IS 6037 (1970): Zinc Oxide-eugenol Dental Impression Paste
[MHD 8: Dentistry]

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Indian Standard

SPECIFICATION FOR ZINC OXIDE-EUGENOL DENTAL IMPRESSION PASTE

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INDIAN STANDARDS INSTITUTION
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 1

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July 1971

Indian Standard

SPECIFICATION FOR ZINC OXIDE-EUGENO'L DENTAL IMPRESSION PASTE

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Indian Standard

SPECIFICATION FOR **ZINC** OXIDE-EUGENOL DENTAL IMPRESSION PASTE

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 7 December 1970, after the draft finalized by the Dental Materials Sectional Committee had been approved by the Chemical Division Council.

0.2 In the preparation of this standard, assistance has been obtained from Specification No. **ASA Z 93.16** Impression paste — zinc oxide-eugenol type, of 1962, published by the American Standards Association, USA.

0.3 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*.** 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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1. SCOPE

1.1 This standard prescribes **the** requirements and the methods of sampling and test for zinc oxide-eugenol impression paste used in dentistry.

2. TYPES

2.1 The impression paste shall be of two types, namely:

a) Type 1 — hard, and

b) Type 2 — soft.

3. REQUIREMENTS

3.1 Ingredients — The impression paste shall be supplied in the form of two collapsible tubes, one containing the zinc oxide paste and the other containing the eugenol paste.

3.2 Description — Both ingredient pastes shall be clean and homogeneous, that is, free of foreign material, granules and crystals. They shall be of such

***Rules** for rounding off numerical **values** (*revised*).

consistency that they can be extruded easily from collapsible tubes. The two pastes shall mix readily when spatulated on a slab. The zinc oxide paste and the eugenol paste shall be of contrasting colours.

3.3 **Irritation** — The paste shall contain no ingredients other than eugenol which are irritating to the oral tissues. The eugenol paste shall contain not more than 17 percent eugenol by weight.

3.4 **Consistency of Mix** — The consistency, when tested as prescribed in A-2, shall be 30 mm *Min* and 50 mm *Max* for Type 1, and 20 mm *Min* and 45 mm *Max* for Type 2.

3.5 Setting **Time -The** initial setting time and final setting time, when tested as prescribed in A-3 and expressed in minutes shall be as follows:

	Initial Setting Time		*Final Setting Time, Max*
	Min	*Max*	
Type 1	3	6	10
Type 2	3	6	15

3.6 **Penetration Hardness** — The penetration hardness, when tested as prescribed in A-4, shall be 0·5 mm *Max* for Type 1, and 0·8 mm *Min* and 1·5 mm *Max* for Type 2.

3.7 **Cast Surface** — When tested as prescribed in A-S, it shall be possible to separate the set material clearly from a hardened gypsum cast.

3.8 **Instructions for Use** — The manufacturer shall supply with each package instructions for use of the material. These instructions shall include preferred proportions of the two components by weight and by volume, instructions for mixing them and instructions for preparing gypsum mix for test for cast surface.

4. PACKING AND MARKING

4.1 Packing — The material shall be packed as agreed to between the purchaser and the supplier.

4.2 **Marking** — The containers shall be marked with the following information:

a) Name and type of the material,

b) Lot number or month and year of manufacture,

c) Net weight, and

d) Eugenol content of eugenol paste (see 3.3).

4.2.1 The containers may also be marked with the ISI Certification Mark.

NOTE -**The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act, and the Rules and Regulations made thereunder. Presence of this mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard, under a well-defined system of inspection, testing and quality control during production. This system, which is devised and supervised by ISI and operated by the producer, has the further safeguard that the products as actually marketed are continuously checked by IS1 for conformity to the standard. Details of conditions, under which a licence for the use of the IS1 Certification Mark may be granted to manufacturers or processors,. may be obtained from the Indian Standards Institution.**

5. SAMPLING

5.1 Representative samples of the material shall be drawn as prescribed in Appendix B or as agreed to between the purchaser and the supplier.

APPENDIX A

(*Clauses* 3.4, 3.5 *and* 3.6)

METHODS OF TEST FOR ZINC OXIDE-EWGENOL DENTAL IMPRESSION PASTE

A-l. PREPARATION OF TEST SPECIMENS

A-l.1 Conduct preparation of test specimens at a temperature of 27 ±2°C and relative humidity of 50 ± 5 percent. Measure the ingredient pastes by weight in proportions specified by the manufacturer. Follow the mixing **technique** recommended by the manufacturer.

A-2. DETERMINATION OF CONSISTENCY

A-2.1 Apparatus — Any apparatus of the type shown in Fig. 1 may be used. It consists of a glass tube ('inside -diameter approximately 10 mm) which will deliver a definite volume (0·5 ml) of mixed paste, two flat glass plates, a 500-g weight and two thin plastics sheets. The combined weight of the top plate and the weight shall be 520 ± 2 g.

