BRITISH STANDARD

BS 3221-7: 1995

Medicine measures —

Part 7: Specification for oral syringes delivering doses up to and including 5 ml

Confirmed December 2011

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/20, Medical measuring vessels, upon which the following bodies were represented:

Association of the British Pharmaceutical Industry
British Glass Manufacturers' Confederation
British Medical Association
Department of Health
Guild of Hospital Pharmacists
Medical Sterile Products Association
National Association of Health Care Supplies Managers
National Pharmaceutical Association
Paediatric Pharmacists' Group
Pharmaceutical Services Negotiating Committee
Royal Pharmaceutical Society of Great Britain
Royal Society of Medicine
Scottish Pharmaceutical Federation

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Contents

Foreword

This Part of BS 3221 has been prepared by Technical Committee CH/20 and supersedes BS 3221-7:1986 which will be withdrawn on 1st May 1996.

This revision introduces the addition of the 2.5 ml mark on the 5 ml syringe.

It also clarifies the test method for the determination of the capacity of a syringe given in Annex C.

Other current Parts of BS 3221 are as follows.

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

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

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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 Scope

This Part of BS 3221 specifies general design and performance requirements for three size ranges of oral syringe for containing and delivering liquid medicines in measured volumes of up to and including 5 ml.

2 References

2.1 Normative references

This Part of BS 3221 incorporates, by dated or undated reference, provisions from other publications. These normative references are made at the appropriate places in the text and the cited publications are listed on the inside back cover. For dated references, only the edition cited applies; any subsequent amendments to, or revisions of, the cited publication apply to this Part of BS 3221 only when incorporated in the reference by updating or revision. For undated references, the latest edition of the cited publication applies, together with any amendments.

2.2 Informative references

This Part of BS 3221 refers to other publications that provide information or guidance. Editions of these publications current at the time of issue of this standard are listed on the inside back cover, but reference should be made to the latest editions.

3 Definitions

For the purposes of this British Standard the following definition applies.

graduated capacity

the volume of water at (20 ± 2) °C expelled by the syringe when the fiducial line on the piston traverses the interval between a given graduation line and the zero line

4 Materials

Materials used for the construction of syringe barrels shall be 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 syringe barrel.

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

5 Design

5.1 Function

It shall be possible to displace the measured contents of the syringe directly into the patient's mouth.

NOTE 1 It is desirable that when the syringe is put down on a flat surface any part that normally enters the patient's mouth during delivery of the medicine should not be in contact with that surface.

NOTE 2 If an adaptor is supplied with the syringe for the purpose of filling the syringe directly from a medicine container, the adaptor should:

a) be made of materials having the properties described in Annex A;

b) form a leak-free seal with the syringe during aspiration of the medicine;

c) show no distortion or other deleterious effects when tested for resistance to washing as described in Annex B.

5.2 Surface finish

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

5.3 Finger grips

The open end of the barrel shall be provided with finger grips that shall also ensure that the syringe will not roll when it is placed with the scale uppermost on a flat surface inclined at an angle of 10° to the horizontal.

NOTE Finger grips should be of adequate size, shape and strength for the intended purpose and should enable the syringe to be held securely during use.

5.4 Delivery ends of barrel

It shall not be possible to attach directly to the delivery end of the barrel a hypodermic needle having a Luer (6 %) conical taper fitting conforming to BS EN 20594-1:1994.

5.5 Fiducial line

For determining the capacity corresponding to any scale reading of the syringe, the fiducial line shall be a clearly visible and distinct edge at the leading end of the piston, and shall be in contact with the inner surface of the barrel.

5.6 Plunger

The protruding part of the plunger or piston rod shall be equipped with a button.

NOTE The button may be of circular or other shape and should have a plane or, preferably, a concave face. The button and plunger should be of a suitable size and design to:

a) allow digital pressure to be applied to the piston for the ejection of liquid from the syringe; and

b) facilitate the withdrawal of the piston when filling the syringe.

6 Capacity

6.1 Nominal capacity

The nominal capacity of the syringe shall be defined as the total graduated capacity and shall be within the range of capacities shown in Table 1.

Table 1 — Nominal capacity and intervals at which syringes are graduated

Nominal capacity of syringe ml	Graduated at intervals of: ml
Over 3 and up to and including 5	0.5
Over 1, up to and including 3	0.25
1 or less	0.1

6.2 Tolerance on graduated capacities

When the capacity at each graduation line is determined in accordance with the method given in Annex C, the tolerance on the capacity shall not differ by more than 5 % of the capacity indicated at that graduation.

