IS 12797 : 1989
(Reaffirmed 1994)

Indian Standard

DENTAL MATERIALS — DENTAL GLASS POLYALKENOATE CEMENTS — SPECIFICATION

भारतीय मानक

दन्त सामग्री — दंत्य कांच पालिएलकिनोएट सीमेंट — विशिष्टि

UDC 615·463 : 616·314

BUREAU OF INDIAN STANDARDS
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NEW DELHI 110002

July 1990

Price Group 4

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards on 20 September 1989, after the draft finalized by the Dental Materials Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard is based on ISO 7489-1986 'Dental glass polyalkenoate cements', issued by the International Organization for Standardization (ISO).

The term 'glass polyalkenoate' is now preferred to 'glass ionomer' which is deprecated.

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, 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 the standard.

Indian Standard

DENTAL MATERIALS — DENTAL GLASS POLYALKENOATE CEMENTS — SPECIFICATION

1 SCOPE

1.1 This standard prescribes requirements for dental glass polyalkenoate cements produced by the reaction between a powder of acid soluble, aluminosilicate glass and an aqueous solution of a polyalkenoic acid.

1.2 Polyalkenoate cements prepared by the addition of water to a mixture of dry acid and aluminosilicate glass are also covered by this standard.

2 REFERENCES

The following Indian Standards are necessary adjuncts to this standard:

IS No.	*Title*
1070 : 1977	Specification for water for general laboratory use (*second revision*)
2088 : 1983	Method of determination of arsenic (*second revision*)

3 TYPES

3.1 The cements covered by this standard shall be classified according to their intended use as follows:

Type 1 — Luting agent

Type 2 — Restorating material

3.1.1 Materials used to fill or seal pits and fissures may be of either *Type 1* or *Type 2*.

4 REQUIREMENTS

4.1 Components

4.1.1 *Liquid*

The liquid shall be free from visible deposits or filaments on the inside of its container. There shall be no visible signs of gelling.

4.1.2 *Powder*

The powder shall be free from extraneous material and, if coloured, the pigments shall be uniformly dispersed throughout the powder.

4.2 Cement

The cement prepared and mixed in accordance with **6.1.3** shall be of uniform, smooth texture and shall not evolve gases.

4.3 Colour of Set Cement

For those cements with a shade guide supplied by the manufacturer, the following additional test shall be carried out. After immersion in water at 37 ± 1°C for 7 days, the colour of the set cement, when viewed under water and in natural day light, shall, within the limits of professional acceptance, match the manufacturers' shade card.

4.4 Physical Requirements

The film thickness, setting time, working time, compressive strength, water leachable content, opacity, acid-soluble arsenic content, and lead content shall be as specified in Table 1, when tested in accordance with the appropriate test methods given in **6**.

Table 1 Requirements for Dental Glass Polyalkenoate Cements

(*Clauses* 4.4, 6.5.3.3, *and* 6.6.4.2)

Sl No.	Characteristic	Requirement		Test Method (Clause Ref)
		Type 1	Type 2	
i)	Film thickness, μm, *Max*	25	—	6.2
ii)	Setting time, minutes, *Max*	7·5	5	6.3
iii)	Working time, minutes, *Max*	2·0	1·75	6.4
iv)	Compressive strength, MPa, *Min*	65	125	6.5
v)	Water leachable content, percent *m/m*, *Max*	1·0	0·7	6.6
vi)	Opacity, $C_{0\cdot70}$ value, *Min*	—	0·35	6.7
	Max		0·90	
vii)	Acid soluble arsenic content, mg/kg (ppm), *Max*	2·0	2·0	6.8
viii)	Lead content, mg/kg (ppm), *Max*	50	50	6.9

4.5 Freedom from Toxicity

The mixed cements, when used in accordance with the manufacturers instructions shall neither cause prolonged damage to oral tissues nor have any adverse systemic effect (*see* **4.6**).

