 1.600 g of lead nitrate in water and make up the solution of 1.000 ml. Pipette out 10 ml of the solution and dilute again to 1.000 ml with water. One millilitre of this solution contains 0.01 mg of lead (as Pb).

#### F-4 PROCEDURE

Weigh about 2.000 g of material in a crucible and heat on a hot plate and then in a muffle furnace to ignite it at 600 °C to constant mass. Add 3 ml of dilute hydrochloric acid, warm (wait till no more dissolution occurs) and make up the volume to 100 ml. Filter the solution. Transfer 25 ml of the filtrate into a Nessler's cylinder. In the second Nessler's cylinder, add 2 ml of dilute acetic acid, 1.0 ml of standard lead solution and make up the volume with water to 25 ml.

Add 10 ml of hydrogen sulphide solution to each Nessler cylinder and make up the volume with water to 50 ml. Mix and allow standing for 10 min. compare the colour produced in the two nessler's cylinders. Blank determinations without samples are recommended to avoid errors arising out of reagents.

#### F-5 RESULTS

The sample may be taken to have passed the test, if the colour developed in the sample solution is less than that of standard solution.

## ANNEX G

[ Table 1 Sl No. (vi) ]

### TEST FOR ARSENIC

#### G-1 OUTLINE OF THE METHOD

Arsenic present in a solution of the material is reduced to arsine, which is made to react with mercuric bromide paper. The stain produced is compared with a standard stain.

#### G-2 REAGENTS

**G-2.1 Mixed Acid** — Dilute one volume of concentrated sulphuric acid with four volumes of water. Add 10 g of sodium chloride for each 100 ml of the solution.

**G-2.2 Ferric Ammonium Sulphate Solution** — Dissolve 64 g of ferric ammonium sulphate in water containing 10 ml of mixed acid and make up to one litre.

**G-2.3 Concentrated Hydrochloric Acid** — See IS 265.

**G-2.4 Stannous Chloride Solution** — Dissolve 80 g of stannous chloride ( $\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$ ) in 100 ml of water containing 5 ml of concentrated hydrochloric acid.

#### G-3 PROCEDURE

Carry out the test as prescribed in IS 2088, adding into the Gutzeit bottle, 2 ml of ferric ammonium sulphate solution, 0.5 ml of stannous chloride solution and 25 ml of sample solution as prepared in F-4.

For comparison, prepare a stain using 0.001 mg of arsenic trioxide.

## ANNEX H

( Foreword and Clause 5 )

### ABRASIVITY (RDA) MEASUREMENT TEST (HEFFERREN)

#### H-1 SCOPE

This Annex identifies the specific procedures for determination of dentifrice abrasively using the ADA laboratory method.

#### H-2 SAMPLING

A representative sample shall be taken from at least two batches.

#### H-3 PROCEDURE

##### H-3.1 Standard Reference Abrasive.

The standard reference abrasive is from a specific lot of calcium phosphate held by the Monsanto company<sup>1)</sup>.

“Calcium pyrophosphate is an example of a suitable product available commercially. This information is given for the convenience of users of this Standard and does not constitute an endorsement by BIS of this product. A sample of the material may be obtained by contacting the company at the address below and requesting the ADA abrasion standard. Slight shifts (less than 10 percent) in abrasivity between lots have been reported.

Monsanto Company  
Detergent Division  
800 N Lindbergh Boulevard  
St Louis MO  
USA 63167

##### H-3.2 Apparatus

**H-3.2.1 Brushing Machine** — A cross brushing machine is the apparatus of choice<sup>1)</sup>. The apparatus should have eight positions for holding specimens. A toothbrush shall be positioned to pass reciprocally over the mounted specimens with a designated tension on the brush while immersed in dentifrice slurry. The distance traversed by the brush should not be longer than the brush head, so that the specimen does not lose contact with the brush. The mechanism for holding the dentifrice slurry may vary with different machine designs, but should allow for easy removal of the slurry sample. It is important to have some mechanism for agitation of the slurry while the brushing is taking place. A convenient method to accomplish this is to attach rubber mixing vanes just below the brush head. As the brushing takes place, these vanes will prevent the abrasive from settling to the bottom of the slurry container.

**H-3.2.2 Radioactivity Detector** — The two recommended methods for determination of the radioactivity of the used dentifrice slurries are a Gieger – Muller planchet counter or liquid scintillation detector. The use of the Geiger counter requires that the samples be dried under defined controlled conditions. The liquid scintillation method has the advantage of reading directly from the slurry.

