INTERNATIONAL STANDARD

ISO 8362-1

Third edition
2009-12-15

Injection containers and accessories —

Part 1: Injection vials made of glass tubing

Récipients et accessoires pour produits injectables —

Partie 1: Flacons en verre étiré

Reference number
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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 8362-1 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This third edition cancels and replaces the second edition (ISO 8362-1:2003), which has undergone minor revision by including further types of neck finishes for injection vials [model B – neck finish with blow back (European style) and model C – neck finish with blow back (American style)].

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 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*

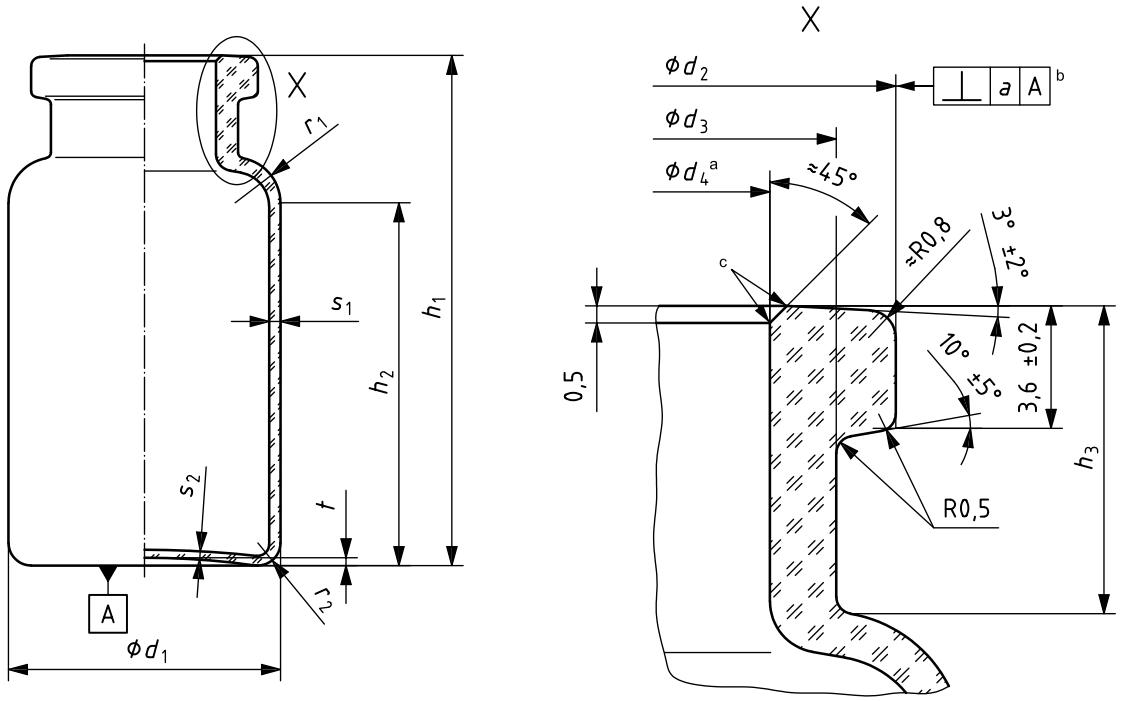
3 Terms and definitions

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.

Dimensions in millimetres



[a] The opening of the vial should have a constant diameter, over the entire distance, h_3, i.e. it should exhibit a cylindrical shape. A slightly conical shape can be accepted if the following requirements are fulfilled:

— the truncated cone has the height h_3;

— the larger diameter is located at the flange or as agreed upon;

— the larger diameter does not exceed the smaller one by more than 0,3 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 part and the axis of the vial at the upper edge of the flange; it is measured at the brim.