4.6 Manufacturers' Instructions

Instructions for the preparation, mixing and manipulation shall accompany each container of liquid and shall include the following:

a) The recommended temperature range for preparation, condition and type of both the slab and spatula, or the type of mixing machine;

b) The optimum powder/liquid ratios over the recommended temperature range

(*see* 4.6). This requirement, however, shall not apply to capsulated materials for which it is inappropriate;

c) The method of mixing and the time of mixing and, in the case of hand-mixed materials, the rate of incorporation of the powder;

d) The manipulation time after completion of mixing;

e) A statement recommending that, when clinical conditions warrant, a linear should be placed between the cement and dentine;

f) For materials where the polyacid is present in aqueous solution, a recommendation that the liquid should be kept in a moisturetight container to avoid contamination or less of moisture;

g) The precise powder/liquid ratio on a mass basis to an accuracy of 0·1, at a temperature of 27 ± 2°C and a relative humidity of 65 ± 5 percent, to be used when it is desired to carry out tests on the material;

and

h) A technique for protecting the cement against early contamination by water.

5 SAMPLING

A sample drawn from each batch shall provide sufficient powder and liquid to complete all the prescribed tests.

6 TEST METHODS

6.1 Preparation of Test Specimens

6.1.1 *Conditioning*

Prepare the test specimens at a temperature of 27 ± 2°C and a relative humidity of 65 ± 5 percent.

6.1.2 *Apparatus*

6.1.2.1 *Polished glass mixing slab*

Approximately 150 mm long × 75 mm wide × 20 mm thick slab of glass.

6.1.2.2 *Spatula*

Made of a material which will not react with, or be abraded by the components.

NOTE — Apparatus used for mixing and testing should be kept clean, dry and free from hardened particles of cement.

6.1.3 *Method of Mixing*

Completely mix the powder and liquid as quickly as possible to a uniform smooth texture in accordance with the manufacturers' instructions (*see* 4.6).

6.2 Film Thickness (for Type 1 Cements Only)

6.2.1 *Apparatus*

6.2.1.1 *Two optically-flat, square or circular glass plates*

Having a contact surface area of approximately 200 mm² and of a uniform thickness of not less than 5 mm.

6.2.1.2 *Loading device*

The type shown in Fig. 1, generating a force of 147 N obtained by using a mass of 15 kg. The bottom surface of the rod supporting the load shall be horizontal and parallel to the base and large enough to cover one of the glass plates. The loading device shall be capable of applying the load smoothly and with no rotational motion. The glass plates shall be held on the base by guides to prevent movement or rotation when the load is applied.

6.2.1.3 *Micrometer*, accurate to ·001 mm (1 μm).

6.2.2 *Procedure*

Measure the thickness of the two optically-flat glass plates (*see* **6.2.1.1**) stacked in contact to an accuracy of ± 0·5 μm (reading A). Place a small quantity of mixed cement on the centre of one of the glass plates and place the plate in the guides. Place the other glass plate centrally on the first plate.

6.2.2.1 Two minutes after the start of mixing, carefully apply a force of 147 N vertically on the top plate and leave for 7 minutes. Ensure that the cement completely fills the space between the two glass plates.

6.2.2.2 Ten minutes after the start of mixing, remove the force that had been applied and measure the thickness of the two glass plates and cement film (reading B).

6.2.2.3 Calculate the thickness of the film as the difference between reading B and reading A. Record the mean result of three such tests to the nearest 1 μm.

6.3 Setting Time

6.3.1 *Apparatus*

6.3.1.1 *Oven or cabinet*

Oven shall be capable of being maintained at a temperature of 37 ± 1°C and a relative humidity of at least 90 percent.

6.3.1.2 *Indentor*

Indentor shall have mass 400 ± 5 g and a flat end of diameter 1·0 ± 0·01 mm. The needle tip shall be cylindrical for a distance of approximately 5 mm and the needle end shall be plane and perpendicular to the long axis of the needle.

