Injection containers and accessories - Part 4: Injection vials made of moulded glass (ISO 8362-4:2011)

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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 8362-4:2011 sisaldab Euroopa standardi EN ISO 8362-4:2011 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 8362-4:2011 consists of the English text of the European standard EN ISO 8362-4:2011.
Standard on kinnitatud Eesti Standardikeskuse 30.09.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.09.2011 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 01.09.2011.	Date of Availability of the European standard text 01.09.2011.
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Injection containers and accessories - Part 4: Injection vials made of moulded glass (ISO 8362-4:2011)

Récipients et accessoires pour produits injectables - Partie 4: Flacons en verre moulé (ISO 8362-4:2011)

Injektionsbehältnisse und Zubehör - Teil 4: Injektionsflaschen aus Hüttenglas (ISO 8362-4:2011)

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Foreword

This document (EN ISO 8362-4:2011) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing 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of an identical text or by endorsement, at the latest by March 2012, and conflicting national standards shall be withdrawn at the latest by March 2012.

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Endorsement notice

The text of ISO 8362-4:2011 has been approved by CEN as a EN ISO 8362-4:2011 without any modification.

Introduction

The purpose of this part of ISO 8362 is to specify the shape, dimensions and capacities of, and performance requirements for, glass vials intended for medical use. Containers made from moulded glass are considered to be suitable for the packaging and storage of injectable preparations until they are administered for medicinal purposes. Such containers can be made from different types of glass, which can affect the chemical resistance properties. For example, those made from borosilicate glass will have a very high level of chemical resistance, whereas those made from soda-lime-silica glass will have a lower chemical resistance but one that is adequate for the purpose for which the containers are intended. The chemical resistance of the internal surface of containers made from soda-lime-silica glass can be improved by a treatment during production to produce a chemical resistance equal to that of containers made from borosilicate glass for single use. This level of chemical resistance will be maintained as long as the interior surface is not destroyed by chemical attack, in which case it will be reduced to that of untreated soda-lime-silica glass.

Because containers can be made from different types of glass and because it is the chemical behaviour of the internal surface that 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 specified in this part of ISO 8362 will allow 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 procedures also allow containers to be tested and to determine whether the hydrolytic resistance is due to the composition of the glass, or to a treatment of the internal surface.

Injection containers and accessories —

Part 4:
Injection vials made of moulded glass

1 Scope

This part of ISO 8362 specifies the shape, dimensions and capacities of glass vials for injectable preparations. It also specifies the material from which such containers are made and the performance requirements for the containers.

It applies to colourless or amber glass containers moulded from borosilicate or soda-lime-silica glass, with or without an internal surface treatment, 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 719:1985, *Glass — Hydrolytic resistance of glass grains at 98 °C — Method of test and classification*

ISO 720:1985, *Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification*

ISO 4802-1:2010, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification*

ISO 4802-2:2010, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification*

ISO 7458, *Glass containers — Internal pressure resistance — Test methods*

ISO 7459, *Glass containers — Thermal shock resistance and thermal shock endurance — Test methods*

3 Terms and definitions

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