

# **Sterile hypodermic syringes and needles**

## **Part 1. Specification for sterile, single-use hypodermic syringes for manual use**

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# Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/2, upon which the following bodies were represented:

- Association of British Health-care Industries
- Association of Clinical Pathologists
- British Diabetic Association
- British Glass Manufacturers' Confederation
- British Surgical Trades Association
- Department of Health
- Disposable Hypodermic and Allied Equipment Manufacturers' Association (UK)
- Medical Sterile Products Association
- Royal Pharmaceutical Society of Great Britain
- Co-opted members

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# National foreword

This Part of BS 5081 has been prepared under the direction of the Health Care Standards Policy. It is identical with ISO 7886-1 : 1993 *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*, published by the International Organization for Standardization (ISO). It supersedes BS 5081 : Part 1 : 1987, which is withdrawn.

BS 5081 was first published in 1976 and specified requirements for sterile hypodermic syringes and needles for single use. A two-Part revision was published in 1987, Part 1 covering sterile, single-use hypodermic syringes and Part 2 covering sterile single-use hypodermic needles

The major differences between this standard and BS 5081 : Part 1 : 1987 are as follows.

- a) This standard applies to syringes for manual use. A further Part of ISO 7886 is in preparation, and deals with syringes for use with power-driven syringe pumps. It is expected that, when published, it will be implemented as a new Part of BS 5081.
- b) An informative annex on forces required to operate the syringe plunger has been added.
- c) The informative annex on test methods for compatibility between syringes and injection fluids has been revised.

Hypodermic syringes specified in this Part of BS 5081 are suitable for use with needles specified in BS 5081 : Part 2. Attention is drawn to the specifications for syringes for use with insulin given in BS 1619 and BS 7548 and to the reusable syringes specified in BS 1263.

### Cross-references

| International standard | Corresponding British Standard                                                                                                                                                          |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO 594-1 : 1986       | BS 3930 <i>Conical fittings with a 6 % (Luer) taper for syringes, needles and other medical equipment</i><br>Part 1 : 1987 <i>Specification for general requirements</i><br>(Identical) |
| ISO 594-2 : 1991       | Part 2 : 1991 <i>Specification for lock fittings</i><br>(Identical)                                                                                                                     |
| ISO 3696 : 1987        | BS 3978 : 1987 <i>Specification for water for laboratory use</i><br>(Identical)                                                                                                         |
| ISO 8601 : 1988        | BS 7151 : 1989 <i>Specification for representation of dates and times in information interchange</i><br>(Identical)                                                                     |

It is recommended that syringes be manufactured and sterilized in accordance with the recommendations in *Quality systems for sterile medical devices and surgical products 1990. Good manufacturing practice* <sup>1)</sup>.

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

<sup>1)</sup> HMSO, 49 High Holborn, London WC1 for personal callers or by post from HMSO, PO Box 276, London SW8 5DT.

## Introduction

This part of ISO 7886 does not give requirements or test methods for freedom from biological hazard. Guidance on biological tests relevant to hypodermic syringes is given in ISO 10993-1, and it is suggested that manufacturers take this guidance into account when evaluating products. Such an evaluation should include the effects of the process whereby the syringes are sterilized. However, national regulations may exist in some countries, and these will override the guidance in ISO 10993-1.

Materials to be used for the construction of syringes are not specified as their selection will depend to some extent upon the design, process of manufacture and method of sterilization employed by individual manufacturers. Guidance on some aspects of the selection of materials is given in annex E.

The materials of the syringe should be compatible with injection fluids. If this is not the case, the attention of the user should be drawn to the exception by labelling the primary container. It is not practicable to specify a universally acceptable test method for incompatibility. However, recommended methods are given in annex F. These test methods can be regarded only as a means of indicating compatibility. The only conclusive test is that of an individual injection fluid with a specific syringe.

Manufacturers of pharmaceuticals use solvents in injectable preparations. Such solvents should be tested by the manufacturer of the injectable preparation for any possible incompatibility with the materials frequently used in syringe construction. The types of material that have received wide acceptance are included in annex E. If an incompatibility exists, the injection should be suitably labelled. The impossibility of testing any one injection fluid with all available syringes is recognized and it is strongly recommended that regulatory authorities and relevant trade associations should recognize the problem and take appropriate measures to assist manufacturers.

Hypodermic syringes specified in this part of ISO 7886 are intended for use with hypodermic needles specified in ISO 7864.