The drawings and blue prints of the machine may be obtained from the American Dental Association.

Counting should be done for a period expected to reduce the alpha value for counting error to less than 2 percent. Counting should be performed for a minimum of 1,000 counts and at least 1 min. The number of brushing strokes may be increased if counting times become too long.

##### H-3.3 Presentation of Tooth Specimens

###### H-3.3.1 Dentin Specimens

###### H-3.3.1.1 Selection

Human root dentin of extracted permanent teeth is used as the substrate. Single – rooted teeth that were vital at extraction should be selected. An exception, because of the small size are, mandibular incisors: these should not be used. The specimen should be at least 14 mm long and 2 mm wide at the narrow end. All roots shall be caries-free and free of anatomical defects. After extraction, the roots should be stored in neutralized 4 percent formaldehyde solution.

###### H-3.3.1.2 Preparation

Scrape the roots clean of all soft tissue and cementum. Then remove the crown and the root tips using a separating disc under a flow of water.

###### H-3.3.1.3 Irradiation

For each set of eight specimens to be irradiated, add one or two extra roots for use in correction factors. Pack the specimens in 4 percent formaldehyde solution and submit to a nuclear reactor for irradiation. The neutron flux should be sufficient to product about 1m Ci of 32P beta radiation after several hours. Elevated temperatures in the reactor should be avoided. It is also advisable to shield the samples from fast neutrons and gamma radiation. Handling of the irradiated specimens should be done with care using good laboratory practice. The specimens should not be used during the first half life because of excess radiation and should be used before the end of the third half – life because of

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lack of activity. The half-life of  $^{32}\text{P}$  is 14.3 days so the usable life-span of a set of teeth is 4 weeks.

### H-3.3.1.4 Mounting of specimens

The specimens should be mounted individually in cold cure methyl methacrylate denture resin: the type of mould used will depend upon the holder on the brushing machine. The specimens should be mounted so that they protrude above the resin surface in a buccal/lingual orientation by at least 2 mm. The brushing surface of the root shall be parallel in buccal lingual orientation to the resin holder and situated so that the brushing will take place perpendicular to the long dimension of the root. Storage of the mounted specimens should be in 4 percent formaldehyde.

### H-3.3.2 Enamel Specimens

#### H-3.3.2.1 Selection

Selection criteria for the enamel specimens are the same as for dentin. The enamel specimens should be obtained from human maxillary incisors.

#### H-3.3.2.2 Preparation

The entire labial surface of the specimen is used after removing the root. Clean the enamel in the same way as the root.

#### H-3.3.2.3 Irradiation

Irradiation of the enamel is identical to the method used with the roots. The roots and enamel specimens may be packed together for submission to the reactor.

#### H-3.3.2.4 Mounting

Mount the enamel specimens in the same way as the roots. The labial surface shall protrude 2 mm and be parallel to the resin surface.

### H-3.4 Tooth Brushes

The tooth brushes if used should have nylon bristles of medium hardness. The bristle ends should lie in a plane rather than in separated or end-raised tuft design. The bristle length should be about 10 mm. A 50 tuft medium-texture brush is a commercially available brush that meets acceptable criteria.

Store the brushes in water overnight prior to their first use and then keep them in water until they are discarded. Use a new set of brushes for each set of teeth. Do not remove the brushes from the machine between runs but raise the tufts of the specimen so as not to bend the bristles. At the beginning of each run, set the tension, of the brush on the specimen to 150 g using a Chatillon spring gauge or equivalent. This tension should be re-checked at least twice daily. The method of adjusting the tension will vary depending upon the type of mechanism on the brushing machine.

### H-3.5 Reference Diluent

The diluents are a 0.5 percent carboxymethylcellulose (CMC) (7MF) solution in 10 percent glycerine. To prepare 1 litre of the dilute, heat 50 ml of glycerine to 60°C and add 5 g of CMC while stirring. After the mixture is homogeneous, add another 50 ml of heated glycerine and continue stirring for 60 min. Transfer the solution to a 1 litre flask and add 900 ml of distilled water. Allow to cool but continue stirring slowly overnight. To stabilize the viscosity, allow the solution to stand overnight before using. This solution is used to make up slurries of the reference abrasive or any other powder being tested.