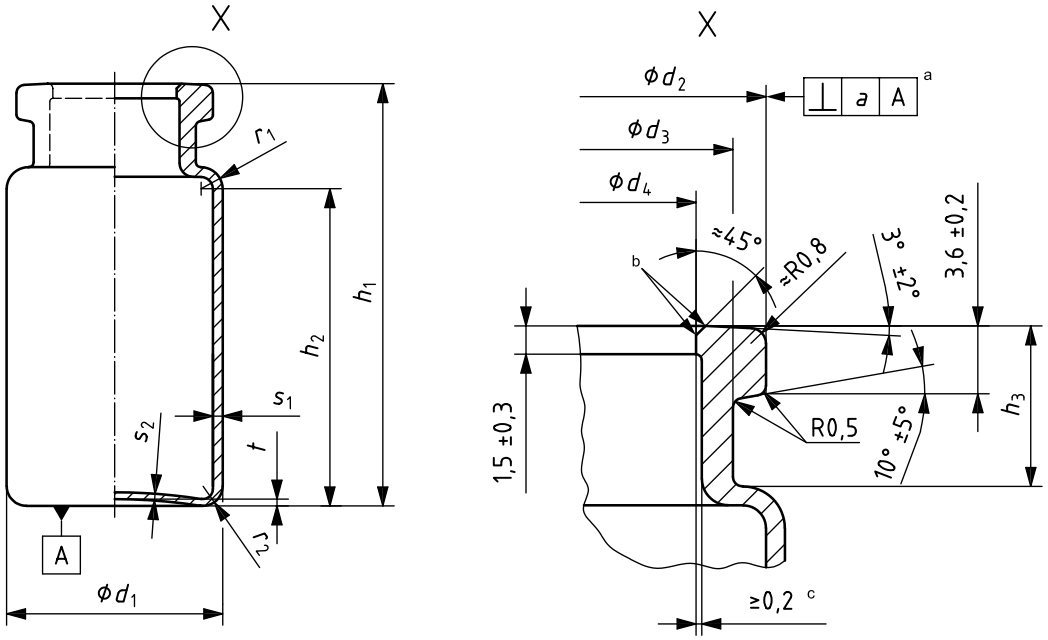
[c] Edges slightly rounded.

Figure 1 — Typical example of injection vial made of glass tubing containing a neck finish without blow back — Model A

Table 1 — Dimensions, overflow capacity and mass

Size designation of injection vial	Overflow capacity		a	d_1		d_2	d_3	d_4	h_1		h_2	h_3		r_1	r_2	s_1		s_2	t	Mass
	ml		mm	mm		mm	mm	mm	mm		mm	mm		mm	mm	mm		mm	mm	g
		tol			tol.	+0,2 −0,3	max.	± 0,2		tol.	min.		tol.	≈	≈		tol.	min.	max	≈
2R	4	± 0,5	1	16	± 0,15	13	10,5	7	35	± 0,5	22	8	± 0,5	2,5	1,5	1	± 0,04	0,6	0,7	5
4R	6								45		32									6,1
6R	10		1,2	22	± 0,2	20	16,5	12,6	40		26	8,5		3,5	2			0,7		8,3
8R	11,5								45		31									9,4
10R	13,5	± 1		24					45		30	9		4,0						10,2
15R	19								60		45							0,7		12,8
20R	26	± 1,5	1,5	30	± 0,25		17,5		55	± 0,7	35	10	± 0,75	5,5	2,5	1,2	± 0,05		1	17,4
25R	32,5								65		45									20
30R	37,5								75		55									22,7

Dimensions in millimetres



a 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 part and the axis of the vial at the upper edge of the flange; it is measured at the brim.

