भारतीय मानक
Indian Standard

IS 10258 (Part 1) : 2022
ISO 7886-1 : 2017

[*Superseeding* IS 10258 : 2002
and IS 12050 : 1986]

एक बार उपयोग की जाने वाली निर्जर्म अधः त्वचीय सीरिंजें

भाग 1 मैनुअल उपयोग के लिए सीरिंज

(तीसरा पुनरीक्षण)

Sterile Hypodermic Syringes for Single Use

Part 1 Syringes for Manual Use

(Third Revision)

ICS 11.040.25

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NATIONAL FOREWORD

This Indian Standard (Part 1) (Third Revision) is identical with ISO 7886-1 : 2017 'Sterile hypodermic syringes for single use — Part 1: Syringes for manual use' issued by the International Organization for Standardization was adopted by Bureau of Indian Standards on recommendation of the Hospital Equipment and Surgical Disposable Products Sectional Committee and after approval of the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1982. It was revised in 1995 to incorporate method of test for carrying out sterility test and to harmonize with ISO 7886-1 : 1993 to the extent possible. Its second revision was taken up to align its requirements with ISO 7886-1 : 1993 and adopt it as a dual number standard as IS 10258 : 2002/ISO 7886-1 : 1993 'Sterile hypodermic sringes for single use'. The third revision of this standard has been undertaken to align it with the latest edition of ISO 7886-1 : 2017.

On publication of this Indian Standard, IS 12050 : 1986 'Sterile hypodermic syringes with needle attached for single use' shall be treated as withdrawn.

This Indian Standard is published in various parts. The other part of this series is:

Part 3 Auto-disable Syringes for fixed-dose immunization

The text of ISO standard may be approved as suitable for publication as an Indian Standard without deviations. Certain terminologies and conventions are, however, not identical to those used in the Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker, while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their respective places, are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 15223-1 : 2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	IS/ISO 15223-1 : 2016 Medical devices — symbols to be used with medical device labels, labelling and information to be supplied: Part 1 General requirements (*second revision*)	Identical
ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications	IS/ISO 80369-7 : 2016 Small-Bore Connectors for liquids and Gases in healthcare applications: Part 7 Connectors for intravascular or hypodermic applications	Identical with ISO 80369-7 : 2016

The technical committee has reviewed the provisions of the following International Standard referred in this adopted standard and has decided that it is acceptable for use in conjunction with this standard:

International Standard	*Title*
ISO 23908	Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

(*Continued on third cover*)

Introduction

The ISO 7886 series covers hypodermic syringes primarily intended for human use and provides performance and testing requirements. It permits broader variation in design so as not to limit innovation and methods of packaging. Its appearance and layout are consistent with other related standards which are designed to be more performance-based compared to design prescriptive.

General requirements as design guidelines for manufacturers are introduced in this document. Several limits for requirements which are historic based but confirmed in practice for many years have been kept.

Materials to be used for the construction and lubrication of sterile syringes for single use are not specified as their selection will depend to some extent upon the design, process of manufacture and sterilization method employed by individual manufacturers. 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 on unit packaging. It is not practicable to specify a universally acceptable test method for incompatibility, as the only conclusive test is that an individual specific injection fluid is compatible 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. If an incompatibility is identified, the injection fluid 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 of injectable preparations.

Syringes should be manufactured and sterilized in accordance with recognized national or international codes of good manufacturing practice for medical devices.

The sampling plans for inspection selected for the ISO 7886 series are intended to verify the design at a high confidence level. The sampling plans for inspection do not replace the more general manufacturing quality systems requirements that appear in standards on quality systems, for example the ISO 9000 series and ISO 13485.

Manufacturers are expected to follow a risk-based approach and employ usability engineering during the design, development and manufacture of syringes.

Guidance on transition periods for implementing the requirements of ISO 7886 (all parts) is given in ISO/TR 19244.

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Indian Standard

STERILE HYPODERMIC SYRINGES FOR SINGLE USE

PART 1 SYRINGES FOR MANUAL USE

(Third Revision)

1 Scope

This document specifies requirements and test methods for verifying the design of empty sterile single-use hypodermic syringes, with or without needle, made of plastic or other materials and intended for the aspiration and injection of fluids after filling by the end-users. This document does not provide requirements for lot release. The syringes are primarily for use in humans.

Sterile syringes specified in this document are intended for use immediately after filling and are not intended to contain the medicament for extended periods of time.

It excludes syringes for use with insulin (see ISO 8537), single-use syringes made of glass, syringes for use with power-driven syringe pumps, syringes pre-filled by the manufacturer, and syringes intended to be stored after filling (e.g. in a kit for filling by a pharmacist).

Hypodermic syringes without a needle specified in this document are intended for use with hypodermic needles specified in ISO 7864.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 23908, *Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
nominal capacity
capacity of the syringe as designated by the manufacturer

EXAMPLE 1 ml, 5 ml, 50 ml

3.2
graduated capacity
volume of water, at 18 °C to 28 °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

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

3.5
fiducial line
leading edge on the plunger stopper that is in contact with and perpendicular to the syringe barrel and aligns with the zero marking on the syringe barrel when the piston is fully inserted

3.6
unit packaging
packaging which has direct contact with the device and maintains the sterility of the product

3.7
user packaging
packaging designed to contain one or more unit packages or self-contained syringe units

Note 1 to entry: Self-contained syringe units can be packed in multiple unit packs.

3.8
two-piece syringe
syringe assembly comprises the barrel and piston, whereas plunger and plunger stopper form one component made of the same material

3.9
three-piece syringe
syringe assembly includes the barrel and piston, whereas plunger and plunger stopper are two separate components of different materials

3.10
nozzle cap
sheath intended to physically protect the nozzle prior to use

3.11
plunger stopper
component connected to the leading end of the plunger and seals the open end of the syringe barrel

3.12
self-contained syringe
syringe with protective end caps [i.e. plunger cap, and nozzle cap or *needle cap* (3.17)] intended to maintain the sterility of the interior of the syringe

3.13
dead space
residual volume of fluid left in syringe when the *plunger stopper* (3.11) is fully depressed

3.14
multiple unit pack
multiple syringes packaged with a single seal that maintains the sterility of the product

3.15
piston
assembled component of plunger and *plunger stopper* (3.11)

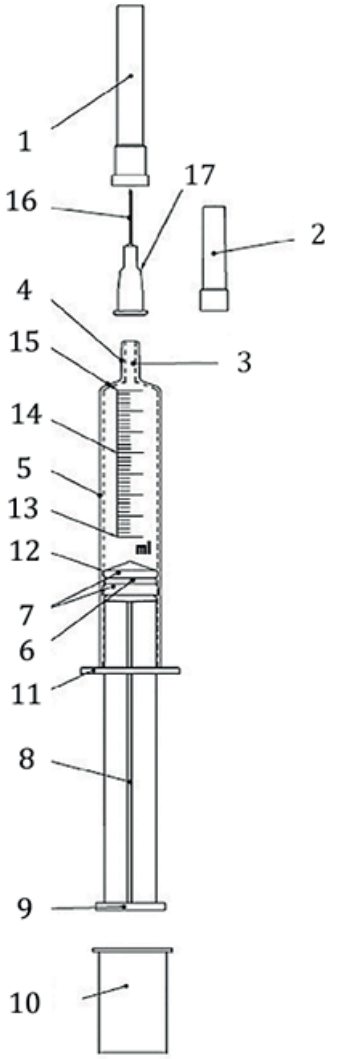
3.16
barrel flanges
flanges that protrude from the barrel (also referred to as finger grips) to provide the user an ergonomic means of gripping the syringe during injection

