INTERNATIONAL STANDARD

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Containers and accessories for pharmaceutical preparations —

Part 5: Dropper assemblies

Récipients et accessoires pour préparations pharmaceutiques —

Partie 5: Compte-gouttes

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Contents

Page

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).

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword — Supplementary information.

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 which has been revised in order to update the references.

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*

Containers and accessories for pharmaceutical preparations —

Part 5: Dropper assemblies

1 Scope

This part of ISO 11418 specifies the design, dimensions, material, and requirements of dropper assemblies consisting of a screw cap, dropper bulbs, and pipettes for the application and dosage of liquid pharmaceutical preparations.

This part of ISO 11418 is applicable to dropper assemblies used in the medical field in order to deliver pharmaceutical preparations contained in screw neck bottles according to ISO 11418-1.

Dropper assemblies are applicable to primary packs used in direct contact with the drug.

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 8362-2, *Injection containers and accessories – Part 2: Closures for injection vials*

ISO 11418-1, *Containers and accessories for pharmaceutical preparations — Part 1: Drop-dispensing glass bottles*

3 Dimensions and designation

3.1 Dimensions

The design of the dropper assembly (see Figure 1) may vary, however the dimensions shall be as shown in Figures 2, 3, 4 and 5 and as given in Tables 1, 2, 3 and 4.

Application shall be directed to the location indicated from the diagnostic or therapeutic point of view and shall enable dosage in drops.