INTERNATIONAL STANDARD

ISO 8536-1

First edition
1991-08-15

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 8536-1:1991(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.

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.

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

ISO 8536-1 is a revision, in part, of ISO 1135:1977; this first edition of ISO 8536-1 together with the other parts of ISO 8536 and of ISO 1135 will cancel and replace ISO 1135:1977.

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*

— *Part 5: Burette type infusion sets*

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

— *Part 7: Infusion caps made of aluminium-plastics combinations*

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 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 dimensions, performance and requirements of infusion glass bottles necessary to ensure functional interchangeability. It applies only to infusion bottles for single use.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 8536. 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 8536 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 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 1101:1983, *Technical drawings — Geometrical tolerancing — Tolerances of form, orientation, location and run-out — Generalities, definitions, symbols, indications on drawings.*

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 7458:1984, *Glass containers — Internal pressure resistance — Test methods.*

ISO 7459:1984, *Glass containers — Thermal shock resistance and thermal shock endurance — Test methods.*

3 Definitions

For the purposes of this part of ISO 8536, the definitions given in ISO 4802-1 and ISO 4802-2 apply.

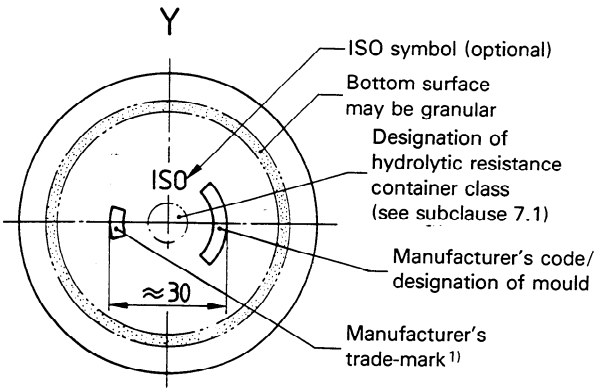
4 Dimensions and designation

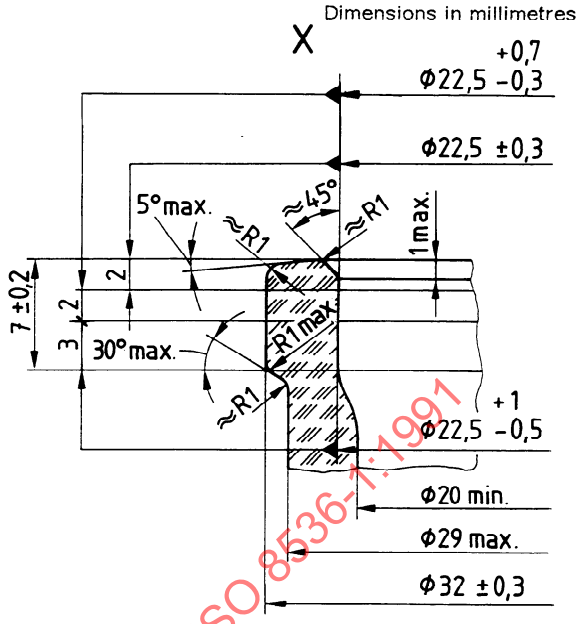
4.1 Dimensions

The dimensions of the infusion glass bottle shall meet the requirements of figure 1 and table 1.