### H-3.6 Reference Abrasive Slurry

The reference material is that described above (*see* H-3.4). Dilute 10 g of the abrasive with 50 ml of the diluents (*see* H-3.5). The same ratio is used for all powders. It is possible for the reference abrasive to be used as a dentifrice, if that has to be done. It shall be made up as a 40 percent abrasive dentifrice with the rest of the constituents being conventional dentifrice components. The slurry is then made with 25 g of reference dentifrice and 40 ml of water.

### H-3.7 Dentifrice Slurries

To prepare the test slurries, add 40 ml of water to 25 g of each dentifrice. For the machine, prepare eight slurries of each dentifrice. This dilution produces a final slurry volume and concentration similar to those of the reference abrasive slurry. All slurries reference and test should be used shortly after preparation and after vigorous mechanical stirring to prevent particle setting

#### H-3.8.1 Dentin

To reduce the variation caused by dentin surface differences, precondition the specimens prior to each use. The preconditioning treatment consists of brushing with slurry of the reference abrasive but not taking a sample. The first time dentin specimens are used, the preconditioning should be for 6.000 strokes. Each successive daily run should begin with a shorter precondition brushing of 1.000 strokes. The tension of the toothbrush on the roots shall be 150 g.

Discard the preconditioning slurries.

#### H-3.8.2 Enamel

Preconditioning of the enamel is similar to that of the dentin, except 10.000 strokes are used prior to the first use and 1.000 strokes are given at the beginning of each day.

Discard the preconditioning slurries.

### H-3.9 Test Design

#### H-3.9.1 Test Design for Dentin

The test design may be either a sandwich design or a Latin square design. The sandwich design is such that a set of reference slurries is run (pre-test), followed by a second set of reference slurries (post-test). This second set of reference slurries then acts as the pre-test slurries for the next test group. This continues until all the test groups are run.

The Latin square design is such that a set of reference slurries is run first. All the test groups are randomized over the eight brushing heads for the next few runs (depending on the number of test groups). Then a post-test reference set of slurries is run as the final procedure.

In both test designs, the brush tension is set at 150 g and brushing is performed for 1.500 to 3.000 strokes depending on the radioactivity level of the specimens.

#### H-3.9.2 Test Design for Enamel

The test design for enamel is identical to that for dentin, except the number of strokes is 5.000 to 7.500 depending on the activity of the specimens.

### H-3.10 Sampling of Slurries

The sampling of the slurries following the brushing is identical for both dentin and enamel. An aliquot of each slurry is removed immediately following brushing. The size of the aliquot will depend upon the counting method and equipment, but 3 ml is usually adequate to provide a detectable level of radioactivity. A convenient method for removing the sample is a syringe fitted with a blunt needle. Take care to ensure no carry-over between samples. This can best be done by a complete rinsing of the syringe between samples. It is also important to remove the same quantity of sample from each slurry. Dry the sample if a planchet counters system is being used to detect the radioactivity. If drying is needed, the samples should be air-dried for at least 1 h and then dried in an oven at 60 °C with forced air overnight.

### H-3.11 Correction Factors

Correction factors are needed for both dentin and enamel abrasion tests when using the planchet counting method and are identically prepared in both methods. When testing dentifrices with abrasive systems different from the reference materials, the self – absorption and back scattering characteristics of the abrasives for beta radiation may also differ. Real differences in abrasivity may then be significantly distorted. The correction

factor is a means to reduce this variable. The correction factor is determined differently depending on the counting method used.

#### H-3.11.1 Preparation of Correction Factor Slurries for Geiger-Muller Planchet Counting

Dissolve one piece of irradiated dentin (or enamel) in 5 ml of concentrated HCL. Transfer the solution to a 250 ml volumetric flask and add water to the mark. Add 1.0 ml of this radioactive solution to slurries of reference abrasive and to each of the tests abrasives prepared in the same manner as in the test. To neutralize the acid, add 1.0 ml of 0.5 mol/NaOH. Mix the slurries thoroughly, sample and dry the samples along with those from the test runs. Do not brush with these correction factor slurries.

These samples are counted along with the test samples.