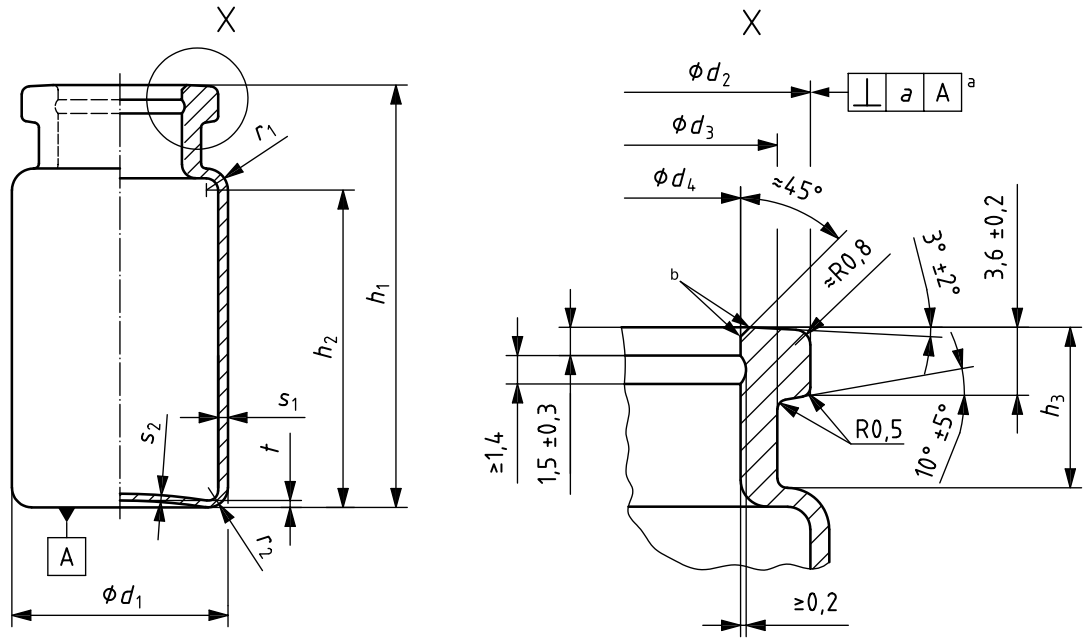
b Edges slightly rounded.

c This value should not exceed 0,4 mm in order to avoid the wall becoming too weak. This dimension has not been given as a requirement because it is not possible to measure it adequately.

NOTE Figures 2 and 3 illustrate ideal presentations. The transition to blow back is not sharp-edged but slightly rounded.

Figure 2 — Typical example of injection vial made of glass tubing containing a neck finish with blow back (European style) — Model B

Dimensions in millimetres



a 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 part and the axis of the vial at the upper edge of the flange; it is measured at the brim.

b Edges slightly rounded.

Figure 3 — Typical example of injection vial made of glass tubing containing a neck finish with blow back (American style) — Model C

5 Designation

EXAMPLE 1 An injection vial (model A), size 10 (10R), made of amber glass (br) tubing of hydrolytic resistance container class ISO 4802 – HC 1 (1) complying with the requirements specified in this part of ISO 8362 is designated as follows:

Vial ISO 8362-1 – A – 10R – br – 1

EXAMPLE 2 An injection vial (model B), size 10 (10R), made of amber glass (br) tubing of hydrolytic resistance container class ISO 4802 – HC 1 (1) complying with the requirements specified in this part of ISO 8362 is designated as follows:

Vial ISO 8362-1 – B – 10R – br –1

EXAMPLE 3 An injection vial (model C), size 15 (15R), made of colourless (cl) glass of hydrolytic resistance container class ISO 4802 – HC 1 (1) complying with the requirements specified in this part of ISO 8362 is designated as follows:

Vial ISO 8362-1 – C – 15R – cl – 1

6 Material

Colourless (cl) or amber (br) borosilicate glass or soda-lime glass of one of the following hydrolytic resistance grain classes:

— ISO 720 – HGA 1

— ISO 719 – HGB 3 or ISO 720 – HGA 2

shall be used.

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

7 Performance

7.1 Injection vials shall not contain seed or bubbles to an extent which will interfere with the visual examination of the contents.

7.2 Injection vials shall have a sealing surface that is flat and free from ripples of undulations which would affect the sealing performance of the closure.

8 Requirements

8.1 Hydrolytic resistance

When tested in accordance with ISO 4802-1 or ISO 4802-2, the hydrolytic resistance of the internal surface of injection vials shall comply with the requirements specified for one of the following hydrolytic resistance container classes:

— ISO 4802 – HC 1

— ISO 4802 – HC 2

— ISO 4802 – HC 3

8.2 Annealing quality

The injection vials shall be annealed so that when the vials are viewed in a strain viewer, the maximum residual stress does not produce an optical retardation exceeding 40 nm per millimetre of glass thickness.

9 Marking

The number of pieces and the designation in accordance with Clause 5 together with the name or symbol of the manufacturer shall be shown on the package.

Further information may be given, subject to agreement.

ICS 11.040.20

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