3.17
needle cap or shield
sheath intended to physically protect the needle prior to use

3.18
plunger
device component which advances the *plunger stopper* (3.11) to deliver the medicinal product

4 Nomenclature

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



Key

1	needle cap or shield (if used)	10	plunger cap
2	nozzle cap	11	barrel flanges (finger grips)
3	nozzle lumen	12	fiducial line
4	nozzle	13	nominal capacity
5	barrel	14	graduation lines
6	plunger stopper (3-piece only)	15	zero line
7	seals	16	needle tube
8	plunger	17	hub
9	push-button		

NOTE The figure is intended to be illustrative of the components of a syringe. The plunger stopper/plunger assembly can or cannot be of integral construction and can or cannot incorporate more than one seal.

Figure 1 — Schematic representation of hypodermic syringe for single use

5 General requirements

The general requirements are considered to be design inputs for manufacturers.

a) Syringes shall be free from defects affecting appearance, safety and performance for their intended use. Syringes with integrated or add-on sharps protection shall comply with ISO 23908.

   — The syringe's barrel flanges shall be of adequate size, shape and strength for the intended purpose. The design specifications for the barrel flanges shall be determined through risk analysis and confirmed through usability validation testing.

   — The materials shall not cause the syringes to yield, under conditions of normal use, significant amounts of toxic substances and shall permit them to satisfy the appropriate national requirements or regulations for freedom from pyrogenic materials and abnormal toxicity.

   — Materials used in the construction of the wall of the syringe barrel shall have sufficient clarity to enable dosages to be read without difficulty.

   — The standard does not specify materials to be used for the construction and lubrication of sterile syringes with or without needles for single use, because their selection will depend, to some extent, upon the manufacturers specific syringe design, process of manufacture and sterilization method.

b) The design and validation of the packaging shall take into consideration the final use of the syringe and the storage and shipping conditions and the defined shelf life.

6 Extraneous matter

6.1 General

The surfaces of the syringe that come in contact with injection fluids during normal use shall be free from particles and extraneous matter.

NOTE Compliance with this requirement will be determined through inspection by an individual with normal vision (or corrected-to-normal vision), without magnification.

6.2 Limits for acidity or alkalinity

Exposure of distilled water to the finished syringe product shall not change its pH value by more than one unit.

Compliance with this requirement shall be demonstrated by preparing the solutions described in Annex A. The results shall show that the pH value of the syringe assessment fluid is within one pH unit of the pH value of the control fluid.

The pH value of both solutions may be determined with a laboratory potentiometric pH meter using a general purpose electrode.

6.3 Limits for extractable metals

Exposure of distilled water to the finished syringe product shall not change its content of metals by more than a combined total of 5 mg/kg of lead, tin, zinc and iron; the cadmium content shall be less than 0,1 mg/kg.

Compliance with this requirement shall be demonstrated by preparing the solutions described in Annex A and testing them using a recognized micro-analytical method, for example, by an atomic absorption method or by an inductively coupled plasma mass spectrometry method (ICP).

7 Lubricant

When the plunger stopper is fully inserted the amount of lubricant applied into the barrel shall not reach the Luer channel of the nozzle.

For lubricants applied to interior surface of the syringe, the quantity of lubricant applied shall not exceed 0,25 mg/cm^2 of the interior surface area of the syringe in contact with the injection fluid.

The amount and distribution of lubricant applied should be optimized to minimize lubricant visibility.

NOTE 1 An acceptable lubricant is silicone complying with a national or the European pharmacopoeia and ISO 10993-1.

For lubricants incorporated in the polymer formulation, the quantity of lubricant shall not exceed 0,6 % (w/w) of the mass of the component, but attention is drawn to the fact that some national regulations may specify a lower maximum concentration.

NOTE 2 If a lubricant is incorporated in the polymer formulation, visible particles can become apparent when the lubricant blooms to the surface of the syringe barrel and the plunger stopper scrapes it off.

NOTE 3 Example of acceptable lubricants incorporated in the polymer formulation are fatty acid amides of erucic and/or oleic acids complying with ISO 10993-1.

NOTE 4 See Annex F for a test method for the quantity of silicone oil.

8 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 V ml	**Tolerance on any graduated capacity**		**Maximum dead space** ml	**Minimum overall length of scale to nominal capacity mark** mm	**Scale interval** ml	**Increment between graduation lines to be numbered** ml	**Forces for leakage testing (see Annex D)**	
	Less than half nominal capacity	**Equal to or greater than half nominal capacity**					**Side force** (±5 %) N	**Axial pressure** (gauge) (±5 %) 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	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	2,0	300

NOTE Expelled volume means all the liquid ejected with the seal brought to the physical limit that was designed to be coincident with the zero mark of the scale.

EXAMPLE 1 For a 3 ml syringe, when filled to the 1 ml graduation (less than 1/2 capacity), the required tolerance would be ±(1,5 % × 3 ml + 2 % × 1 ml) = 0,065 ml

EXAMPLE 2 For a 3 ml syringe, when filled to the 2 ml graduation (greater than 1/2 capacity), the required tolerance would be ±(5 % × 2 ml) = 0,100 ml.

Table 1 *(continued)*

Nominal capacity of syringe V ml	Tolerance on any graduated capacity		Maximum dead space ml	Minimum overall length of scale to nominal capacity mark mm	Scale interval ml	Increment between graduation lines to be numbered ml	Forces for leakage testing (see Annex D)	
	Less than half nominal capacity	Equal to or greater than half nominal capacity					Side force (±5 %) N	Axial pressure (gauge) (±5 %) kPa
$20 \leq V < 30$	±(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
$V \geq 50$	±(1,5 % of V + 1 % of expelled volume)	±4 % of expelled volume	0,20	75	5,0	10	3,0	200

NOTE Expelled volume means all the liquid ejected with the seal brought to the physical limit that was designed to be coincident with the zero mark of the scale.

EXAMPLE 1 For a 3 ml syringe, when filled to the 1 ml graduation (less than 1/2 capacity), the required tolerance would be ±(1,5 % × 3 ml + 2 % × 1 ml) = 0,065 ml

EXAMPLE 2 For a 3 ml syringe, when filled to the 2 ml graduation (greater than 1/2 capacity), the required tolerance would be ±(5 % × 2 ml) = 0,100 ml.

9 Graduated scale

9.1 Scale

9.1.1 The syringe shall have either only one scale or more than one identical scales, which shall be graduated and numbered at least at the intervals given in Table 1. The unit of volume shall be marked on the barrel.

NOTE The scale interval can be less (finer) than the scale interval given in Table 1.

If necessary by a specific application, the scale may vary and this requirement does not preclude the provision of additional graduation marks within the scale or as extensions to the scale. Any variation of the scale or graduation is recommended to be assessed for risk according to ISO 14971 and for usability according to IEC 62366.