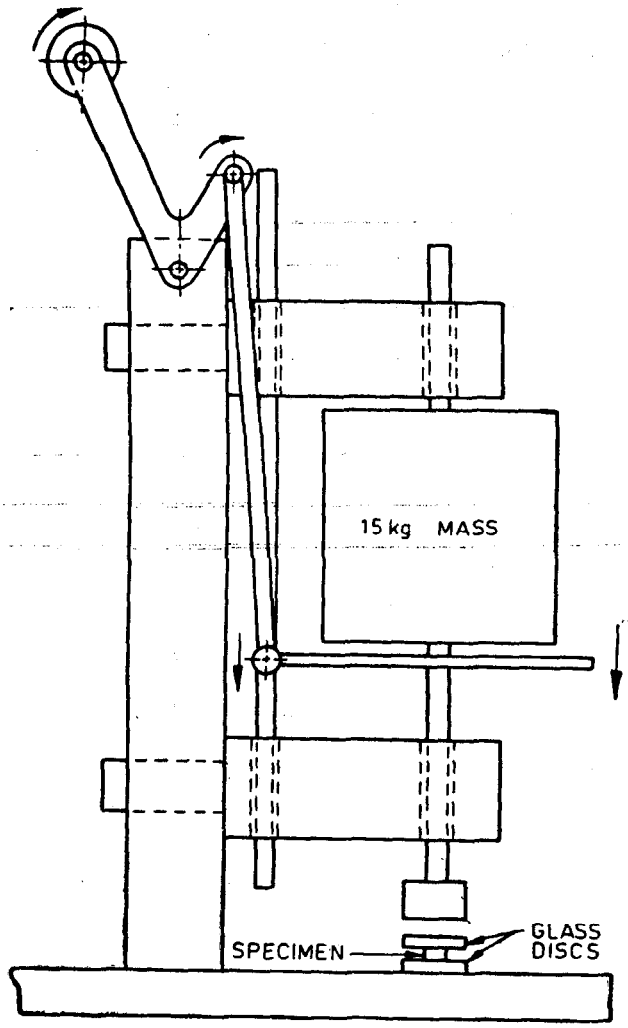


FIG. 1 LOADING DEVICE FOR FILM THICKNESS TEST

6.3.1.3 *Metal mould*

Metal mould shall be similar to that shown in Fig. 2 made of non-corrodible metal.

6.3.1.4 *Metal block*

Minimum dimensions 8 mm × 75 mm × 100 mm.

6.3.1.5 *Non-reactive aluminium foil*

6.3.2 *Procedure*

Place the mould (*see* **6.3.1.3**), conditioned to 37 ± 1°C, on the aluminium foil (*see* **6.3.1.5**) and fill to a level surface with mixed cement.

6.3.2.1 Two minutes after start of mixing, place the assembly comprising mould, foil and cement specimen, on the block (*see* **6.3.1.4**), conditioned to 37 ± 1°C, and replace in the oven (*see* **6.3.1.1**). Ensure good contact between the mould, foil and block.

6.3.2.2 Two and half minutes after start of mixing, carefully lower the indentor (*see* **6.3.1.2**) vertically on to the surface of the cement and allow it to remain there for 5 s. Carry out a trial run, to determine the approximate setting time, repeating the indentations at 30 s intervals until the needle fails to make a complete circular indentation in the cement, when viewed using a hand lens of low magnification. Clean the needle, if necessary, between indentations. Repeat the process, starting the indentations at 30 s before the approximate setting time, making indentations at 10 s intervals.

6.3.2.3 Record the setting time as the time which elapses between the start of mixing to the time when the needle fails to make complete circular indentation in the cement.

6.3.2.4 Take the mean of three such tests, rounded to the nearest 10 s as the result.

6.4 Working Time

6.4.1 *Apparatus*

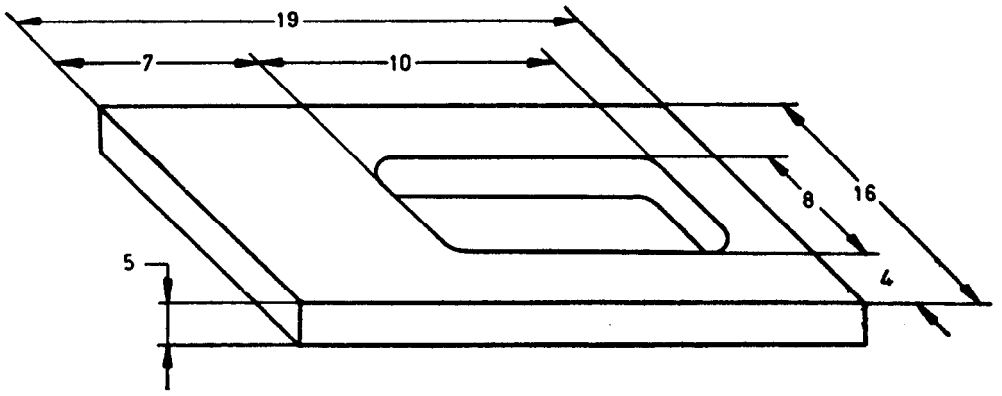
6.4.1.1 Indentor of mass 28 ± 0·25 g and having a flat end of diameter 2·0 ± 0·05 mm. The

needle tip shall be cylindrical for a distance of approximately 5 mm and the needle end shall be plane and perpendicular to the long axis of the needle.

