Injection containers and accessories - Part 1: Injection vials made of glass tubing

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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 8362-1:2010 sisaldab Euroopa standardi EN ISO 8362-1:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 8362-1:2010 consists of the English text of the European standard EN ISO 8362-1:2009.
Standard on kinnitatud Eesti Standardikeskuse 28.02.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 28.02.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 15.12.2009.	Date of Availability of the European standard text 15.12.2009.
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Injection containers and accessories - Part 1: Injection vials made of glass tubing (ISO 8362-1:2009)

Récipients et accessoires pour produits injectables - Partie 1: Flacons en verre étiré (ISO 8362-1:2009)

Injektionsbehältnisse und Zubehör - Teil 1: Injektionsflaschen aus Röhrenglas (ISO 8362-1:2009)

This European Standard was approved by CEN on 21 December 2009.

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Foreword

This document (EN ISO 8362-1:2009) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2010, and conflicting national standards shall be withdrawn at the latest by June 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 8362-1:2009 has been approved by CEN as a EN ISO 8362-1:2009 without any modification.

Introduction

The purpose of this part of ISO 8362 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 part of ISO 8362 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 part of ISO 8362 specifies the form, dimensions and capacities of glass vials for injectable preparations. It also specifies the material from which such containers shall be made and the performance requirements of those containers.

This part of ISO 8362 applies 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 referenced documents are indispensable for the application 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 °C — Method of test and classification*

ISO 720, *Glass — Hydrolytic resistance of glass grains at 121 °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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4802-1 and ISO 4808-2 apply.

4 Dimensions

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