9.1.2 The total graduated capacity may be equal to, or greater than, the nominal capacity. If the scale is extended beyond the nominal capacity, the extended portion shall be differentiated from the rest of the scale.

Examples of means of differentiation are the following:

a) encircling the scale number of the nominal capacity line;

b) using smaller scale numbers for the extra graduation lines;

c) using shorter graduation lines for the extra graduation lines;

d) using a broken line for the optional vertical line of the extra scale length.

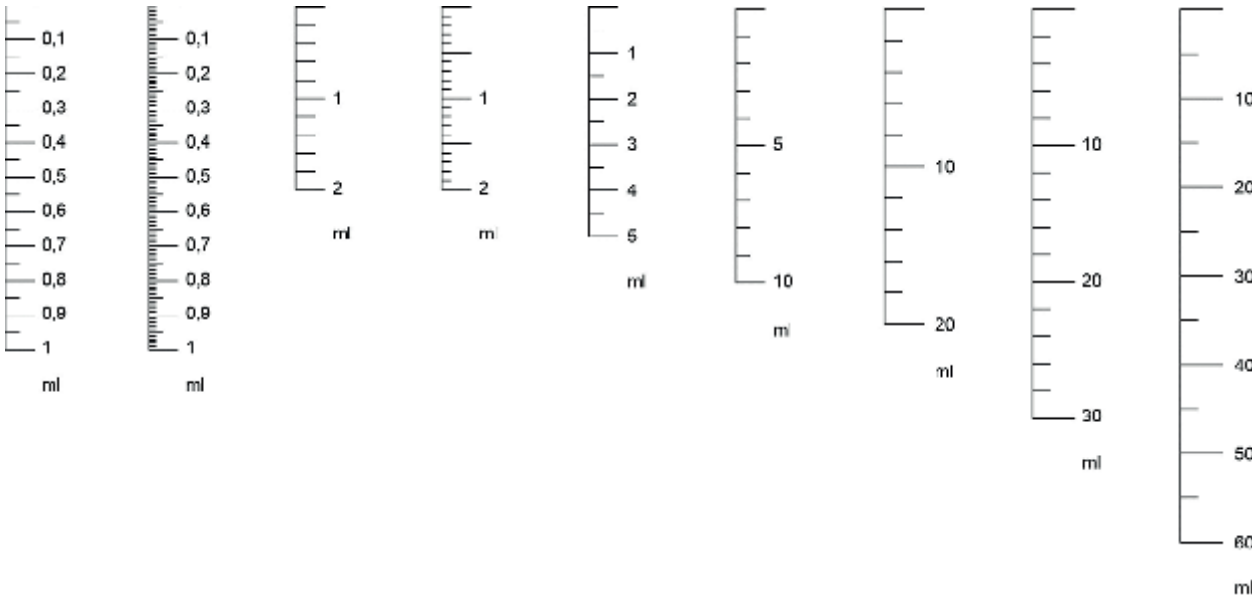
9.1.3 Graduation lines shall be of uniform thickness. They shall lie in planes at right angles to the axis of the barrel.

9.1.4 Graduation lines shall be evenly spaced along the longitudinal axis between the zero graduation line and the line for the total graduated capacity.

9.1.5 When the syringe is held vertically, the ends of all graduation lines of similar length shall be vertically beneath each other.

The lengths of the short graduation lines on each scale are recommended to be approximately half the length of the long lines. If different graduation line configurations are used, this could be submitted to usability evaluation according to IEC 62366.

Examples of scales and the numbering of graduation lines are shown in Figure 2.



NOTE 1 The vertical line of the scale may be omitted.

NOTE 2 The figure is not to scale.

Figure 2 — Examples of scale graduations

9.2 Numbering of scales

9.2.1 Graduation lines shall be numbered at least at the volume increments given in Table 1. In addition, the line denoting the nominal capacity or the lines denoting the nominal capacity and the total graduated capacity, if these differ, shall be numbered.

Examples of scale numbering are shown in Figure 2.

9.2.2 When the syringe is held vertically with the conical tip uppermost and with the scale to the front, the numbers shall appear vertical on the scale and be approximately centred on the graduation lines to which they relate. The numbers shall be close to, but shall not touch, the ends of the graduation lines to which they relate.

9.3 Overall length of scale to nominal capacity line

The overall length of the scale shall be as given in Table 1.

9.4 Position of scale

When the plunger stopper is fully inserted, the zero graduation line of the scale shall coincide with the fiducial line on the plunger stopper in order to achieve the graduated capacity tolerance as stated in Table 1.

10 Barrel

10.1 Dimensions

Maximum capacity shall be determined by risk assessment with consideration of, for example, removal of air bubbles or risk of overdose.

10.2 Barrel flanges

The open end of the barrel shall be provided with barrel flanges. Barrel flanges shall be of adequate size, shape and strength for the intended purpose and shall enable the syringe to be held securely during use. The syringe design, such as barrel flanges, shall be such that the syringe will not roll more than 180° when it is placed on a flat surface at an angle of 10° to the horizontal. The barrel flanges shall be free from flash and sharp edges.

Finger grip configurations that do not conform to these requirements are recommended to be assessed for risk according to ISO 14971 and for usability according to IEC 62366.

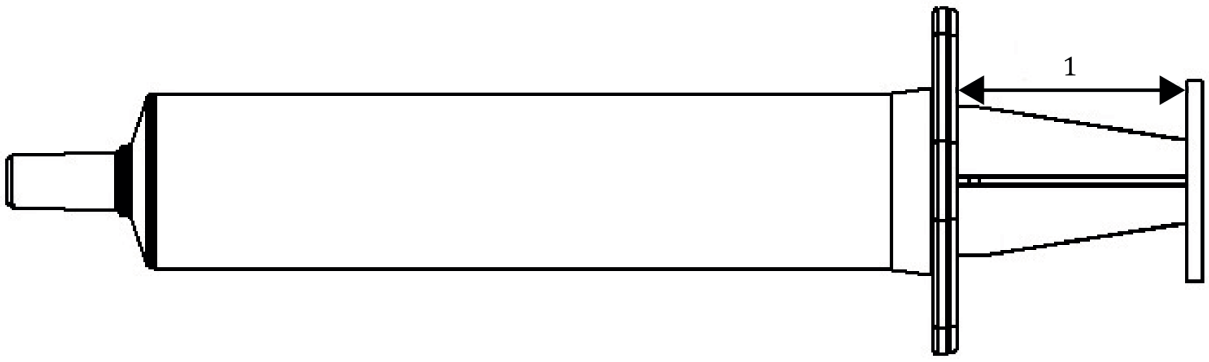
11 Plunger stopper/plunger assembly

11.1 Design

When tested in accordance with Annex B, the plunger stopper shall not become detached from the plunger.

The plunger shall be of a length adequate to allow the plunger stopper to traverse the full length of the barrel, but it shall not be possible to easily withdraw the piston completely from the barrel.

The projection of the plunger and the configuration of the push-button should be such as to allow the plunger to be operated without difficulty. When the fiducial line of the plunger stopper coincides with the zero graduation line, the minimum length of the plunger from the surface of the barrel flanges nearer to the push-button, as shown in Figure 3, shall be at least 8 mm.