6.4.1.2 Metal mould similar to that shown in Fig. 2.

6.5.1.2 *Split moulds and plates*

Split moulds and plates shall be as shown in Fig. 3, made of stainless steel or other suitable material that will not be attacked or corroded by the cement. The internal dimensions of the mould shall be 12 mm high and 6 mm diameter.



NOTE — Internal corners may be rounded.

All dimensions in millimetres.
(Tolerances on dimensions ± 0·15)

FIG. 2 MOULD FOR USE IN DETERMINING SETTING TIME AND WORKING TIME

6.4.1.3 Metal block of minimum dimensions 8 mm × 75 mm × 100 mm.

6.4.1.4 *Non-reactive aluminium foil*

6.4.2 *Procedure*

6.4.2.1 Place the mould (*see* **6.4.1.2**), conditioned to 37 ± 1°C, on the aluminium foil (*see* **6.4.1.4**) and fill to a level surface with mixed cement.

6.4.2.2 One minute after completion of mixing, place the assembly, comprising mould, foil and cement specimen on the block, conditioned to 37 ± 1°C. Ensure good contact between mould, foil and block.

6.4.2.3 Two minutes after start of mixing, carefully lower the indentor vertically on to the surface of the cement and allow it to remain there for 5 s. Repeat at 10 s intervals until the needle fails to make a complete circular indentation in the cement, when viewed using a hand lens of low magnification. Clean the needle, if necessary, between indentations.

6.4.2.4 Record the working time as the time which elapses between the start of mixing to the time when the needle fails to make a complete circular indentation in the cement.

6.4.2.5 Take the mean of three such readings, rounded to the nearest 10 s, as the result.

6.5 Compressive Strength

6.5.1 *Apparatus*

6.5.1.1 *Oven or cabinet*

Oven shall be capable of being maintained at a temperature of 37 ± 1°C and a relative humidity of at least 30 percent.

6.5.1.3 *Individual screw clamps*, as shown in Fig. 3.

6.5.1.4 *Apparatus*

Apparatus shall be suitable for testing compressive strength, having a cross-head speed of 1·0 mm/min.