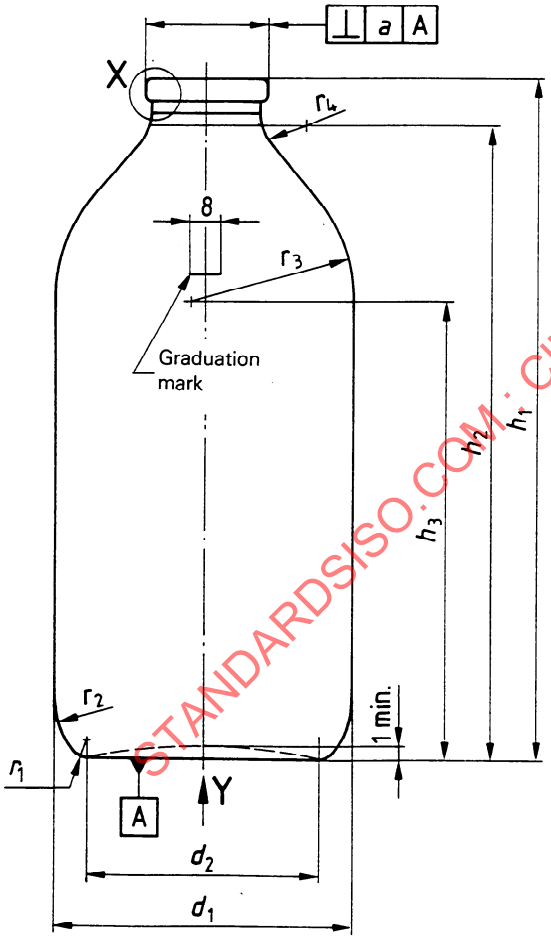
4.2 Designation marks

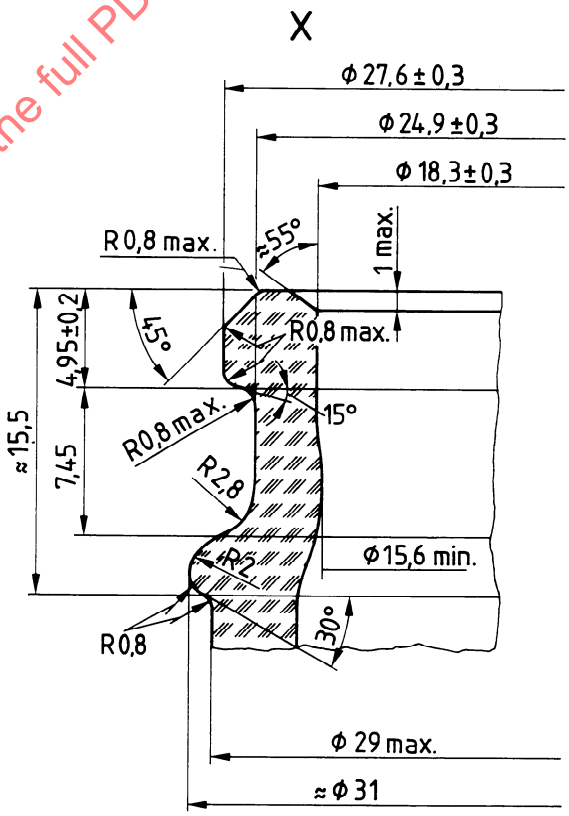
The designation marks on the bottom as specified in figure 1, view Y may be fixed also at the bottom of the bottle but not at the cylindrical part. The manufacturer's code can also be placed at the shoulder of the bottle. If marked at the lower bottom radius, r_2, or at the shoulder, r_3, the diameter at these places should not exceed the diameter d_1 of the bottle.





Model A: Infusion bottle with 32 mm neck finish





Model B: Infusion bottle with 28 mm neck finish

1) The manufacturer's trade-mark (optional) or other markings according to view "Y" may be placed at the bottom or at the bottom radius (r_2) of the infusion bottle. The drawing represents a typical example.

Figure 1 — Infusion glass bottle with two typical neck finishes

Table 1 — Dimensions and capacity of infusion bottle

Dimensions in millimetres

Nominal capacity	Approx. brimful capacity	a [1]	d_1		d_2	h_1		h_2	h_3	r_1	r_2	r_3	r_4
ml	ml			tol.	≈		tol.	≈	≈	≈	≈	≈	≈
50	67	1	46	±0,8	34,5	68	±0,7	58,5	36,5	3	19	20,5	8
100	128	1,3	49	±0,8	36,7	104	±0,8	94,5	68,5	3,5	20	25	8
125	147	1,3	54,4	±0,8	38,9	98	±0,8	87,5	63	4,5	20	17	12
250	297	1,6	68	±1	48,9	125	±1	114,5	78	7	32	28	12
500	570	1,9	86	±1,2	61,5	147	±1	136,6	93,4	8	32	27	12
1 000	1125	3	95	±1,5	65,6	230	±1,3	220,5	153	10	45	52	22

1) The tolerance a of the perpendicularity (defined as 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.

4.3 Designation example

Designation example of an infusion bottle (IL) with a nominal capacity of 500 ml, made of colourless glass (cl) of the hydrolytic resistance container class HC 2 (see 7.1) complying with the requirements laid down in this part of ISO 8536:

Infusion bottle ISO 8536-1 IL-cl-HC 2

5 Material

Infusion bottles shall be constructed from

a) colourless (cl) or amber (br) borosilicate glass[1]; or

b) soda-lime-silica glass[1] of the hydrolytic resistance grain class

ISO 720 — HGA 1,
ISO 719 — HGB 3, or ISO 720 — HGA 2.

NOTE 1 A change in the chemical composition of the glass material or of the colouring oxides should be notified to the user at least nine months in advance.

6 Performance

The performance requirements of infusion bottles, such as seed or bubbles, sealing surface, etc., shall comply with existing quality standards and have to be agreed between manufacturer and user.

1) For definitions, see ISO 4802-1 and ISO 4802-2.

7 Requirements

7.1 Hydrolytic resistance

When tested according to ISO 4802-1 or ISO 4802-2, the hydrolytic resistance of the internal surface of the bottles shall comply with the requirements for one of the following hydrolytic resistance container classes:

ISO 4802 — HC 1
ISO 4802 — HC 2
ISO 4802 — HC 3

7.2 Internal pressure resistance

Infusion bottles shall withstand an internal test pressure of 600 kPa (6 bar), when tested according to ISO 7458.

7.3 Thermal shock resistance

Infusion bottles shall withstand a thermal shock when subjected to a temperature difference of Δt 42 °C in the case of soda-lime silica glass and Δt 60 °C in the case of borosilicate glass in accordance with the thermal shock resistance test specified in ISO 7459.

7.4 Annealing quality

The infusion bottles shall be annealed so that the maximum residual stress does not produce an optical retardation exceeding 40 nm per millimetre of glass thickness, when the bottles are viewed in a strain viewer.

8 Marking

8.1 The base shall be permanently marked with the information specified in figure 1, view Y.

The hydrolytic resistance container class shall be designated as follows:

— Hydrolytic resistance container class ISO 4802 — HC 1: I

— Hydrolytic resistance container class ISO 4802 — HC 2: II

— Hydrolytic resistance container class ISO 4802 — HC 3: III

8.2 The number of pieces and the standard designation together with the name or the symbol of the manufacturer of the infusion bottle shall be shown on the package. Further declarations may be included at the discretion of the manufacturer or by agreement between user and manufacturer.

NOTE 2 The marking HC 3 may be omitted by the manufacturer. In this case, infusion bottles not bearing any hydrolytic resistance container class number are deemed to belong to the hydrolytic container class HC 3.