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Indian Standard

DENTAL MATERIALS — DENTAL ZINC POLYCARBOXYLATE CEMENTS — SPECIFICATION

UDC 616·314 : 615·463

BUREAU OF INDIAN STANDARDS
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NEW DELHI 110002

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Price Group 4

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Dentistry Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

In this standard, wherever possible, appropriate test methods have been specified as per the relevant Indian Standards concerning dental cements. However, in view of a number of unique properties exhibited by the carboxylate cements, it has been considered necessary to introduce certain new test methods.

This standard is based on ISO 4104 : 1984 'Dental zinc polycarboxylate cements' issued by the International Organization for Standardization (ISO).

This standard is one of a series of Indian Standards on dental cements. Other standards in the series are:

IS 6035 : 1986	Zinc phosphate dental cement (*first revision*)
IS 6039 : 1970	Zinc oxide-eugenol dental cement
IS 6043 : 1970	Copper phosphate-zinc phosphate dental cement
IS 6884 : 1983	Dental silicate cement.

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.

Indian Standard

DENTAL MATERIALS — DENTAL ZINC POLYCARBOXYLATE CEMENTS — SPECIFICATION

1 SCOPE

1.1 This standard specifies requirements for dental zinc polycarboxylate cements, the principal constituents of which are zinc oxide and aqueous solutions of polyacrylic acid or similar polycarboxylic compounds, or zinc oxide-polycarboxylic acid powders to be mixed with water.

1.1.1 The cements covered by this standard are used for joining or sealing appliances to oral structures or to other appliances, or to serve as a base or foundation for other filling materials or to serve as a temporary filling material.

2 REFERENCES

2.1 The Indian Standards listed below are necessary adjuncts to this standard:

IS No.	*Title*
1070 : 1992	Reagent grade water (*third revision*)
2088 : 1973	Methods for determination of arsenic (*second revision*)
7223 : 1986	Potassium chloride, analytical reagent (*first revision*)
7348 (Part 3) : 1975	Glossary of terms relating to dentistry Part 3 Dental materials
12572 (Part 10) : 1989	Guide for evaluation of medical devices for biological hazards: Part 10 Biological testing and evaluation of dental materials.

3 TERMINOLOGY

3.1 For the purpose of this standard, the definitions given in IS 7348 (Part 3) : 1975 shall apply.

4 TYPES

4.1 The cements covered by this specification shall be of two types, namely:

Type 1 — Luting material

Type 2 — Filling material

5 REQUIREMENTS

5.1 Material

The cement components shall consist of a powder and a liquid which, when mixed according to the manufacturer's instructions, will set to a condition suitable for its intended use.

5.2 Components

5.2.1 *Liquid*

The liquid shall be clear and there shall be no deposit or sediment inside the container. It shall be sufficiently free flowing for clinical use.

5.2.2 *Powder*

The powder shall be free from extraneous material such as dirt or lint. The pigment, if any, shall be uniformly dispersed throughout the powder.

5.3 Unset Cement

The cement, when mixed according to the manufacturer's instructions, shall be of a uniformly smooth consistency, completely mixed and shall not evolve gases.

5.4 Set Cement

The requirements for manipulation time, setting time, compressive strength, diametral strength, water-leachable material content, film thickness, and maximum arsenic content, shall be as given in Table 1 when tested as given in 7.

Table 1 Physical Requirements for Set Cement

Type	Minimum Manipulation Time	Maximum Setting Time	Minimum Compressive Strength	Minimum Diametral Strength	Maximum Water-Leachable Material Content	Maximum Film Thickness	Maximum Acid Soluble Arsenic Content
	Min	Min	MPa	MPa	S. m-1 kg-1	μm	ppm
1	1·5	9·0	50	6	40	25	2·0
2	1·5	5·0	50	6	40	—	2·0

NOTE — Both the manipulation time and setting time are measured from the end of the mixing time (setting time is usually measured from the start of mixing).

5.5 Freedom From Toxicity

The mixed material, when used in accordance with the manufacturer's instructions, shall neither cause prolonged damage to oral tissues, nor have any adverse systemic effect [*see* IS 12572 (Part 10) : 1989].

5.6 Instructions to be Provided by the Manufacturer

Instructions for proportioning and manipulating the cement shall include the following details:

a) information regarding the mixing temperature and its effects, the nature of the slab or pad and of the spatula to be used;

b) the powder/liquid ratio (stated as a mass: mass ratio, in grams of powder per gram of liquid); and a recommended technique for dispensing this powder/liquid ratio;

c) the rate of incorporation of the powder into the liquid;

d) the time of mixing; and

e) the minimum satisfactory manipulation time after the end of mixing, including conditions required for testing.