A-2.2 **Procedure** — Place 0·5 ml of the mixed paste (see **A-l.1**) with the glass measuring tube on-a. thin plastics -sheet on the glass plate. One and half minutes after starting the mix, place carefully on the soft paste a second plastics sheet, a second glass plate and the 500 g weight. Remove the weight ten minutes after starting the mix-and measure to the nearest mm the

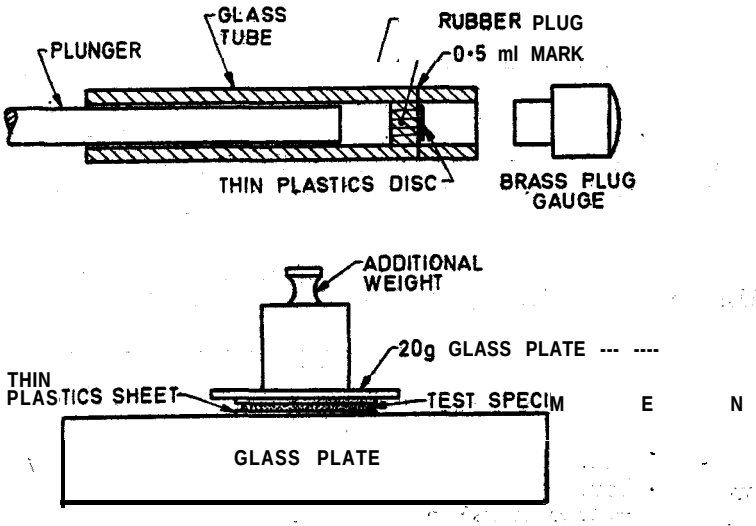


FIG. 1 APPARATUS FOR MEASURING CONSISTENCY

major and the minor diameters of the slumped mass of paste. Determine the average value of the diameter for three test specimens and report-. to the nearest mm.

A-3. DETERMINATION OF SETTING TIME

A-3.1 **Apparatus**

A-3.1.1 *Cup* — 25 mm diameter and 3 mm deep.

A-3.1.2 Steel Rod — 2·4 mm. in diameter with hemispherical ends and weighing 10 g.

A-3.1.3 *Pen&meter* — Xrebs or any other of similar accuracy. It shall be equipped with a- cylindrical indenter 1·58 to 1·60 mm in diameter, loaded so that the weight of the indenter and load shall be 50 g.

A-3.2 Procedure

A-3.2.1 *For Initial Setting* — Overfill the cup with the impression paste (see A-l.1) and strike off level the surfaee with a spatula. Measure time from the instant mixing is commenced. Apply to the surface of the paste the steel rod at 30-second intervals. Wipe the end of the rod clean after each application. The number of minutes, to the nearest half minute, elapsed from the starting of the mix to the time at which the paste ceases

to string when the rod is withdrawn shall be taken to the time of initial setting. Carry out three determinations and report the average to the nearest half minute as the time of initial setting.

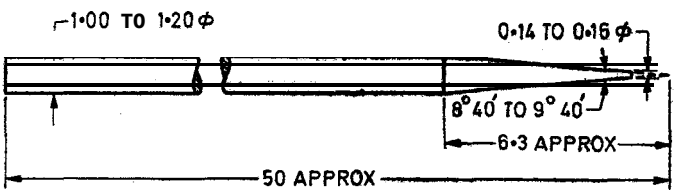
A-3.2.2 *For Final Setting- Use* the cup containing the set paste (A-3.2.1) for determining the time of final setting. Place the cup on the platen of the penetrometer, apply the indenter, to the surface of the paste for 10 seconds at 30-second intervals and measure the penetration. Record the number of minutes elapsed from the starting of the mix to the time when the penetration falls below 0·2 mm. Carry out three determinations and report the average, to the -nearest half-minute, as the time of final setting. Use the cup containing the set paste for test in A-4.2.

A-4. DETERMINATION OF PENETRATION HARDNESS

A-4.1 Apparatus

A-4.1.1 *Penetrometer* — any penetrometer permitting movement of the spindle without appreciable friction and which has been calibrated to yield results accurate to tenths of a millimetre. When the needle is mounted in a ferrule, the weight of the moving spindle shall be 47·5 ± 0·5 g. The total weight of the needle and spindle assembly shall be 50·0 ± 0·1 g. A weight of 50·00 ± 0·05 g shall also be provided for total load of 100 g.