#### H-3.11.2 Calculation of correction Factors

The correction factor  $C_1$  to be applied to all values of the test samples is calculated as follows:

$$C_f = \frac{\text{Mean counts for 4 reference samples}}{\text{Mean counts for 4 test samples}}$$

#### H-3.11.2.1 Correction factors for liquid scintillation counting

The correction is with regard to the amount of sample mixed with the scintillation cocktail. Each sample is weighed and the net count per minute (CPM) is divided by the mass to get a net CPM per gram of slurry. This net CPM per gram of values are then used in calculating abrasivity in place of net CPM values in **A-3.12**, and there is no  $C_f$  term.

#### H-3.11.2.2 Correction factors for liquid scintillation detection

Self-absorption and backscatter are less of a concern because of the liquid medium being used. Most modern liquid scintillation equipment will automatically colour-correct, so this is not a problem. The differences in mass of the samples do need to be accounted for in the calculation. To do this, each sample taken after brushing needs to be weighed to an accuracy of 0.01 g.

#### H-3.11.2.3 Applying the correction factor

Before calculating the relative abrasion values, the net CPM of each slurry is divided by the mass of the slurry used, to get a net CPM per gram of slurry. These values are then used in the calculation of relative abrasive values.



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### H-3.12 Calculation of Abrasivity Using Gieger-Muller Counting

#### H-3.12.1 Dentin Abrasivity

The dentin Abrasivity of the test dentifrices (or abrasives) is calculated as follows:

Mean reference net CPM =

$$\frac{\text{Pre} - \text{net CPM} + \text{Post} - \text{net CPM}}{2}$$

$$C_1 \times 100 \times \text{Test dentifrice}$$

$$\text{Dentifrice Abrasivity} = \frac{\text{net CPM}}{\text{Mean reference net CPM}}$$

#### H-3.12.2 Enamel Abrasivity

The enamel abrasivity of the test dentifrices for abrasives is calculated as follows:

Mean reference net CPM =

$$\frac{\text{Pre} - \text{net CPM} + \text{Post} - \text{net CPM}}{2}$$

$$C_1 \times 10 \times \text{Test dentifrice}$$

$$\text{Dentifrice Abrasivity} = \frac{\text{net CPM}}{\text{Mean reference net CPM}}$$

### H-3.13 Calculation of Abrasivity using Liquid Scintillation

#### H-3.13.1 Dentin Abrasivity

The dentin Abrasivity of the test dentifrices (or abrasives) is calculated as follows:

Mean reference net CPM per gram =

$$\frac{\text{Pre} - \text{net CPM per gram} + \text{Post} - \text{net CPM per gram}}{2}$$

Dentifrice Abrasivity =

$$\frac{100 \times \text{Test dentifrice net CPM per gram}}{\text{Mean reference net CPM per gram}}$$

#### H-3.13.2 Enamel Abrasivity

The enamel Abrasivity of the test dentifrices (or abrasives) is calculated as follows:

Mean reference net CPM per gram =

$$\frac{\text{Pre} - \text{net CPM per gram} + \text{Post} - \text{net CPM per gram}}{2}$$

Dentin Abrasivity =

$$\frac{10 \times \text{Test dentifrice net CPM per gram}}{\text{Mean reference net CPM per gram}}$$

NOTE — Centres for measuring toothpaste Abrasivity via RDA route:

Indiana University, School of Dentistry  
Oral Health Research Institute  
415 Lansing Street  
Indianapolis, Indian 46202  
USA

Missouri Analytical Grade Laboratories  
Marcus Research Laboratories, INC  
1820 Delmar Boulevard  
St. Louis, MO 63103 – 1798  
USA

## ANNEX J

[ Clause 4.4, Table 1, Sl No. (vii) ]

### DETERMINATION OF FLUORIDE ION

#### J-1 GENERAL

This method is suitable for the determination of water soluble fluoride species in tooth powder, including free fluoride and hydrolyzable complexes, for example, sodium mono fluorophosphate.

##### J-1.1 Principle

Water soluble species are converted to fluoride ion by acid hydrolysis. The fluoride ion activity is then determined potentiometrically with the help of fluoride ion sensitive electrode.