7 Graduated scale

7.1 Scale

The scale shall comprise graduation lines and numbers. The scale shall be located on the external surface of the barrel. There shall be not more than one scale.

7.2 Graduation lines

The graduation lines shall be legible, indelible (see clause **9**) and of uniform thickness not exceeding 0.6 mm.

Graduation lines shall be evenly spaced between zero and the total graduated capacity and shall lie in planes at right angles to the longitudinal axis of the barrel.

Graduation lines shall be located at the intervals specified in Table 1.

When the syringe is held vertically with the delivery end uppermost and with the scale towards the viewer, the left hand ends of all the graduation lines shall lie vertically beneath each other.

NOTE The left hand ends of the graduation lines may optionally be joined by a line parallel to the longitudinal axis of the barrel.

7.3 Overall length of scale

The minimum length of the scale between the zero line and the total graduated capacity line shall be 35 mm.

7.4 Position of scale

When the piston is fully inserted, that is as near to the delivery end of the barrel as it will go, the zero graduation line of the scale shall appear to touch the fiducial line (see **5.5**).

7.5 Numbering of scale

The graduation lines to be numbered shall be as given in Table 2.

Table 2 — Intervals at which syringes are numbered

Nominal capacity of syringe ml	Graduated at intervals of: ml
5	1.0 and 2.5[a]
Over 3 and up to 5	1.0
Over 1, up to and including 3	0.5
1 or less	0.2
[a] See **7.5.2**.	

The numbers shall be bold and legible.

When the syringe is held vertically with the delivery end uppermost and with the scale towards the viewer, the numbers shall be upright.

The numbers shall be close to, but shall not touch, the ends of the graduation lines to which they relate.

7.5.1 *Numbering of syringe of nominal capacity of up to 5 ml*

The numbers shall either:

a) be on the right of the scale, and in a position such that they would be bisected by a prolongation of the graduation lines to which they relate; or

b) bisect the graduation lines to which they relate.

7.5.2 *Numbering of syringe of nominal capacity of 5 ml*

The numbers shall:

a) be on the right of the scale, and in a position such that they would be bisected by a prolongation of the graduation lines to which they relate; and

b) the 2.5 ml mark shall be on the left of the scale, and in a position such that it would be bisected by a prolongation of the graduation line.

7.6 Length of graduation lines

The numbered graduation lines shall be of uniform length, which shall be not less than 9 % of the circumference of the barrel. The combined length of the line and the width of the number, including the space between the two, shall be not more than 30 % of the circumference of the barrel.

The unnumbered graduation lines shall be of uniform length which shall be less than, but not less than half, the length of the numbered graduation lines.

8 Freedom from liquid leakage

When tested in accordance with the method given in Annex D, the loss of mass shall be not greater than 0.025 g.

9 Resistance to washing

When tested in accordance with the method given in Annex B, the syringe shall not become asymmetrical or otherwise distorted, there shall be no loss of clarity or legibility of markings and the syringe shall retain conformity to **5.2**, **6.2**, and clauses **8**, **10** and **11**.

10 Resistance to breakage (bite forces)

When tested in accordance with the method given in Annex E, neither the end of the syringe which is intended to enter the mouth during delivery of the medicine, nor the syringe barrel shall break into fragments or crack.

11 Freedom from air leakage

When tested in accordance with the method given in Annex F, no air bubbles shall be visible in the liquid in the barrel.

12 Marking and labelling

12.1 Marking

The syringe shall be permanently and legibly marked with the following information:

a) the abbreviation "ml" either below the total graduated capacity number on the scale or beside the numbered graduation lines;

b) the words "FOR ORAL USE ONLY";

c) the number and date of this British Standard, i.e. BS 3221-7:1995[1)], or an abbreviated version (e.g. BS 3221-7:1995).

NOTE The syringe may be marked with the name or trademark of the manufacturer or vendor.

12.2 Labelling

Printed instructions shall be supplied with each syringe for the guidance of users, and shall make reference to the following:

a) the purpose of the syringe;

b) the method of filling the syringe, including guidance on the transfer of medicine from the original container and the removal of air bubbles;

c) the method of measuring the prescribed dose;

d) the method of administration of the medicine, including:

1) the need to avoid too rapid a displacement of the dose;

2) the correct placement of the end of the syringe in the patient's mouth;

3) the need for the patient, especially if a child, to be in a sitting position at the time of administration;

e) the method of cleaning.

NOTE The form of presentation of the instructions is not specified in this British Standard. It is recommended that pictures or diagrams be used to clarify or reinforce the printed instructions.

