INTERNATIONAL STANDARD

ISO 11418-4

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Containers and accessories for pharmaceutical preparations —

Part 4: Tablet bottles

Récipients et accessoires pour préparations pharmaceutiques —

Partie 4: Piluliers

Reference number
ISO 11418-4:1996(E)

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 11418-4 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use*.

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

— *Part 1: Drop-dispensing bottles*

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

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

— *Part 4: Tablet bottles*

— *Part 5: Dropper assemblies*

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Containers and accessories for pharmaceutical preparations —

Part 4:
Tablet bottles

1 Scope

The purpose of this part of ISO 11418 is to specify the design, dimensions, material and requirements of tablet bottles. Tablet bottles are applicable to primary packs used in direct contact with a drug.

This part of ISO 11418 applies to tablet bottles used in pharmacy. Together with the corresponding closure systems, they serve for packaging of tablets which are not intended for parenteral use.

NOTE 1 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 standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 11418. 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 11418 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:—[1], *Technical drawings — Geometrical tolerancing — Tolerancing 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 7459:1984, *Glass containers — Thermal shock resistance and thermal shock endurance — Test methods.*

ISO 8113:1985, *Glass containers — Resistance to vertical load — Test method.*

1) To be published. (Revision of ISO 1101:1983)

3 Dimensions and designation

3.1 Dimensions

The dimensions of tablet 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

EXAMPLE

A tablet bottle of nominal volume 60 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:

Tablet bottle ISO 11418-4 - 60 - cl

4 Requirements

4.1 Material

The material shall be colourless (cl) or amber (br) borosilicate glass[2] or soda-lime-silica glass[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 tablet bottles shall comply with the requirements of the following hydrolytic resistance container class ISO 4802 - HC 3.

4.2.3 Thermal shock resistance

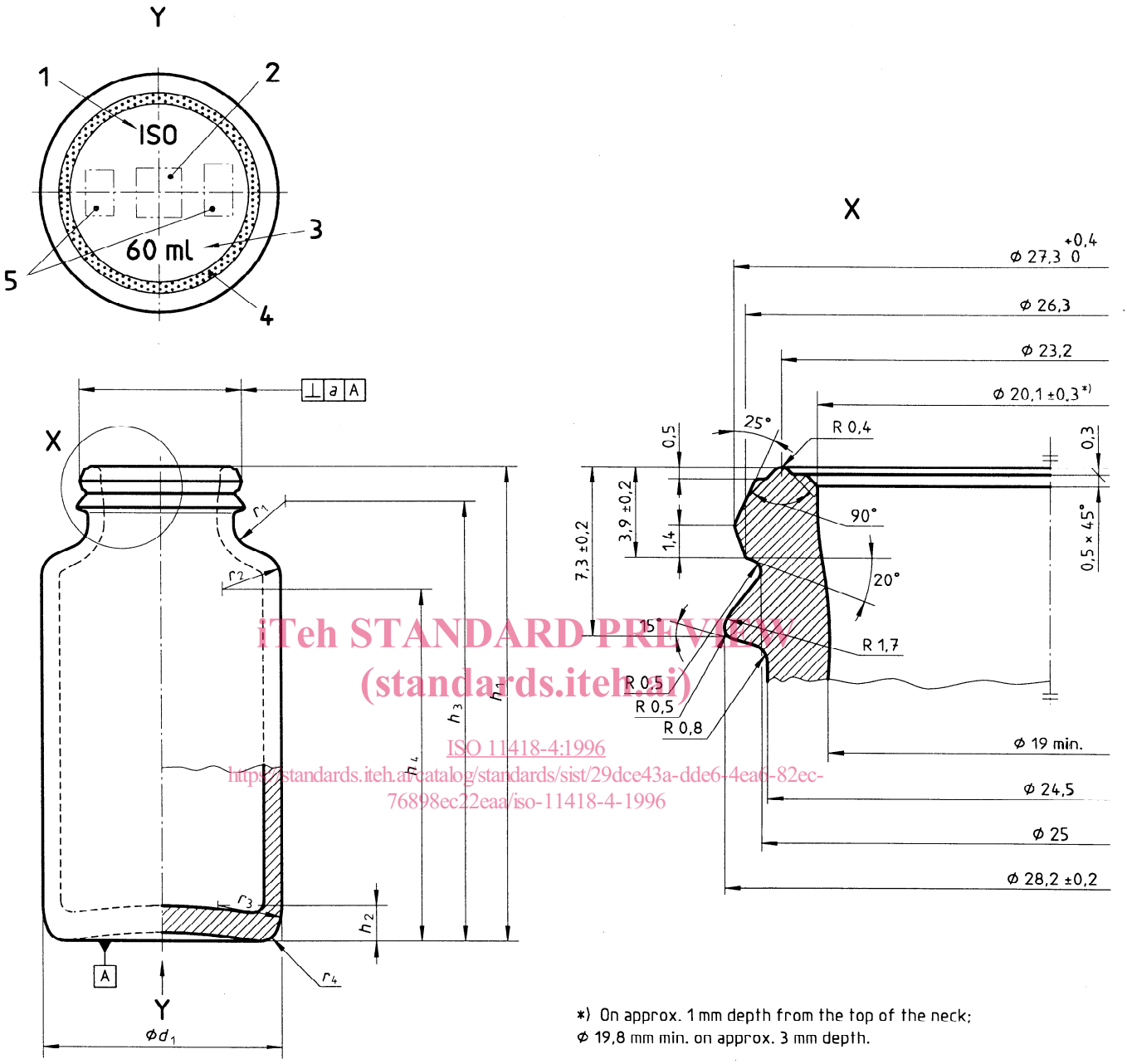
Tablet bottles shall withstand the thermal shock of a temperature difference of 42 °C when tested in accordance with the thermal shock resistance test specified in ISO 7459.