6 SAMPLING AND INSPECTION

6.1 Sampling

The method of sampling shall be subject to the agreement between the purchaser and the supplier. A test sample shall consist of one or more retail packages from the same batch, containing sufficient material to carry out the tests plus an allowance for repeats, if necessary.

6.2 Inspection

The components of the cement shall be inspected visually under a magnification of 10 X to determine compliance of the requirements given in **5.2.1** and **5.2.2**.

7 TEST METHODS

7.1 Preparation of Test Specimens

7.1.1 *Conditioning*

Unless otherwise stated, all specimens shall be prepared at 27 $\pm$1°C and at a relative humidity of 65 $\pm$ 5 percent.

7.1.2 *Apparatus for Mixing*

7.1.2.1 *Mixing slab* as specified by the manufacturer [*see* **5.6**(a)].

7.1.2.2 *Spatula*, made from a material not affected by the cement [*see* **5.6**(a)].

NOTES

1 It shall be ensured that all instruments and apparatus used in mixing and testing the cements are clean, dry, and free from particles of hardened cement.

2 Before commencing mixing of the cement all the apparatus and equipment shall be brought to the conditions specified in **7.1.1**.

7.1.3 *Method of Mixing*

a) Place the correct quantities of powder and liquid, using the powder/liquid ratio as stated in the manufacturer's instructions, on the mixing slab (*see* **7.1.2.1**).

b) Mix the material in accordance with the manufacturer's instructions.

c) Do not allow any powder or liquid to remain on the mixing slab when mixing has been completed.

7.1.4 *Powder/Liquid Ratio for Testing*

The powder/liquid ratio stated in the manufacturer's instructions [*see* **5.6**(b)] shall be used for all testing procedures in this Standard.

7.2 Manipulation Time

7.2.1 *Apparatus*

7.2.1.1 *Polished glass slab* — approximately 150 mm long × 75 mm wide × 20 mm thick.

7.2.1.2 Spatula, made from a material not attacked or corroded by the cement.

7.2.1.3 Two flat glass plates, each 50 mm square and approximately 3 mm thick.

7.2.1.4 A dispensing device consisting of a glass tube and a polytetrafluoroethylene (PTFE) plunger, to deliver 0·5 ml of mixed cement in the form of a cylinder 6 mm high and 10 mm in diameter.

7.2.1.5 A 100 g mass, or equivalent loading device.

7.2.1.6 *Stopwatch*

7.2.2 *Procedure*

Place on one glass plate (*see* **7.2.1.3**) 0·5 ml of the mixed cement from the dispensing device (*see* **7.2.1.4**). One minute after completion of mixing, place the other glass plate (*see* **7.2.1.3**) on top followed by the application of the mass of 100 g (*see* **7.2.1.5**). Remove the load 10 min after the start of mixing and record the disc diameter as the average of at least two measurements at 90° to each other. Continue trials at least in triplicate at increases of 30 s intervals until the disc diameter is reduced by 10 percent or more from the diameter obtained from the first test at 1 min after the completion of mixing.

7.2.2.1 Determine the manipulation time as the time elapsed from the end of mixing to the time at which the application of the load results in a reduction of disc diameter by 10 percent from the diameter obtained from the first test at 1 min after the completion of mixing.

7.3 Setting Time

7.3.1 *Apparatus*

7.3.1.1 A cabinet capable of being controlled at 37 ± 1°C and a relative humidity of at least 30 percent.

7.3.1.2 Indentor. A mass of 400 ± 1 g, having a flat end of diameter 1·0 ± 0·1 mm. The needle tip shall be cylindrical for a distance of approximately 5 0 mm. The needle end shall be plane and at right angles to the axis of the rod.

7.3.1.3 Metal moulds as shown in Fig. 1.

7.3.1.4 Metal block of dimensions 8 mm × 20 mm × 10 mm minimum, either as part of **7.3.1.1** or **7.3.1.2** or as a separate item.

7.3.1.5 *Aluminium foil*

7.3.2 *Procedure*

Place the mould (*see* **7.3.1.3**) conditioned to 27 ± 1°C on a piece of the aluminium foil (*see* **7.3.1.5**) of convenient size and fill to a level surface with cement.

One minute after completing the mix, place the assembly containing the specimen on the metal block (*see* **7.3.1.4**), which has been conditioned to 37 ± 1°C in the cabinet (*see* **7.3.1.1**) and replace the block, mould and specimen in the cabinet. One and a half minutes after completing the mix, carefully lower the indentor (*see* **7.3.1.2**) vertically on to the surface of the cement and allow to remain there for 5 s. Repeat this operation at 30 s intervals until near the expected time of setting, at which stage it should be carried out at 15 s intervals. Maintain the needle in a clean condition by cleaning, if necessary, between indentations. A trial run may be necessary for determining the approximate setting time.