[1)] Marking BS 3221-7:1995 on or in relation to a product represents a manufacturer's declaration of conformity, i.e. a claim by or on behalf of the manufacturer that the product meets the requirements of the standard. The accuracy of the claim is solely the claimant's responsibility. Such a declaration is not to be confused with third party certification of conformity, which may also be desirable.

Annex A (informative)
Guidance for selection of materials

Past experience has shown that plastics materials with appropriate thermal and mechanical properties that conform to the recommendations [1] of the British Plastics Federation for food contact are suitable for the manufacture of oral syringes. 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.

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

Glass used for the construction of syringes should be of the colourless soda-lime-silica or colourless borosilicate type. Lead-containing glass should not be used.

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

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.

Attention is drawn to the Materials and Articles in Contact with Foodstuffs Regulations, 1978 (SI 1927), and the Amendment 1980 (SI 1838) [2].

Annex B (normative)
Test for resistance to washing

Disassemble the syringe and completely immerse the components in an aqueous solution containing 0.03 % of total active detergent materials[2)] at a temperature of (70 ± 2) °C. After not less than 120 s, remove the components, place them on a flat surface and allow them to cool to ambient temperature. Repeat the procedure until 20 immersions have been performed.

Examine the components by normal or corrected vision for signs of deterioration. If there are no signs of deterioration, reassemble the components and perform the following tests on the syringe:

a) determine the freedom from liquid leakage in accordance with Annex D;

b) determine the capacity at each numbered graduation line in accordance with Annex C;

c) determine the resistance to breakage in accordance with Annex E;

d) determine the freedom from air leakage in accordance with Annex F.

Annex C (normative)
Test for determination of capacity

Fill the syringe to the selected graduated line with purified water at a temperature of (20 ± 2) °C, taking care to exclude air bubbles by setting the fiducial line against the graduation, then weigh the syringe and contents on a balance of accuracy of 0.002 g.

Expel the water by depressing the plunger to its full extent and re-weigh the syringe. Calculate the difference in mass, in grams, between the filled and the emptied syringe. Record this value as the capacity in millilitres, using the assumption that the density of water equals 1 000 kg/m^3.

Annex D (normative)
Test for freedom from liquid leakage

Fill the syringe to the maximum graduated capacity with water at (20 ± 2) °C, dry the outside surface, then weigh the syringe and contents on a balance of accuracy of 0.002 g. Set the syringe on a dry, horizontal, level surface. After 5 min dry the outside surface if necessary, and re-weigh the syringe and contents. Subtract the second weighing from the first and record any change in mass.

Annex E (normative)
Test for resistance to breakage (bite forces)

Withdraw the plunger to the nominal capacity graduation. Place the syringe on a solid plane surface with a further support under the delivery end.

[2)] The detergent solution known as "Teepol GD 53", manufactured by Shell Chemicals Ltd. has been found to be satisfactory. It is a blend of linear alkyl benzenesulphonates, alcohol ethoxysulphates and alcohol ethoxylates, and contains approximately 30 % of active material.

Apply a static load equivalent to a force of 110 N to the surface of the delivery end of the barrel at a point not more than 16 mm from its tip, and then to the surface of the barrel not more than 40 mm from the tip of the delivery end, using whichever is appropriate of the following methods:

