INTERNATIONAL STANDARD

ISO 11418-7

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Containers and accessories for pharmaceutical preparations —

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

Récipients et accessoires pour préparations pharmaceutiques —

Partie 7: Flacons avec bague à vis en verre étiré pour diagnostics forme liquide

Contents

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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 11418-7 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*

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

Introduction

The purpose of this part of ISO 11418 is to specify the dimensions, capacities, form and requirements of screw-neck vials made from tubular glass intended for medical use. Vials made from glass tubing are considered to be suitable for the packaging and storage of pharmaceutical preparations until they are administered for medicinal purposes. Such vials may be made of different types of glass which can affect chemical resistance properties. For example, those made from borosilicate glass will have a very high level of chemical resistance where others made from soda-lime-silica glass will have a lower but adequate chemical resistance for the purposes for which they are intended.

Because vials may be made from different types of glass and because it is the chemical behaviour of the internal surface which is important when they are filled with pharmaceutical preparations, it is essential to specify the test procedures by which this performance can be measured.

Containers and accessories for pharmaceutical preparations —

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

1 Scope

This part of ISO 11418 specifies the form, dimensions and capacities of glass vials for pharmaceutical preparations. It also specifies the material from which such containers shall be made and the performance requirements of those containers.

This part of ISO 11418 applies to colourless or amber glass vials made from borosilicate or soda-lime-silica glass, made from glass tubing and intended to be used in the packaging, storage or transportation of pharmaceutical products.

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 listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 719:1985, *Glass — Hydrolytic resistance of glass grains at 98 degrees C — Method of test and classification.*

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

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

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

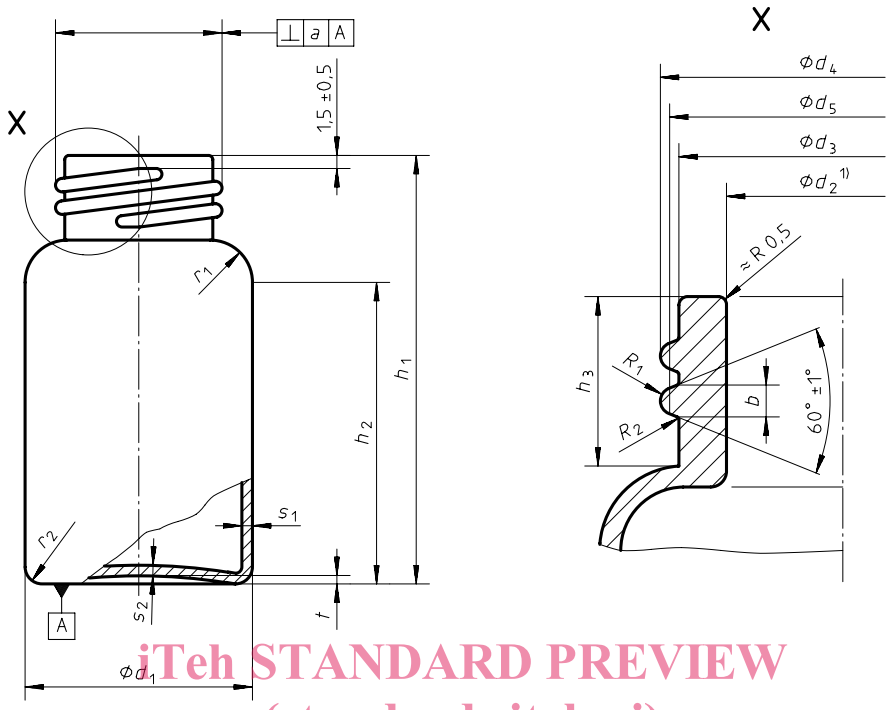
3 Dimensions and designation

3.1 Dimensions

The dimensions of screw-neck vials shall be as shown in figure 1 and as given in table 1.

Dimensions in millimetres

Form AR



$$b = p \cdot k$$

$$d_5 = d_4 - p\left[\frac{\sqrt{3}}{2} + k\left(1 - \sqrt{3}\right)\right]$$

$$R_1 = 0{,}366 \cdot b$$

d_5 = Diameter of the flank

b = Width of the thread profile

c = Depth of the thread profile

k = 0,675 (constant for construction of the thread profile)

p = Pitch

1) The neck finish shall be cylindrical and shall have the diameter d_2 until the depth h_3.

A form of a truncated cone is permitted if at the same time the following conditions are fulfilled:

— the truncated cone has the height h_3;

— the admissible tolerances of d_2 are retained;

— the larger diameter is located at the bottle opening;

— the larger diameter is a maximum of 0,3 mm longer than the smaller one.

Figure 1 — Typical example of a screw-neck vial with a round thread (knuckle thread) with two complete threads

3.2 Designation

Screw-neck vials for pharmaceutical preparations in liquid form made of glass tubing and complying with the requirements of this part of ISO 11418 are designated by the descriptor word « vial » followed by a reference to this part of ISO 11418, then the letters Glt, for glass tubing, together with the nominal tubing size, followed by the colour of the glass, followed by the hydrolytic resistance class.