A-4.1.2 *Needle* — as shown in Fig. 2, made of stainless steel. It shall be symmetrically tapered at one end to a cone. After tapering, the cone shall be ground off to a truncated cone. The truncation shall be square with the needle axis within 2 deg and the edge shall be sharp and free from burrs.



All dimensions in millimetres.

FIG. 2 NEEDLE FOR PENETRATION TEST

A-4.2 Procedure — Place the cup containing the set paste (A-3.2.2) on the platen of the penetrometer. Load so that the combined weight of the needle and the additional weight is 100 g. Thirty minutes after mixing of the paste is commenced, apply the loaded needle to the surface of the specimen and record penetration to the nearest 0·1 mm. Report the average of three determinations rounded off to the nearest 0·1 mm.

A-5. TEST FOR CAST SURFACE

A-5.1 Procedure — Prepare a specimen as prescribed in A-3.2.1. Box the specimen with a strip of wax so that the wax extends 25 mm above the surface of the specimen. Five minutes after final setting (see A-3.2.2) prepare a mix of gypsum according to manufacturer's directions and pour it into the boxed specimen and vibrate it to eliminate air bubbles at the interface. Two hours later, place the specimen in water at 60°C for 15 minutes. Separate the cast from the impression and examine visually the surfaces in contact for adherence.

A-5.1.1 The material shall be taken to have passed. the test if there is no 'evidence of adherence of the impression to the cast or of the cast to the impression.

APPENDIX B

(*Clause* 5.1)

SAMPLING OF ZINC OXIDE-EUGENOL DENTAL IMPRESSION PASTE

El. GENERAL REQUIREMENTS OF SAMPLING

R-l.0 In drawing, preparing, storing and handling test samples, the following precautions and directions shall be observed.

B-l.1 Samples shall not be taken in an exposed'place.

B-1.2 The sampling instrument shall be clean and dry.

B-1.3 Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument and the containers for samples from adventitious contamination.

B-l.4 To draw a representative sample, the contents of each container selected for sampling shall be mixed as thoroughly as possible by suitable means.

B-1.5 The samples shall be placed in clean, dry, air-tight glass or other suitable containers.

B-1.6 The sample containers shall be of such size that they are almost completely filled by the sample.

B-l.7 Each sample container shall be sealed air-tight with a suitable stopper after filling, and marked with full details of sampling, the date of sampling and the year of manufacture of the material.

B-2. SCALE OF SAMPLING

B-2.1 Lot-All the containers in a single consignment of the material drawn from a single batch of manufacture shall constitute a lot. If a consignment is declared or known to consist of different batches of manufacture, the containers belonging to the same batch shall be grouped together and each such group shall constitute a separate lot.

B-2.1.1 Samples shall be tested from each lot for ascertaining conformity of the material to the requirements of this specification.

B-2.2 The number of containers(n) to be selected from the lot shall depend on the size of the lot (N) and shall be as given in Table 1, subject to the provision that if n containers do not provide sufficient material for carrying out all the tests specified in 3, then at least as many containers as will provide sufficient material shall be taken out.

TABLE 1 NUMBER OF CONTAINERS TO BE SELECTED FOR SAMPLING

LOT SIZE (N)	NO. OF CONTAINERS TO BE SELECTED (n)
(1)	(2)
3 to 50	3
51 ,, 200.	4
201 ,, 400	5
401 ,, 650	6
651 ,, 1 000	7

B-3. TEST SAMPLES AND REFEREE SAMPLE

B-3.1 Preparation of Test Samples

B-3.1.1 *Zinc Oxide Paste* — Empty the contents of all the zinc oxide tubes selected into a 'clean-stoppered bottle. Thoroughly mix the contents and divide the composite sample into three equal parts, one for the purchaser, another for the supplier and the third-for the referee.

B-3.1.2 *Eugenol Paste* — Empty the contents of all the eugenol paste tubes -selected into a clean-stoppered bottle and thoroughly mix the contents. Divide the composite sample into three equal parts, one for the purchaser, another for the supplier and the third for the referee.

B-3.2 Referee **Sample** — The referee sample shall consist of one composite sample each of zinc oxide paste and eugenol paste, marked for this purpose

and shall bear the seal of the purchaser and the supplier. These shall be kept at a place agreed to between the purchaser and the supplier and shall be used in case of dispute.

B-4. NUMBER OF TESTS

B-4.1 Tests for all the characteristics given in 3 shall be conducted on the composite sample.

B-5. CRITERIA FOR CONFORMITY

B-5.1 A lot shall be declared as conforming to this specification if the composite sample satisfies the requirements for each of the characteristics listed in 3. If the requirements for any of the characteristics are not met, the lot shall be declared to have not satisfied the requirement of the specification.

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*6036-1970	Alginate dental impression material	—
6037.1970	Zinc oxide-eugenol dental impression paste	3.50
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