6.5.2 *Preparation of Test Specimens*

6.5.2.1 Condition the moulds, top and bottom plates (*see* **6.5.1.2**), and the screw clamps, to 27 ± 2°C.

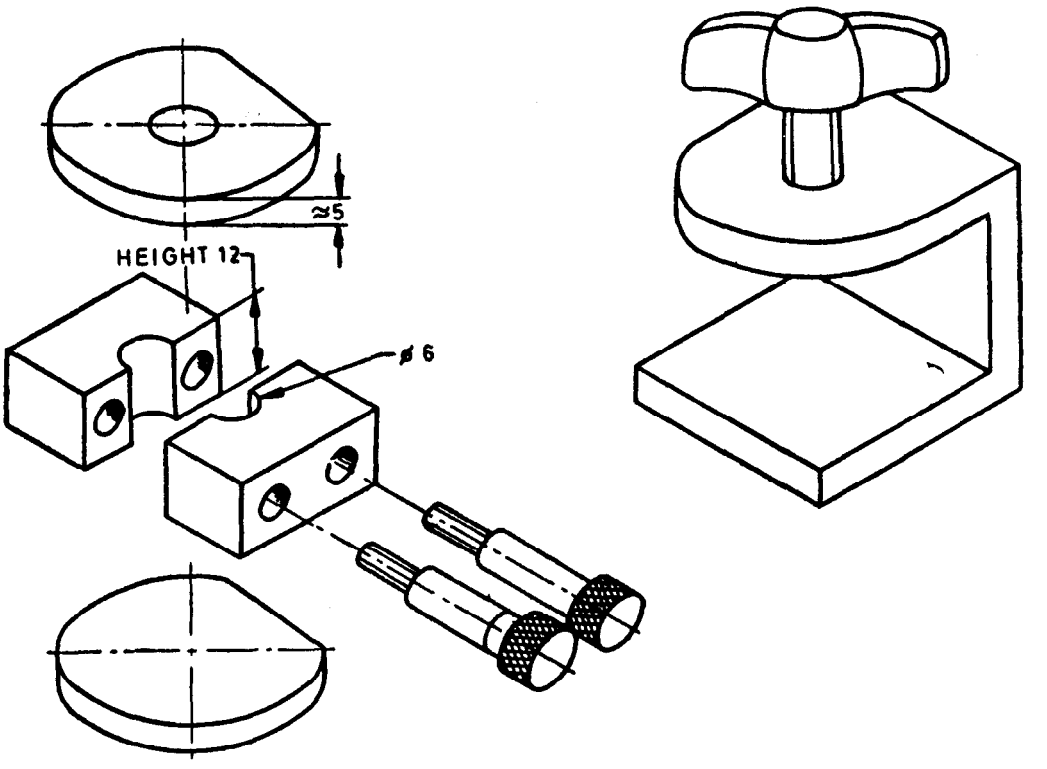
NOTE — To facilitate the removal of the hardened cement specimen, the internal surface of the mould and plates may be evenly coated, prior to filling, with a 3 percent solution of micro-crystalline or paraffin wax in pure toluene. Alternatively, a thin film of silicone grease or polytetrafluoroethylene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

6.5.2.2 Pack the mixed cement to a slight excess into the assembled split mould within 2 minutes of start of mixing.

NOTE — In order to consolidate the cement and to 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.

6.5.2.3 Fill the mould to excess and place on the bottom plate with the application of slight pressure.

6.5.2.4 Remove any bulk extruded cement, place the top plate in position and manually squeeze together. Put the mould and plates in the clamp (**6.5.1.3**) and screw tightly together. Not later than 3 minutes after start of mixing, transfer the whole assembly to the oven (**6.5.1.1**).



All dimensions in millimetres.

FIG. 3 MOULD AND CLAMP FOR PREPARATION OF COMPRESSIVE STRENGTH SPECIMENS

6.5.2.5 One hour after start of mixing, remove the plates and grind the ends of the specimen flat so that they are at right angles to its long axis. Grinding and the removal of the excess cement may be effected by drawing the specimen back and forth on a glass plate with a small amount of 350 mesh (maximum particle size 45 μm) silicon carbide powder, mixed with water. Keep both ends of the specimen wet during grinding and rotate the specimen by one quarter turn every few strokes.

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

6.5.2.7 Immerse the specimen in water complying with IS 1070 : 1977 and maintain at 37 ± 1°C for 23 hours. Five specimens shall be prepared and tested.

6.5.3 *Procedure*

Calculate the diameter by taking the mean of four measurements, two at each end of the specimen at right angles to each other, to an accuracy of ± 0·01 mm. Twenty-four hours after start of mixing, determine the compressive strength of the test specimens using an apparatus having a cross-head speed of 1·0 mm/minute (**6.5.1.4**).

6.5.3.1 Place each specimen with the flat ends between the platens of the apparatus so that the load is applied along the long axis of the specimen.

NOTE — A small disc of damp filter paper may be placed between each end of the specimen and the jaws of the testing machine in order to reduce scatter of results arising from surface roughness of the ends of the specimen.

6.5.3.2 Record the load applied when the specimen fractures, and calculate the compressive strength, k, in megapascals, using the formula:

$$k = \frac{4F}{\pi d^2}$$

where

F = maximum applied load, in newtons; and

d = measured mean diameter of the specimen, in millimetres.

6.5.3.3 If four out of five of the results obtained are below the limit specified in Table 1, the material shall be deemed to have failed the test. If four out of five of the results are above the limit specified in the table, the material shall be deemed to have met the requirements of the table. In other cases, prepare a further 10 specimens and calculate the median result for all 15 specimens. Round this value to two significant places and record as the compressive strength.

6.6 Water Leachable Content

6.6.1 *Apparatus*

6.6.1.1 *Oven or cabinet*

Capable of being maintained at a temperature of 37 ± 1°C and a relative humidity of at least 30 percent.

