BRITISH STANDARD

BS 3221-6: 1987

Medicine measures —

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

Confirmed December 2011

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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

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The following BSI references relate to the work on this standard:
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Amendments issued since publication

Amd. No.	Date of issue	Comments

Contents

Foreword

This revision of BS 3221-6 has been prepared under the direction of the Health Care Standards Committee. BS 3221-6 was first published in 1983 at the request of the Pharmaceutical Society of Great Britain, responding to the need for a more robust spoon that would be easier to manipulate.

This revision of BS 3221-6, in addition to superseding the 1983 edition (which is now withdrawn), also supersedes BS 3221-4:1969 which, after running concurrently with the 1983 edition of BS 3221-6, was withdrawn in May 1986.

BS 3221-4, dealing with plastics medicine measuring spoons of 5 mL capacity, was first published in 1966 in order to meet the need for a simple device, mainly for domestic use, which would measure and deliver all liquid medicines in a standard metric dose. The provision of the 5 mL spoon was an essential element in the changeover to the metric system in the dispensing and supply of medicine, which took effect in March 1969. BS 3221-4 was revised in 1969 primarily to give an improved method of test for the capacity of the spoon and to provide additional details for dimensional requirements.

BS 3221-6:1983 retained the basic design of the bowl of the spoon specified in BS 3221-4:1969, together with a number of the requirements and test methods, but differed in several major respects. The handle was redesigned in order to make handling and filling of the spoon easier, to reduce the risk of spillage, to provide a more positive grip for the user and to maintain the filled spoon in a level state when it was set down on a flat surface. For reasons of hygiene, the design of the spoon specified in BS 3221-4 precluded it being set down on a flat surface when filled. The view of the Technical Committee that prepared BS 3221-6:1983 was that the risks arising from setting down a filled spoon were outweighed by the advantages of a free-standing spoon in terms of reduced spillage and consequent increased accuracy of dosage, especially when medicines were administered to young or uncooperative children, or by adults of reduced manual dexterity or coordination. Test methods and requirements for rigidity, impact resistance, resistance to breakage and resistance to hot water were also introduced. It was not found practicable to specify requirements or tests for the biological safety of the materials of which the spoon was made, neither were tests given for resistance to staining by commonly used pharmaceutical colourants nor for resistance to detergent and disinfectant solutions. Appendix A, however, gave guidance for the selection of materials for the manufacture of spoons.

This revision of BS 3221-6 differs from the 1983 edition in the following ways. The fluid used in measuring the capacity of the spoon has been changed from water to a sucrose solution because the latter gives more reproducible test results and is more representative of the fluids with which the spoon is typically used in practice. The tolerances on some of the bowl dimensions have been widened slightly in order to facilitate achievement of the specified volumetric accuracy, and graduation marks on the bowl are actively proscribed. The marking requirements have been amended in order to provide for abbreviated markings on the spoon, and the inclusion of the date of the standard is now optional.

Other current Parts of this British Standard are:

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

— *Part 7: Specification for oral syringes delivering doses of less than 5 mL.*

Part 2 dealing with glass measures of 30 mL capacity, Part 3 dealing with plastics measures of 50 mL capacity and Part 5 dealing with plastics measures of 10 mL capacity have been withdrawn, being superseded by Part 1.

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 to iv, pages 1 to 4, 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.

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1 Scope

This Part of BS 3221 specifies the basic requirements for free-standing medicine measuring spoons of 5 mL capacity made from plastics materials.

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

2 Material of construction

The spoon shall be made of a plastics material that is either non-coloured and transparent or translucent, or is coloured white.

NOTE 1 For ease of differentiation of medicine spoons from other spoons made of plastics material, the spoon should preferably be non-coloured and transparent or translucent.
NOTE 2 Further guidance on the selection of materials of construction is given in Appendix A.

3 Capacity

The nominal capacity of the spoon shall be 5 mL. The capacity of the spoon, when tested in accordance with Appendix B, shall be 5.0 ± 0.25 mL.

4 Design

4.1 Surface finish

The surfaces of the spoon, when inspected by normal or corrected vision, shall be smooth and free from blisters, delaminations, flow lines and other visible defects. There shall be no sharp edges and all edges and corners shall be radiussed.

4.2 Bowl

The dimensions of the bowl shall be in accordance with those shown in Figure 1. The rim of the bowl shall lie in one plane. The bowl shall not be graduated.

4.3 Handle

The dimensions of the handle shall be in accordance with those shown in Figure 1.

