BRITISH STANDARD

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CONFIRMED
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Medicine measures —

Part 1: Specification for medicine measures of 50 mL total graduated capacity

Confirmed
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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Committee (HCC/-) to Technical Committee HCC/20, upon which the following bodies were represented:

Association of National Health Service Supplies Officers
Association of the British Pharmaceutical Industry
British Medical Association
British Surgical Trades Association Incorporated
Department of Health and Social Security
Glass Manufacturers' Federation
Guild of Hospital Pharmacists
Medical Sterile Products Association
National Pharmaceutical Association
Paediatric Pharmacists' Group
Pharmaceutical Services Negotiating Committee
Pharmaceutical Society of Great Britain
Proprietary Association of Great Britain
Royal Society of Medicine
Scottish Pharmaceutical Federation

This British Standard, having been prepared under the direction of the Health Care Standards Committee, was published under the authority of the Board of BSI and comes into effect on 31 October 1985

BS 3221-1 first published February 1960
BS 3221-2 first published September 1962
BS 3221-3 first published February 1966
BS 3221-5 first published November 1966
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The following BSI references relate to the work on this standard:
Committee reference HCC/20
Draft for comment 84/52445 DC

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Amendments issued since publication

Amd. No.	Date of issue	Comments
5368	August 1986	Indicated by a sideline in the margin

Contents

Foreword

This Part of BS 3221 has been prepared under the direction of the Health Care Standards Committee. It is a combined revision of the following Parts of BS 3221.

— *Part 1:1960: Glass medicine measures of 50 mL capacity;*

— *Part 2:1962: Glass medicine measures of 30 mL capacity;*

— *Part 3:1966: Plastics medicine measures of 50 mL capacity;*

— *Part 5:1966: Plastics medicine measures of 10 mL capacity.*

This Part supersedes all four Parts listed above. Part 1:1960 and Part 3:1966 are withdrawn. Parts 2 and 5 were withdrawn in 1983. Plastics medicine measuring spoons are covered by Parts 4 and 6 as follows.

— *Part 4: Plastics medicine measuring spoons of 5 mL capacity*[1)]*;*

— *Part 6: Specification for free-standing plastics medicine measuring spoons of 5 mL capacity.*

This Part of BS 3221 specifies general requirements and essential performance requirements for measures made either of glass or of plastics materials, and which are graduated at doses ranging from 10 mL to 50 mL. The accuracy of measurement specified aligns with that specified for plastics medicine spoons, but the design of the measure has not, apart from the scale and graduations, been specified in detail, thus allowing some variation in overall configuration. Test methods and requirements for rigidity and for resistance to hot water are introduced.

It has not been found practicable to specify requirements or tests for the biological safety of the materials of which the measure is made, and neither are tests given for resistance to staining by commonly used pharmaceutical colorants nor for resistance to detergent and disinfectant solutions. Appendix A, however, contains guidance for the selection of plastics materials for the manufacture of measures.

Attention is drawn to BS 1922 which specifies measures for use by the pharmacist in the preparation of medicines.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 6, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

[1)] It is intended that Part 4 will be withdrawn in 1986.

1 Scope

This Part of BS 3221 specifies general design and performance requirements for medicine measures of 50 mL total graduated capacity made from either glass or plastics materials.

NOTE The titles of the publications referred to in this standard are listed on the inside back cover.

2 Definition

For the purposes of this Part of BS 3221, the following definition applies.

graduated capacity

the volume of water at 20 ± 2 °C required to fill a medicine measure to a given graduation mark

3 Materials

3.1 Glass

Glass used for the construction of medicine measures shall be of the colourless soda-lime-silica, or colourless boro-silicate, type. Lead-containing glass shall not be used.

NOTE The glass should be as free as possible from visible defects and from internal stress.

3.2 Plastics

Plastics measures shall be made of plastics materials that are non-coloured and either transparent or translucent. The clarity shall be such that the surface of a colourless liquid can be seen by normal or corrected vision through the side of the measure.

NOTE Further guidance on the selection of plastics materials is given in Appendix A.