6.6.1.2 *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 1·5 ± 0·3 mm and the internal diameter 20 ± 1 mm.

6.6.1.3 *Individual screw clamps*

6.6.1.4 Platinum wire or, alternatively, waxed dental floss or other non-corrodible material.

6.6.1.5 Three wide-mouthed, tared, stoppered glass weighing bottles as shown in Fig. 5.

6.6.2 *Preparation of Test Specimens*

6.6.2.1 Place the mould (**6.6.1.2**) on a thin polyethylene or cellulose acetate sheet backed by a flat plate.

6.6.2.2 Insert a convenient tared (mass *E*) length of platinum wire (**6.6.1.4**) through the split ring so that at least 13 mm projects into the ring.

NOTE — A release agent, such as polytetrafluoroethylene (PTFE) dry film lubricant may be applied to the split ring to facilitate removal of the specimen.

6.6.2.3 Fill the split ring with mixed cement.

6.6.2.4 Cover with a plate, faced with a sheet of polyethylene or cellulose acetate, press firmly together and apply the screw clamp (**6.6.1.3**).

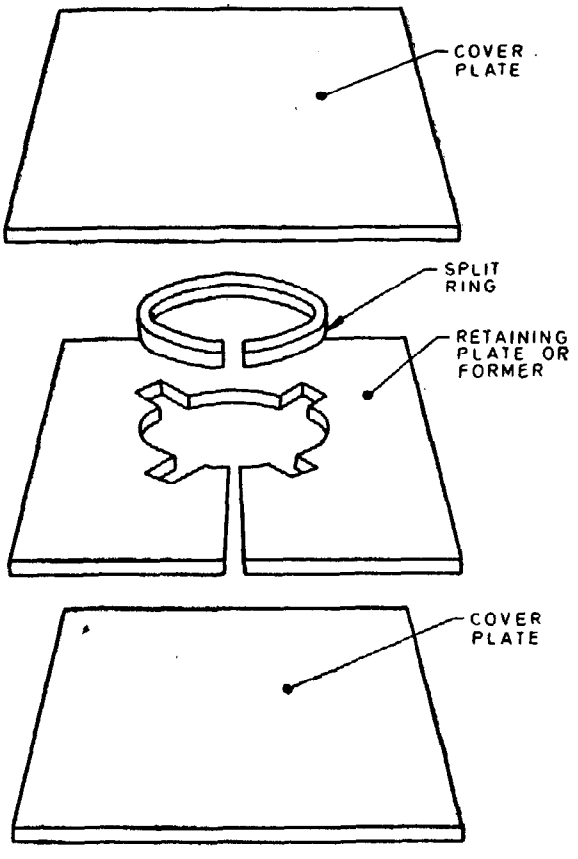
6.6.2.5 Three minutes after start of mixing, place the mould, plates and the screw clamp in the oven (**6.6.1.1**) maintained at 37 ± 1°C and a relative humidity of at least 30 percent.

6.6.2.6 After 1 hour remove the plates and polyethylene or cellulose acetate sheets from the clamp and carefully separate the cement disc and attached platinum wire 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 four specimens.

NOTE — Due to the comparatively brittle nature of the cement at this stage, it is advisable to clean the excess of cement from the surface of the ring before attempting to remove the specimen.

6.6.3 *Preparation of Test Solution*

6.6.3.1 For each pair of specimens, use a clean weighing bottle (**6.6.1.5**) together with a third bottle for a blank estimation to be carried out simultaneously. Dry the bottles at 150 ± 5°C for at least 2 hours. Cool the bottles for 1 hour at room temperature in a desiccator containing



NOTE — The dimensions of the moulds are different for the two tests (*see* 6.6.1.2 and 6.7.1.4).