Key

1 minimum 8 mm

Figure 3 — Minimum length between barrel flanges and plunger push-button

12 Nozzle

12.1 Conical fitting

The male conical fitting of the syringe nozzle shall be in accordance with ISO 80369-7.

If the syringe has a locking fitting, it shall be in accordance with ISO 80369-7.

12.2 Position of nozzle on end of barrel

12.2.1 On syringes of nominal capacity of less than 5 ml, the syringe nozzle shall be situated centrally, i.e. it shall be coaxial with the barrel.

12.2.2 On syringes of nominal capacity of 5 ml and greater, the syringe nozzle shall be situated either centrally or eccentrically.

12.2.3 If the syringe nozzle is eccentric, its axis shall be vertically below the axis of the barrel when the syringe is lying on a flat surface with the scale uppermost. The distance between the axis of the nozzle and the nearest point on the internal surface of the bore of the barrel shall be not greater than 4,5 mm.

12.3 Nozzle lumen

The nozzle lumen shall have a diameter of not less than 1,2 mm.

13 Performance

13.1 Dead space

Dead space shall be minimized to reduce waste and transmission of infectious agents.

When tested in accordance with Annex C, the maximum volume of liquid contained in the barrel and the nozzle when the plunger stopper is fully inserted shall be as given in Table 1.

13.2 Freedom from air and liquid leakage past plunger stopper

When tested in accordance with Annex D, there shall be no leakage of water past the plunger stopper or seal(s). Small droplets between the seals are not considered failure.

When tested in accordance with Annex B, there shall be no leakage of air past the plunger stopper or seal(s), and there shall be no fall in the manometer reading.

13.3 Force to operate the piston

It is recommended to measure the force to operate the piston. A suggested test method and performance criteria for the forces requirement to move the plunger stopper is given in Annex E.

13.4 Fit of plunger stopper/plunger in barrel

When the syringe is filled with water to the nominal capacity and held vertically with first one end and then the other end uppermost, the piston shall not move by reason of its own mass and the water contained.

14 Packaging

14.1 Unit packaging and self-contained syringe units

14.1.1 Unit packaging

The syringe, together with the needle if supplied, shall be sealed individually in a unit packaging.

The needle may be packaged in its own packaging inside the unit packaging.

The materials and design of the unit packaging should have no detrimental effects on the contents and shall ensure the following:

a) maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions;

b) minimum risk of contamination of the contents during opening and removal from the packaging;

c) adequate protection of the contents during normal handling, transit and storage;

d) that once opened, the packaging cannot be easily resealed, and it shall be obvious that the packaging has been opened.

14.1.2 Self-contained syringe units

The syringe shall be fitted with needle cap and plunger cap.

The materials and design of the syringe unit shall ensure the following:

a) maintenance of sterility of the interior of the syringe unit (e.g. the outside surface of the needle, the protruding part of the plunger and its push-button and the fluid path of the syringe, and needle, if fitted) under dry, clean and adequately ventilated conditions;

b) minimum risk of contamination of the contents during opening of the unit;

c) adequate protection of the contents during normal handling, transit and storage.

The syringe or the syringe unit may be provided with a means of indicating that the unit may have been opened previously.

14.2 Multiple unit pack

The materials and design of the multiple unit pack shall ensure the following:

a) minimum risk of contamination of the syringe unit during opening of the pack;

b) adequate protection of the syringe units during normal handling, transit and storage;

c) that once opened, it shall be obvious that the multiple pack has been opened.

14.3 User packaging

A number of unit packaging, syringe units, or a number of multiple unit packs shall be packed in a user packaging.

The packaging system shall provide physical protection and integrity of the sterile barrier system during normal handling, transit, and storage over the shelf life, i.e. until the expiration date.

15 Information supplied by the manufacturer

15.1 General

The syringe shall be accompanied by the information that is sufficient for its safe use, taking account of the training and knowledge of potential users. The information shall include the identity of the manufacturer.

15.2 Syringes

15.2.1 General

The barrels of syringes shall be marked with the following information:

a) appropriate graduated scale in accordance with Clauses 8 and 9;

b) total graduated capacity in millilitres.

15.2.2 Additional marking for self-contained syringe units

The syringe or unit shall additionally be marked with the following information:

a) the words "For single use" or equivalent, such as the symbol for "Do not re-use" (see ISO 15223-1:2016, Table 1, symbol number 5.4.2); the term "disposable" shall not be used;

b) name and/or registered trademark of the manufacturer and, where applicable, reference to its authorized representative.

A warning to check the integrity of the seals of the self-contained syringe unit before use may be given.

All information appearing on the barrel should be marked in such a position as to interfere as little as possible with the reading of the graduated scale.

15.3 Unit packaging

The unit packaging shall be marked with the following information:

a) the word "STERILE" or equivalent, such as the symbol for "Sterile" (see ISO 15223-1:2016, Table 1, symbol number 5.2.1);

b) the words "For single use" or equivalent, such as the symbol for "Do not re-use" (see ISO 15223-1:2016, Table 1, symbol number 5.4.2); the term "disposable" shall not be used;

c) an identification reference to the batch code or lot number, prefixed by the symbol "Batch code" (see ISO 15223-1:2016, Table 1, symbol number 5.1.5), or the word "LOT";

d) the external diameter and length of the needle in millimetres, if included; the gauge size of the needle may also be marked.

A warning to check the integrity of the unit packaging before use may be given; such as using the symbol for "Do not use if package is damaged". See ISO 15223-1:2016, Table 1, symbol number 5.2.8.

Symbols that indicate the sterilization method may also be used. See ISO 15223-1:2016, Table 1, symbol numbers 5.2.2 to 5.2.5.

The unit packaging shall also be marked with the following information unless the product bears the information and is visible through the unit packaging:

e) identity of the contents, including the capacity of the syringe;

f) name and/or trademark and address of the manufacturer and/or his authorized representative;

g) the words “EXP” or equivalent, such as the symbol for “Use-by date” (see ISO 15223-1:2016, Table 1, symbol number 5.1.4).

15.4 Multiple unit packs

15.4.1 General

The multiple unit packs for syringes shall be marked with the following information:

a) the words “For single use” or equivalent, such as the symbol for “Do not re-use” (see ISO 15223-1:2016, Table 1, symbol number 5.4.2); the term “disposable” shall not be used;

b) name and/or trademark and address of the manufacturer and/or his authorized representative, unless the product bears this information and is visible through the multiple unit pack;

c) an identification reference to the batch code or lot number, prefixed by the symbol “Batch code” (see ISO 15223-1:2016, Table 1, symbol number 5.1.5); or the word “LOT”.

d) the external diameter and length of the needle in millimetres, if included; the gauge size of the needle may also be marked;

e) identity of the contents, including the capacity of the syringe to be used unless the information is visible through the multiple unit pack.

f) the words “EXP” or equivalent, such as the symbol for “Use-by date” (see ISO 15223-1:2016, Table 1, symbol number 5.1.4).

15.4.2 Multiple unit packs with self-contained syringes

The multiple unit packs for self-contained syringes shall be marked with the following information:

a) the words “Syringe interior sterile” or equivalent, such as the symbol for “Sterile fluid path” (see ISO 15223-1:2016, Table 1, symbol number 5.2.9);

b) a warning to check the integrity of the seals of the self-contained syringe units before use, unless this warning is given on the syringe unit.

