

มาตรฐานผลิตภัณฑ์อุตสาหกรรม
เครื่องมือให้สารละลายทางหลอดเลือด
สำหรับการใช้ทางการแพทย์
เล่ม 1 ขวดแก้วบรรจุสารละลายที่ให้ทางหลอดเลือด

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้กำหนดโดยรับ ISO 8536-1 : 1991 Infusion equipment for medical use - Part 1 : Infusion glass bottles มาใช้ในระดับเหมือนกันทุกประการ (Identical) โดยใช้ ISO ฉบับภาษาอังกฤษเป็นหลัก

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้กำหนด มิติและขนาดบรรจุระบุตั้งแต่ 50 มิลลิลิตร ถึง 1000 มิลลิลิตร การแสดงเครื่องหมายและฉลาก วัสดุที่ใช้ทำ คุณลักษณะภายนอก คุณลักษณะที่ต้องการอื่น ๆ เช่น ความต้านทานไฮโดรไลติก ความต้านทานความดันภายใน ความต้านทานความร้อนแบบเฉียบพลัน และคุณภาพหลังการอบของขวดแก้วบรรจุสารละลายที่ให้ทางหลอดเลือด ซึ่งมีวัตถุประสงค์ใช้เพียงครั้งเดียว รายละเอียดให้เป็นไปตาม ISO 8536-1 : 1991

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.

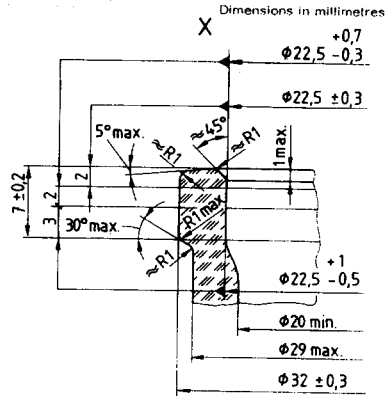
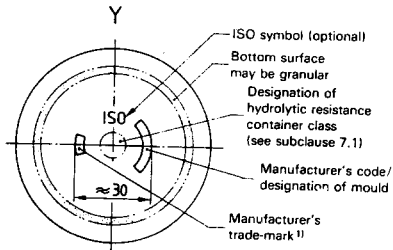
4 Dimensions and designation

4.1 Dimensions

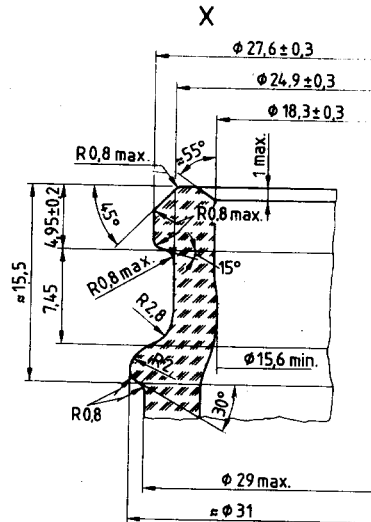
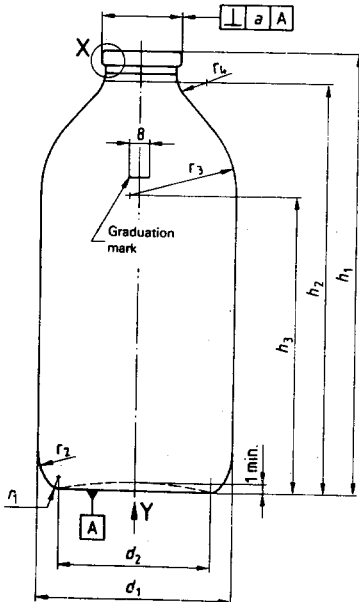
The dimensions of the infusion glass bottle shall meet the requirements of figure 1 and table 1.

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 ml	Approx. brimful capacity ml	a 1)	d_1		d_2		h_1		h_2	h_3	r_1	r_2	r_3	r_4
			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 glass¹⁾; or

b) soda-lime-silica glass¹⁾ 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

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

comply with existing quality standards and have to be agreed between manufacturer and user.

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.