FIG. 4 MOULD FOR PREPARATION OF WATER-LEACHABLE CONTENT AND OPACITY SPECIMENS

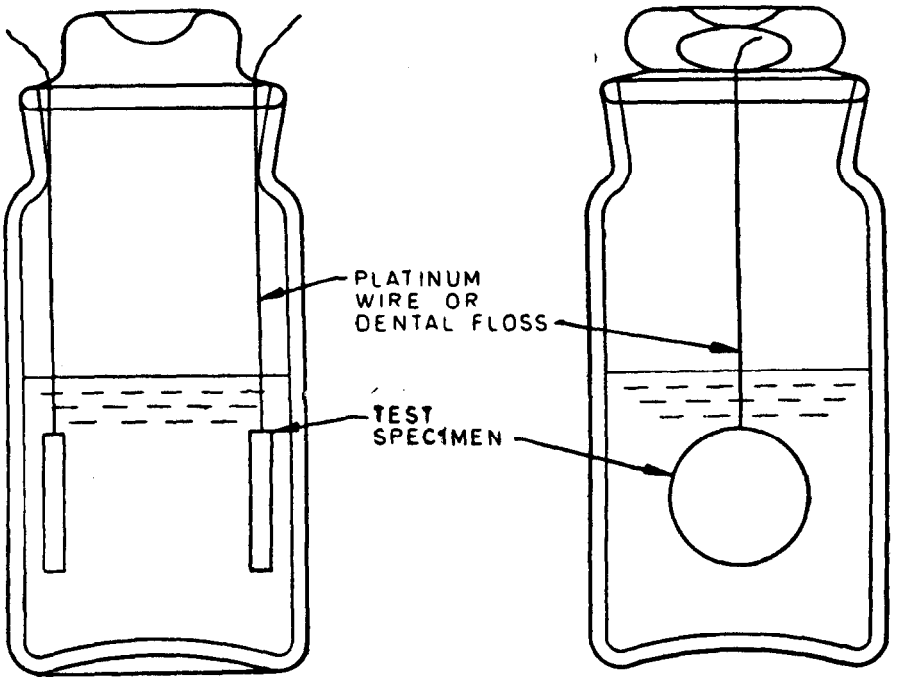


FIG. 5 WEIGHING BOTTLE CONTAINING WATER-LEACHABLE CONTENT SPECIMENS

thoroughly dry anhydrous calcium sulphate or active silica gel, and weigh to 0·1 mg (mass *A*). During these operations, the bottles should be handled as little as possible to prevent contamination.

6.6.3.2 Place two specimens immediately after preparation in each bottle except the blank bottle, and weigh the whole mass (mass *D*). The mass of each pair of specimens shall then be:

$$\text{Mass } D - (\text{Mass } A + \text{Mass } E)$$

where

E is the sum of the masses of platinum wires.

6.6.3.3 Immediately submerge the two discs by pouring 50 ml of distilled water into the bottle and suspending the specimens by the wire, so that they neither touch each other, nor rest against the side of the bottle. Close the bottle as tightly as possible and store for 23 hours at 37 ± 1°C. Place 50 ml of the same water in the blank bottle and store in the oven containing the specimens.

6.6.3.4 After 23 hour immersion, remove the specimens from the water and evaporate the water from the specimen bottle and from the blank bottle at a temperature just below 100°C and dry the bottles for 24 hours at 150 ± 5°C. Cool and weigh the bottles as earlier directed for weighing when empty. The mass of the specimen bottle, in each case, shall be mass *B*, and the increase in mass of the blank bottle shall be mass *C*.

6.6.4 *Expression of Results*

6.6.4.1 Express the water-leachable contents, for each pair of specimens as a percentage by mass, using the equation:

$$S = \frac{B - (C + A)}{D - (A + E)} \times 100$$

6.6.4.2 The average of duplicate test results (that is two weighing bottles each containing two specimens), calculated to the nearest 0·1 percent shall be the water-leachable content. If one of the results is above the limit given in Table 1, repeat the test; discard the highest and the lowest results and calculate the mean of the two remaining results to the nearest 0·1 percent.

6.7 Opacity

NOTE — This is applicable to Type 2 cements only.

6.7.1 *Apparatus*

6.7.1.1 *Oven or cabinet*

Oven shall be capable of being maintained at a temperature of 37 ± 1°C and a relative humidity of at least 30 percent.

6.7.1.2 *Opal glass standards*

With $C_{0\cdot70}$ values of 0·35 and 0·90, respectively.

NOTE — The contrast ratio $C_{0\cdot70}$ is the ratio between the light reflected by the specimen on a black background, and the light reflected by the specimen on a white background which has a reflectance of 70 percent.