#### J-2 Apparatus

**J-2.1 pH Meter (Potentiometer)** — Scale readable to  $\pm 0.5$  mV or better.

**J-2.2 Fluoride Ion Sensitive Electrode** — Orion 94-09 or similar.

**J-2.3 Single Junction Reference Electrode** — Orion 90-01, or similar, with filling solution.

**J-2.4 Magnetic Stirrer**

**J-2.5 Polythene/Polypropylene Beakers and Volumetric Flasks** — 100, 250 ml and pipettes.

**J-2.6 Semi-log Graph Papers** — 2/3 cycles.

### J-3 REAGENTS

**J-3.1 Sodium Fluoride (Analytical Grade)**

**J-3.2 Trisodium citrate (Analytical Grade)**

**J-3.3 Sodium chloride (Analytical Grade)**

**J-3.4 Hydrochloric acid (Analytical Grade)** — 1 M.

**J-3.5 Sodium Hydroxide** — 1 M.

**J-3.6 Sodium Acetate Trihydrate (Analytical Grade)**

**J-3.7 Glacial Acetic Acid**

**J-3.8 Tisab L (Total Ionic Strength Adjusting Buffer) Solution** — Dissolve 294 g trisodium citrate, 29 g sodium chloride and 68 g sodium acetate trihydrate in 600 ml of hot water. Cool, adjust to pH 6.4 with glacial acetic acid. Dilute to 1 litre with distilled water.

**J-3.9 Tisab LF (TISAB Containing Fluoride) Solution** — Prepare 100 ml of 1 mg F-/100 ml solution. As described in I-3.8. Dissolve 294 g trisodium citrate, 29 g sodium chloride and 68 g sodium acetate trihydrate in 600 ml of hot water. Cool, pipette in 10 ml of 1mg F-/100ml solution and adjust to pH 6.4 with glacial acetic acid. Dilute to 1 litre with distilled water. Store in a polythene or polypropylene bottle.

**J-3.10 Fluoride Blank Solution**

Take 100 ml hydrochloric acid (1M) solution in 1 litre flask and then add 200 ml sodium hydroxide (1 M), by measuring cylinder. Dilute to 1 litre with distilled water and mix well.

**J-3.11 Standard Sodium Fluoride Solution (0.01 mg F per ml)**

Dry the sodium fluoride at 110 °C for 4 hours and transfer accurately 0.222 g to 100 ml volumetric flask. Add distilled water to dissolve the sodium fluoride and make up to the mark (Solution-X). Each ml of Solution-X contains 1mg fluoride ion (F<sup>-</sup>). Take 10 ml of this Solution-X in 1000 ml volumetric flask and make up this volume to the mark (Solution-Y). Each ml of Solution-Y contains 0.01 mg fluoride (F<sup>-</sup>) ion. Transfer Solution-X and Solution-Y to polythene bottles for storing.

**J-3.12 Preparation of Standard Solutions of Sodium Fluoride**

Take 1, 2, 5, 10, 20, 25 ml of Solution-Y (see I-3.11) in 100 ml volumetric flask marked A, B, C, D, E and F respectively. From Solution X (see I-3.11), pipette

out 0.5 and 1.0 mL and transfer to two separate 100 mL volumetric flasks marked as G, H. To each add 50 ml of TISAB L buffer solution and 10 ml of fluoride blank solution. Check that the pH is in the range of  $6.4 \pm 0.1$ , and if necessary correct with 1M NaOH or 1M HCl. Transfer quantitatively to a 100 ml polypropylene volumetric flask and make up the volume to 100 ml with distilled water. Now the solutions A, B, C, D, E, F, G and H are containing 0.01, 0.02, 0.05, 0.1, 0.2, 0.25, 0.5 and 1 mg of F per 100 ml respectively. Transfer the solutions to 150 ml polythene beaker for new measurement.

NOTE — Calibration curve can be plotted using any 5 consecutive concentrations depending on the expected concentration of fluoride from sample.

### J-4 MV MEASUREMENT OF STANDARD SOLUTIONS OF SODIUM FLUORIDE

#### J-4.1 Preparation of Electrodes

Remove protective cap and soak the fluoride electrode in TISAB L F solution for 15 min.

**J-4.2** Fill the reference electrode with filling solution.

**J-4.3** Rinse the electrodes with de-ionized water and keep the tips immersed in TISAB L F solution until immediately before use.

**J-4.4** Check that the electrodes are correctly connected to the pH meter.

**J-4.5** Rinse the electrodes with deionized water before use and carefully blot dry with a paper tissue.

### J-5 MV MEASUREMENT

**J-5.1** Transfer the contents of solution A from 100 ml flask into a clean, dry 150 ml polypropylene beaker.

**J-5.2** Immerse the tips of the electrodes in the solution while stirring the solution with a magnetic stirrer.

Ensure that no air bubbles adhere to the electrode surfaces.

