

BS ISO 11418-3:2016



BSI Standards Publication

# Containers and accessories for pharmaceutical preparations

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

**National foreword**

This British Standard is the UK implementation of ISO 11418-3:2016. It supersedes BS ISO 11418-3:2005 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

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

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**Containers and accessories for  
pharmaceutical preparations —**

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

*Réipients et accessoires pour préparations pharmaceutiques —*

*Partie 3: Flacons en verre à bouchon à vis (veral) pour formes sèches  
et liquides*



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.

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](http://www.iso.org/directives)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

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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](http://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 third edition cancels and replaces the second edition (ISO 11418-3:2005), which has been technically revised by

- updating [Figure 1](#) on typical screw-neck glass bottle and [Table 1](#) on nominal volume, brimful capacity and dimensions of screw-neck glass bottles,
- including a normative annex on neck finishes, and
- editorially revising this document.

A list of all the parts of ISO 11418 can be found on the ISO website.

# Containers and accessories for pharmaceutical preparations —

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

### 1 Scope

This document specifies the design, dimensions, material and requirements of screw-neck glass bottles (veral) for pharmaceutical preparations in solid and liquid dosage forms. Screw-neck glass bottles are applicable to primary packs used in direct contact with a drug.

This document is applicable to screw-neck glass bottles (veral) used in pharmacy. Together with the corresponding closure systems, they serve for packaging of pharmaceutical preparations in solid and liquid dosage forms 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 documents are referred to in the text in such a way that some or all of their content constitutes requirements 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, *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 1101, *Geometrical product specifications (GPS) — Geometrical tolerancing — Tolerances of form, orientation, location and run-out*

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*

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

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

### 3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at <http://www.electropedia.org/>

— ISO Online browsing platform: available at <http://www.iso.org/obp>

## 4 Dimensions and designation

### 4.1 Dimensions

The dimensions of screw-neck glass bottles [veral]<sup>1)</sup> for pharmaceutical preparations in solid and liquid dosage forms shall be as shown in [Figure 1](#) and as given in [Table 1](#).

The neck finish of screw-neck glass bottles (veral) for solid and liquid dosage shall comply with [Figure A.1](#) or [Figure A.2](#) as appropriate.

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

### 4.2 Designation

Screw-neck glass bottles (veral) for pharmaceutical preparations in solid and liquid dosage forms shall be designated by a reference to this document, followed by the nominal volume, the colour of the glass and bore size.

EXAMPLE A screw-neck glass bottle (veral) of nominal volume 100 ml, made of amber glass (br) of hydrolytic resistance container class ISO 4802-HC 3, in accordance with this document is designated as follows:

**Screw-neck glass bottle ISO 11418-3 - 100 - br**

## 5 Requirements

### 5.1 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.

### 5.2 Performance

#### 5.2.1 Vertical load resistance

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

#### 5.2.2 Hydrolytic resistance

When tested in accordance with ISO 4802-1 and ISO 4802-2, the hydrolytic resistance of the internal surface of the screw-neck glass bottle shall comply with the requirements of the hydrolytic resistance container class ISO 4802-HC 3.

#### 5.2.3 Thermal shock resistance

Screw-neck glass bottles (veral) 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.

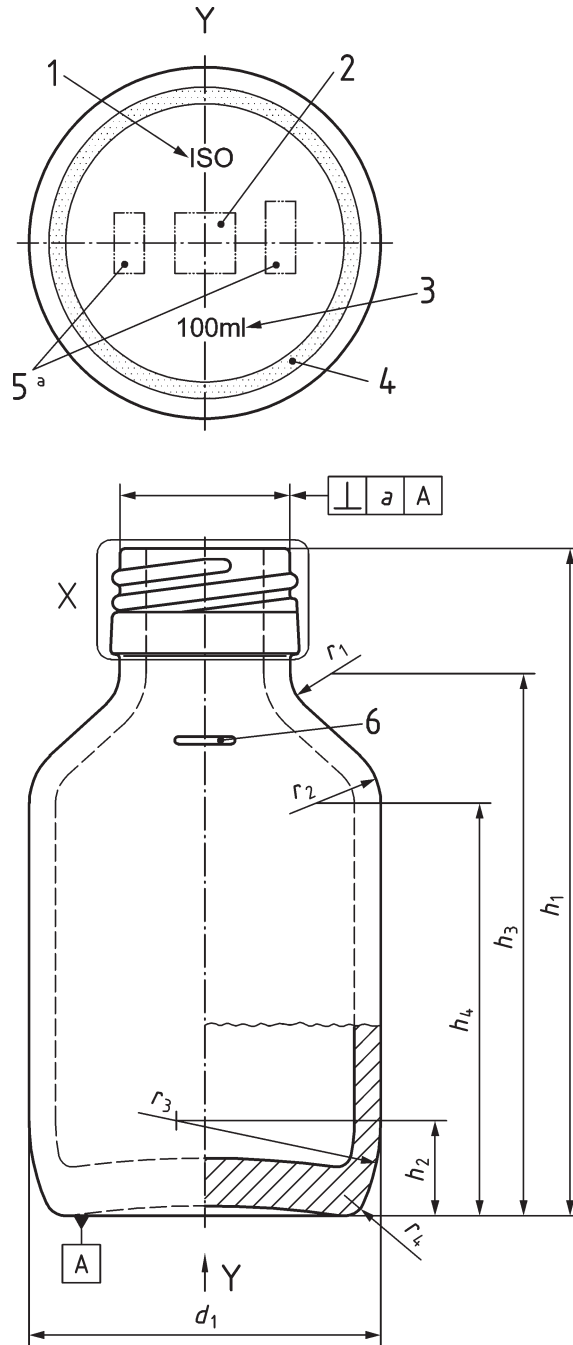
## 6 Marking

The screw-neck glass bottle (veral) shall be marked with the information specified in [Figure 1](#).