The design of the handle shall be such that:

a) its distal end provides a steadying support and also positions the rim of the bowl in a horizontal plane when the spoon is placed on a flat horizontal surface;

b) it provides two vertical surfaces a minimum of 8 mm apart which can be gripped between forefinger and thumb when the spoon is held in the hand;

c) it is of sufficient rigidity that, when tested in accordance with Appendix C, the tip of the bowl is not displaced vertically by more than 4 mm;

d) it is either of hollow or solid construction.

5 Impact resistance

The spoon shall be capable of withstanding a free fall from a height of 1.3 m on to a concrete or similar hard surface without breaking or showing visible damage.

6 Resistance to breakage

When tested in accordance with Appendix D, the spoon shall not break into fragments.

NOTE Permanent or temporary deformation of the spoon or the occurrence of cracks does not constitute failure of the test.

7 Resistance to hot water

When tested in accordance with Appendix E, the spoon, immediately after testing, shall not be asymmetrical or otherwise visibly distorted, nor shall there be any deterioration in surface finish (see **4.1**). The rigidity of the handle shall be as specified in **4.3** c). The impact resistance of the spoon shall be as specified in clause **5**, the resistance to breakage of the spoon shall be as specified in clause **6** and the capacity of the spoon shall be as specified in clause **3**.

8 Marking

The spoon shall be clearly and permanently marked with the following particulars:

a) on the upper surface of the handle, the words "5 ml dose", the dimensions of which shall comply with those shown in Figure 1;

b) on any surface of the handle, other than the upper surface, the number of this British Standard, i.e. BS 3221-6[1)], either in full or in abbreviated form. Abbreviated marking shall contain the number "BS 3221" in full, immediately followed on the same level by an indication of the Part number.

NOTE 1 The word "Part" may be abbreviated to "Pt" or may be replaced by a symbol, preferably the oblique stroke (/). The full or abbreviated date of this Part of BS 3221 may also be marked behind, above or below the standard number, and close to it.
NOTE 2 The name or trade mark of the manufacturer or vendor may also be marked on any surface of the handle other than the upper surface.

[1)] Marking BS 3221-6 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 should be addressed to the appropriate certification body.

Appendix A Guidance for selection of materials

Past experience has shown that plastics materials with appropriate thermal and mechanical properties and which comply with the recommendations[2)] of the British Plastics Federation for food contact, are suitable for the manufacture of measuring spoons. If any colouring substances are added they should be of a material that is physiologically inert and of a grade suitable for food contact. The plastics material should not include in its composition any substance which, under conditions of use, could be extracted by vehicles used in oral liquid medicines in quantities sufficient to cause a toxic hazard.

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

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

Attention is drawn to the Materials and Articles in Contact with Foodstuffs Regulations SI 1978 number 1927 and the Amendment SI 1980 number 1838.

Appendix B Method for determination of capacity

Set the measuring spoon on a flat, level surface. Clamp a steel needle vertically over the centre of the bowl and adjust the height of the needle point to 1.70 mm above the plane of the rim, using a feeler gauge. Run a solution of sucrose 440 g/L in distilled water [equivalent to a 50 % (*V*/*V*) solution of syrup BP], at 20 ± 2 °C, into the spoon from a 10 mL burette until the meniscus just touches the needle point and record the volume of liquid added. Perform 10 determinations and calculate the average value of the liquid volume. This shall then be taken as the capacity of the spoon.

Appendix C Test for rigidity of handle

Clamp the handle of the spoon 10 mm from its distal end so that the bowl of the spoon is horizontal. Place a vertical scale, calibrated in millimetres, beside the tip of the bowl.

Apply a force equivalent to a load of 20 g through the point of maximum depth of the bowl (see point D in Figure 1) and read from the scale the vertical displacement of the tip of the bowl. Record the value of the displacement.

Appendix D Test for resistance to breakage

Place the spoon in an inverted position with the rim of the bowl on a rigid plane. Apply a total static load equivalent to a force of 110 N to the bowl of the spoon via a steel ball of 6 mm diameter, positioned so that the ball makes contact with the surface of the inverted bowl at the point of maximum depth (see point D in Figure 1).

Apply the load for 15 s and then remove it.

Examine the spoon by normal or corrected vision for evidence of fragmentation.

NOTE The applied load, equivalent to a force of 110 N, includes the force due to the mass of the steel ball and of the appropriate parts of the test apparatus. Details of a suitable test apparatus are shown in Figure 2.