15.5 User packaging

The user packaging shall be marked with the following information:

a) the word “STERILE” or equivalent, such as the symbol for “Sterile” (see ISO 15223-1:2016, Table 1, symbol number 5.2.9);

b) for self-contained syringes, the words “Syringe interior sterile” or equivalent, such as the symbol for “Sterile fluid path” (see ISO 15223-1:2016, Table 1, symbol number 5.2.9);

c) the words “For single use” or equivalent, such as the symbol for “Do not reuse” (see ISO 15223-1:2016, Table 1, symbol number 5.4.2); the term “disposable” shall not be used;

d) an identification reference to the batch code or lot number, prefixed by the symbol “Batch code“(see ISO 15223-1:2016, Table 1, symbol number 5.1.5);or the word “LOT”.

e) name and/or trademark and address of the manufacturer and/or his authorized representative;

f) description of contents;

g) the words “EXP” or equivalent, such as the symbol for “Use-by date” (see ISO 15223-1:2016, Table 1, symbol number 5.1.4).

A warning to check the integrity of the unit packaging before use may be given; such as using the symbol for “Do not use if package is damaged”. See ISO 15223-1:2016, Table 1, symbol number 5.2.8.

Symbols that indicate the sterilization method may also be used. See ISO 15223-1:2016, Table 1, symbol numbers 5.2.2 to 5.2.5.

15.6 Storage container

If user packaging comes in a storage container, the storage container shall be marked with at least the following information:

a) identity of the contents, including the capacity of the syringe;

b) an identification reference to the batch code or lot number, prefixed by the symbol “Batch code” (see ISO 15223-1:2016, Table 1, symbol number 5.1.5); or the word “LOT”;

c) the word “STERILE” or equivalent, such as the symbol for “Sterile” (see ISO 15223-1:2016, Table 1, symbol number 5.2.1);

d) the name and address of the manufacturer and, where applicable, reference to its authorized representative;

e) information for handling, storage and transportation of the contents.

f) the word “EXP” or equivalent, such as the symbol for “Use-by date” (see ISO 15223-1:2016, Table 1, symbol number 5.1.4).

Symbols that indicate the sterilization method may also be used. See ISO 15223-1:2016, Table 1, symbol numbers 5.2.2 to 5.2.5.

An indication to keep the storage container away from sunlight and keep dry may be given. See ISO 15223-1:2016, Table 1, symbol numbers 5.3.2 and 5.3.4.

15.7 Transport wrapping

If a storage container is not used but the user containers are wrapped for transportation, the information required by 15.6 shall either be marked on the wrapping or shall be visible through the wrapping.

Annex A
(normative)

Method for preparation of extracts

A.1 Principle

The syringe is filled with water in order to extract soluble components.

A.2 Apparatus and reagents

A.2.1 Distilled water.

A.2.2 Selection of laboratory borosilicate glassware.

A.3 Procedure

A.3.1 Fill at least three syringes to the nominal capacity graduation line with water (A.2.1).

A.3.2 Expel air bubbles and maintain the syringes at a temperature of 37 °C to 40 °C for 8 h to 8 h and 15 min.

A.3.3 Eject the contents and combine them in a vessel made of borosilicate glass (A.2.2).

A.3.4 Prepare the control fluid by reserving a portion of the unused water (A.2.1).

Annex B
(normative)

Test method for air leakage past syringe plunger stopper during aspiration, and for separation of plunger stopper and plunger

B.1 Principle

The syringe nozzle is connected to a compatible connection and the syringe partially filled with water. A negative pressure is applied through the nozzle, and the syringe inspected for leakage past the plunger stopper and seal(s) and to determine if the plunger stopper becomes detached from the plunger.

B.2 Apparatus and reagents

B.2.1 Tubing set with compatible conical fitting, in accordance with ISO 80369-7.

B.2.2 Support and device, for clamping the syringe plunger in a fixed position.

B.2.3 Equipment for producing, controlling and measuring vacuum, comprising a vacuum generator, a manometer and a vacuum-tight valve system, different configurations of such equipment are possible, with syringe nozzle upwards or downwards (e.g. Figure B.1).

B.2.4 Distilled water at a temperature of 18 °C to 28 °C.

B.3 Procedure

B.3.1 Draw into the syringe a volume of water (B.2.4) of not less than 25 % of the nominal capacity.

B.3.2 Withdraw the plunger stopper axially until the fiducial line is at the nominal graduated capacity and clamp (B.2.2) the plunger in this position.

B.3.3 Connect the syringe nozzle to the conical fitting (B.2.1).

B.3.4 Generate the vacuum.

B.3.5 Adjust the bleed control so that a gradual reduction in pressure is obtained and a manometer reading of 88 kPa below ambient atmospheric pressure is reached.

NOTE 1 kPa = 7,5 mmHg.

B.3.6 Examine the syringe for leakage of air past the plunger stopper or seal(s).

B.3.7 Isolate the syringe and manometer assembly by means of the vacuum-tight valve.

B.3.8 Observe the manometer reading for 60 s and record any fall in the reading.

B.3.9 Examine the syringe to determine if the plunger stopper is detached from the plunger.

B.4 Test report

The test report shall contain at least the following information:

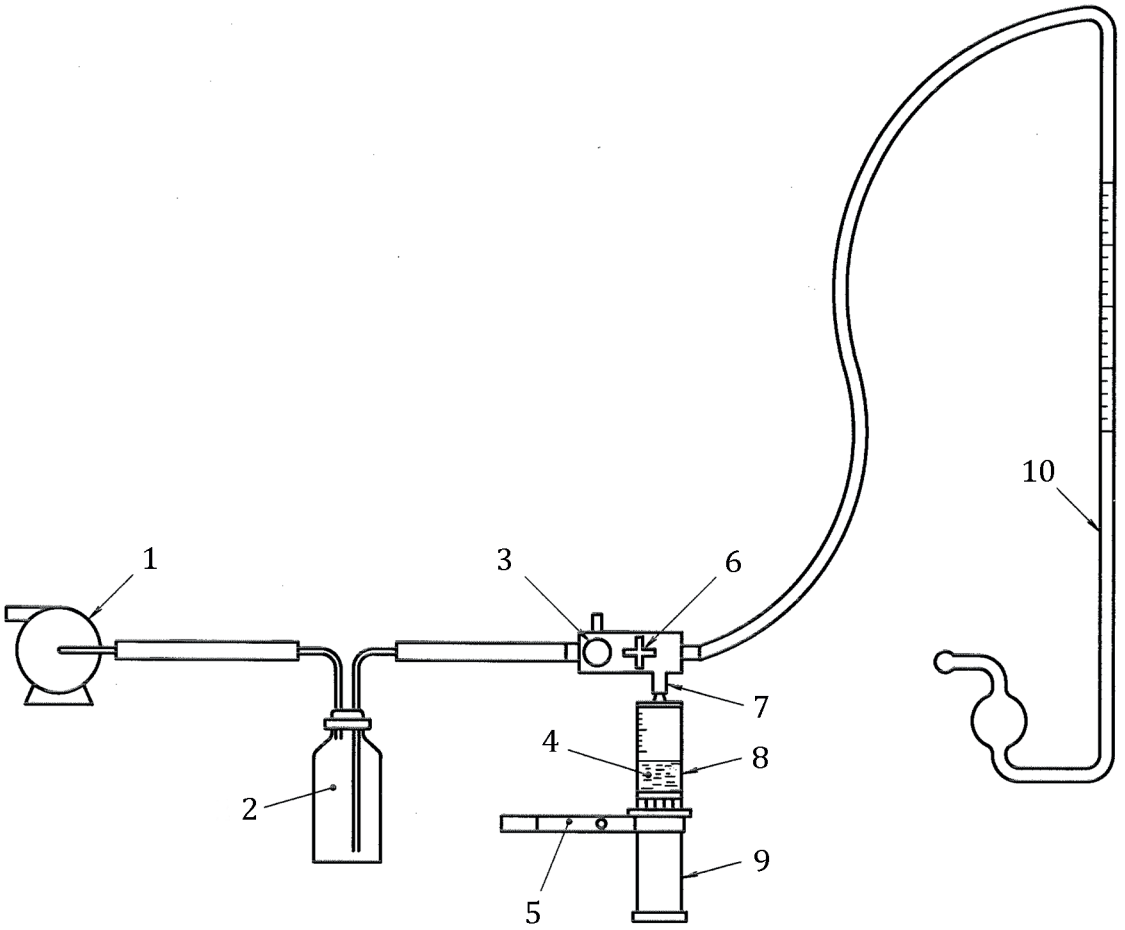
a) identity and nominal capacity of the syringe;

