INTERNATIONAL STANDARD

ISO 8362-1

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Injection containers for injectables 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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Contents

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

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

ISO 8362 consists of the following parts under the general title *Injection containers for injectables 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*

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. For example, those made from borosilicate glass will have a very high level of chemical resistance whereas others made from soda-lime-silica 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-silica 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-silica 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 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 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 for injectables 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-silica 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 standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 8362. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 8362 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

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 : 1983, *Technical drawings — Geometrical tolerancing — Tolerancing of form, orientation, location and run-out — Generalities, definitions, symbols, indications on drawings.*

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.*

3 Definitions

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

4 Dimensions and designation

4.1 Dimensions

The dimensions of injection vials made of glass tubing shall be as shown in figure 1 and as given in table 1; the overflow capacity and mass shall be as given in table 1.

Dimensions in millimetres

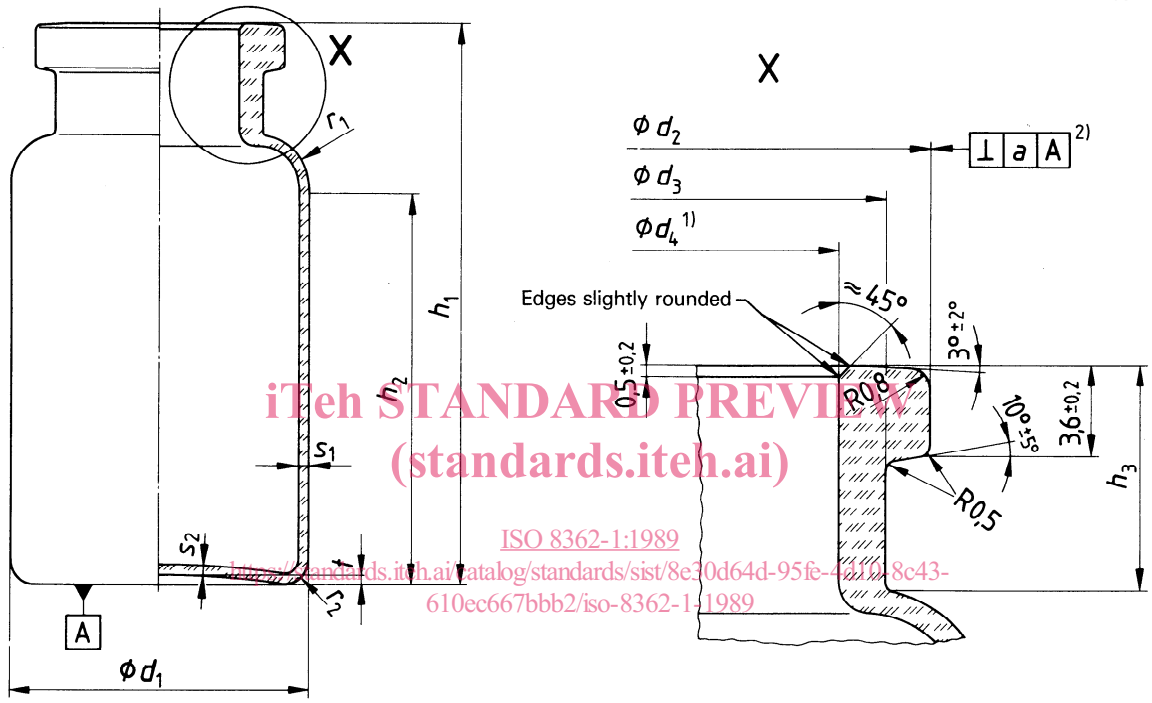

Figure 1 — Typical example of injection vial made of glass tubing

1) The opening of the vial should have a constant diameter, as specified by d_4, over the entire distance given by h_3, i.e. it should exhibit a cylindrical shape. A slightly conical shape can be accepted if the following requirements are complied with:

a) the truncated cone shall have the height as specified by h_3;

b) the larger diameter shall be located at the flange;

c) the larger diameter shall not exceed the smaller one by more than 0,3 mm.

2) 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.

Table 1 — Dimensions, overflow capacity and mass

Dimensions in millimetres

Size designation of injection vial	Overflow capacity ml		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 g
		tol.			tol.	$^{+0,2}_{-0,3}$	max.	±0,2		tol.	min.		tol.	≈	≈		tol.	min.	max.	≈
2R	4	±0,5	1	16	±0,2	13	10,5	7	35	±0,5	23	8	±0,5	2,5	1,5	1	±0,04	0,7	0,7	5
4R	6								45		33									6,1
6R	10		1,2	22		20	16	12,6	40		27	8,5		3,5	2					8,3
8R	11,5								45		32									9,4
10R	13,5	±1		24			16,5		45		31	9								10,2
15R	19								60		46									12,8
20R	25	±1,5	1,5	30	±0,3		17,5		55	±0,7	35	10	±0,75	5,5	2,5	1,2	+0,05		1	17,4
25R	30,5								65		45									20
30R	36								75		55									22,7

4.2 Designation

Designation example of an injection vial, 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:

Vial ISO 8362-1 10R - br - 1

5 Material

Colourless (cl) or amber (br) borosilicate glass[1] or soda-lime-silica glass[1] 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.

NOTE — 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.

6 Performance

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

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

7 Requirements

7.1 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.

7.2 Annealing quality

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

8 Marking

The number of pieces and the designation according to 4.2 together with the name or symbol of the manufacturer shall be shown on the package.

Further information may appear subject to agreement.

1) For definitions, see ISO 4802-1 and ISO 4802-2.

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Descriptors : medical equipment, parenteral infusion equipment, containers, glassware, flasks, specifications, dimensions, designation, marking.

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