7.3.2.1 Record the setting time as the period which elapses from the completion of mixing to the time when the needle fails to make a perceptible circular indentation on the surface of the cement, when viewed under a hand lens of magnification X 2. Make three such tests and determine the mean setting time, rounded off to the nearest15 s.

7.4 Compressive Strength

7.4.1 *Apparatus*

7.4.1.1 Water bath at 37 ± 1°C or a cabinet capable of being controlled at 37 ± 1°C and a relative humidity of 90 to 100 percent.

7.4.1.2 Split moulds and plates such as those shown in Figure 2, of internal height 6·0 ± 0·1 mm and internal diameter 4·0 ± 0·1 mm, made of stainless steel or other suitable material that will not be attacked or corroded by the cement.

NOTE — To facilitate the removal of the hardened cement specimen, the internal surface of the moulds and plates should be evenly coated, prior to filling, with a 3 percent solution of micro-crystalline or paraffin wax in pure toluene. Alternatively a thin film of silicone grease of PTFE dry film lubricant may be used.

7.4.1.3 Individual screw clamps such as those shown in Fig. 2.

7.4.1.4 Compressive strength testing apparatus having a crosshead speed of 1 mm/min.

7.4.1.5 *Filter paper*

7.4.1.6 Micrometer or similar measuring instrument, accurate to 10 μm.

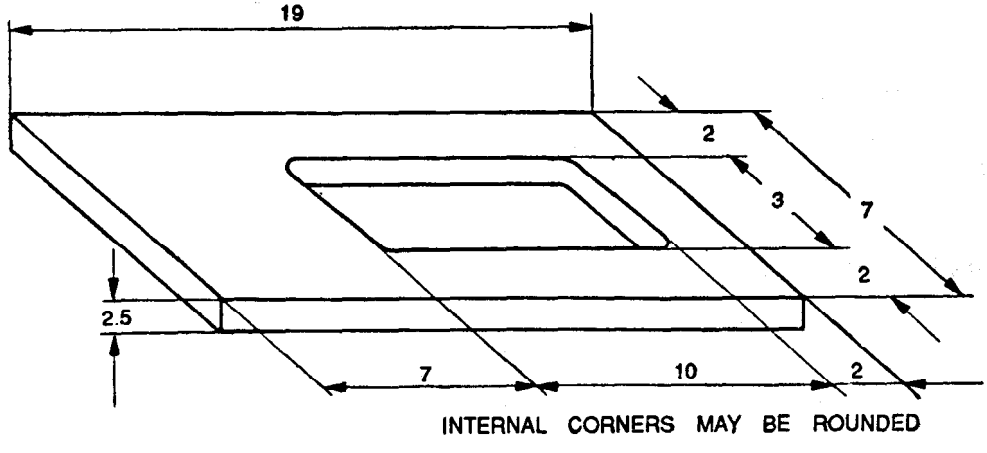

FIG. 1 MOULD FOR USE IN DETERMINING SETTING TIME

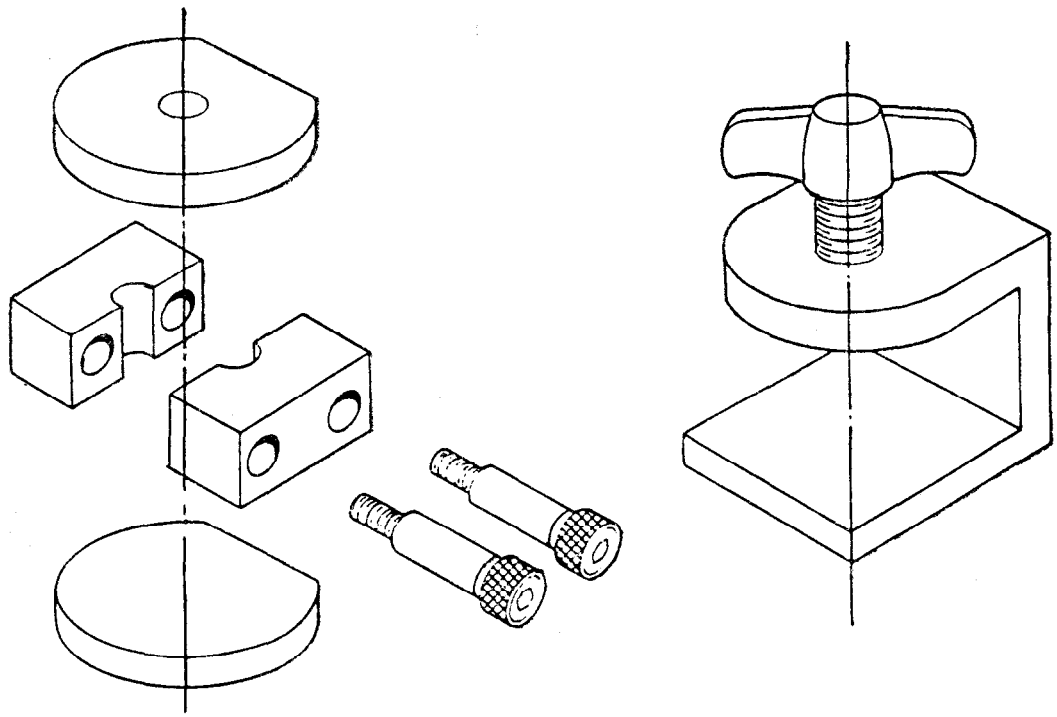

FIG. 2 MOULD AND CLAMP FOR PREPARATION OF COMPRESSIVE TEST SPECIMEN

7.4.2 *Preparation of Test Specimens*

7.4.2.1 Condition the moulds (*see* **7.4.1.2**), screw clamps (*see* **7.4.1.3**), and top and bottom plates (*see* **7.4.1.2**) at 27 ± 1°C. After mixing in accordance with the manufacturer's instructions, pack the cement, to a slight excess, into the split mould within 1 min of the completion of mixing.

NOTE — In order to consolidate the cement and avoid trapping of air, it is advisable to convey the largest convenient portions of mixed cement to the mould and apply to one side with a suitable instrument. Fill the mould to excess in this manner and then place on the bottom plate with some pressure.

7.4.2.2 Remove any bulk extruded cement, place the top metal plate in position and manually squeeze together. Put the moulds and plates in the clamp and screw tightly together. Not later than 3 min after the completion of mixing, transfer the whole assembly to water bath or cabinet (*see* **7.4.1.1**), controlled at 37 ± 1°C and 90 to 100 percent relative humidity.

