INTERNATIONAL STANDARD

ISO 8536-1

Third edition
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Infusion equipment for medical use —

Part 1: Infusion glass bottles

Matériel de perfusion à usage médical —

Partie 1: Flacons en verre pour perfusion

Reference number
ISO 8536-1:2006(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 8536-1 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This third edition cancels and replaces the second edition (ISO 8536-1:2000) and amendment ISO 8536-1:2000/Amd.1:2004, of which it constitutes a minor revision.

ISO 8536 consists of the following parts, under the general title *Infusion equipment for medical use*:

— *Part 1: Infusion glass bottles*

— *Part 2: Closures for infusion bottles*

— *Part 3: Aluminium caps for infusion bottles*

— *Part 4: Infusion sets for single use, gravity feed*

— *Part 5: Burette infusion sets for single use, gravity feed*

— *Part 6: Freeze drying closures for infusion bottles*

— *Part 7: Caps made of aluminium-plastics combinations for infusion bottles*

— *Part 8: Infusion equipment for use with pressure infusion apparatus*

— *Part 9: Fluid lines for use with pressure infusion equipment*

— *Part 10: Accessories for fluid lines for use with pressure infusion equipment*

— *Part 11: Infusion filters for use with pressure infusion equipment*

— *Part 12: Check valves*

Introduction

Infusion bottles are suitable primary packaging materials for the storage of infusion solutions until they are administered to the patient. Due to the direct contact between infusion solution and the primary container components and in view of the extended storage periods, possible interactions must be avoided in order to guarantee the patient's safety. Adequate means to achieve this goal include the proper selection of the primary packaging materials, the choice of suitable package design and the availability of specific criteria and methods for testing of individual container systems.

Infusion equipment for medical use —

Part 1:
Infusion glass bottles

1 Scope

This part of ISO 8536 specifies the dimensions, performance and requirements of infusion glass bottles necessary to ensure functional interchangeability. It is applicable only to infusion bottles for single use.

2 Normative references

The following referenced documents are indispensable for the application 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 719:1985, *Glass — Hydrolytic resistance of glass grains at 98 °C — Method of test and classification*

ISO 720:1985, *Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification*

ISO 1101:2004, *Geometrical Product Specifications (GPS) — Geometrical tolerancing — Tolerances of form, orientation, location and run-out*

ISO 4802-1:1988, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification*

ISO 4802-2:1988, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification*

ISO 7458:2004, *Glass containers — Internal pressure resistance — Test methods*

ISO 7459:2004, *Glass containers — Thermal shock resistance and thermal shock endurance — Test methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4802-1 and ISO 4802-2 apply.

4 Dimensions

The dimensions of the infusion glass bottles shall meet the requirements of Figure 1 and Tables 1, 2 and 3.

