BS ISO 11418-7:2016

BSI Standards Publication

Containers and accessories for pharmaceutical preparations

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

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National foreword

This British Standard is the UK implementation of ISO 11418-7:2016.

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A list of organizations represented on this committee can be obtained on request to its secretary.

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INTERNATIONAL STANDARD

ISO 11418-7

Second edition
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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

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Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
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Contents

Page

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 11418-7:1998), which has been technically revised by

— amending the mass of screw-neck vials in Table 1, and

— editorially revising this part of ISO 11418.

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*

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 the performance can be measured.

INTERNATIONAL STANDARD ISO 11418-7:2016(E)

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 design, dimensions, material and requirements of screw-neck vials for pharmaceutical preparations. Screw-neck vials are applicable to primary packs used in direct contact with a drug.

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.

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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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

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

ISO 4802-2, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification*

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.

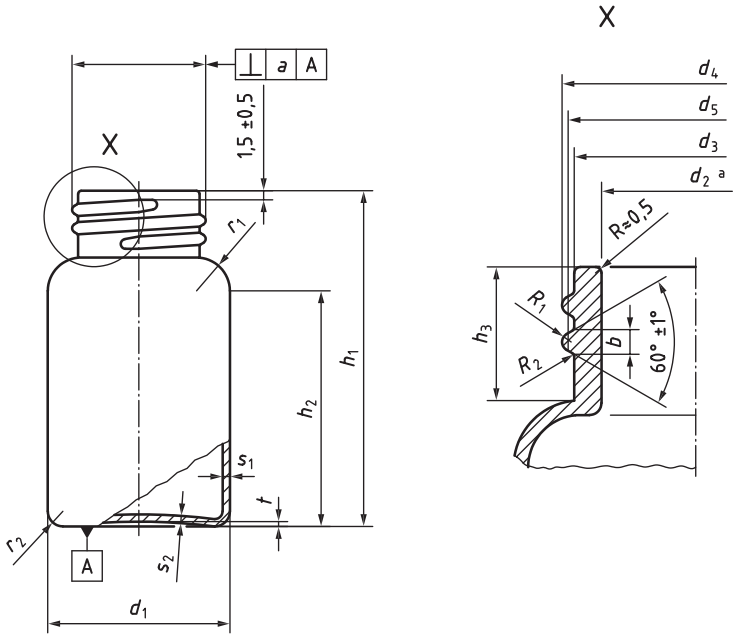
3.2 Designation

Screw-neck vials for pharmaceutical preparations in liquid form made of glass tubing shall be designated by a reference to this part of ISO 11418, followed by 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, made of amber glass (br), glass tubing of nominal size 10, of hydrolytic resistance container class ISO 4802 – HC 1, in accordance with this part of ISO 11418 is designated as follows:

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

Dimensions in millimetres



$$b = p \cdot k$$

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

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

Key

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

a 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 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

4 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 one of the following hydrolytic resistance grain classes.

— ISO 720 – HGA 1 or

— ISO 719 – HGB 3 or ISO 720 – HGA 2.

5 Characteristics

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

5.2 Screw-neck vials shall have a sealing surface which shall not affect the sealing 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 hydrolytical 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.[1)] or USP[2)].

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 plastic carton or a shrink-pack in foil can be agreed upon between manufacturer and customer.

1) See https://www.edqm.eu

2) See http://www.usp.org/

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[c]		d_3		R_1 ≈	R_2	d_4		h_1		h_2 min.	h_3 ±0,5	r_1	r_2[a]	S_1 ±0,05	S_2[b] +0,3 -0,2	t		**Mass**[d, e] g ≈
					tol.		tol.																tol.	
5	6,5	1,0	14 × 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	7,1
7,5	9,0	1,2	18 × 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	8,8
10	12,5	1,2	18 × 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	10,5
15	17,5	1,2	18 × 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	13,7
20	25,5	1,5	22 × 30	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	16,5
25	31,5	1,5	22 × 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	18,6
30	37,5	1,5	22 × 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	21,2

[a] In case of using 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.

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

[c] 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.

[d] Mean values that can deviate about 10 %.

[e] The mass specifications apply to screw-neck vials made of colourless borosilicate glass having a linear expansion coefficient of approximately $5{,}1 \times 10^{-6}\ K^{-1}$, density $2{,}34\ g/cm^2$. The mass of vials made of other glass types (e.g. amber glass or borosilicate glass 3.3) need to be calculated using the density of the particular glass.

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BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

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