EXAMPLE — A screw-neck vial for pharmaceutical preparations in liquid form, and complying with the requirements of this part of ISO 11418, made of amber glass tubing of nominal size 10, of hydrolytic resistance container class ISO 4802 - HC 1 is designated as follows:

Vial ISO 11418-7 - Glt 10 - br - 1

4 Material

Colourless (cl) or amber (br) borosilicate glass or soda-lime-silica glass, in accordance with ISO 4802-1 or ISO 4802-2, of one of the following hydrolytic resistance grain classes:

— ISO 720 - HGA 1 or

— ISO 720 - HGA 2 or

— ISO 719 - HGB 3

shall be used.

5 Characteristics

5.1 Screw-neck vials shall not contain seeds or bubbles to an extent which interfere with visual examination of the contents.

5.2 Screw-neck vials shall have a sealing surface which shall not affect the seal performance of the closure.

6 Requirements

6.1 Hydrolytic resistance

When tested in accordance with ISO 4802-1 or ISO 4802-2, the hydrolytic resistance of the internal surface of the screw-neck vials shall comply with the requirements specified for one of the following hydrolytic resistance container classes:

— ISO 4802 - HC 1

— ISO 4802 - HC 2

— ISO 4802 - HC 3.

6.2 Annealing quality

The screw-neck vials 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 vials are inspected in a strain viewer.

6.3 Light resistance

Light-resistance requirements met by using amber-coloured glass are not specified in this part of ISO 11418; light-resistance test methods are, however, specified in relevant pharmacopoeias, e.g. Ph. Eur. or USP.

7 Marking

The number of pieces and the designation, together with the name or symbol of the manufacturer, shall be shown on the package. Further information may appear, subject to agreement.

8 Packaging

The recommended packaging size for a paper carton, a plastics carton or a shrink-pack in foil should be agreed upon between manufacturer and customer.

Table 1 — Dimensions, overflow capacity, thread designation and mass of screw-neck vials

Dimensions in millimetres

Nominal size	Overflow capacity (brimful) ml ≈	a	Nominal thread d × Pitch p	d_1		d_2 3)		d_3		R_1 ≈	R_2 ≈	d_4		h_1		h_2	h_3	r_1	r_2 1)	S_1	S_2 2)	t		Mass g ≈
					tol.		tol.									min.	± 0,5			± 0,05	+ 0,3 − 0,2		tol.	
5	6,5	1,0	14 x 2,5	18	± 0,20	8,6	± 0,20	12,3	− 0,4	0,62	0,25	14,0	− 0,4	45	± 0,5	29	10,5	3,0 ± 1	1,5 ± 0,5	1,2	0,8	0,5	± 0,3	7,5
7,5	9,0	1,2	18 x 3,0	22	± 0,20	11,5	± 0,20	16,0	− 0,5	0,74	0,3	18,0	− 0,5	40	± 0,5	23	11,0	3,5 ± 1	2,0 ± 0,5	1,2	0,8	0,5	± 0,3	9,4
10	12,5	1,2	18 x 3,0	24	± 0,20	11,5	± 0,20	16,0	− 0,5	0,74	0,3	18,0	− 0,5	45	± 0,5	28	11,0	3,5 ± 1	2,0 ± 0,5	1,2	0,8	0,5	± 0,3	11,2
15	17,5	1,2	18 x 3,0	24	± 0,20	11,5	± 0,20	16,0	− 0,5	0,74	0,3	18,0	− 0,5	60	± 0,5	43	11,0	3,5 ± 1	2,0 ± 0,5	1,2	0,8	0,5	± 0,3	14,6
20	25,5	1,5	22 x 3,0	30	± 0,30	15,2	± 0,25	20,0	− 0,5	0,74	0,3	22,0	− 0,5	55	± 0,7	36	11,0	5,5 ± 1,5	2,5 ± 1	1,2	0,8	0,6	± 0,4	17,5
25	31,5	1,5	22 x 3,0	30	± 0,30	15,2	± 0,25	20,0	− 0,5	0,74	0,3	22,0	− 0,5	65	± 0,7	46	11,0	5,5 ± 1,5	2,5 ± 1	1,2	0,8	0,6	± 0,4	19,8
30	37,5	1,5	22 x 3,0	30	± 0,30	15,2	± 0,25	20,0	− 0,5	0,74	0,3	22,0	− 0,5	75	± 0,7	56	11,0	5,5 ± 1,5	2,5 ± 1	1,2	0,8	0,6	± 0,4	22,5

1) In the case of screw-neck vials for freeze-drying, radius r_2 may be possibly bigger than the value specified in table 1. This value and the concavity of the bottom shall be agreed upon between manufacturer and customer.

2) The pip in the middle of the bottom internal surface should be not more than 0,5 mm high.

3) In the case of special closure types, the bore d_2 could differ from the specified value. The difference shall be agreed upon between manufacturer and customer.