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Third edition  
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## **Injection containers and accessories — Part 4: Injection vials made of moulded glass**

*Réipients et accessoires pour produits injectables —  
Partie 4: Flacons en verre moulé*



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## Foreword

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The main task of technical committees is to prepare International Standards. 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.

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.

ISO 8362-4 was prepared by Technical Committee 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 8362-4:2003), of which it constitutes a minor revision.

The principle changes to the second edition are the updating of normative references to ISO 4802-1 and ISO 4802-2, and the revision of Figure 2 and Table 2.

ISO 8362 consists of the following parts, under the general title *Injection containers and accessories*:

- *Part 1: Injection vials made of glass tubing*
- *Part 2: Closures for injection vials*
- *Part 3: Aluminium caps for injection vials*
- *Part 4: Injection vials made of moulded glass*
- *Part 5: Freeze drying closures for injection vials*
- *Part 6: Caps made of aluminium-plastics combinations for injection vials*
- *Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part*

## 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.