Dimensions in millimetres

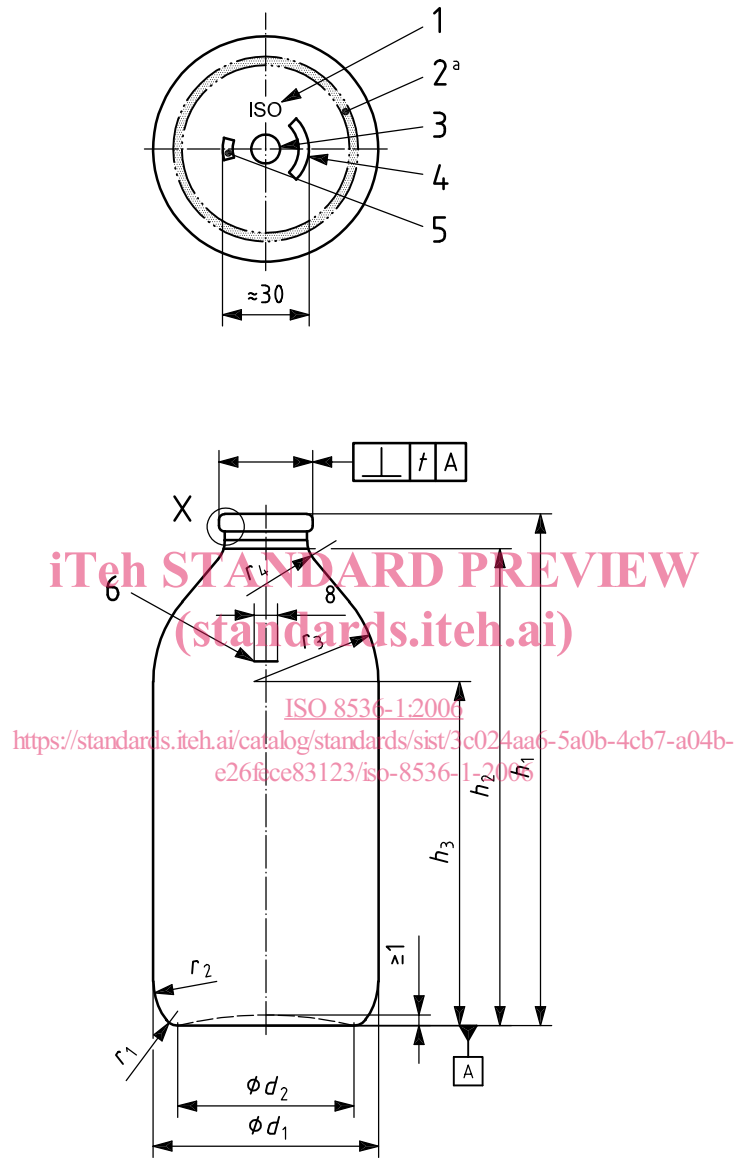
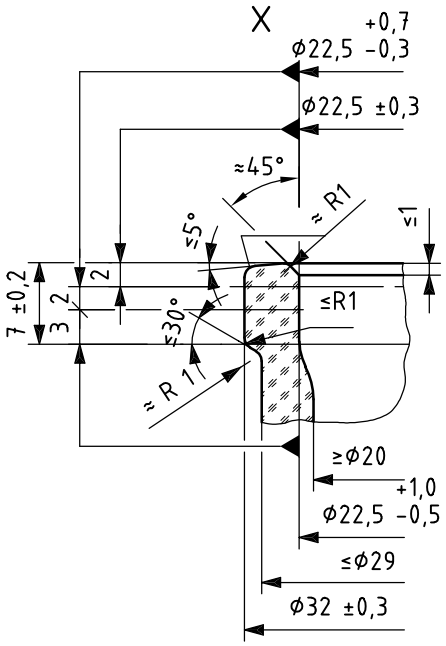
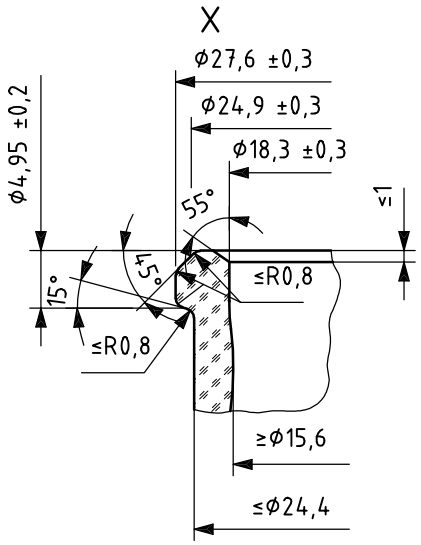


Figure 1 — Infusion glass bottle, showing three typical neck finishes

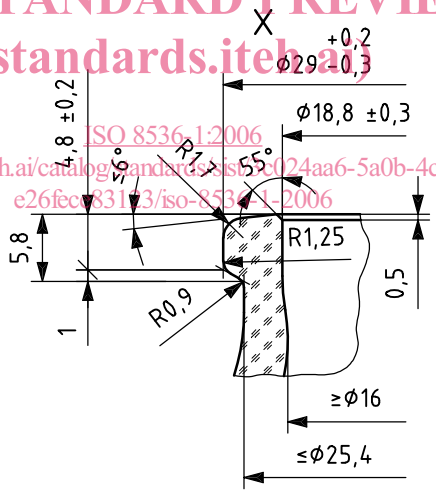
Dimensions in millimetres



a) Model A: Infusion bottle with 32 mm neck finish



b) Model B: Infusion bottle with 28 mm neck finish



c) Model C: Infusion bottle with 29 mm neck finish

NOTE The marks (optional) or other markings in accordance with the view from below may be placed on the bottom or at the bottom radius, r_2, of the infusion bottle. The drawing represents a typical example.

Key

1 ISO symbol
2 bottom surface
3 designation of hydrolytic resistance container class (see 9.1)
4 manufacturer's code/designation of mould
5 manufacturer's trade mark
6 graduation mark

[a] Bottom surface may be granular.

Figure 1 (*continued*)

Table 1 — Dimensions and capacity of infusion glass bottles with 32 mm neck finish (model A)

Dimensions in millimetres

Nominal capacity	Approximate brimful capacity		t [a]	d_1		d_2	h_1		h_2	h_3	r_1	r_2	r_3	r_4
ml	ml	tol.			tol.			tol.						
50	68	± 5	1	46	± 0,8	37	68	± 0,7	58	36,5	2	12	20,5	8
100	128	± 5	1,3	49	± 0,8	39	104	± 0,8	94	68,5	3	12	25	8
125	147	± 5	1,3	54,4	± 0,8	38,9	98	± 0,8	88	63	4,5	20	17	12
250	297	± 8	1,6	68	± 1	48,9	125	± 1	114,5	78	7	32	28	12
500	584	± 8	1,9	86	± 1,2	61,5	147	± 1	137	93,4	8	32	27	12
1 000	1120	± 15	3	95	± 1,5	69,6	225	± 1,3	215	148	8,5	55	52	22

[a] The tolerance t of the perpendicularity (as defined in ISO 1101) is a limit for the deviation of the plumb-line through the centre of the bottom part and the axis of the bottle at the upper edge of the flange.