7.4.2.3 One hour after the completion of mixing, remove the plates and level the ends of the specimen plane, at right angles to its long axis. Grind the ends flat and remove any excess cement by drawing back and forth on a glass plate with a small amount of 45 μm (350 mesh) silicon carbide powder mixed with water, or equivalent waterproof silicon carbide abrasive paper. Keep both ends of the specimen wet during the grinding and rotate about one-quarter turn every few strokes.

7.4.2.4 Remove the specimen from the mould immediately after surfacing and rapidly check for air voids or chipped edges. Discard any defective specimen.

7.4.2.5 Immerse each acceptable specimen in distilled water or water of equivalent purity and maintain at 37 ± 1°C for 23 hours.

7.4.3 *Procedure*

Twenty-four hours after the completion of mixing, determine the compressive strength of the test specimens in the following manner using the testing apparatus (*see* **7.4.1.4**) at a cross-head speed of 1 mm/min. Measure the diameter of the test specimen using a micrometer (*see* **7.4.1.6**). Place the specimen with the flat ends covered with a piece of wet filter paper (*see* **7.4.1.5**) between the platens of the testing apparatus such that the load is applied in the long axis of the specimen. Record the maximum load applied when the specimen fractures.

7.4.4 *Expression of Results*

Calculate the compressive strength, P, in megapascals, using the formula:

$$P = \frac{4F}{D^2}$$

where

F = is the maximum applied load, in newtons;

D = is the diameter of the specimen, in millimetres.

Carry out five determinations.

If all the five, or four out of the five results obtained are below the appropriate limit specified in the Table 1, the material shall be deemed to have failed the test. If all the five, or four out of five results obtained are above the appropriate limits specified in the Table 1, the material shall be deemed to have passed the test. In other cases, prepare a further 10 specimens and obtain the median result for all 15 specimens. Round off this value to the nearest two significant figures and record as the compressive strength.

7.5 Diametral Strength

7.5.1 *Apparatus*

As detailed in **7.4.1.**

7.5.2 *Preparation of Test Specimens*

As detailed in **7.4.2.**

7.5.3 *Procedure*

Twenty-four hours after the completion of mixing, determine the diametral strength of the test specimens in the following manner, using the testing apparatus (*see* **7.4.1.4**) at a cross-head speed of 1 mm/min. Measure the diameter and length of the test specimen using a micrometer (*see* **7.4.1.6**).

Place the specimen with the diametral surfaces covered with a piece of wet filter paper between the platens of the testing apparatus so that the load is applied in the short axis of the specimen. Record the maximum load applied, when the specimen fractures.

