INTERNATIONAL STANDARD

ISO 11418-7

Second edition
2016-06-15

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

Reference number
ISO 11418-7:2016(E)

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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).

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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*

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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.

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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.

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