INTERNATIONAL STANDARD

ISO 11418-1

Second edition
2005-02-01

Containers and accessories for pharmaceutical preparations —

Part 1: Drop-dispensing glass bottles

Récipients et accessoires pour préparations pharmaceutiques —

Partie 1: Flacons compte-gouttes en verre

Reference number
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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 11418-1 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use.*

This second edition cancels and replaces the first edition (ISO 11418-1:1996), which has been technically revised.

ISO 11418 consists of the following parts, under the general title *Containers and accessories for pharmaceutical preparations*:

— *Part 1: Drop-dispensing glass bottles*

— *Part 2: Screw-neck glass bottles for syrups*

— *Part 3: Screw-neck glass bottles (veral) for solid and liquid dosage forms*

— *Part 4: Tablet glass bottles*

— *Part 5: Dropper assemblies*

— *Part 7: Screw-neck vials made of glass tubing for liquid dosage forms*

Containers and accessories for pharmaceutical preparations —

Part 1:
Drop-dispensing glass bottles

1 Scope

This part of ISO 11418 specifies the design, dimensions, material and requirements of drop-dispensing glass bottles. Drop-dispensing glass bottles are applicable to primary packs used in direct contact with a drug.

This part of ISO 11418 is applicable to drop-dispensing glass bottles used in pharmacy. Together with the corresponding closure systems, they serve for packaging of pharmaceutical preparations which are not intended for parenteral use.

NOTE The potency, purity, stability and safety of a drug during its manufacture and storage can be strongly affected by the nature and performance of the primary pack.

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

ISO 8113:2004, *Glass containers — Resistance to vertical load — Test method*

3 Dimensions and designation

3.1 Dimensions

The dimensions of drop-dispensing glass bottles shall be as shown in Figure 1 and as given in Table 1.

Tolerancing of form, orientation, location and run-out not specified in this part of ISO 11418 shall be in accordance with ISO 1101.

3.2 Designation

Drop-dispensing glass bottles for pharmaceutical use shall be designated by a reference to this part of ISO 11418, followed by the nominal volume and the colour of the glass.

EXAMPLE A drop-dispensing glass bottle of nominal volume 100 ml, made of colourless glass (cl) of hydrolytic resistance container class ISO 4802 – HC 3, in accordance with this part of ISO 11418 is designated as follows:

Drop-dispensing glass bottle ISO 11418-1 – 100 – cl

4 Requirements

4.1 Material

The material shall be colourless (cl) or amber (br) borosilicate glass (see ISO 4802-1 or ISO 4802-2) or soda-lime-silica glass (see ISO 4802-1 or ISO 4802-2) of hydrolytic resistance grain class ISO 719–HGB 3 or ISO 720–HGA 2.

4.2 Performance

4.2.1 Vertical load resistance

The resistance to vertical load shall be in accordance with ISO 8113.

4.2.2 Hydrolytic resistance

When tested in accordance with ISO 4802-1 or ISO 4802-2, the hydrolytic resistance of the internal surface of the drop-dispensing glass bottle shall comply with the requirements of the hydrolytic resistance container class ISO 4802 – HC 3.

