INTERNATIONAL STANDARD

ISO 11040-4

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Prefilled syringes —

Part 4:
Glass barrels for injectables

Seringues préremplies —

Partie 4: Cylindres en verre pour produits injectables

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ISO 11040-4:1996(E)

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 voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 11040-4 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use*.

ISO 11040 consists of the following parts, under the general title *Prefilled syringes*:

— *Part 1: Glass cylinders for dental local anaesthetic cartridges*

— *Part 2: Plungers and discs for dental local anaesthetic cartridges*

— *Part 3: Aluminium caps for dental local anaesthetic cartridges*

— *Part 4: Glass barrels for injectables*

— *Part 5: Plungers for injectables*

Annex A of this part of ISO 11040 is for information only.

Introduction

For the parenteral use of liquid pharmaceutical products, ampoules and injection vials are mainly used at present. However, for the injection of the liquid pharmaceutical products contained in those vials, a hypodermic syringe combined with the appropriate injection needle is also needed. This means the liquid pharmaceutical product has to be transferred into the hypodermic syringe before its final use. This procedure is not only time-consuming, but also presents a great number of possibilities for contamination.

To ensure safe use of a liquid pharmaceutical product, prefilled syringes for single use are already on the market. Without doubt, such prefilled syringes permit immediate injection of the product contained after relatively simple handling.

Based on the diameter of the prefilled syringes, appropriate components, such as rubber plungers and aluminium caps, can also be standardized. The producers of filling machines can apply this part of ISO 11040 to achieve a degree of standardization in the equipment of the machines.

Prefilled syringes —

Part 4:
Glass barrels for injectables

1 Scope

This part of ISO 11040 applies to tubing-glass barrels (single-chamber design) for injection preparations and specifies materials, dimensions and performance details.

Glass barrels from tubing glass in accordance with this part of ISO 11040 are intended for single use only. In conjunction with the right sealing components, they offer a safe system for parenteral use.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 11040. 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 11040 are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 720:1985, *Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification.*

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 Dimensions and designation

3.1 Dimensions

The dimensions of the glass barrel shall be as shown in figure 1 and given in table 1.

3.2 Designation

The barrel designation shall comprise, in the following order, the descriptor "Barrel", a reference to this part of ISO 11040, the nominal volume, expressed in millilitres, the letters "lg" if the long version, and the glass colour.

EXAMPLE

A barrel with a nominal volume of 1 ml with long version (lg) made of colourless glass (cl) complying with the requirements of this part of ISO 11040 is designated as follows:

Barrel ISO 11040-4 - 1 - lg - cl

4 Requirements

4.1 Material

4.1.1 The material shall be colourless (cl) or amber (br) glass of the hydrolytic resistance grain class HGA 1 in accordance with ISO 720.

It shall correspond to glass type 1 of the European Phamacopoeia and United States Pharmacopoeia.

4.1.2 If the glass tubing supplier wants to change the chemical composition of the glass material or the colouring, the user shall be notified of the change at least nine months in advance.