7.5.4 *Expression of Results*

Calculate the diametral strength, T, in megapascals, using the formula:

$$T = \frac{2F}{lD}$$

where

F = maximum applied load, in newtons;

D = diameter of the specimen, in millimeters;

l = length of the specimen, in millimeters.

Carry out five determinations.

If all the five, or four out of the five results obtained are below the appropriate limits specified in Table 1, the material shall be deemed to have failed the test. If all the five, or four out of the five results obtained are above the appropriate limits specified in Table 1, the material shall be deemed to have passed the test. In other cases, prepare a further 10 specimens and obtain the median result for all 15 specimens. Round off this value to the nearest two significant figures and record as the diametral strength.

7.6 Film Thickness (*Type 1* cements only)

7.6.1 *Apparatus*

7.6.1.1 Two optically flat round glass plates of minimum 5 mm thickness, having a contact area of 200 ± 10 mm^2.

7.6.1.2 Loading device, such as that shown in Fig. 3, to apply a load of mass 15 kg on anvils.

7.6.1.3 Micrometer or a similar measuring instrument, accurate to 1 μm.

7.6.2 *Procedure*

Measure the combined thickness of the two glass plates (*see* **7.6.1.1**) in contact to an accuracy of 1 μm. Deposit a sufficient (approximate 0·1 ml) quantity of cement, mixed as described in **7.1,** to cover the plate on the centre of one of the glass plates (*see* **7.6.1.1**). Place the second glass plate centrally on this cement. One and a half minutes after completing mixing, carefully apply, by means of the loading device (*see* **7.6.1.2**), a load of mass 15 kg vertically on the top plate and leave for 7 min. It is essential to ensure that the cement completely fills the area between the two glass plates. Ten minutes after the commencement of mixing, measure the thickness of the two glass plates and the cement film, using the micrometer (*see* **7.6.1.3**). Calculate the difference in the thickness of the plate with and without the cement film and record this as the thickness of the film. Report the mean of three such tests to the nearest 5 μm.

7.7 Water-leachable Material Content

Carry out the determination in duplicate.

7.7.1 *Apparatus*

7.7.1.1 A cabinet, capable of being controlled at 37 ± 1°C and a relative humidity of 90 to 100 percent.

7.7.1.2 Mould, consisting of a split brass or stainless steel ring contained in a former or retaining ring as shown in Fig. 4. The height of the ring shall be $1{\cdot}0 \pm 0{\cdot}03$ mm and the internal diameter $10 \pm 0{\cdot}3$ mm.

7.7.1.3 *Individual screw clamps*

7.7.1.4 *Platinum wire, thread or unwaxed dental floss*

7.7.1.5 Two wide mouthed polyethylene bottles of approximately 50 ml capacity, as shown in Fig. 5.

7.7.1.6 *Wheatstone bridge*

7.7.1.7 A conductivity cell, consisting of two platinum electrodes approximately 15 mm in diameter and mounted parallel to each other 7 mm apart.