Appendix E Test for resistance to hot water

Completely immerse the spoon in water at a temperature of 70 ± 2 °C. After not less than 120 s remove the spoon, 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 spoon by normal or corrected vision for signs of deterioration. If there are no signs of deterioration perform the following tests:

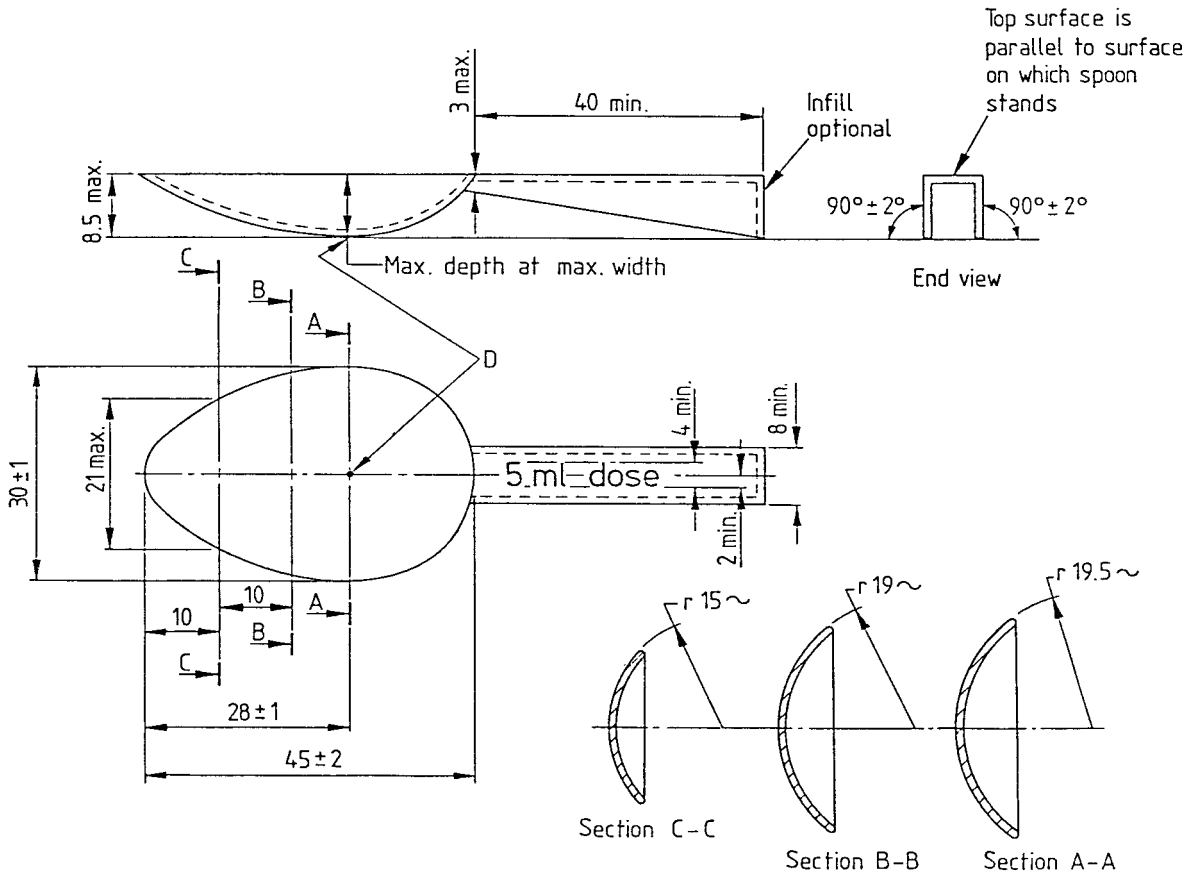
a) determine the capacity of the spoon in accordance with Appendix B;

b) determine the rigidity of the handle in accordance with Appendix C;

c) determine the impact resistance of the spoon in accordance with clause **5**;

d) determine the resistance to breakage of the spoon in accordance with Appendix D.