4 Design

4.1 Style

The body of the medicine measure shall be in the shape of a truncated cone, symmetrical about its vertical axis, with its larger diameter uppermost.

NOTE Examples of designs are depicted in Figure 1.

4.2 Surface finish

The surfaces of the measure, when inspected by normal or corrected vision, shall, except for the graduation marks, be smooth and free from striae, blisters, delamination and other visible defects. Junctions of surfaces shall be uniformly rounded.

4.3 Rim

The rim shall be smooth and uniformly rounded; it shall not have sharp edges.

4.4 Base

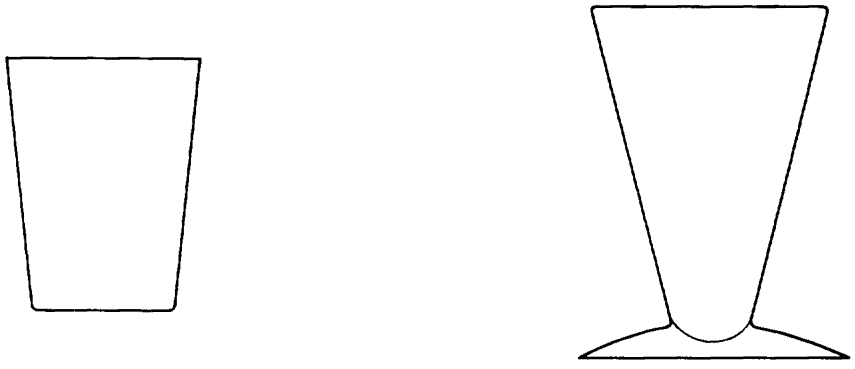
The base shall be such that the measure does not rock when placed on a flat horizontal surface.

4.5 Wall thickness

The wall thickness shall show no local departure from uniformity.

5 Hydrolytic resistance of glass measures

Glass measures, when tested in accordance with BS 3473-4:1983 shall require not more than 7.8 mL of 0.01 mol/L hydrochloric acid for the titration of 100 mL of extract solution.



NOTE The designs shown are for example only and do not form part of this specification.

Figure 1 — Examples of designs for 50 mL medicine measures

6 Capacity

6.1 Total capacity

The total capacity of the measure shall be not less than 65 mL and shall be such that, when tested in accordance with clause **8**, no liquid shall spill from the measure.

6.2 Total graduated capacity

The total graduated capacity shall be 50 mL.

6.3 Tolerance on graduated capacities

When the capacity at each graduation mark is determined in accordance with Appendix B, the tolerance on the capacity shall be ± 5 % of the nominal capacity at that graduation mark.

7 Scale

7.1 General

The measure shall bear one scale only, which shall be as shown in either Figure 2(a) or Figure 2(b). The scale shall be located on the external surface of the measure, shall be indelibly marked and shall have clean edges. All scale lines shall be distinct and of uniform thickness not exceeding 0.5 mm.

7.2 Length of scale

The vertical distance between the horizontal planes of the 10 mL and 50 mL graduation marks shall be not less than 28 mm.

7.3 Graduation marks

The graduation marks shall lie in planes parallel to the plane of the base of the measure; the length of each mark shall be as shown in either Figure 2(a) or Figure 2(b).

If marks that extend around the entire circumference of the measure are used, in accordance with Figure 2(b), all graduation marks on that scale shall be of this type.

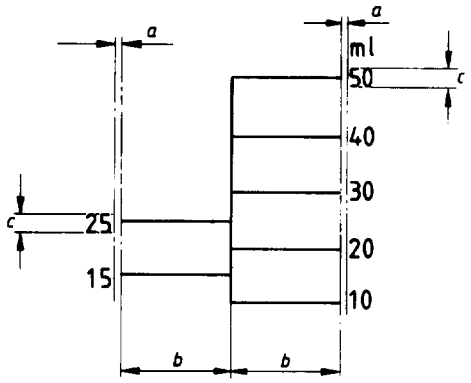
7.4 Numbering of graduation marks

Every graduation mark shall be numbered. The numbers shall be of height between 2 mm and 3 mm, and shall be situated as shown in Figure 2(a) and Figure 2(b) in such a position that they would be bisected by a prolongation of the graduation marks to which they refer. The abbreviation "ml" shall appear above the number designating the 50 mL graduation mark.