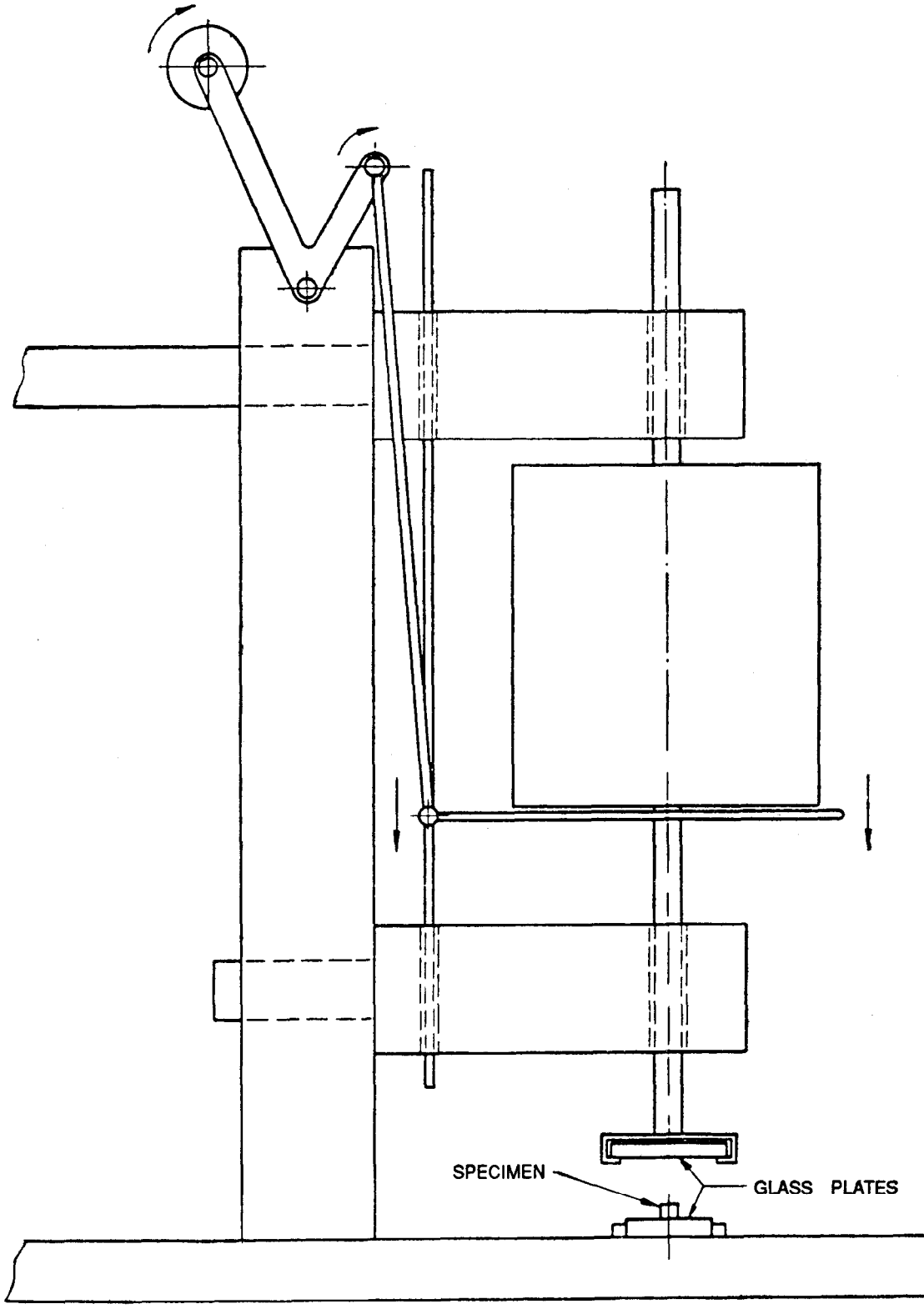

FIG. 3 LOADING DEVICE FOR USE IN FILM THICKNESS TEST

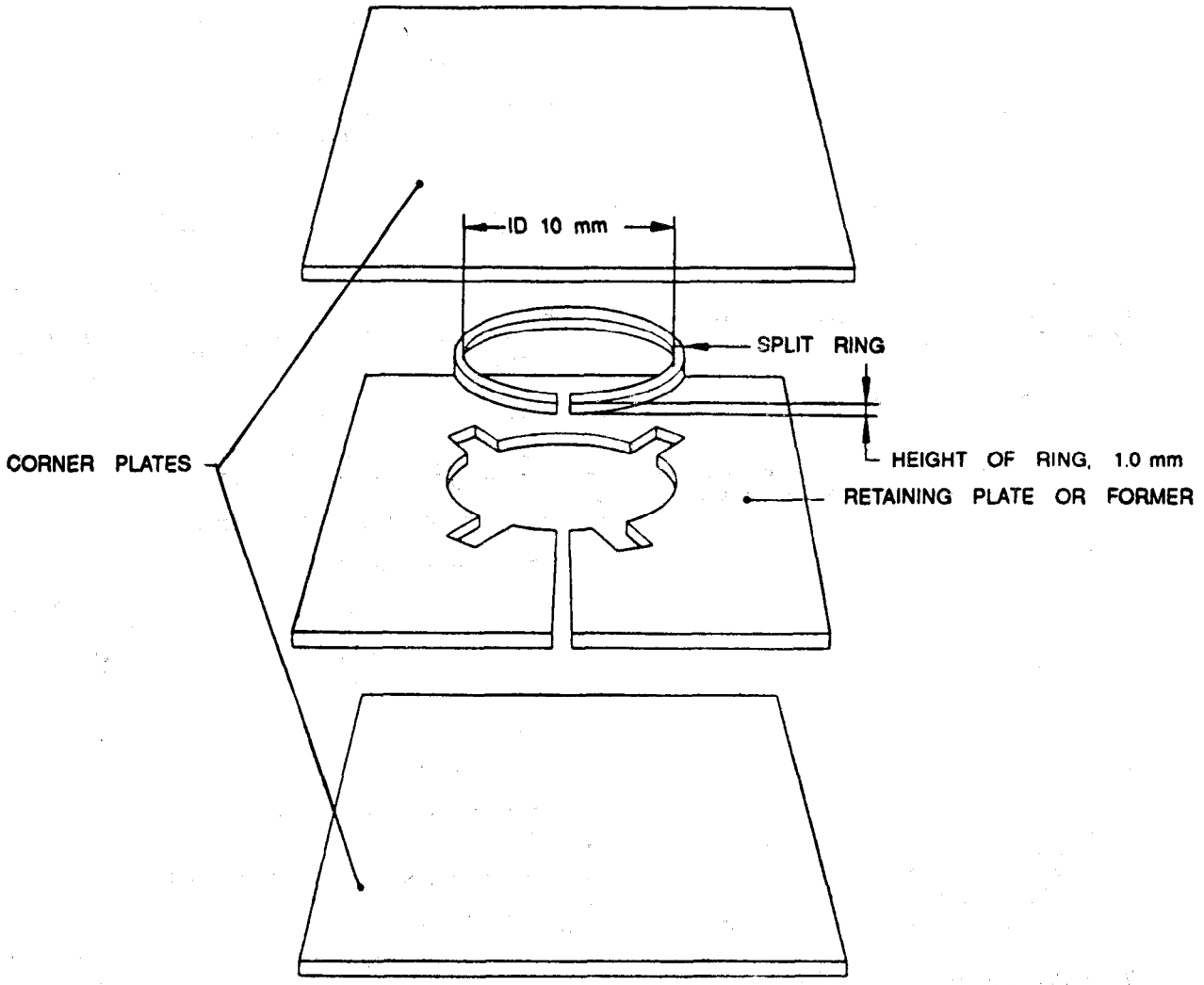

FIG. 4 MOULD FOR PREPARATION OF SPECIMENS FOR WATER-LEACHABLE MATERIAL CONTENT TEST

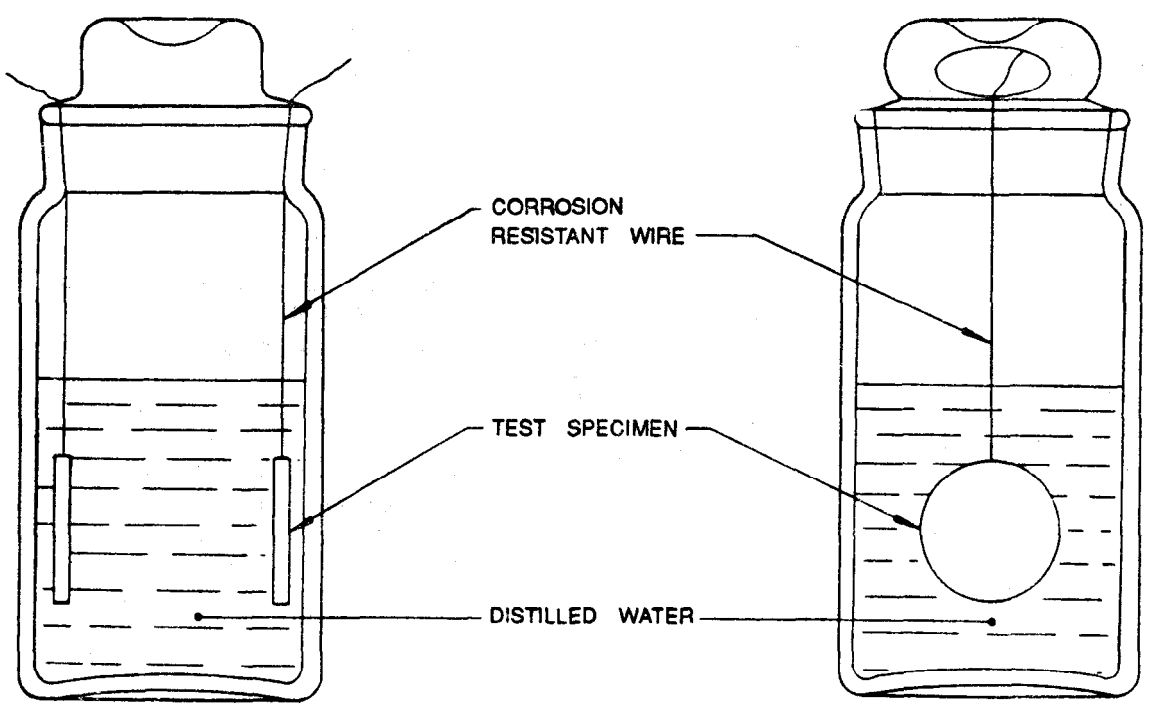

FIG. 5 WEIGHING BOTTLES CONTAINING SPECIMENS FOR WATER-LEACHABLE MATERIAL CONTENT TEST

7.7.1.8 Thin sheets of polyethylene or cellulose acetate.

7.7.1.9 Flat metal or glass plate.

7.7.2 *Reagent*

Potassium chloride analytical grade (*see* IS 7223 : 1986) standard solution [c(KCl)=0·1 mol/l].

