INTERNATIONAL STANDARD

ISO 11418-5

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Containers and accessories for pharmaceutical preparations —

Part 5:
Dropper assemblies

Récipients et accessoires pour préparations pharmaceutiques —

Partie 5: Compte-gouttes

Reference number
ISO 11418-5:1997(E)

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 11418-5 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*

Annex A of this part of ISO 11418 is for information only.

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet central@iso.ch
X.400 c=ch; a=400net; p=iso; o=isocs; s=central

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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 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 8362-2:1988, *Injection containers for injectables and accessories – Part 2: Closures for injection vials.*

ISO 11418-1:1996, *Containers and accessories for pharmaceutical preparations — Part 1: Drop-dispensing 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.