8 Stability

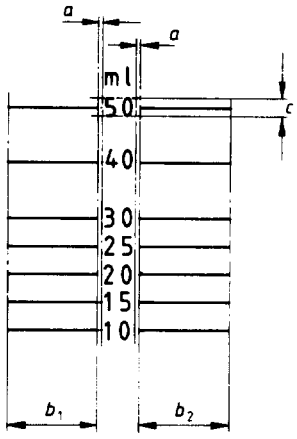
When the measure is filled with water to the 50 mL graduation mark and placed on a flat surface which is then inclined until it is at angle of 15° to the horizontal, the measure shall not topple over.

NOTE It may be necessary to prevent the measure from sliding down the inclined surface, for example by means of a small stop made of wood, modelling clay, etc.



a = 1 mm to 2 mm
b = 9 % to 11 % of the circumference of the measure at each graduation mark
c 2 mm to 3 mm

Scale (a)



a = 1 mm to 2 mm
b_1, b_2 = at least 10 % of the circumference of the measure at each graduation mark, and of equal length
c = 2 mm to 3 mm

NOTE Graduation marks may extend around the entire circumference, in which case dimensions b_1 and b_2 do not apply (see **7.3**).

Scale (b)

Figure 2 — Scales for 50 mL medicine measures

9 Resistance to hot water

When tested in accordance with Appendix C:

a) plastics measures, immediately after testing, shall not be asymmetrical or otherwise distorted and shall comply with the requirements of **4.2** to **4.5**. The rigidity of the measure shall be as specified in clause **10**;

b) glass measures shall not break or crack;

c) there shall be no visible deterioration in the clarity of the scale markings of either plastics or glass measures and the tolerance on capacities shall be as specified in clause **6**.

10 Rigidity

When tested in accordance with Appendix D, plastics measures shall show no change in diameter greater than 6 % of the original diameter of the measure.

11 Marking

The medicine measure shall be clearly and indelibly marked with the number and date of this Part of this British Standard, i.e. BS 3221-1:1985[2)]. This information shall be located either above the "ml" mark or on the underside of the base.

The name or trademark of the manufacturer or vendor, if marked, shall be situated on the underside of the base.

[2)] Marking BS 3221-1:1985 on or in relation to a product is a claim by the manufacturer that the product has been manufactured to the requirements of the standard. The accuracy of such a claim is therefore solely the manufacturer's responsibility. Enquiries as to the availability of third party certification to support such claims should be addressed to the Director, Quality Assurance Division, BSI, PO Box 375, Milton Keynes MK14 6LO for certification marks administered by BSI or to the appropriate authority for other certification marks.

Appendix A Guidance for selection of plastics materials

Past experience has shown that plastics materials with appropriate thermal and mechanical properties and which comply with the recommendations[3)] of the British Plastics Federation for food contact, are suitable for the manufacture of medicine measures. The plastics material should not include in its composition any substance which, under conditions of use, could be extracted by oral liquid medicines in quantities sufficient to cause a toxic hazard.

The measure should be resistant to staining by colouring substances commonly used in pharmaceutical practice, and should withstand, without deterioration, treatment with detergent solutions, and hypochlorite solution and other antiseptic solutions in common use.

It is not intended that plastics measures which comply with this standard should be used with paraldehyde or certain other medicaments which are known to react with plastics materials.

It is important that if materials are used other than those known to be satisfactory by long usage, their performance and characteristics should not be inferior to the traditional materials used.

Appendix B Method for determination of capacity

Set the clean and dry medicine measure on a flat, horizontal surface. Position the line of sight of the operator so that it is at the same level as the selected graduation mark. Run distilled water at 20 ± 2 °C into the measure from a burette complying with class B of BS 846 until the measure has been filled to the selected graduation mark, in accordance with either a) or b) as appropriate:

a) for plastics measures, when the surface of the water appears level with the top edge of the graduation mark;

b) for glass measures, when the lower surface of the water meniscus appears to touch the top edge of the graduation mark.