Table 2 — Dimensions and capacity of infusion glass bottles with 28 mm neck finish (model B)

Dimensions in millimetres

Nominal capacity	Approximate brimful capacity		t [a]	d_1		d_2	h_1		h_2	h_3	r_1	r_2	r_3	r_4
ml	ml	tol.			tol.			tol.						
50	68	± 5	1	46	± 0,8	37	68,7	± 0,7	60,5	37	2	12	20	8
100	128	± 5	1,3	49	± 0,8	39	104,7	± 0,8	96,5	69	3	12	25	8
125	147	± 5	1,3	54,4	± 0,8	38,9	98,7	± 0,8	90,5	62,5	4,5	20	17	8
250	300	± 8	1,6	68	± 1	48,9	125	± 1	117,5	78	7	32	28	12
500	584	± 8	1,9	86	± 1,2	61,5	147,7	± 1	139,5	93,4	8	32	27	13
1 000	1120	± 15	3	95	± 1,5	69,6	225	± 1,3	216,8	148	8,5	55	52	15

[a] The tolerance t of the perpendicularity (as defined in ISO 1101) is a limit for the deviation of the plumb-line through the centre of the bottom part and the axis of the bottle at the upper edge of the flange.

Table 3 — Dimensions and capacity of infusion glass bottles with 29 mm neck finish (model C)

Dimensions in millimetres

Nominal capacity	Approximate brimful capacity		t [a]	d_1		d_2	h_1		h_2	h_3	r_1	r_2	r_3	r_4
ml	ml	tol.			tol.			tol.						
50	68	± 5	1	46	± 0,8	37	68	± 0,7	60,4	37,5	2	12	20,5	8
100	128	± 5	1,3	49	± 0,8	39	104	± 0,8	96,4	68,5	3	12	25	8
125	147	± 5	1,3	54,4	± 0,8	38,9	98,7	± 0,8	91,1	63,7	4,5	20	17	10
250	300	± 8	1,6	68	± 1	48,9	125	± 1	117,4	78	7	32	28	10
500	572	± 8	1,9	86	± 1,2	61,5	147	± 1	139,4	93,4	8	32	27	12
1 000	1120	± 15	3	95	± 1,5	69,6	224,1	± 1,3	216,8	147,4	8,5	55	52	15

[a] The tolerance t of the perpendicularity (as defined in ISO 1101) is a limit for the deviation of the plumb-line through the centre of the bottom part and the axis of the bottle at the upper edge of the flange.

5 Designation

5.1 General

An infusion glass bottle for medical use complying with the requirements laid down in this part of ISO 8536 is designated using the descriptor “Infusion bottle” followed by, in the order given, a reference to this part of ISO 8536, the model of the infusion bottle, the nominal capacity, the colour and the hydrolytic resistance container class (see 8.1).

EXAMPLE 1 An infusion bottle (model A) with a nominal capacity of 500 ml, made of colourless glass (cl) of hydrolytic resistance container class HC 2 complying with the requirements laid down in this part of ISO 8536 is designated as follows:

Infusion bottle ISO 8536-1 – A – 500 – cl – HC 2

EXAMPLE 2 An infusion bottle (model C) with a nominal capacity of 500 ml, made of colourless glass (cl) of hydrolytic resistance container class HC 2 complying with the requirements laid down in this part of ISO 8536 is designated as follows:

Infusion bottle ISO 8536-1 – C – 500 – cl – HC 2

5.2 Location of designation marks

The designation marks on the bottom as specified in Figure 1, view from below, may also be fixed at the body of the bottle but not at the cylindrical part. The manufacturer's code can also be placed at the shoulder of the bottle. If marked at the lower bottom radius, r_2, or at the shoulder, r_3, the diameter at these places should not exceed the diameter, d_1 of the bottle. The designation of hydrolytic resistance container class is abbreviated as given in 9.1.

6 Material

Infusion bottles shall be constructed from

a) colourless (cl) or amber (br) borosilicate glass; see 4.2 of ISO 4802-1:1988 and ISO 4802-2:1988

or

b) soda-lime glass (see 4.4 of ISO 4802-1:1988 and ISO 4802-2:1988) of the hydrolytic resistance grain class

ISO 720 – HGA 1,

ISO 719 – HGB 3 or ISO 720 – HGA 2.

A change in the composition of the glass material or of the colouring oxides shall be notified to the user at least nine months in advance.

7 Performance

The performance requirements of infusion bottles, such as seed or bubbles, sealing surface, etc., shall comply with existing quality standards, e.g. defect evaluation lists and shall be agreed upon between manufacturer and user.