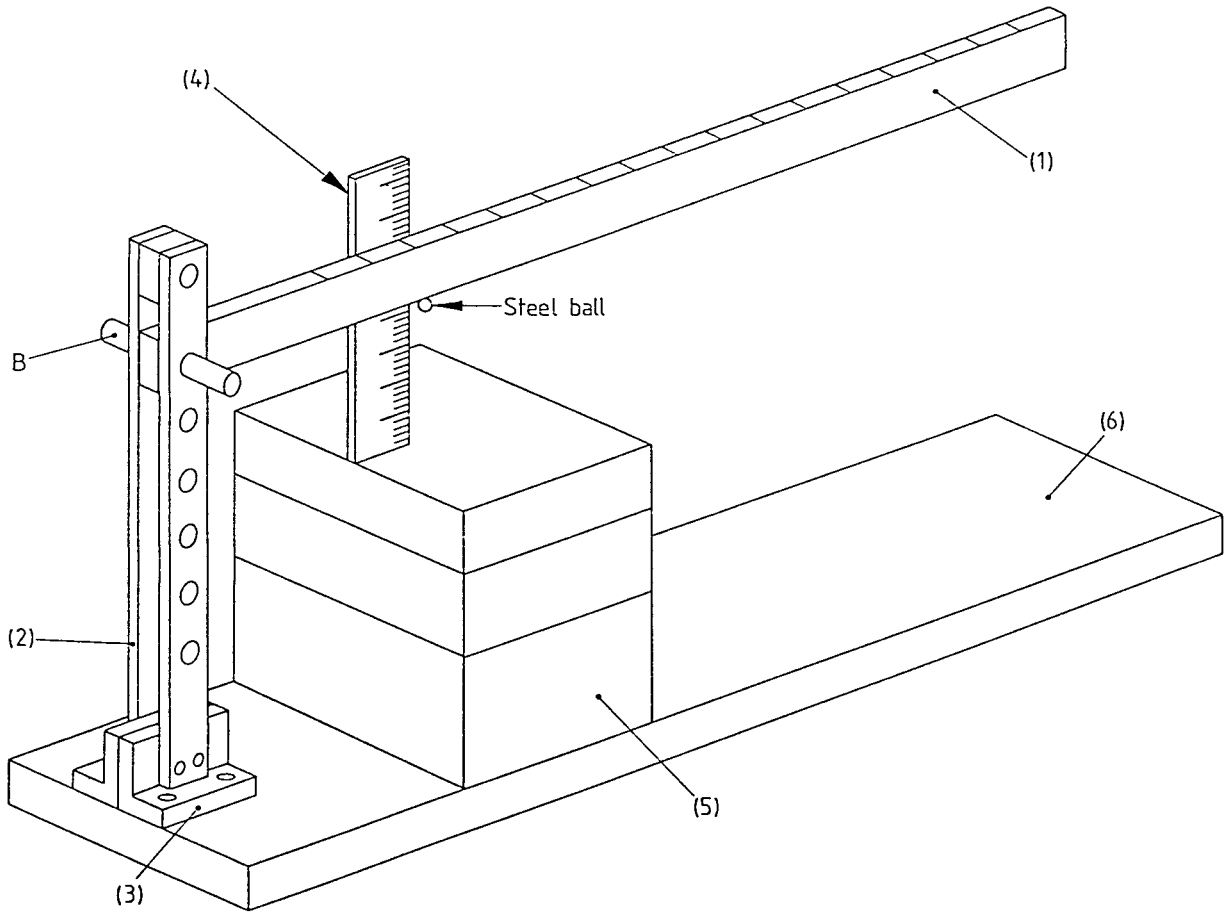
[2)] Plastics for Food Contact Applications. A Code of Practice for Safety in Use, revised edition 1981, published by the British Plastics Federation, with the cooperation of the British Industrial Research Association.



NOTE Only those dimensions shown in the figure or specified in the text are to be regarded as part of the standard. Other designs, e.g. with tapered handles in plan view, or with more than point contact between the distal end of the handle and the surface on which it rests, are permissible provided that compliance with all other requirements is maintained.

All dimensions are in millimetres.

Figure 1 — Dimensions of spoon



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. Measuring scale in millimetres affixed vertically to wooden block.
5. Wood blocks 100 mm × 90 mm of varying thickness, say 60 mm, 40 mm and 30 mm.
6. Wood base 610 mm × 100 mm × 25 mm.

NOTE This apparatus is identical to that described in BS 1679-4 for testing the mechanical strength of plastics containers.

Figure 2 — Suitable apparatus for testing resistance to breakage

Publications referred to

BS 1679, *Specification for containers for pharmaceutical dispensing.*
BS 1679-4, *Plastics containers for tablets and ointments.*
BS 3221, *Medicine measures*[3)].
BS 3221-1, *Specification for medicine measures of 50 mL total graduated capacity.*
BS 3221-7, *Specification for oral syringes delivering doses of less than 5 mL.*

[3)] Referred to in the foreword only.

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