INTERNATIONAL STANDARD

ISO 8362-4

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Injection containers for injectables 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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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 8362-4 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 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-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 4 :
Injection vials made of moulded glass

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 moulded glass, 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.*

ISO 7458 : 1984, *Glass containers — Internal pressure resistance — Test methods.*

ISO 7459 : 1984, *Glass containers — Thermal shock resistance and thermal shock endurance — Test methods.*

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 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 and mass shall be as given in table 1.

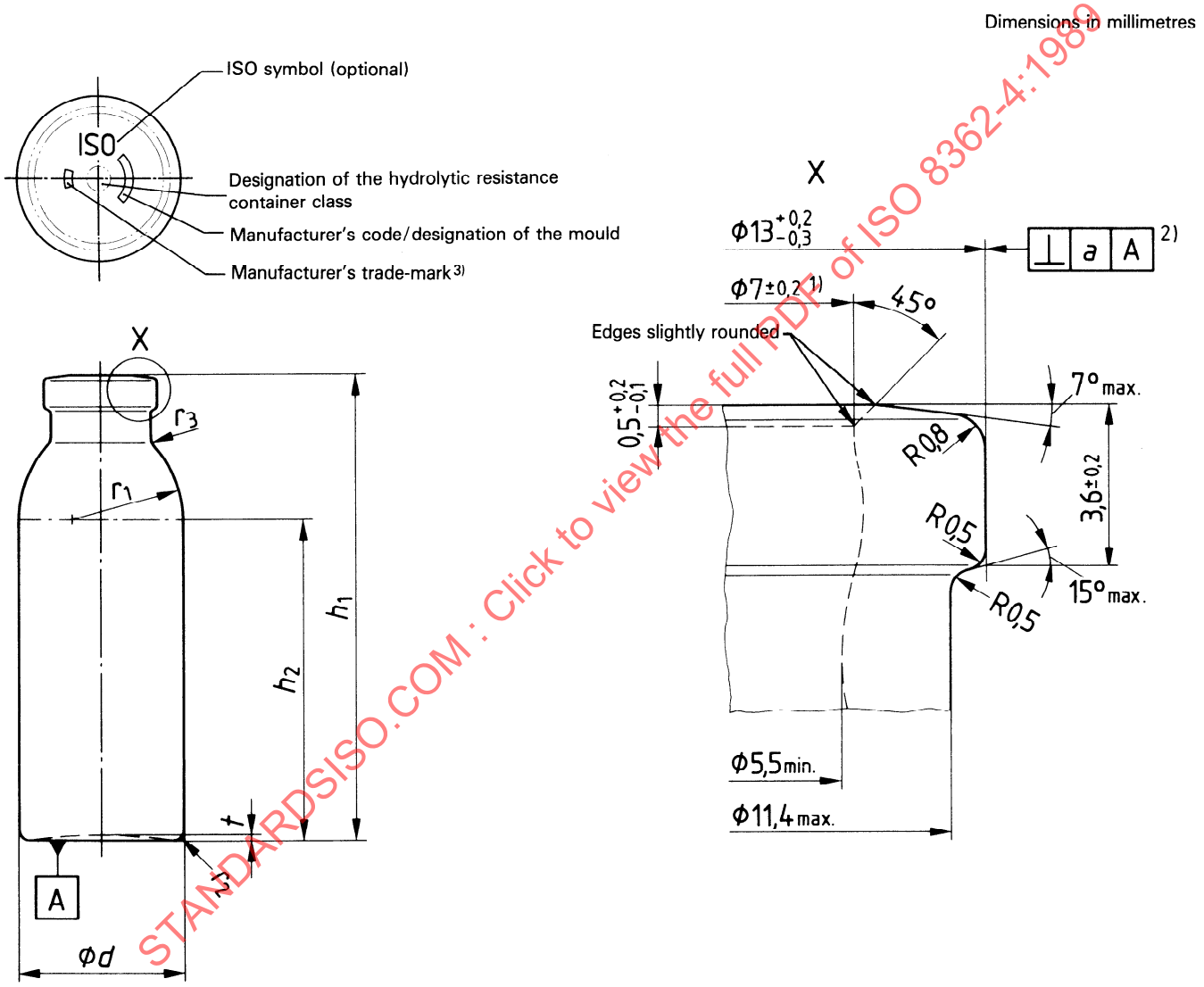

Figure 1 — Typical example of injection vial for insulin

1) Dimension to be maintained over a depth of 1 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.

3) The manufacturer's trade-mark (optional) may be placed at the bottom of the vial. The drawing represents a typical example.

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

Dimensions in millimetres

Size designation of injection vial	Overflow capacity ml		a	d		h_1		h_2	r_1	r_2	r_3	t	Mass g
		tol.			tol.		tol.	min.	≈	≈	≈	≈	≈
2I	3	±0,5	1	18	±0,5	30,6	±0,6	17,6	7,9	1,6	2,5	0,4	8
5I	8	±0,8	1,4	19	±0,6	52,8		36,5	12,7	1,5	1,5	1	12
10I	14	±0,9	1,6	23	±0,6	58,9		42	10,3		2,5	1,5	17

4.1.2 Designation

Designation example of an injection vial for insulin, size 5 (5I), made of amber moulded glass (br) of hydrolytic resistance container class ISO 4802 - HC 1 (1) complying with the requirements specified in this part of ISO 8362:

Vial ISO 8362-4 5I - 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 and mass shall be as given in table 2.