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1) From the French term “verre allégé” “lightweight glass”.





**Key**

- 1 ISO letters (optional)
- 2 manufacturer's trademark
- 3 nominal volume (optional)
- 4 bottom surface may be granular, flat or ruffled
- 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.

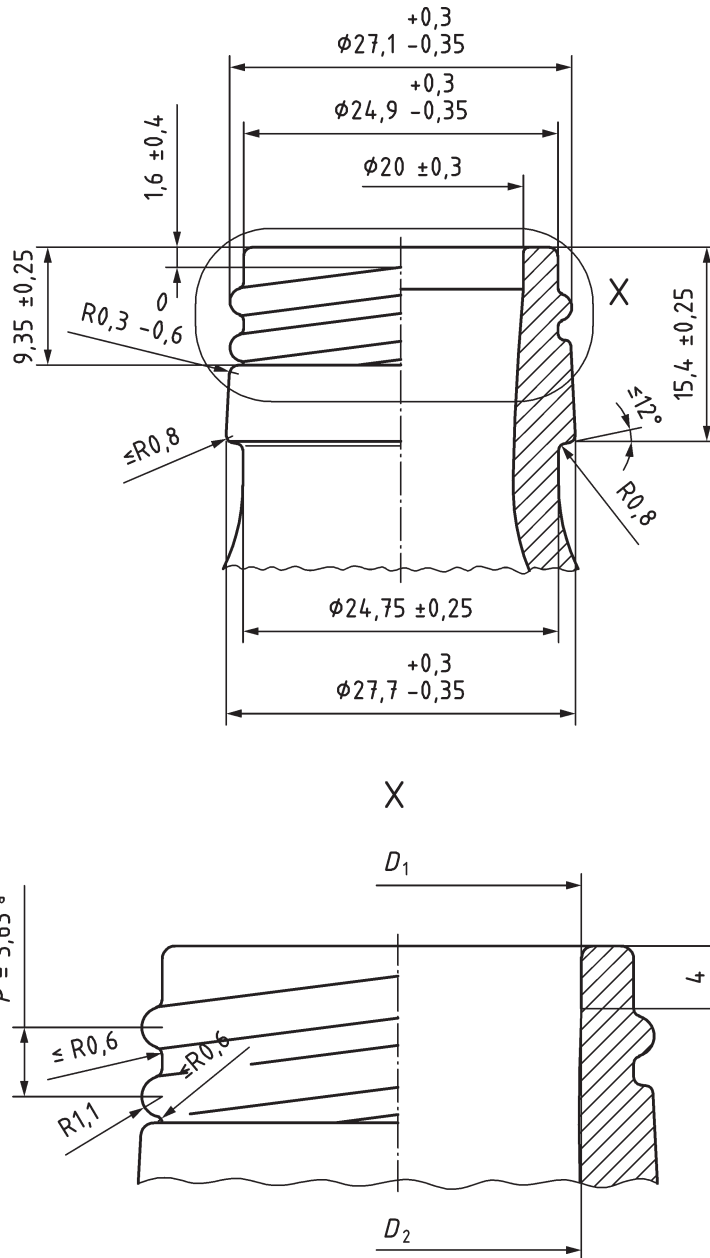
**Figure 1 — Typical screw-neck glass bottle (veral), showing marking locations**

**Table 1 — Nominal volume, brimful capacity and dimensions of screw-neck glass bottles (veral)  
for solid and liquid dosage forms**

Dimensions in millimetres

Nominal volume ml	Minimum brimful capacity ml	$d_1$		$h_1$		$h_2$	$h_3$	$h_4$	$r_1$	$r_2$	$r_3$	$r_4$	Mass g
		nom.	tol.	nom.	tol.								
		≈	≈	≈	≈								
30	33,5	34,2	±1	70,5	±1,0	2,0	52,6	38,0	8,0	17,0	2,0	2,0	47
50	58,0	40,5	±1	81,0	±1,0	13,0	62,6	49,5	4,0	6,0	30,0	3,0	55
60	70,5	44,0	±1,1	82,0	±1,0	12,5	64,5	51,0	3,5	8,0	26,0	2,0	63
75	83,8	47,4	±0,8	91,4	±0,8	13,0	73,0	56,5	6,0	9,0	28,0	2,8	86
100	115,0	51,2	±0,8	96,8	±0,9	13,0	78,8	61,5	5,0	9,0	22,0	4,0	86
125	136,0	56,0	±1,2	97,5	±1,0	15,0	79,6	60,5	5,0	10,0	30,0	3,5	102
150	165,0	56,8	±1,2	111,0	±1,1	14,0	89,0	70,0	8,0	12,0	30,0	3,0	115
200	221,5	63,0	±1,3	118,5	±1,1	17,0	100,5	73,5	7,0	14,0	33,0	4,5	125
250	275,0	65,0	±1,3	136,0	±1,2	19,0	118,6	88,0	6,0	15,0	40,0	4,0	160
300	323,0	72,3	±1,2	134,5	±1,2	18,5	117,0	84,5	7,0	16,8	36,0	3,5	200
500	541,0	82,0	±1,5	161,0	±1,3	18,3	143,5	105,3	7,5	18,0	29,3	5,0	285
1 000	1 079,0	100,6	±1,6	206,2	±1,2	24,0	187,5	140,5	10,0	23,0	45,0	5,0	480





NOTE Diameter  $d_2$  at 4 mm depth and  $\geq \phi 17$  mm.

**Figure A.2 — 20 mm bore - 28 mm Bottle Neck Finish**







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