This part of ISO 7886 does not cover syringes for the injection of insulin (see ISO 8537).

In some countries, national pharmacopoeia or government regulations are legally binding and their requirements may take precedence over this part of ISO 7886.



# Sterile hypodermic syringes for single use —

## Part 1: Syringes for manual use

### 1 Scope

This part of ISO 7886 specifies requirements for sterile single-use hypodermic syringes made of plastics materials and intended for the aspiration of fluids or for the injection of fluids immediately after filling.

It excludes syringes for use with insulin (see ISO 8537), single-use syringes made of glass, syringes with needles permanently attached, syringes for use with power-driven syringe pumps, syringes pre-filled with the injection by the manufacturer and syringes supplied with the injection as a kit for filling by a pharmacist.

NOTE 1 A second part of ISO 7886 is being prepared to cover syringes for use with power-driven syringe pumps.

### 2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 7886. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7886 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*.

ISO 594-2:1991, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*.

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times*.

### 3 Definitions

For the purposes of this part of ISO 7886, the following definitions apply.

**3.1 nominal capacity:** Capacity of the syringe as designated by the manufacturer.

NOTE 2 Examples are 1 ml, 5 ml, 50 ml.

**3.2 graduated capacity:** Volume of water at  $(20 \pm 5)^\circ\text{C}$  [or, for tropical countries  $(27 \pm 5)^\circ\text{C}$ ] expelled from the syringe when the fiducial line on the piston traverses a given scale interval or intervals.

**3.3 total graduated capacity:** Capacity of the syringe at the graduation line furthest from the zero graduation line.

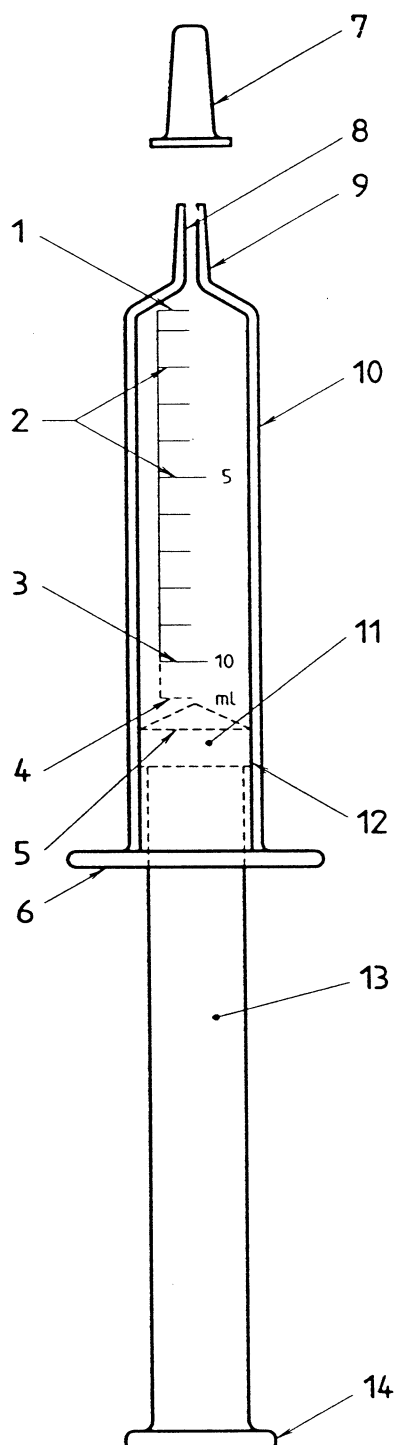
NOTE 3 The total graduated capacity may be equal to, or greater than, the nominal capacity.

**3.4 maximum usable capacity:** Capacity of the syringe when the piston is drawn back to its furthest functional position.

**3.5 fiducial line:** Line circumscribing the end of the piston for determining the capacity corresponding to any scale reading of the syringe.

### 4 Nomenclature

The nomenclature for components of hypodermic syringes for single use is shown in figure 1.



- 1. Zero graduation line
- 2. Graduation lines
- 3. Nominal capacity graduation line
- 4. Total graduated capacity line

- 5. Fiducial line
- 6. Finger grips
- 7. Nozzle cap
- 8. Nozzle lumen
- 9. Nozzle

- 10. Barrel
- 11. Piston
- 12. Seal
- 13. Plunger
- 14. Push-button

NOTE — The drawing is intended to be illustrative of components of a syringe. The piston/plunger assembly may or may not be of integral construction and may or may not incorporate more than one seal.