Record the volume of water added. Make a total of 10 determinations. Calculate the average value of the water volume. Take this as the capacity of the measure at that graduation mark.

Appendix C Test for resistance to hot water

Completely immerse the measure in water at a temperature of 70 ± 2 °C. After not less than 120 s, remove the measure, place it on a flat surface and allow it to cool to ambient temperature. Repeat the procedure until 20 immersions have been performed.

Examine the measure by normal or corrected vision for signs of deterioration. If there are no signs of deterioration perform the following tests.

a) Determine the capacity at each graduation mark in accordance with Appendix B.

b) Determine the rigidity of plastics measures in accordance with Appendix D.

Appendix D Determination of rigidity of plastics medicine measures

D.1 Apparatus

D.1.1 *Test apparatus*, capable of applying a test load equivalent to a force of 16 N via a steel ball of 6 mm diameter.

NOTE A suitable machine is shown in Figure 3. With this machine the test load is exerted by the unweighted lever arm provided that the mass of the arm is 800 g and the steel ball is located 150 mm from the pivot.

D.1.2 *Measuring calipers*, with vernier scale, capable of measurement to the nearest 0.1 mm, and of design suitable for measurement of the outside diameter of medicine measures and the movement of the lever arm; or other measuring apparatus, e.g. a projection microscope, having the same accuracy.

D.2 Procedure

D.2.1 Perform the test at a temperature in the range 18 °C to 25 °C.

D.2.2 Measure and record the outside diameter of the measure at the 30 mL graduation mark, making five measurements.

D.2.3 Position the measure in the test apparatus so that the steel ball is just touching the measure at the highest point of the circumference at the 30 mL graduation mark.

NOTE If the apparatus shown in Figure 3 is used, position the measure on wooden blocks so that the lever arm is level when the steel ball is just touching the measure.

D.2.4 Apply a load of 16 N to the measure. After a period of 15 s, measure and record the depression of the steel ball (or of the lever arm of the steel ball if using the apparatus in Figure 3), making five measurements.

