SLOVENSKI STANDARD
oSIST prEN ISO 8362-1:2019

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Vsebniki za parenteralne farmacevtske oblike in dodatna oprema - 1. del: Viale iz cevnega stekla (ISO 8362-1:2018)

Injection containers and accessories - Part 1: Injection vials made of glass tubing (ISO 8362-1:2018)

Injektionsbehältnisse und Zubehör - Teil 1: Injektionsflaschen aus Röhrenglas (ISO 8362 -1:2018)

Récipients et accessoires pour produits injectables - Partie 1: Flacons en verre étiré (ISO 8362-1:2018)

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INTERNATIONAL STANDARD

ISO 8362-1

Fourth edition
2018-08

Injection containers and accessories —

Part 1: Injection vials made of glass tubing

Récipients et accessoires pour produits injectables —

Partie 1: Flacons en verre étiré

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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 of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This fourth edition cancels and replaces the third edition (ISO 8362-1:2009), which has been technically revised.

The main changes compared to the previous edition are:

— add an alternative for a chamfer shaped with ≈45° in Figure 1;

— add a 3R format in Table 1.

A list of all parts in the ISO 8362 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The purpose of this document is to specify the dimensions, capacities, form and requirements of glass vials intended for medical use. Containers made from glass tubing are considered to be suitable for the packaging and storage of injectable preparations until they are administered for medicinal purposes. Such containers may be made from different types of glass which can affect the chemical resistance properties; e.g., those made from borosilicate glass will have a very high level of chemical resistance whereas others made from soda-lime glass will have a lower, but adequate, chemical resistance for the purpose for which they are intended. The chemical resistance of the internal surface of containers made from soda-lime glass can be improved by means of a treatment during production aimed at producing a chemical resistance equal to that of those made from borosilicate glass for single use. This level of chemical resistance is maintained as long as the interior surface is not destroyed by chemical attack, in which case it is reduced to that of untreated soda-lime glass.

Because containers 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 injectable preparations, it is essential to specify test procedures by which this performance can be measured. The procedures recommended in this document permit this performance, based on the hydrolytic resistance to be measured and, from the result of measurement, it is possible to classify containers into their correct category. The procedure also allows containers to be tested and to determine, after an intermediate stage, whether the hydrolytic resistance is produced by the composition of the glass as a material or by a treatment of the internal surface.

Injection containers and accessories —

Part 1: Injection vials made of glass tubing

1 Scope

This document specifies the form, dimensions and capacities of glass vials for injectable preparations. It also specifies the material from which such containers are made and the performance requirements of those containers.

This document is applicable to colourless or amber glass containers made from borosilicate or soda-lime glass, made from glass tubing, whether internally surface-treated or not, and intended to be used in the packaging, storage or transportation of products intended for injection.

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 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 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4802-1 and ISO 4802-2 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

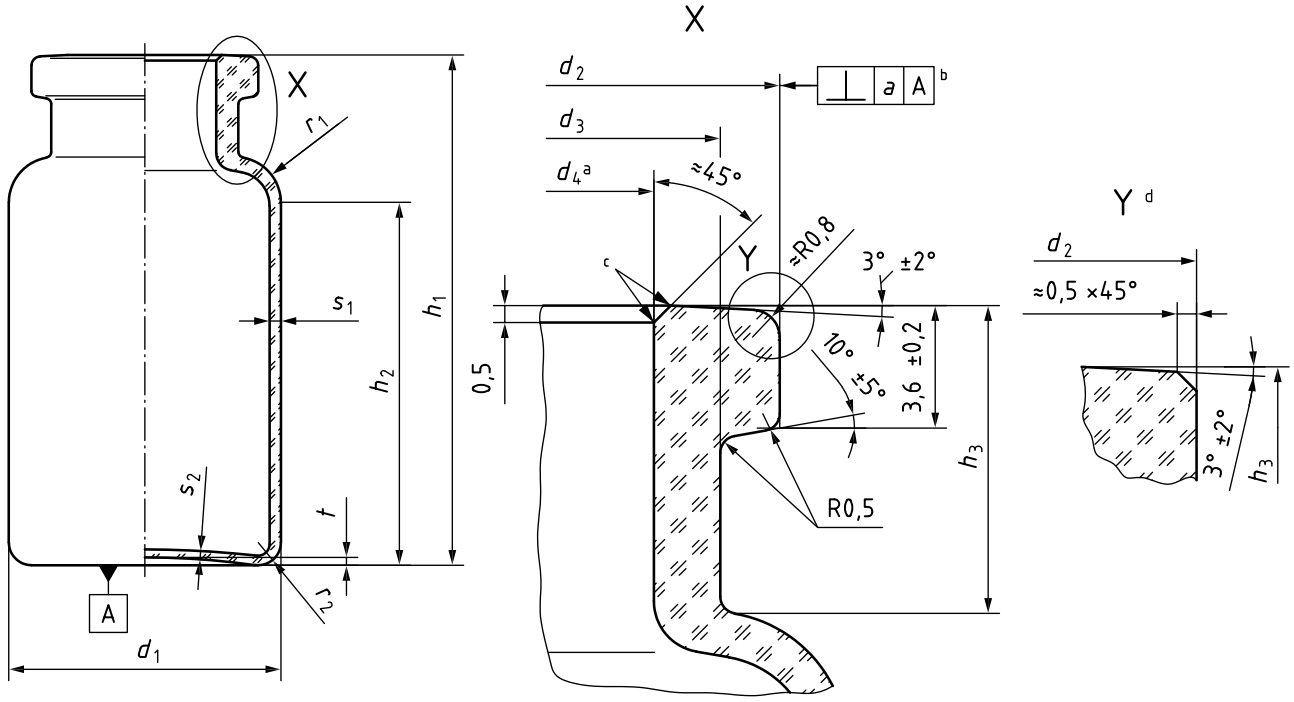
— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Dimensions

The dimensions of injection vials made of glass tubing shall meet the requirements of Figure 1, Figure 2 or Figure 3, as appropriate, and Table 1; the brimful capacity and mass shall be as shown in Table 1.

Dimensions in millimetres



a The opening of the vial should have a constant diameter, over the entire distance, h_3, i.e. it should exhibit a cylindrical shape. A slightly conical shape can be accepted if the following requirements are fulfilled:

- the truncated cone has the height h_3;
- the larger diameter is located at the flange or as agreed upon;
- the larger diameter does not exceed the smaller one by more than 0,3 mm.

b The perpendicularity tolerance *a* (as defined in ISO 1101) is a limit for the deviation of the plumb-line through the centre of the bottom part and the axis of the vial at the upper edge of the flange; it is measured at the brim.

c Edges slightly rounded.

d ≈ R0,8 (a chamfer shaped with ≈ 45° is alternatively also feasable).

Figure 1 — Typical example of injection vial made of glass tubing containing a neck finish without blow back — Model A