5 Marking

The tablet bottle shall be marked with the information specified in figure 1 (view Y).

2) For definition, see ISO 4802-1 or ISO 4802-2.

Dimensions in millimetres



*) On approx. 1 mm depth from the top of the neck;
ø 19,8 mm min. on approx. 3 mm depth.

Key

1 ISO letters (optional)
2 Manufacturer's trademark
3 Nominal volume
4 Bottom surface may be granular, flat or riffled
5 Manufacturer's code/designation of the mould[1)]

1) The number of the mould may be placed on the curve r_3, on the bottom or on the shoulder of the bottle.

Figure 1 — Typical tablet bottle, showing marking locations

Table 1 — Nominal volume, overflow capacity and dimensions of tablet bottles

Dimensions in millimetres

Nominal volume	Overflow (brimful) capacity		a	d_1		h_1		h_2	h_3	h_4	r_1	r_2	r_3	r_4	Mass
ml	ml	tol.			tol.		tol.	approx.	approx.	approx.	approx.	approx.	approx.	approx.	g approx.
10	13	± 1,0	0,65	31	± 0,7	33,7	± 0,5	1,5	24,4	18,6	4	3	—	1,5	20,5
20	25,5	± 1	0,85	31	± 0,7	54,9	± 0,6	2,5	45,6	39,8	4	3	—	2,5	30,5
40	46	± 1,5	1,0	40,2	± 0,8	60	± 0,6	6	49,9	41,2	4	4	10,7	3	43
60	67,5	± 2	1,1	40,2	± 0,8	79,6	± 0,7	6	70	61,2	4	4	10,7	3	48
80	88	± 2,5	1,2	47,5	± 0,8	81	± 0,7	9	71,2	60,2	4	5	25	3	80
100	110	± 4,4	1,2	47,5	± 0,8	97	± 0,8	10	87,2	76,2	4	5	25	3	95

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ICS 11.120

Descriptors: pharmacy, pharmaceutical containers, glass packaging, pills, bottles, specifications, materials specifications, dimensions, capacity, designation, marking.

Price based on 4 pages