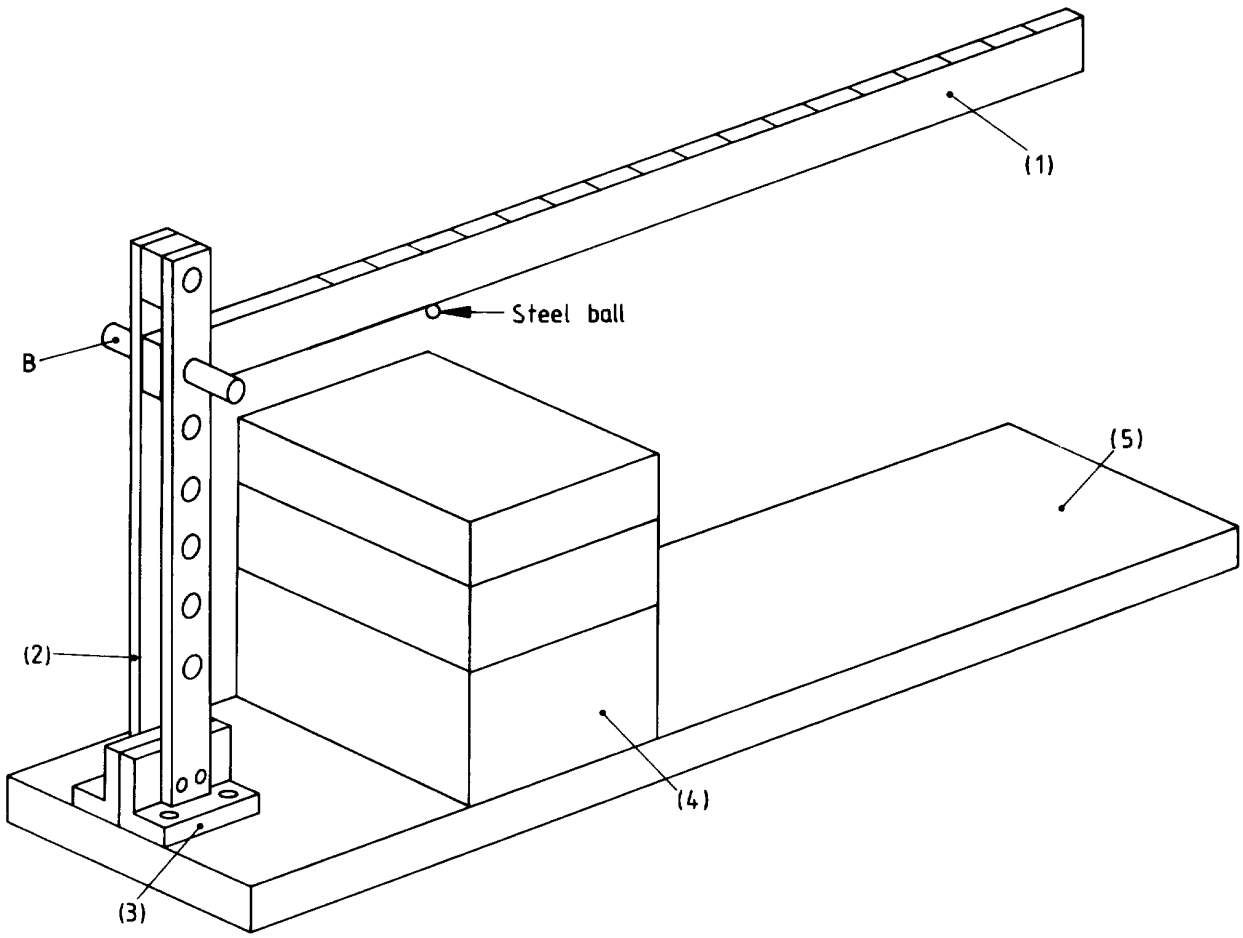
[3)] Plastics for food contact applications. A Code of Practice for safety in use. Revised edition 1981.

D.3 Calculation of results

D.3.1 Calculate the mean external diameter of the measure at the 30 mL graduation mark from the values recorded in **D.2.2**.

D.3.2 Calculate the mean change in external diameter of the measure from the values recorded in **D.2.4**.

D.3.3 Express the extent of deformation as a percentage of the original external diameter of the measure.



Key

(1) Lever arm 25 mm × 6.4 mm × 600 mm, drilled 12 mm from one end for pivot and 150 mm from pivot for 6 mm diameter steel ball, total mass approximately 800 g.

(2) Two uprights 25 mm × 3 mm × 200 mm, drilled at 12 mm intervals for the 6 mm diameter pivot B.

(3) Two bottom brackets 25 mm × 3.5 mm × 50 mm.

(4) Wood blocks 100 mm × 90 mm of varying thickness, e.g. 60 mm, 40 mm and 30 mm.

(5) Wood base 610 mm × 100 mm × 25 mm.

NOTE This apparatus is based upon that described in BS 1679-4 for testing the mechanical strength of plastics containers for tablets and ointments.

Figure 3 — Suitable apparatus for testing rigidity of plastics measures

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Publications referred to

BS 846, *Specification for burettes.*

BS 1679, *Containers for pharmaceutical dispensing.*

BS 1679-4, *Plastics containers for tablets and ointments.*

BS 1922, *Dispensing measures for pharmaceutical purposes*[4)].

BS 3221, *Medicine measures*[4)].

BS 3221-4, *Plastics medicine measuring spoons of 5 mL capacity.*

BS 3221-6, *Specification for free-standing plastics medicine measuring spoons of 5 mL capacity.*

BS 3473, *Chemical resistance of glass used in the production of laboratory glassware.*

BS 3473-4:1983, *Method for determination of hydrolytic resistance of the interior surfaces of glass containers.*

British Plastics Federation. *Plastics for food contact applications. A Code of Practice for safety in use.* Revised edition 1981[5)].

[4)] Referred to in the foreword only.

[5)] Published by the BPF with the cooperation of the British Industrial Biological Research Association.

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