Figure 1 — Schematic representation of hypodermic syringe for single use

## 5 Cleanliness

When inspected by normal or corrected-to-normal vision without magnification under an illuminance of 300 lx to 700 lx, the surface of the hypodermic syringe which comes in contact with injection fluids during normal use shall be free from particles and extraneous matter.

## 6 Limits for acidity or alkalinity

When determined with a laboratory pH meter and using a general purpose electrode, the pH value of an extract prepared in accordance with annex A shall be within one unit of pH of that of the control fluid.

## 7 Limits for extractable metals

When tested by a recognized microanalytical method, for example by an atomic absorption method, an extract prepared in accordance with annex A shall, when corrected for the metals content of the control fluid, contain not greater than a combined total of 5 mg/l of lead, tin, zinc and iron. The cadmium content of the extract shall, when corrected for the cad-

mium content of the control fluid, be lower than 0,1 mg/l.

## 8 Lubricant

If the interior surfaces of the syringe, including the piston, are lubricated, the lubricant shall not be visible, under normal or corrected-to-normal vision, as droplets or particles.

An acceptable lubricant, applied undiluted, for three-piece syringes is polydimethylsiloxane complying with a national or the European pharmacopoeia. The quantity of lubricant used should not exceed 0,25 mg per square centimetre of the internal surface area of the syringe barrel.

An acceptable lubricant for two-piece syringes is fatty acid amides of erucic and/or oleic acids. The quantity of lubricant should not exceed 0,6 % (*m/m*) of the mass of the barrel, but attention is drawn to the fact that some national regulations may specify a lower maximum concentration.

## 9 Tolerance on graduated capacity

The tolerances on the graduated capacity shall be as given in table 1.

**Table 1 — Capacity tolerance, dead space, scale dimensions and test forces**

| Nominal capacity of syringe, <i>V</i><br>ml | Tolerance on any graduated capacity       |                                                | Maximum dead space<br>ml | Minimum overall length of scale to nominal capacity mark<br>mm | Scale interval<br>ml | Increment between graduation lines to be numbered<br>ml | Forces for leakage testing (see annex D) |                                          |
|---------------------------------------------|-------------------------------------------|------------------------------------------------|--------------------------|----------------------------------------------------------------|----------------------|---------------------------------------------------------|------------------------------------------|------------------------------------------|
|                                             | Less than half nominal capacity           | Equal to or greater than half nominal capacity |                          |                                                                |                      |                                                         | Side force<br>(± 5 %)<br>N               | Axial pressure (gauge)<br>(± 5 %)<br>kPa |
| $V < 2$                                     | ± (1,5 % of $V + 2$ % of expelled volume) | ± 5 % of expelled volume                       | 0,07                     | 57                                                             | 0,05                 | 0,1                                                     | 0,25                                     | 300                                      |
| $2 \leq V < 5$                              | ± (1,5 % of $V + 2$ % of expelled volume) | ± 5 % of expelled volume                       | 0,07                     | 27                                                             | 0,2                  | 0,5 or 1                                                | 1,0                                      | 300                                      |
| $5 \leq V < 10$                             | ± (1,5 % of $V + 1$ % of expelled volume) | ± 4 % of expelled volume                       | 0,075                    | 36                                                             | 0,5                  | 1                                                       | 2,0                                      | 300                                      |
| $10 \leq V < 20$                            | ± (1,5 % of $V + 1$ % of expelled volume) | ± 4 % of expelled volume                       | 0,10                     | 44                                                             | 1,0                  | 5                                                       | 3,0                                      | 300                                      |
| $20 \leq V < 30$                            | ± (1,5 % of $V + 1$ % of expelled volume) | ± 4 % of expelled volume                       | 0,15                     | 52                                                             | 2,0                  | 10                                                      | 3,0                                      | 200                                      |
| $30 \leq V < 50$                            | ± (1,5 % of $V + 1$ % of expelled volume) | ± 4 % of expelled volume                       | 0,17                     | 67                                                             | 2,0                  | 10                                                      | 3,0                                      | 200                                      |
| $50 \leq V$                                 | ± (1,5 % of $V + 1$ % of expelled volume) | ± 4 % of expelled volume                       | 0,20                     | 75                                                             | 5,0                  | 10                                                      | 3,0                                      | 200                                      |