INTERNATIONAL STANDARD

**ISO 8362-4**

Second edition
2003-08-01

# Injection containers and accessories —

## Part 4: Injection vials made of moulded glass

*Récipients et accessoires pour produits injectables —*

*Partie 4: Flacons en verre moulé*



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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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 equipment for medical and pharmaceutical use.*



This second edition cancels and replaces the first edition (ISO 8362-4:1989), which has been technically revised.



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 may 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 others made from soda-lime glass will have a lower chemical resistance, but adequate for the purpose for which the containers are intended. The chemical resistance of the internal surface of containers made from soda-lime glass can be improved by a treatment during production to produce a chemical resistance equal to that of those 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 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 their 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 the measurement, it is possible to classify containers into the correct category. The procedures also allow containers to be tested 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 shall be made and the performance requirements for the containers.

It applies to colourless or amber glass containers moulded from borosilicate or soda-lime 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 1101:—[1], *Geometrical Product Specifications (GPS) — Geometrical tolerancing — Tolerances of form, orientation, location and run-out*

ISO 4802-1:1988, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification*

ISO 4802-2:1988, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification*

ISO 7458:—[2], *Glass containers — Internal pressure resistance — Test methods*

ISO 7459:—[3], *Glass containers — Thermal shock resistance and thermal shock endurance — Test methods*

## 3 Terms and definitions

For the purposes of this part of ISO 8362, the terms and definitions given in ISO 4802-1 and ISO 4802-2 apply.

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1) To be published. (Revision of ISO 1101:1983)

2) To be published. (Revision of ISO 7458:1984)

3) To be published. (Revision of ISO 7459:1984)

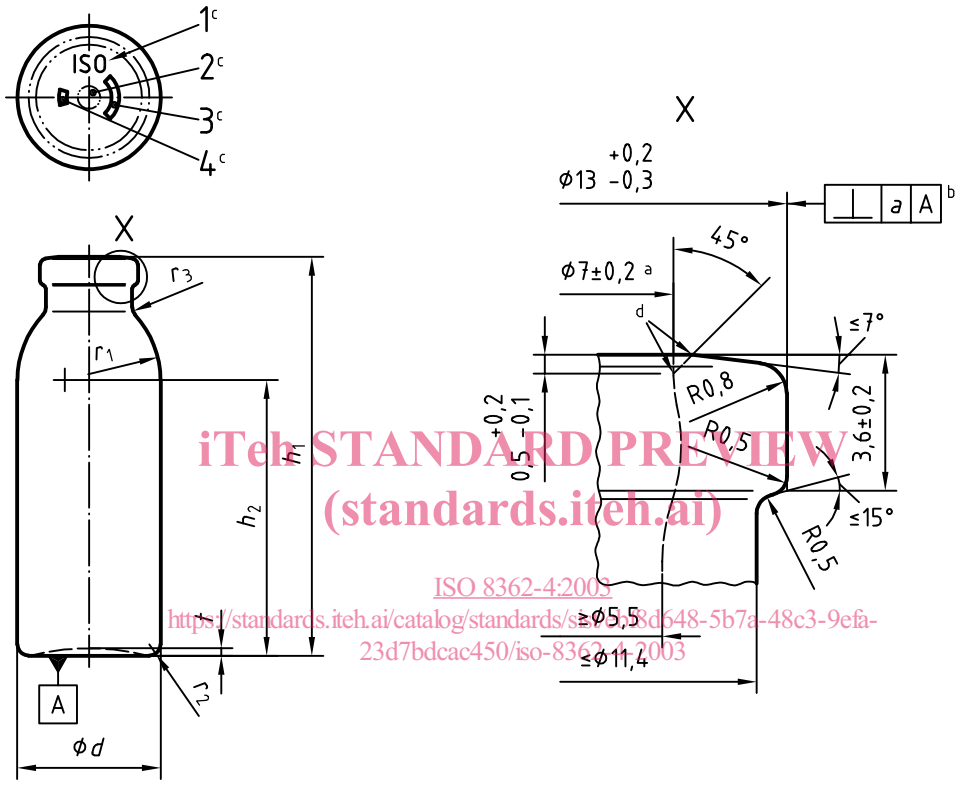
# 4 Dimensions and designation

## 4.1 Injection vials for insulin

### 4.1.1 Dimensions

The dimensions of injection vials for insulin shall be as shown in Figure 1 and as given in Table 1. The overflow capacity shall be as given in Table 1.

Dimensions in millimetres






**Key**

1 ISO symbol (optional)

2 designation of the hydrolytic resistance container class (mandatory for type I and type II — optional for type III)

3 manufacturer's code/designation of the mould

4 manufacturer's trade-mark (optional)

a Dimension to be maintained over a depth of 1 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 of the vial and the axis of the vial at the upper edge of the flange. It is measured at the brim.

c The identification marks and/or coding may be on the bottom, the neck or the shoulder of the vial. The drawing represents a typical example.

d Edges slightly rounded.

**Figure 1 — Typical example of injection vial for insulin**

**Table 1 — Dimensions and overflow capacity of injection vials for insulin**

Dimensions in millimetres

| Size designation for injection vial | Overflow capacity ml min. | $a$ | $d$ | tol. | $h_1$ | tol. | $h_2$ min. | $r_1$ ≈ | $r_2$ ≈ | $r_3$ ≈ | $t$ ≈ |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **2l** | 2,5 | 1 | 18 | ± 0,5 | 30,6 | ± 0,6 | 17,6 | 7,9 | 1,6 | 2,5 | 0,4 |
| **5l** | 7,2 | 1,4 | 19 | ± 0,6 | 52,8 | | 36,5 | 12,7 | 1,5 | 1,5 | 1 |
| **10l** | 13,1 | 1,6 | 23 | ± 0,6 | 58,9 | | 42 | 10,3 | | 2,5 | 1,5 |

### 4.1.2 Designation

Example of a designation of an injection vial for insulin, size 5 (designated by 5l), made of moulded amber glass (br) of hydrolytic resistance container class ISO 4802 – HC 1 (designated by 1), complying with the requirements specified in this part of ISO 8362:

**Vial ISO 8362-4 5l – br – 1**

## 4.2 Injection vials for antibiotics



### 4.2.1 Dimensions

The dimensions of injection vials for antibiotics shall be as shown in Figure 2 and as given in Table 2. The overflow capacity shall be as given in Table 2.