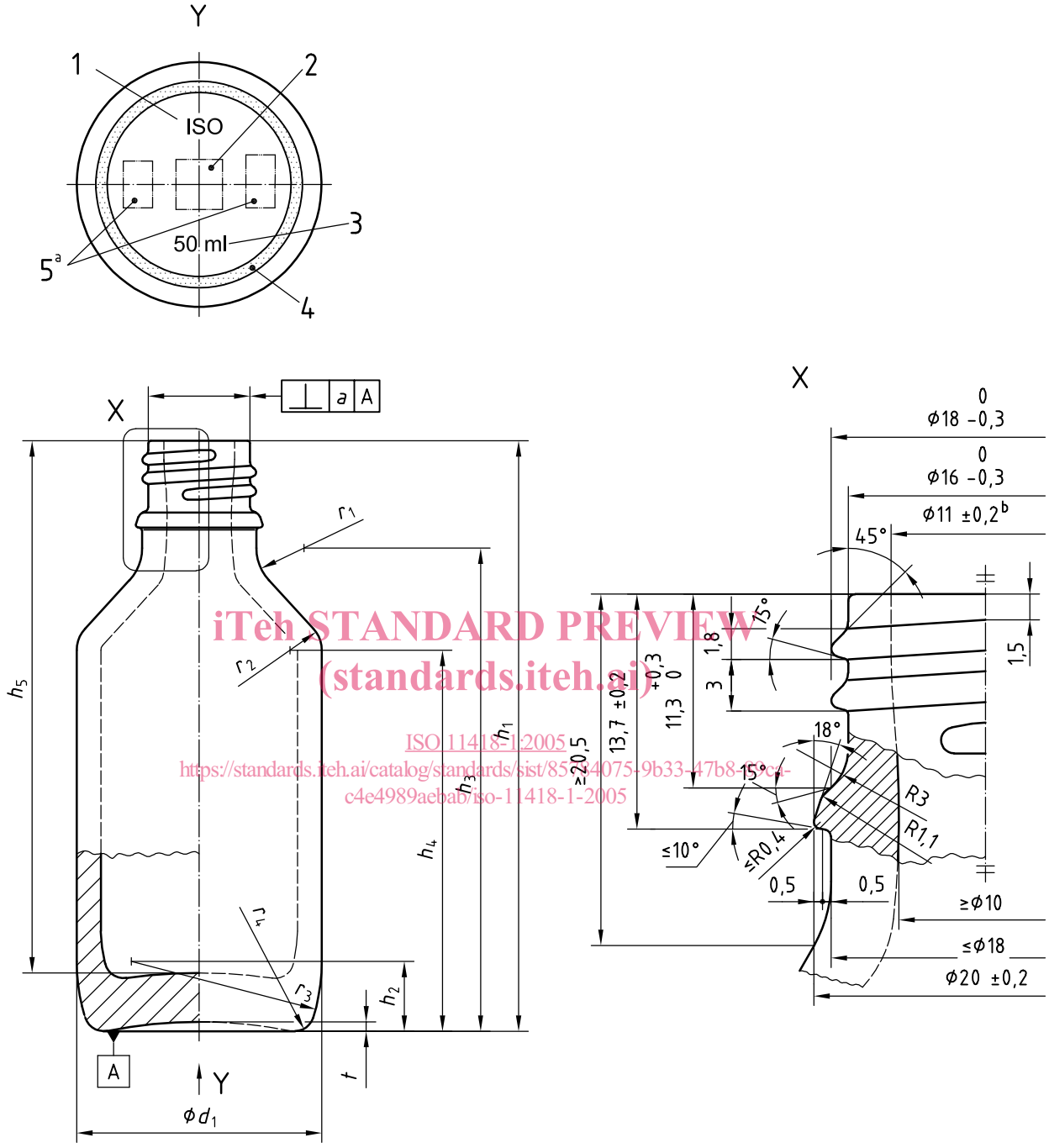
4.2.3 Thermal shock resistance

Drop-dispensing glass bottles shall withstand the thermal shock of a temperature difference of 42 °C when tested in accordance with the thermal shock resistance test specified in ISO 7459.

5 Marking

The drop-dispensing glass bottle shall be marked with the information specified in Figure 1 (view Y).

Dimensions in millimetres



Key

1 ISO letters (optional)
2 manufacturer's trademark
3 nominal volume (optional)
4 bottom surface may be granular, flat or riffled
5 manufacturer's code/designation of the mould

[a] The number of the mould may be placed on the curve *r*3, on the bottom or on the shoulder of the bottle.

[b] On approximately 1 mm depth from the top of the neck.

Figure 1 — Typical drop-dispensing glass bottle, showing marking locations

Table 1 — Nominal volume, overflow capacity and dimensions of drop-dispensing glass bottles

Dimensions in millimetres

Nominal volume	Minimum overflow (brimful) capacity	a	d_1		h_1		h_2	h_3	h_4	h_5	r_1	r_2	r_3	r_4	t	Mass
ml	ml		nom.	tol.	nom.	tol.	≈	≈	≈	≈	≈	≈	≈	≈		g ≈
5	8,4	0,8	22,5	± 0,6	50,7	± 0,6	6	33,5	26	42,2	7,5	3,5	22	1,8	1,0	17
10	14,2	0,85	28	± 0,6	56,7	± 0,6	6,5	39,5	28,5	48,2	7,5	4	24	2	1,0	25
15	18,8	1,0	28	± 0,6	68,2	± 0,7	7,5	51	38	59,7	7,5	4	24	2	1,0	28
20	23,9	1,0	32	± 0,7	68,5	± 0,7	8	51,3	38	60,0	7,5	4	25	2,5	1,0	35
25	29,2	1,0	35	± 0,7	67,9	± 0,7	8,5	50,7	38,5	59,4	7,5	5	25	2,5	1,5	38
30	35	1,05	35	± 0,7	76,6	± 0,7	10	59,4	46	67,1	7,5	5	25	2,5	1,5	43
50	56,2	1,2	38,6	± 0,7	93,3	± 0,8	11	76,1	60	83,8	7,5	5	30	3	1,5	58
75	83,5	1,3	46,1	± 0,8	98	± 0,8	12	80,8	62	88,5	7,5	5,5	35	3	2,0	87
100	110	1,5	51,6	± 0,8	101	± 0,8	12,5	83,8	60,5	91,5	7,5	6	37	3,5	2,0	90