b) whether leakage past the plunger stopper or seal(s) was observed;

c) fall, if any, in the manometer reading;

d) whether the plunger stopper detached from the plunger;

e) date of testing.



Key

1	vacuum pump	6	vacuum-tight valve
2	bottle trap	7	female conical fitting complying with ISO 80369-7
3	fine bleed control	8	water to not less than 25 % of nominal capacity
4	nominal capacity graduation line	9	syringe
5	clamp	10	manometer

Figure B.1 — Apparatus for aspiration test

Annex C
(normative)

Method for determination of dead space

C.1 Principle

The syringe is weighed dry and after having been filled with, and emptied of, water. The dead space is inferred from the mass of the residual water.

C.2 Apparatus and reagents

C.2.1 **Balance** with a resolution of 1 mg or better.

C.2.2 **Distilled water** at a temperature of 18 °C to 28 °C.

C.3 Procedure

C.3.1 Weigh (C.2.1) the empty syringe.

C.3.2 Fill the syringe to the nominal capacity graduation line with distilled water (C.2.2), taking care to expel all air bubbles and to ensure that the level of the meniscus of the water coincides with the end of the nozzle lumen.

C.3.3 Expel the water by fully depressing the plunger, and wipe dry the outer surfaces of the syringe.

C.3.4 Reweight the syringe (C.2.1).

C.4 Calculation of results

Determine the mass, in grams, of water remaining in the syringe by subtracting the mass of the empty syringe from the mass of the syringe after expulsion of the water. Record this value as the dead space in millilitres, taking the density of water as 1 000 kg/m^3.

C.5 Test report

The test report shall contain at least the following information:

a) identity and nominal capacity of the syringe;

b) dead space, in ml;

c) date of testing.

Annex D
(normative)

Test method for liquid leakage at syringe plunger stopper under compression

D.1 Principle

The syringe is filled with water, the syringe nozzle sealed, the plunger rotated to allow the greatest downward deflection in relation to the barrel and a force applied in an attempt to induce leakage past the plunger stopper seal(s).

D.2 Apparatus and reagents

D.2.1 Device for sealing or occluding the syringe nozzle.

NOTE This can comprise the reference steel female conical fitting in accordance with ISO 80369-7, suitably sealed or occluded.

D.2.2 Device for applying a sideways force to the syringe plunger, in the range of 0,25 N to 3 N.

D.2.3 Device for generating pressures of 200 kPa and 300 kPa.

D.2.4 Distilled water at a temperature of 18 °C to 28 °C.

D.3 Procedure

D.3.1 Draw into the syringe a volume of water (D.2.4) exceeding the nominal capacity of the syringe.

D.3.2 Expel air and adjust the volume of water in the syringe to the nominal capacity.

D.3.3 Seal (D.2.1) the syringe nozzle.

D.3.4 Apply a sideways force (D.2.2) to the push-button at right angles to the plunger to swing the plunger radially about the piston seal(s) with a force as given in Table 1. Orientate the plunger to permit the maximum deflection from the axial position.

D.3.5 Apply an axial force (D.2.3) to the syringe so that the pressure given in Table 1 is generated by the relative action of the piston and barrel. Maintain the pressure for 30 s to 35 s.

D.3.6 Examine the syringe for leakage of water past the plunger stopper seal(s).

D.4 Test report

The test report shall contain at least the following information:

a) identity and nominal capacity of the syringe;

b) whether leakage past the piston or seal(s) was observed;

c) date of testing.

Annex E
(informative)

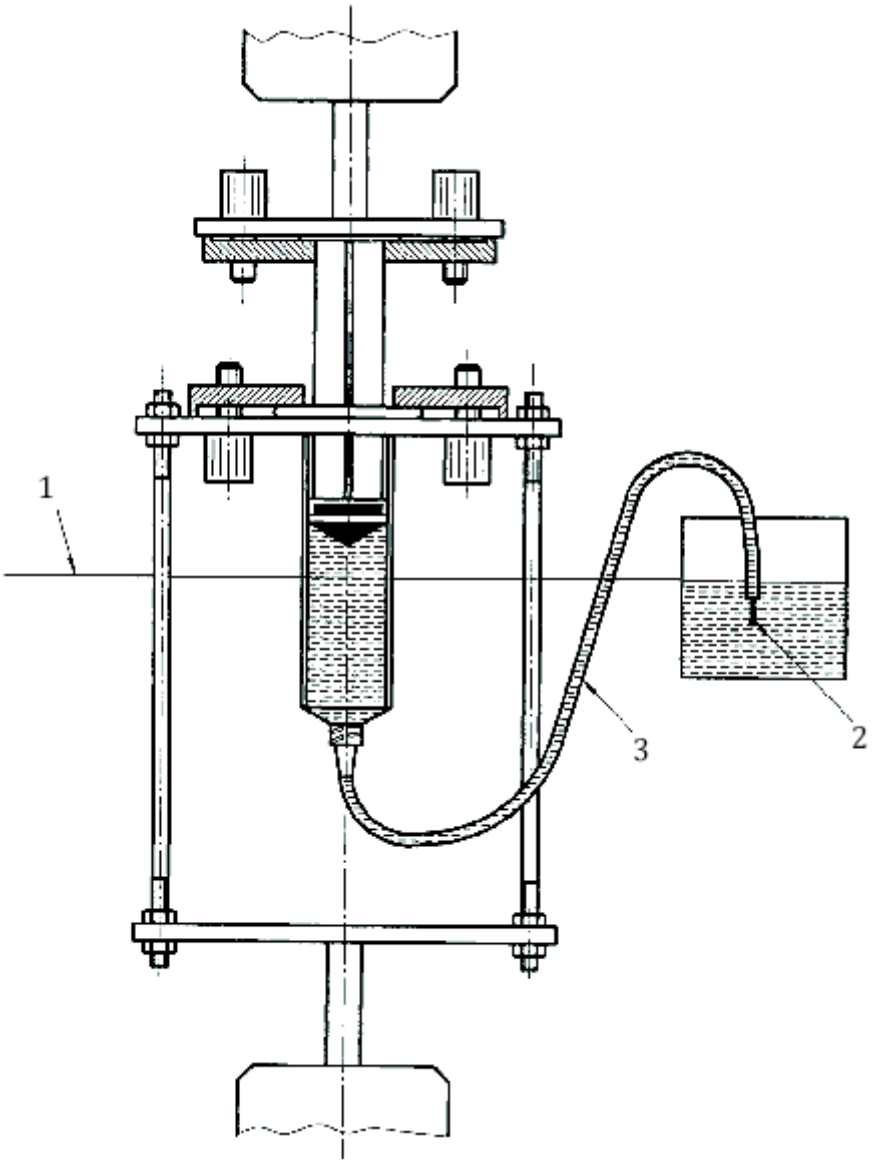
Test method for the determination of forces required to operate the piston

