INTERNATIONAL STANDARD

ISO 8362-4

Third edition
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Injection containers and accessories —

Part 4: Injection vials made of moulded glass

Récipients et accessoires pour produits injectables —

Partie 4: Flacons en verre moulé

Reference number
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Foreword

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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, 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.

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.

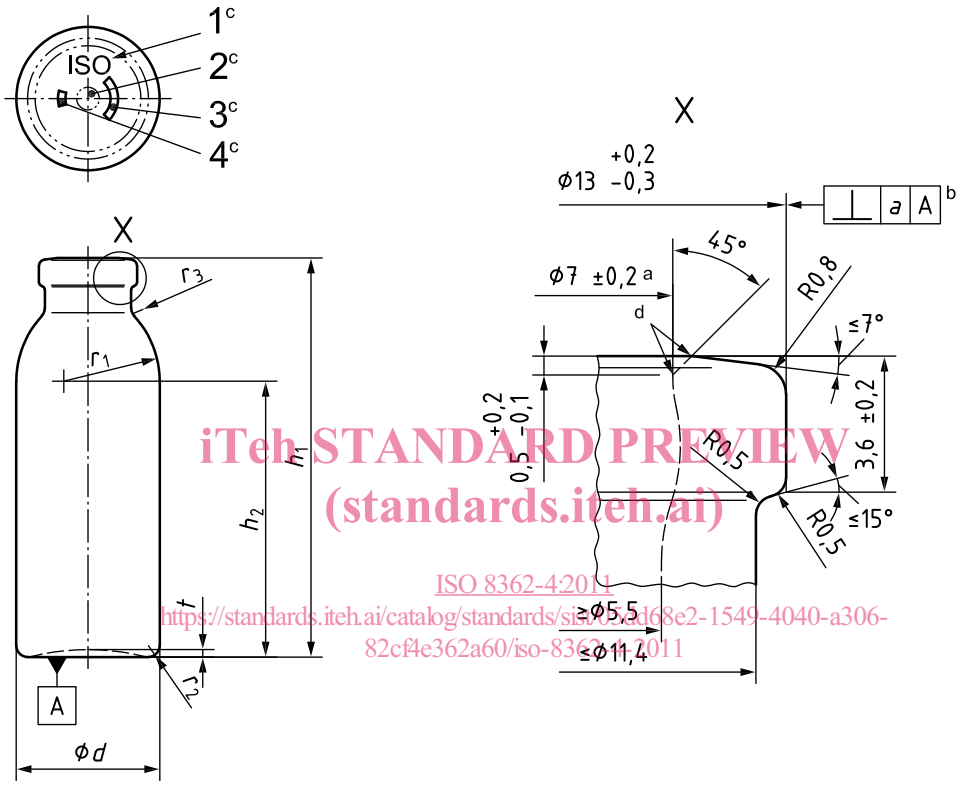
4 Dimensions and designation

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 logo (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 injection 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		h_1		h_2	r_1[a]	r_2[a]	r_3[a]	t
				tol.		tol.	min.	≈	≈	≈	≈
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

[a] Tolerances should be agreed between manufacturer and user.

4.1.2 Designation

EXAMPLE 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, is designated as follows:

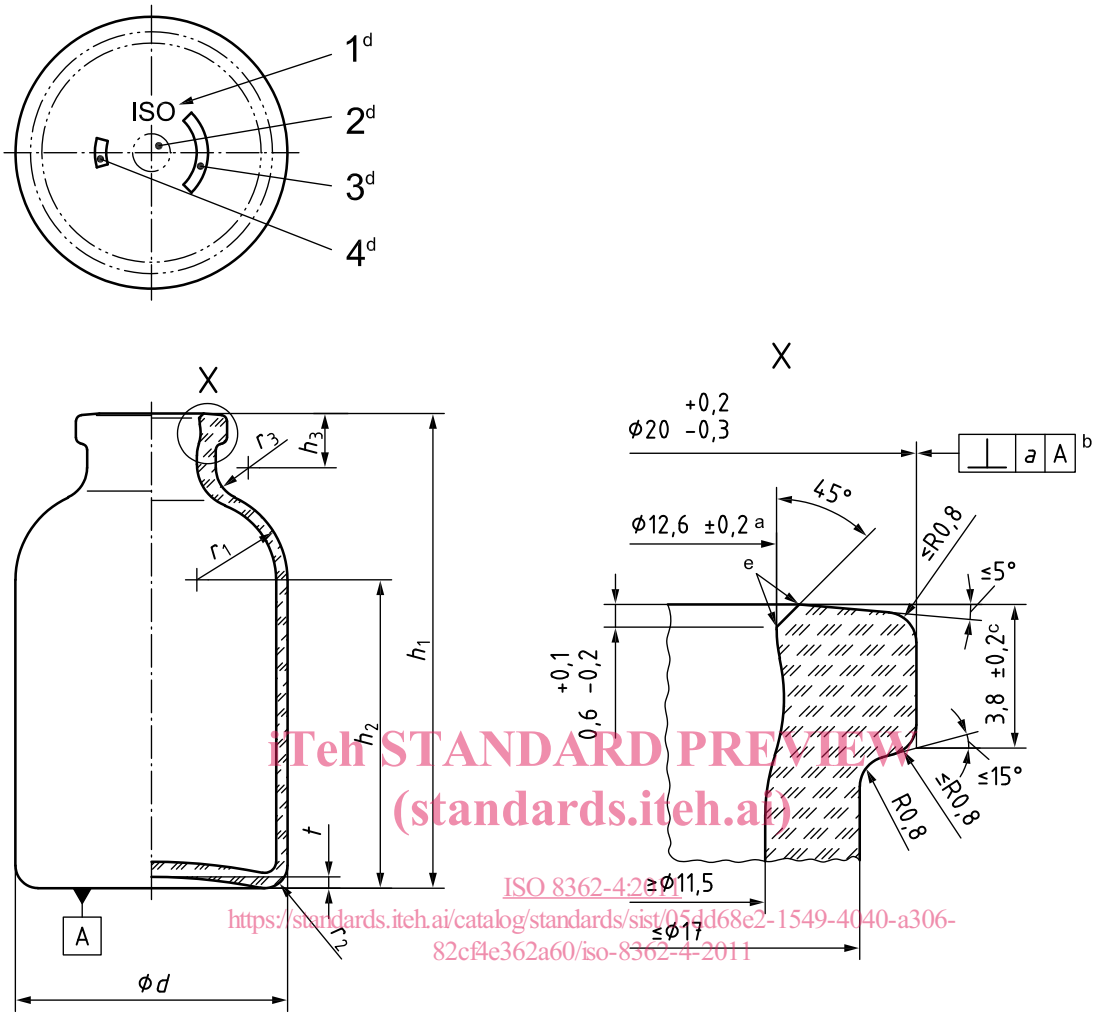
Vial ISO 8362-4 – 5l – br – 1

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.

Dimensions in millimetres



Key

1 ISO logo (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)

NOTE The base area can be grained or plain.

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 Owing to the differences in manufacturing procedures for injection vials made of glass tubing and those made of moulded glass, the measuring point at the brim is different in each case. It follows that the height measured from the lower edge of the flange to the measuring point at the brim of injection vials made of moulded glass is 0,2 mm more than that of injection vials made of glass tubing. But, in practice, the same aluminium caps may be used for both types of vial.

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

e Edges slightly rounded.

Figure 2 — Typical example of injection vial for antibiotics

Table 2 — Dimensions and overflow capacity of injection vials for antibiotics

Dimensions in millimetres

Size designation for injection vial	Overflow capacity ml min.	a	d	tol.	h_1	tol.	h_2 min.	h_3 min.	r_1[a] ≈	r_2[a] ≈	r_3[a] ≈	t ≈
5H	6,3	1,1	20,8	±0,4	41,3	±0,5	26,2	6,5	8,4	1,5	10	1
7H	8,3		22,1		40,8		26,7		5	2	4,4	
8H	9,2	1,2	23		46,8		29,5		9,5	1,5	7	
10H	14	1,4	25,4		53,5	±0,6	35,3		10	2	5	
15H	16	1,5	26,5	±0,45	58,8		36,5		15	2,5	9,5	
20H	24,9		32		58		36,1		12	3	6,1	1,5
25H	30,9		36	±0,5			34				6,5	
30H	36,6	1,6			62,8	±0,7	41,3				4,3	
50H	58,2	1,9	42,5	±0,8	73	±0,8	46		12,5		8,5	2
100H	116,2	2,4	51,6		94,5	±0,9	58		25,6	4	7	

[a] Tolerances should be agreed between manufacturer and user.

4.2.2 Designation

EXAMPLE An injection vial for antibiotics, size 10 (designated by 10H), made of amber moulded glass (br) of hydrolytic resistance container class ISO 4802 – HC 1 (designated by 1), complying with the requirements of this part of ISO 8362 is designated as follows:

Vial ISO 8362-4 – 10H – br – 1

5 Material

Injection vials shall be constructed from

a) colourless (cl) or amber (br) borosilicate glass (see ISO 4802-1:2010, 3.6, and ISO 4802-2:2010, 3.6), or

b) soda-lime-silica glass (see ISO 4802-1:2010, 3.7, and ISO 4802-2:2010, 3.7) of the following hydrolytic resistance grain classes:

— ISO 720 – HGA 1;

— ISO 719 – HGB 3 or ISO 720 – HGA 2.

A change in the composition of the glass material or of the colouring oxides should be notified to the user at least nine months in advance.

6 Defects, sealing surfaces

As far as defects (such as seed or bubbles) and the sealing performance of the sealing surfaces are concerned, the injection vials shall comply with existing quality standards, as agreed between manufacturer and user.