**J-5.3** Leave until the potential reading is constant. This should take approximately 2 or 3 min.

**J-5.4** Record the potential reading in mV and check the temperature of the solution.

**J-5.5** Rinse the electrodes with de-ionised water and blot dry with a paper tissue.

**J-5.6** Repeat the procedure prescribed in I-5.1 to I-5.5 for 5 selected standard solutions to record mV of these solutions.

**J-5.7** Plot the calibration graph on semi log graph paper with the mV reading on the linear ordinate and the final concentration of fluoride in the standard F solution on



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the logarithmic abscissa. The graph should be a straight line with a gradient of -57-59 mV per decade change in concentration.

### J-6 TEST SOLUTION

**J-6.1** Discard the first 5 cm of powder from the container and then weigh about 5 g powder to the nearest mg. Add approximately 30 ml hot (90-95 °C) deionized water, a small amount at a time and slurry the powder with a micro spatula after each water addition.

Allow to cool. Dilute to 100 ml in a polypropylene volumetric flask and mix well.

**J-6.2** Ensure that the dispersion is homogeneous and then centrifuge about 60 ml of the dispersion in a polypropylene centrifuge tube, closed with a cap to prevent evaporation, until clear. This will take about 20 min at 4000 rpm.

**J-6.3** Pipette 20 ml of the clear supernatant into a 250 ml round-bottomed flask.

**J-6.4** Add a few anti-bumping granules then add 10 ml hydrochloric acid solution (1M approximately) by measuring cylinder. Attach a reflux condenser and boil gently for 5 min.

**J-6.5** Add, almost immediately, 20 ml of 1 M sodium hydroxide via the condenser, rinsing down with approximate 20 ml of distilled water. Then transfer quantitatively to a 100 ml polypropylene volumetric flask and dilute to volume with distilled water.

**J-6.6** Pipette 25 ml of the clear solution prepared above into a 100 ml polypropylene beaker, add 25 ml TISAB L (solution L) and check pH. If necessary adjust

to pH 6.4 by addition of approximately 1 M hydrochloric acid or 1 M sodium hydroxide. Transfer quantitatively into a 100 ml volumetric flask and dilute to volume.

**J-6.7** Transfer the contents of 100 ml flask to a clean, dry 100 ml polythene beaker, immerse the tips of the electrode in the solution while stirring the solution with a magnetic stirrer. Ensure that no air bubbles adhere to the electrode surfaces.

**J-6.8** Leave until the potential reading is constant (this should take two or three minutes). Record the potential reading in mV for the test solution. The reading for standard fluoride solutions and test solutions should be taken simultaneously.

### J-7 CALCULATION

A graph is plotted for concentration of F<sup>-</sup> against potential mV on a semi-logarithmic paper for standard F solutions. The potential mV is plotted on X-axis and concentration of Fluoride (mg of ) on Y-axis (on logarithmic scale). Read the F concentration in test solution for measured mV from this graph.

Concentration of F<sup>-</sup> in toothpowder, parts per million =

$$\frac{2a \times 10\,000}{M}$$

where

$a$  = mg of F<sup>-</sup> from calibration graph for test solution; and

$M$  = Mass of sample in g.

Advanced methods such as Ion Chromatography (IC)/Nuclear Magnetic Resonance (NMR) can also be used for the determination of fluoride ion, provided these methods are appropriately validated.

## ANNEX K

( Foreword )

### COMMITTEE COMPOSITION

Cosmetics Sectional Committee, PCD 19

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Fragrance and Flavours Association of India, (FAFAI), Mumbai	SHRI HASMUKH PATEL

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*Member Secretary*

SHRIMATI D. UMA  
SCIENTIST 'D' (PCD), BIS

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Consumer Education and Research Centre, Ahmedabad	SHRI H. S. TRIPATHI
Consumer Guidance Society of India, Mumbai	DR SITARAM DIXIT
	DR M. S. KAMATH ( <i>Alternate</i> )
	DR S. K. LUTHRA
	SHRI PRASUN BANDYOPADHYAY ( <i>Alternate I</i> )
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In Personal Capacity	



( *Continued from second cover* )

The composition of the Committee responsible for formulation of this standard is given at Annex K.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values ( *revised* )'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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This Indian Standard has been developed from Doc No.: PCD 19 (16525).

### Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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