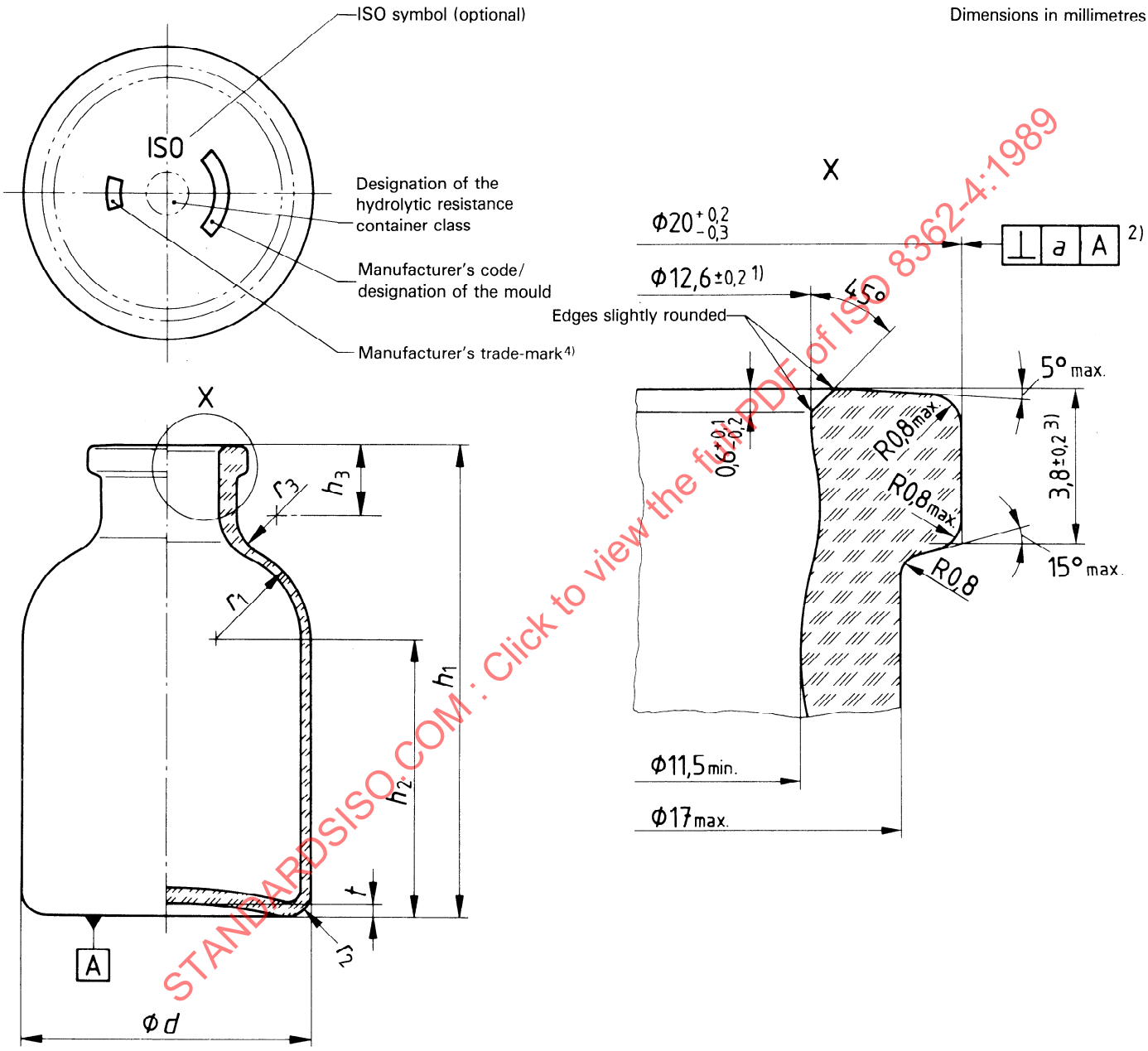

Figure 2 — Typical example of injection vial for antibiotics

1) Dimension to be maintained over a depth of 1 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.

3) Owing to the differences in manufacturing procedures between 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.

4) The manufacturer's trade-mark (optional) may be placed at the bottom of the vial. The drawing represents a typical example.

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

Dimensions in millimetres

Size designation for injection vial	Overflow capacity ml		a	d		h_1		h_2	h_3	r_1	r_2	r_3	t	Mass g
		tol.			tol.		tol.	min.	min.	≈	≈	≈	≈	≈
5H	7	±0,7	1,1	20,8	±0,4	41,3	±0,5	26,2	5,5	8,4	1,5	10	1	14
7H	9			22,1		40,8		26,7	6	5	2	4,4		13
8H	10	±0,8	1,2	23		46,8		29,5		9,5	1,5	7		16
10H	15	±1	1,4	25,4		53,5		35,3	5,7	10	2	5,1		21
15H	17		1,5	26,5	±0,45	58,8	±0,6	36,5	5,8	15	2,5	9,5		24
20H	26	±1,1		32		58		36,1	5,5	12	3	6,1	1,5	29
25H	32			36	±0,5			34	6,5			5		30
30H	38	±1,4	1,6	36		62,8	±0,7	40,8	5,5			4,3		35
50H	60	±1,8	1,9	42,5	±0,8	73	±0,8	46	6	12,5		8,5	2	50
100H	119	±2,8	2,4	51,6		94,5	±0,9	58	5,8	25,6	4	7		89

4.2.2 Designation

Designation example of an injection vial for antibiotics, size 10 (10H), made of amber moulded glass (br) of hydrolytic resistance container class ISO 4802 - HC 1 (1) complying with the requirements of this part of ISO 8362:

Vial ISO 8362-4 10H - br -1