E.1 Principle

A mechanical testing machine is used to expel water from a syringe and simultaneously record the force required to move the piston.

E.2 Apparatus and reagents

E.2.1 Mechanical testing machine, as shown in Figure E.1, capable of attaching on to the syringe under test and of depressing the syringe piston at the constant linear rate, while simultaneously measuring and recording the force required to move the piston with an accuracy of 1 % of full-scale reading.



Key

1 water level adjusted to align with the graduation mark at 50 % of the nominal capacity of the syringe

2 needle [1,2 mm (18 G) and approximately 40 mm length]

3 tubing [(2,7 ± 0,1) mm i.d. and (500 ± 5) mm in length with male and female Luer adapters at each end)]

Figure E.1 — Apparatus for determining forces to operate piston

E.2.2 Reservoir, open to the atmosphere.

E.2.3 Tubing, (2,7 ± 0,1) mm inside diameter and (500 ± 5) mm in length and sufficient flexibility for connecting it per Figure E.1 to the sample syringe via a female Luer to barbed adapter, and to the outlet needle via a male Luer to barbed adapter.

NOTE Tygon®[1)] and polyethylene are some examples of an acceptably flexible tubing material for this application.

E.2.4 Distilled water.

E.3 Procedure

E.3.1 Remove the syringe from the package. Move the syringe plunger once until the fiducial line reaches the total graduated capacity graduation line, and then return it so that the fiducial line reaches the zero graduation line.

E.3.2 Add to the reservoir water (E.2.4) at (23 ± 5) °C and displace any air from the tubing. Maintain the water and the syringe at this temperature.

E.3.3 Connect the nozzle of the syringe to the tubing of the reservoir (E.2.2). Fill the syringe with water (E.2.4) to beyond the nominal capacity, mount the syringe in the test fixture as shown in Figure E.1 and attach the syringe push button to the driving head of the mechanical testing machine (E.2.1).

E.3.4 Adjust the relative positions of the syringe and reservoir so that the water level in the reservoir is approximately level with the mid-point of the syringe barrel (see Figure E.1).

E.3.5 Expel water until the fiducial line of the plunger is at the nominal capacity mark of the syringe.

NOTE The presence of air in the syringe nozzle will not affect the result of the test.

E.3.6 Wait 30 s.

E.3.7 Start the testing machine (E.2.1) at a rate of (100 ± 5) mm/min and stop the machine at no more than 10 % of the nominal volume.

E.3.8 Measure and note the forces required to initiate movement of the piston and sustain the travel of the piston.

E.4 Calculation results

E.4.1 From the recording of plunger travel and force applied (see Figure E.2) determine the following:

a) force required (F_s) to initiate the movement of the plunger;

b) mean force (F) during the plunger travel;

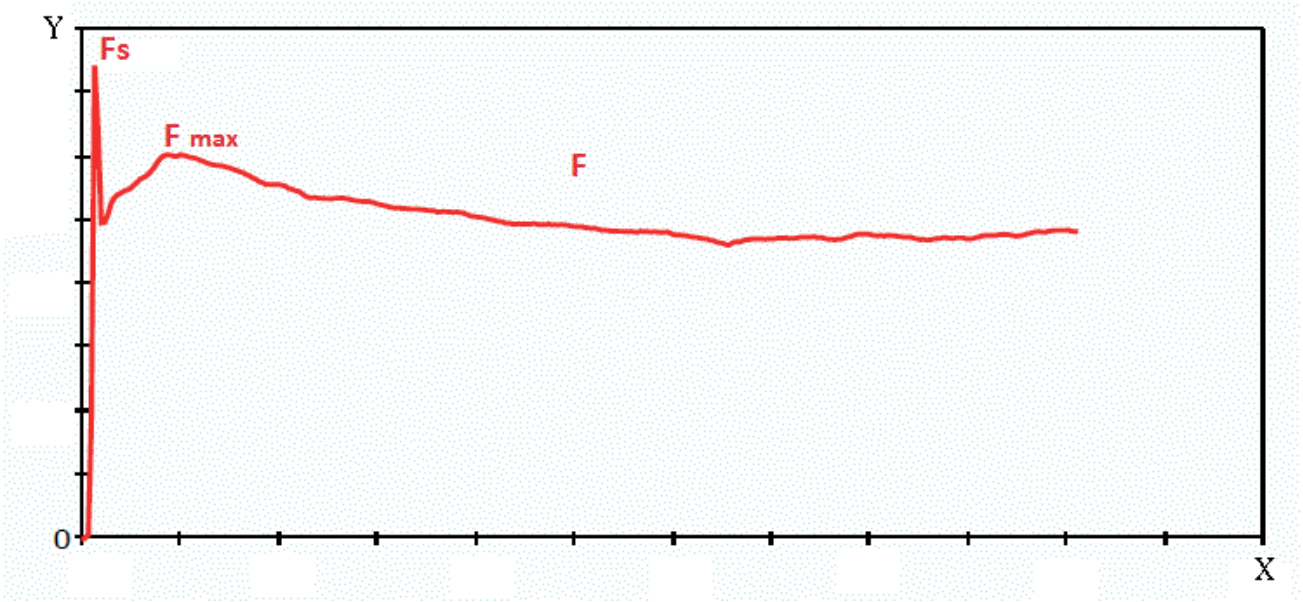
c) maximum force (F_{max}) during the plunger travel.

1) Tygon® is the trade name of a product supplied by the U.S. Plastic Corp.®. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

E.4.2 The values of the forces required to operate the plunger are given in Table E.1.

