INTERNATIONAL STANDARD

ISO 13926-1

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Pen systems —

Part 1:
Glass cylinders for insulin pen-injectors

Systèmes de stylos-injecteurs —

Partie 1: Cylindres en verre pour des stylos-injecteurs pour insuline

Reference number
ISO 13926-1:1996(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 13926-1 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use*.

ISO 13926 consists of the following parts, under the general title *Pen systems*:

— *Part 1: Glass cylinders for insulin pen-injectors*

— *Part 2: Plungers and discs for insulin pen-injectors*

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 pack.

This part of ISO 13926 deals with glass cylinders for insulin cartridges used with pen-injectors. It is applicable to primary packs in direct contact with the drug.

NOTE 1 Aluminium caps for insulin pen-injector systems are covered by ISO 11040-3:1993, *Prefilled syringes — Part 3: Aluminium caps for dental local anaesthetic cartridges.*

Pen systems —

Part 1:
Glass cylinders for insulin pen-injectors

1 Scope

This part of ISO 13926 specifies the design, dimensions, materials, performance and test methods for glass cylinders for insulin used with pen-injectors only.

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

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 13926. 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 13926 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 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 cylinders shall be as shown in figure 1 and as given in table 1.

The dimensions 3,15 mm ± 0,15 mm of the bore shall be maintained for a depth of 5 mm ± 0,2 mm.

Variations in the design of the truncated cone are allowed, if at the same time the following conditions are fulfilled:

— the truncated cone of the neck opening has the height of the neck length (5 mm ± 0,2 mm);

— the stated tolerances of the neck opening are maintained;

— the diameter of the neck opening at the inner end and at the cone may be a maximum of 0,3 mm smaller than at the top (3,15 mm ± 0,15 mm).

3.2 Designation

EXAMPLE

A glass cylinder for insulin pen-injectors with a nominal volume of 1,5 ml, made of colourless glass tubing and complying with the requirements of this part of ISO 13926, is designated as follows.

Cylinder ISO 13926-1 - 1,5

Dimensions in millimetres

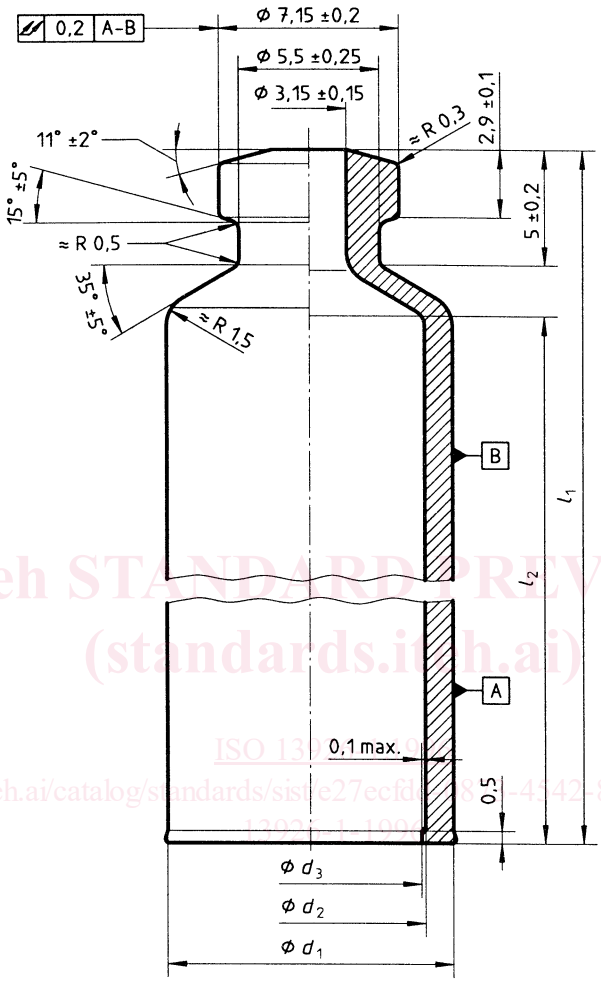

Figure 1 — Configuration of glass cylinders for insulin pen-injectors

Table 1 — Dimensions of glass cylinders for insulin pen-injectors

Dimensions in millimetres

Nominal volume	l_1	d_1		d_2	d_3	l_2
		nom.	tol.			
ml	± 0,2		±	± 0,1	min.	min.
1,5	56,7	8,65	0,1	6,85	6,55	50,45
3	62,3	11,6	0,15	9,65	9,35	55,9

4 Requirements

4.1 Material

Colourless glass of the hydrolytic resistance grain class ISO 720 - HGA 1 shall be used.

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 seed or bubbles to an extent which will interfere with the visual examination of the contents.

4.2 Performance

4.2.1 Application

Dedicated pen-injectors shall not function with non-dedicated cylinders containing the same active ingredient.

4.2.2 Sealing surface

Glass cylinders made of glass tubing shall have a sealing surface which is flat and free from ripples or undulations. This shall not affect the sealing performance of the closure.

4.2.3 Hydrolytic resistance

When tested according to 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 glass in accordance with ISO 4802.

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

4.2.4 Annealing quality

If 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.

The optical retardation test method shall be agreed upon between glass manufacturer and customer.

5 Marking

The package shall be marked with the following information:

a) the number of cylinders it contains;

b) the designation of the cylinders;

c) the name or symbol of the manufacturer;

d) the lot number (if the cylinder is printed) or date of production.