Dimensions in millimetres

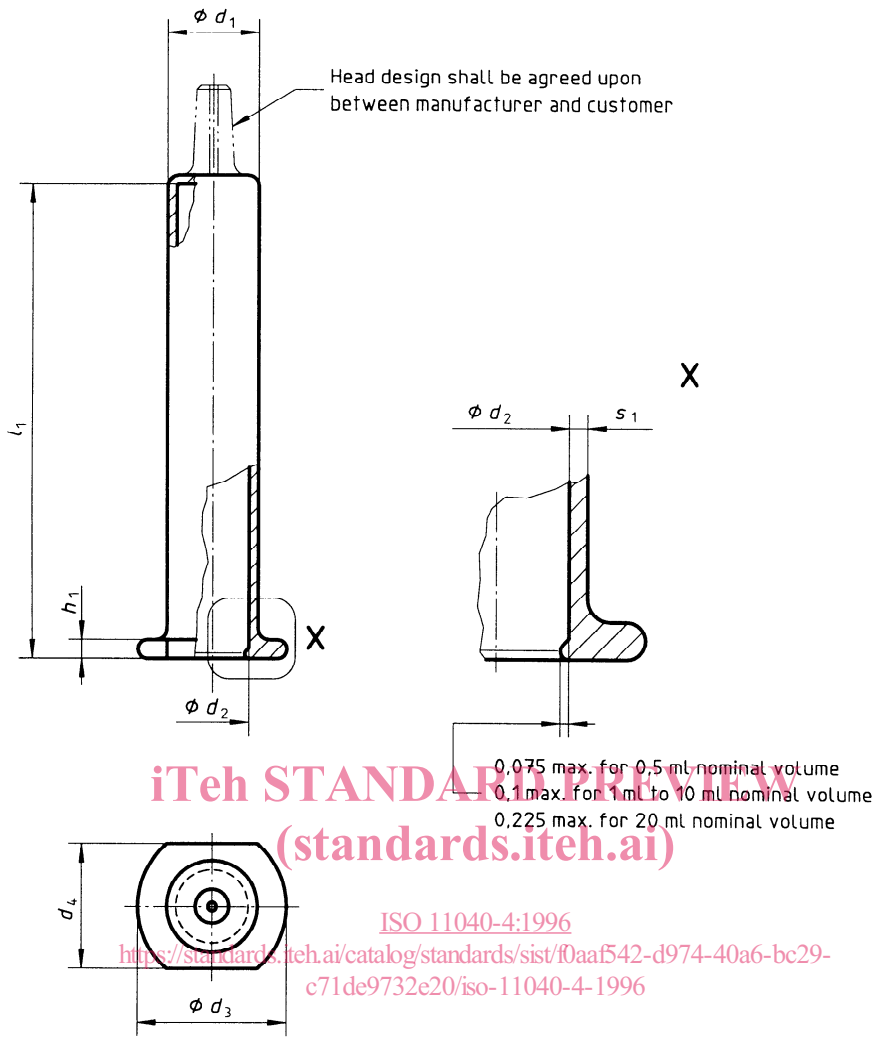

Figure 1 — Typical example of glass barrel and glass finger-grip for prefilled syringe

Table 1 — Barrel dimensions

Dimensions en millimètres

Nominal volume	Glass barrel							Finger-grip					
	d_1		d_2		l_1		s_1	h_1		d_3		d_4	
ml	nom.	tol.	nom.	tol.	nom.	tol.	≈	nom.	tol.	nom.	tol.	nom.	tol.
0,5	6,85	± 0,1	4,65	± 0,1	47,6	± 0,5	1,1	1,8	± 0,5	13,4	± 0,4	10,5	± 0,4
1 (long)	8,15		6,35		54		0,9	1,9		13,8		11	
1	10,85		8,65	± 0,2	35,7		1,1	2,2	± 0,5	17,75	± 0,75	14,7	± 0,5
2	10,85		8,65		49		1,1	2,2		17,75		14,7	
2,25	10,85		8,65		54,4		1,1	2,2		17,75		14,7	
3	10,85		8,65		72,2		1,1	2,2		17,75		14,7	
5	14,45		11,85		66,7	± 0,75	1,3	2,4		23	± 1	19,5	
10	17,05	± 0,2	14,25		87,25		1,4	2,5	± 0,6	27		21,5	
20	22,05		19,05		96,8		1,5	3,1		32,25		25,9	± 0,6

4.2 Performance

4.2.1 Hydrolytic resistance

When tested in accordance with ISO 4802-1 or ISO 4802-2, the hydrolytic resistance of the internal surface of the glass barrel shall comply with the requirements of hydrolytic resistance container class ISO 4802-HC 1.

Before conducting the test, the bottom end of the barrel shall be sealed with a suitable closure element, e.g. a silicon rubber closure.

4.2.2 Annealing quality

If the glass barrel is annealed, the maximum residual stress shall not produce an optical retardation exceeding 40 nm per millimetre of glass thickness, when the glass barrel is viewed in a strain viewer.

The test method for residual stress shall be agreed upon between glass manufacturer and customer.

5 Marking

The number of pieces and the designation (see 3.2), together with the name or the symbol of the manufacturer of the glass barrel, shall be shown on the package.

Further marking shall be made only by arrangement between manufacturer and customer.

Annex A
(informative)

Bibliography

[1] ISO 11040-5:1996, *Prefilled syringes — Part 5: Plungers for injectables.*

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