Table E.1 — Proposed values for forces required to operate plunger

Nominal capacity of syringe (V) ml	Initial force (F_s) N max.	Mean force (F) N max.	Maximum force (F_{max}) N
$V < 2$	10	5	< (2,0 × measured F) or (measured F + 1,5 N), whichever is higher
$2 \leq V < 50$	25	10	< (2,0 × measured F) or (measured F + 1,5 N), whichever is higher
$50 \leq V$	30	15	< (2,0 × measured F) or (measured F + 1,5 N), whichever is higher



Key

X plunger stopper travel

Y force during plunger travel, in N

Figure E.2 — Examples of graph of forces required to operate plunger

E.5 Test report

The test report shall contain at least the following information:

a) identity and nominal capacity of syringe;

b) force (F_s) required to initiate movement of the plunger, in N;

c) mean force (F) during the plunger travel, in N;

d) maximum force (F_{max}) during the plunger travel, in N;

e) date of testing.

Annex F
(informative)

Test method for the quantity of silicone

F.1 Principle

The syringe is filled with a given amount of methyl isobutylketone (MIBK) to dissolve silicone applied inside the barrel. The MIBK solution is collected in a glass test tube as a sample solution. Once the calibration curve is produced, the quantity of silicone in the sample solution is determined by the atomic absorption spectrophotometer.

F.2 Apparatus and reagents

F.2.1 **Silicone oil**, applied on a syringe.

F.2.2 **4-methyl- 2-pentanon** (Methyl isobutylketone: MIBK), appropriate grade or greater.

F.2.3 **Measuring flask**.

F.2.4 **Transfer pipette**.

F.2.5 **Atomic absorption spectrophotometer**.

F.2.6 **Appropriate analytical balance**.

F.3 Test procedures

F.3.1 Preparation of standard solution

The following standard solutions shall be prepared:

a) **10 mg/ml silicone standard solution**: Weight 1,0 g of silicone oil (F.2.1) using the precision electronic balance (F.2.6) and put it in a 100 ml beaker. Add 20 ml of MIBK to dissolve silicone oil completely and transfer the solution to a 100 ml measuring flask.

   Rinse the beaker three times with 20 ml of MIBK and mix the rinsed MIBK with silicone oil in the measuring flask. Fill up the measuring flask with MIBK to an exact volume of 100 ml and close the flask with a stopper. Thoroughly mix the solution by inversion.

b) **0,1 mg/ml silicone standard solution**: Draw up exactly 1 ml of 10 mg/ml silicone standard solution with the transfer pipette (F.2.4) and put it into the 100 ml measuring flask. Fill up the measuring flask with MIBK to an exact volume of 100 ml. Close the flask with a stopper and thoroughly mix the solution by inversion.

c) **0,2 mg/ml silicone standard solution**: Draw up exactly 2 ml of 10 mg/ml silicone standard solution with the transfer pipette (F.2.4) and put it into the 100 ml measuring flask. Fill up the measuring flask with MIBK to an exact volume of 100 ml. Close the flask with a stopper and thoroughly mix the solution by inversion.

d) **0,5 mg/ml silicone standard solution**: Draw up exactly 5 ml of 10 mg/ml silicone standard solution with the transfer pipette (F.2.4) and put it into the 100 ml measuring flask. Fill up the measuring flask with MIBK to an exact volume of 100 ml. Close the flask with a stopper and thoroughly mix the solution by inversion.

e) **0,7 mg/ml silicone standard solution**: Draw up exactly 7 ml of 10 mg/ml silicone standard solution with the transfer pipette (F.2.4) and put it into the 100 ml measuring flask. Fill up the measuring flask with MIBK to an exact volume of 100 ml. Close the flask with a stopper and thoroughly mix the solution by inversion.

f) **1,0 mg/ml silicone standard solution**: Draw up exactly 10 ml of 10 mg/ml silicone standard solution with the transfer pipette (F.2.4) and put it into the 100 ml measuring flask. Fill up the measuring flask with MIBK to an exact volume of 100 ml. Close the flask with a stopper and thoroughly mix the solution by inversion.

F.3.2 Preparation of the test solution

The test solution shall be prepared using the following procedures:

a) Withdraw a given amount of MIBK (see Table F.1) into a syringe and pull the plunger until the plunger stopper aligns with the nominal volume line.

b) Occlude the syringe tip using a stopper (e.g. a metallic plug cap) and invert the syringe for 1 min.

c) Eject the MIBK solution into a glass test tube as testing solution.

d) Use a lid or cool the solution, if necessary, to prevent the MIBK volatilization.

Table F.1 — Amount of MIBK solution for test sample

Nominal volume of syringe	Withdraw volume
50 ml	20 ml/syringe
30 ml	15 ml/syringe
20 ml	10 ml/syringe
10 ml	4 ml/syringe
5 ml	2 ml/syringe
2,5 ml	2 ml/syringe
1 ml, 0,5 ml	5 ml/syringe[a]

[a] If the syringe capacity is less than 1 ml, rinse out the inside barrel and fill up the measuring flask with MIBK to a volume of 5 ml.

F.3.3 Set-up of testing device

Testing devices shall be set up following these steps.

a) Power up the atomic absorption spectrophotometer (F.2.5), PC, cool water circulation system and compressor.

b) Set up the lamp, lamp current and burner height as specified in Table F.2.

Table F.2 — Analytical conditions

Item	Specification
Burner head	High temperature burner
Flammable gas	Acetylene
Support gas	Nitrous oxide
Hollow cathode lamp	Element: Silicone
Analysis line	251,6 nm
Lamp current	10 mA
Burner height	10 mm
Slit width	0,4 nm

F.3.4 Measurement procedures

The measurement shall be carried out with the following procedures:

a) Measure silicone MIBK standard solutions [(0,1~1,0) mg/ml] and the blank MIBK solution by atomic absorption spectrophotometer (F.2.5) to produce a calibration curve. Correlation coefficient shall be greater than 0,995. If this is not satisfied, re-measurement or re-preparation of standard solutions shall be required. Each time the standard solution is changed, auto zero adjusting shall be performed by absorbing sufficient MIBK solution to rinse out the flow channel.

b) Once the calibration curve is produced, measure the test solution. If the absorbance value exceeds the range of calibration curve, dilute the test sample to be within the range and re-measure the sample. Each time the sample is changed, auto zero adjusting shall be performed by absorbing sufficient MIBK solution to rinse out the flow channel.

F.3.5 Proposed compliance criterion

The proposed criterion is that the quantity of silicone shall be less than 0,25 mg/cm^{2}of the internal surface area of the syringe in contact with the injection fluid. See Clause 7.

F.4 Test report

The test report shall contain at least the following information:

a) identity and nominal capacity of the syringe;

b) quantity of silicone contained;

c) status (pass or fail) of the test;

d) date of testing.

Bibliography

[1] ISO 384, *Laboratory glassware — Principles of design and construction of volumetric glassware*

[2] ISO 7864, *Sterile hypodermic needles for single use*

[3] ISO 8537, *Sterile single-use syringes, with or without needle, for insulin*

[4] ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

[5] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

[6] ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

[7] ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

[8] ISO 14971, *Medical devices — Application of risk management to medical devices*

[9] ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

[10] IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

[11] ISO 80369-20, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

National Annex A

(*National Foreword*)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

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(*Continued from second cover*)

The standard also makes a reference to the BIS certification marking of the product, details of which are given in National Annex A.

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 or analysis shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*second revision*)’.

Bureau of Indian Standards

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the website- www.bis.gov.in or www.standardsbis.in.

This Indian Standard has been developed from Doc No.: MHD 12 (14869).

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