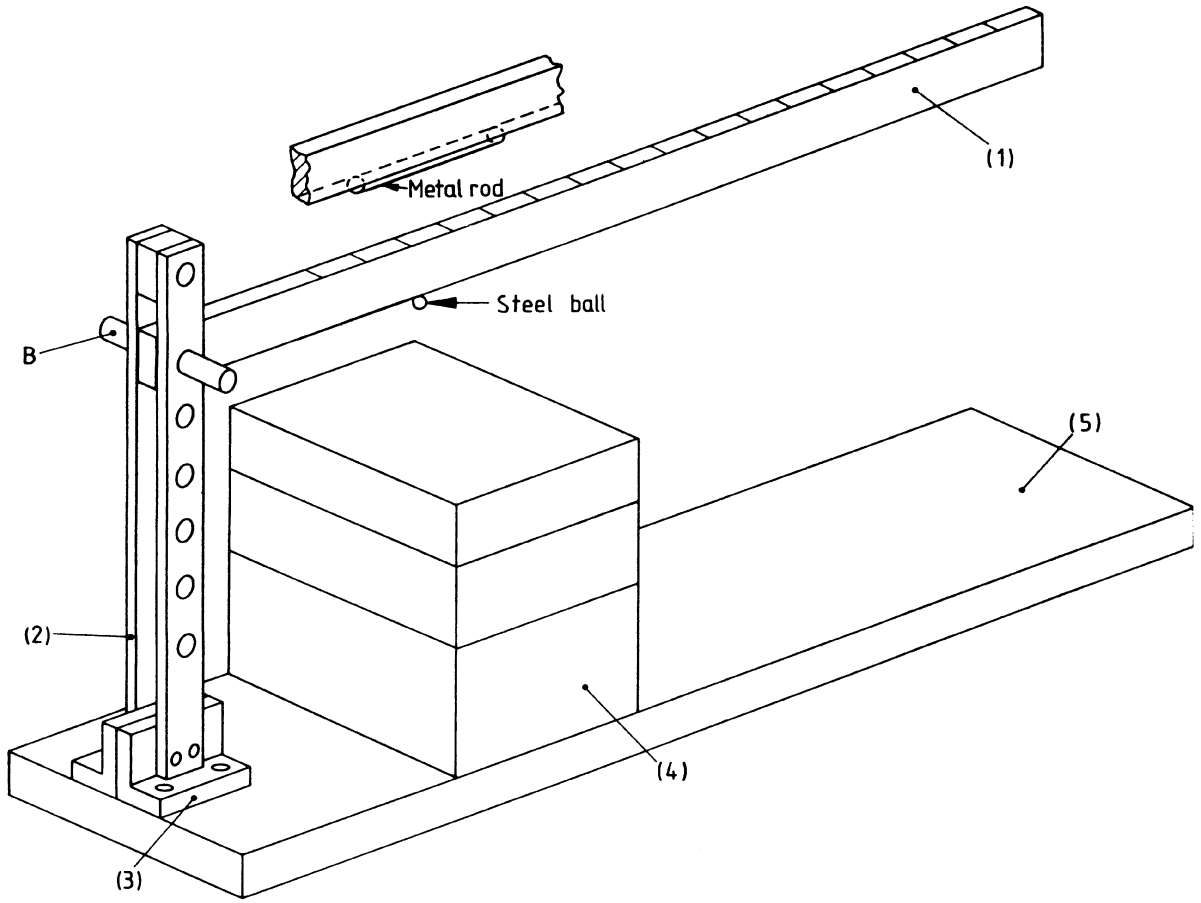
a) if at these points, the surface of the syringe is cylindrical, apply the load via a metal cylinder of 6 mm diameter set at 90° to the axis of the syringe;

b) if a plane surface is present at these points, apply the load via a steel ball of 6 mm diameter.

Apply the load for 15 s each time and then remove it.

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

NOTE The applied load, equivalent to a force of 110 N, includes the force due to the mass of the metal cylinder or steel ball and of the appropriate parts of the test apparatus. Details of a suitable test apparatus are given in Figure E.1.



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.
When applying the test force to cylindrical or tapered surfaces, the lever arm is inverted. A metal rod of 6 mm diameter is fixed to the lower edge of the arm with its axis in the same plane as the bar and its mid point 150 mm from the pivot (see inset).
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 1679-8 for testing the mechanical strength of plastics containers for tablets and ointments.

Figure E.1 — Suitable apparatus for testing resistance to breakage (bite forces)

Annex F (normative)
Test for freedom from air leakage

Partially fill the syringe with chemically pure glycerol conforming to BS 2621-5. Invert the syringe and expel all air. Empty the contents of the syringe by depressing the plunger to its full extent.

Immerse the tip of the syringe in glycerol and fill the syringe by withdrawing the plunger so that the fiducial line is coincident with the graduation line signifying the nominal total graduated capacity. Perform the filling operation in a time of between 4 s and 8 s.

Examine the liquid in the barrel and determine if air bubbles are present.

List of references

Normative references

BSI publications

BRITISH STANDARDS INSTITUTION, London

BS 2621-5:1979, *Specifications for glycerol.*

BS EN 20594, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment.*

BS EN 20594-1:1994, *General requirements.*

Informative references

BSI publications

BRITISH STANDARDS INSTITUTION, London

BS 1679, *Containers for pharmaceutical dispensing.*

BS 1679-8:1992, *Specification for glass and plastics containers for solid dosage forms, semi-solids and powders.*

BS 3221, *Medicine measures.*

BS 3221-1:1985, *Specification for medicine measures of 50 mL total graduated capacity.*

BS 3221-6:1987, *Specification for free-standing plastics medicine measuring spoons of 5 mL capacity.*

Other references

[1] *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 Biological Research Association.

[2] GREAT BRITAIN. Materials and Articles in Contact with Foodstuffs Regulations 1978 and the Amendment 1980. London: HMSO.

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