6.7.1.3 *A sheet of white water proof material*

Approximately 110 mm × 40 mm, marked, along its entire length, with black stripes 2 mm wide and 3 mm apart.

6.7.1.4 *Moulds*

Consisting of a split brass or stainless steel ring contained in a former as shown in Fig. 4. The height of the ring shall be 1·00 ± 0·03 mm and the internal diameter 30 ± 1 mm.

6.7.1.5 *Flat glass plates*

Approximately 35 mm × 35 mm and 5 mm thick, and two polytetrafluoroethylene or cellulose acetate sheets 35 mm × 35 mm.

6.7.1.6 *Individual screw clamps*

6.7.2 *Preparation of Test Specimens*

6.7.2.1 Clamp a sufficient amount of mixed cement between the two polytetrafluoroethylene or cellulose acetate sheets and two flat glass plates (**6.7.1.5**) to form a disc of approximately 30 mm diameter and 1 ± 0·025 mm thick. Three minutes from the start of mixing, place the assembly in the oven (**6.7.1.1**). After 1 hour remove the specimen from the plates and store for 7 days in distilled water at 37 ± 1°C.

6.7.3 *Procedure*

6.7.3.1 Compare the opacity of the cement specimen with that of the two opal glass standards (**6.7.1.2**) having $C_{0\cdot70}$ values of 0·35 and 0·90, respectively, by placing the specimen and standards against the variegated black and white background. During observations, cover the cement specimens, the standards, and the space between them and the black and white backing with a film of distilled water. If the opacity of the specimen is between or equal to either of the opacities of the standards, the cement is deemed to have met the requirement.

6.7.3.2 If preferred, a suitable photometric method may be used to obtain the $C_{0\cdot70}$ values provided that the accuracy is within $\pm\ _{0\cdot02}\ C_{0\ 70}$

6.8 Acid-Soluble Arsenic Content

6.8.1 *Preparation of Sample*

Powder the set cement, and sieve through a 75 μm (200 mesh) sieve. Disperse 2 ± 0·01 g of the sieved powder in 30 ± 0·5 ml of water and add 10 ± 0·01 of hydrochloric acid, 36 percent (*m/m*) (d = 1·18 g/ml). Maintain the mixture at 37 ± 1°C for 1 h, then filter the solution and use it.

6.8.2 *Procedure*

Determine the arsenic content by the method described in IS 2088 : 1983.

6.9 Lead-Content

6.9.1 *Reagents*

During the analysis, use only reagents of recognized analytical grade and of a 'low in lead' grade. Use only distilled water or laboratory grade water (*see* IS 1070 : 1977).

6.9.1.1 *Hydrochloric acid*

Hydrochloric acid 20 percent (*m/m*) prepared by diluting lead-free hydrochloric acid 36 percent (*m/m*) (d = 1·18 g/ml) with distilled water.

6.9.2 *Preparation of Sample*

Mix sufficient powder and liquid to give 2 g of cement. Place the mixed cement in a clean plastic bag and seal the bag. Flatten the cement in the bag, using finger pressure to produce a very thin disc. Place the disc in an oven at 37 ± 1°C for 24 hours. Remove the disc of set cement and crush to a fine powder with an agate pestle and mortar. Accurately weigh about 2 ± 0·01 g of the powdered cement and transfer to a 130-ml conical flask. Add 50 ± 0·5 ml of the 20 percent hydrochloric acid. Stopper the flask, shake and allow to stand for 16 hours.

Pour the solution into a centrifuge tube, and centrifuge for 10 minutes. Using a pipette, transfer the clear solution into a sample container and stopper it.

6.9.3 *Procedure*

Determine the lead content directly by atomic absorption spectroscopy.

7 PACKING AND MARKING

7.1 Packaging

The components shall be supplied in securely sealed containers, made from materials which do no react with or permit contamination of the contents.

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

7.2 Marking of Containers

7.2.1 Each container shall be clearly marked with the following particulars:

a) Name and/or trade-mark of the manufacturer, and type of cement;
b) Shade of the powder according to manufacturer's shade guide, if supplied;
c) Minimum net mass, in grams, of the powder and the minimum net volume, in millilitres of the liquid;
d) Date of manufacture; and
e) Batch number.

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