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

Reference number
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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.