Disssolve 7·455 g of potassium chloride in 1 000 ml of distilled water or water of equivalent purity (*see* IS 1070 : 1992).

7.7.3 *Preparation of Test Specimen*

Place the mould (*see* **7.7.1.2**) on a thin polyethylene or cellulose acetate sheet (*see* **7.7.1.8**) backed by a flat plate (*see* **7.7.1.9**). Insert a convenient tared length of wire or dental floss through the split ring so that at least 4 mm projects into the ring. Fill the split ring with cement mixed as described in **7.1**. Cover with a further plate faced with a sheet of polyethylene or cellulose acetate, press firmly together and apply the screw clamp. Two minutes after the completion of mixing, place the mould, plates and the screw clamp into the cabinet (*see* **7.7.1.1**).

After 1 h, remove the plates and polyethylene or cellulose acetate sheets from the clamp and carefully separate the cement disc and attached wire or dental floss from the split ring. Remove any surplus cement from the edge of the disc and lightly brush the surface to remove any loose material. Prepare two such specimens.

7.7.4 *Preparation of Test Solution*

Weigh the two prepared specimens immediately and suspend, by means of the wire or unwaxed dental floss, in 40·0 ml of water contained in the polyethylene bottle (*see* **7.7.1.5**). Ensure that the specimen only just touches the side of the bottle. Close the lid as tightly as possible and store for 23 hours at 37±1°C.

7.7.5 *Procedure*

Remove the specimens from the bottle. Immerse the conductivity cell in the test solution (40·0 ml) and measure the electrical conductance *G*. Record the conductance *Go*, of distilled water [after storage at 37°C for 24 h in a polyethylene bottle (*see* **7.7.1.5**)]. Measure the conductance, *Gs*, of the standard potassium chloride solution. Make all determinations of conductance at 27±1°C.

Calculate the cell constant, *K*, in metres to the power of minus one, using the literature value of specific conductance of 0·1 mol/l potassium chloride solution at 27°C (that is 1·338 $S.m^{-1}$) in the formula:

$$K = \frac{1{\cdot}338}{Gs - Go}$$

Convert the conductance reading for the test solution to a specific conductance value in Siemens per metre ($S.m^{-1}$) using the equation for specific conductance:

$$\sigma = K(G - Go)$$

This specific conductance, σ, should be divided by the mass of the sample to give a conductivity value in Siemens per metre per g ($S.m.^{-1}.g^{-1}$) which is then multiplied by 1000 to give the result in the recognized SI units of Siemens per metre per kilogram.

NOTE — The value of specific conductance 0·1 mol/l aqueous potassium chloride at 27°C (that is 1·338 siemens per metre) has been derived from the known specific conductance of potassium chloride solution at 23°C, that is, 1·239 siemens per meter, under the assumption that the conductance of inorganic compounds in water generally varies about 2 percent per °C for ±10°C variation around 25°C.

7.8 Acid-Soluble Arsenic Content

7.8.1 *Preparation of Sample*

Powder the set cement and sieve through a 75 μm (200 mesh) sieve. Disperse 2 g of the sieved powder in 40 ml of water and add 10 ml of hydrochloric acid (35 percent m/m, 1·18 g/ml). Use this solution for determination of acid-soluble arsenic content.

7.8.2 *Procedure*

Method as given in IS 2088 : 1983 shall be followed.

8 PACKAGING AND MARKING

8.1 Package

The components shall be supplied in securely sealed containers made from materials which neither react with, nor permit contamination of the contents.

NOTE — For the purpose of this standard the container shall be considered to be the immediate wrapping of the component.

8.2 Instructions for Use

Instructions for proportioning and handling the powder and liquid shall accompany each package.

8.3 Marking Containers

Each container shall be clearly marked with the following particulars:

a) The indication of the source of manufacture and type of cement;

b) A serial number or code and the date of manufacture for that particular lot of cement powder or liquid (*see* **5.1**);

c) The minimum net mass, in grams, of the powder and the liquid, as appropriate;

d) For capsulated materials, where the manufacturer supplies different materials or quantities of the same type of capsule, each capsule shall be suitably coded to indicate its contents; and

e) Recommended storage conditions.

Standard Mark

The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The Standard 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 which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

Bureau of Indian Standards

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Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Handbook' and 'Standards Monthly Additions'. Comments on this Indian Standard may be sent to BIS giving the following reference:

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