BS ISO 11418-1:2016

BSI Standards Publication

Containers and accessories for pharmaceutical preparations

Part 1: Drop-dispensing glass bottles

bsi.

National foreword

This British Standard is the UK implementation of ISO 11418-1:2016. It supersedes BS ISO 11418-1:2005 which is withdrawn.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.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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INTERNATIONAL STANDARD

ISO 11418-1

Third edition
2016-11-15

Containers and accessories for pharmaceutical preparations —

Part 1: Drop-dispensing glass bottles

Récipients et accessoires pour préparations pharmaceutiques —

Partie 1: Flacons compte-gouttes en verre

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).

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 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 third edition cancels and replaces the second edition (ISO 11418-1:2005), which has been technically revised by

— updating Figure 1 on typical drop-dispensing glass bottle and Table 1 on nominal volume, brimful capacity and dimensions of drop-dispensing glass bottles,

— deleting the sizes 25 ml and 75 ml in Table 1, and

— editorially revising this document.

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

INTERNATIONAL STANDARD ISO 11418-1:2016(E)

Containers and accessories for pharmaceutical preparations —

Part 1: Drop-dispensing glass bottles

1 Scope

This document specifies the design, dimensions, material and requirements of drop-dispensing glass bottles. Drop-dispensing glass bottles are applicable to primary packs used in direct contact with a drug.

This document is applicable to drop-dispensing glass bottles used in pharmacy. Together with the corresponding closure systems, they serve for packaging of pharmaceutical preparations 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