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Fourth edition
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Pen systems —

Part 1: Glass cylinders for pen-injectors for medical use

Systèmes de stylos-injecteurs —

Partie 1: Cylindres en verre pour des stylos-injecteurs à usage médical

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This fourth edition cancels and replaces the third edition (ISO 13926-1:2004), which has been technically revised. The main changes compared to the previous edition are as follows:

— changing the dimension d_1, d_2 and d_3 in Table 1 from normative to informative.

A list of all parts in the ISO 13926 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The potency, purity, stability and safety of a drug during its manufacture and storage can be strongly affected by the nature and performance of the primary packaging.

This document deals with glass cylinders used with pen-injectors in accordance with ISO 11608-1.

Pen systems —

Part 1:
Glass cylinders for pen-injectors for medical use

1 Scope

This document specifies the design, materials, performance and test methods, and gives recommendations for dimensions for glass cylinders used with pen-injectors for medical use.

It applies to the primary containers used in direct contact with the drug.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 720, *Glass — Hydrolytic resistance of glass grains at 121 degrees C — Method of test and classification*

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*

ISO 11608-3, *Needle-based injection systems for medical use — Requirements and test methods — Part 3: Finished containers*

ISO 13926-2, *Pen systems — Part 2: Plunger stoppers for pen-injectors for medical use*

ISO 13926-3, *Pen systems —Part 3: Seals for pen-injectors for medical use*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

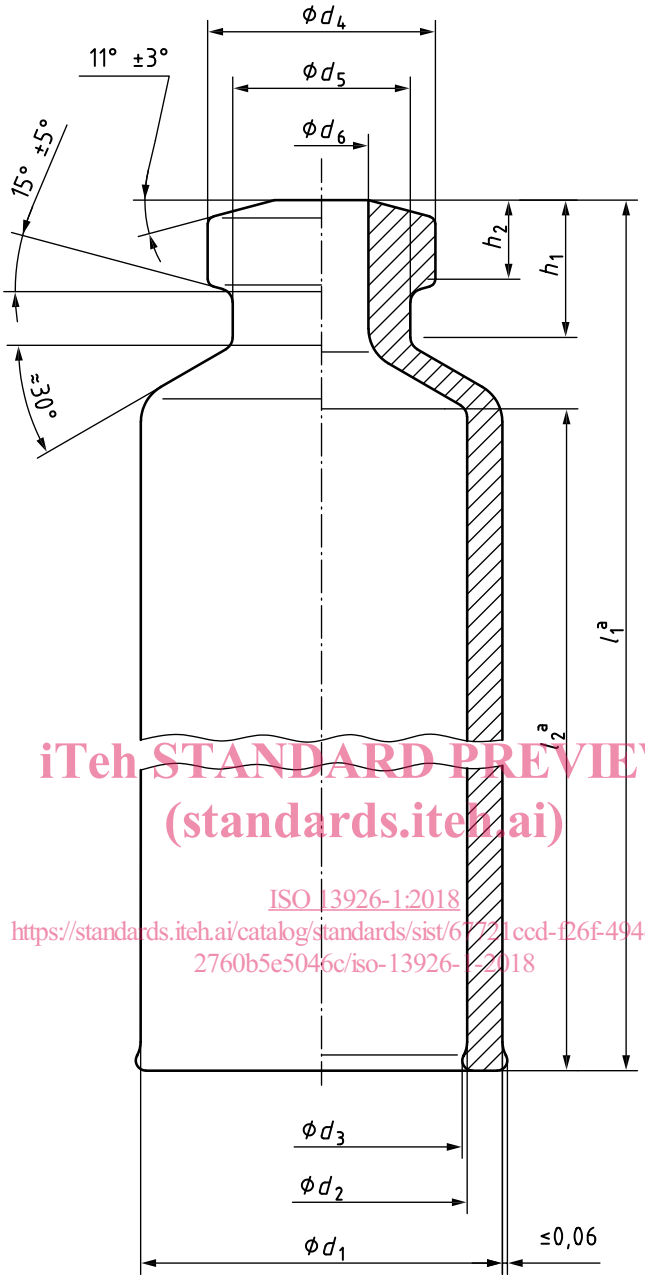
— IEC Electropedia: available at http://www.electropedia.org/

4 Dimensions

The dimensions of the glass cylinders shall be as shown in Figure 1 and as given in Table 1, except for the diameters d_1, d_2 and d_3, which are for information only.

Glass cylinder, as shown in Figure 1 and Table 1 are typically available in different diameters d_1, d_2 and d_3. Diameters as they are available are given for information only in Table 1.

Dimensions in millimetres



Key

a Length l_1 and l_2 shall be agreed upon between manufacturer and customer.

Figure 1 — Configuration of glass cylinders for pen-injectors

The dimension d_2 shall be specified in such a way that in combination with the selected plunger stopper according to ISO 13926-2 and the selected seal as per ISO 13926-3, the system can be validated as described in ISO 11608-3.

The dimensions of the bore (d_6) shall be maintained for a depth of h_1.

The opening of the glass cylinder should have a constant diameter, over the entire distance, h_1, 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_1;

— 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.

Table 1 — Dimensions of glass cylinders for pen-injectors

Dimensions in millimetres

d_1[a]		d_2[a]		d_3[a]	d_4		d_5		d_6		h_1		h_2	
	tol. ±		tol. ±	min.		tol. ±		tol. ±		tol. ±		tol. ±		tol. ±
8,65	0,1	6,85	0,1	6,55	7,15	0,2	5,5	0,35	3,15	0,2	5,0	0,20	2,9	0,1
10,85	0,1	8,65	0,1	8,35	7,15	0,2	5,5	0,35	3,15	0,2	5,0	0,20	2,9	0,1
10,95	0,15	9,25	0,1	8,95	7,15	0,2	5,5	0,35	3,15	0,2	5,0	0,20	2,9	0,1
11,60	0,15	9,65	0,1	9,35	7,15	0,2	5,5	0,35	3,15	0,2	5,0	0,20	2,9	0,1

[a] The values for dimensions d_1, d_2 and d_3 are for information only.

For rubber plunger stoppers, refer to ISO 13926–2 and for seals, refer to ISO 13926–3.

The compatibility of the components (glass barrel, rubber plunger stopper and seal) shall be validated as described in ISO 11608–3.

5 Requirements

5.1 Material

Colourless (cl) or amber (br) glass of the hydrolytic resistance grain glass in accordance with ISO 720 – HGA 1 shall be used.

It shall correspond to the glass type 1 of the relevant pharmacopoeia.

A change in the chemical composition of the glass material shall be notified to the user at least nine months in advance.

The glass material used for glass cylinders shall not contain seeds or bubbles to an extent which will interfere with the visual examination of the contents.

5.2 Performance

5.2.1 Sealing surface

Glass cylinders shall have a sealing surface which is flat and free from ripples or undulations.

5.2.2 Hydrolytic resistance

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

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

5.2.3 Annealing quality

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

