INTERNATIONAL STANDARD

ISO 11040-1

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Prefilled syringes —

Part 1:
Glass cylinders for dental local anaesthetic cartridges

Seringues préremplies —

Partie 1: Tubes en verre pour cartouches dentaires d'anesthésie locale

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

International Standard ISO 11040-1 was prepared jointly by Technical Committees ISO/TC 76, *Transfusion, infusion and injection equipment for medical use* and ISO/TC 106, *Dentistry*.

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*

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Prefilled syringes —

Part 1:
Glass cylinders for dental local anaesthetic cartridges

1 Scope

This part of ISO 11040 specifies the design, dimensions, materials, performance and test methods for glass cylinders for dental local anaesthetic cartridges intended for single use only.

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

NOTE 1 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.

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 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 cylinder shall be as shown in figure 1.

3.2 Designation

Example for the designation of a glass cylinder for dental local anaesthetic cartridges (cylinder), made of clear glass (cl) tubing of hydrolytic resistance container class ISO 4802 - HC 1, complying with the requirements of this part of ISO 11040:

Cylinder ISO 11040-1 - cl - 1

Dimensions in millimetres

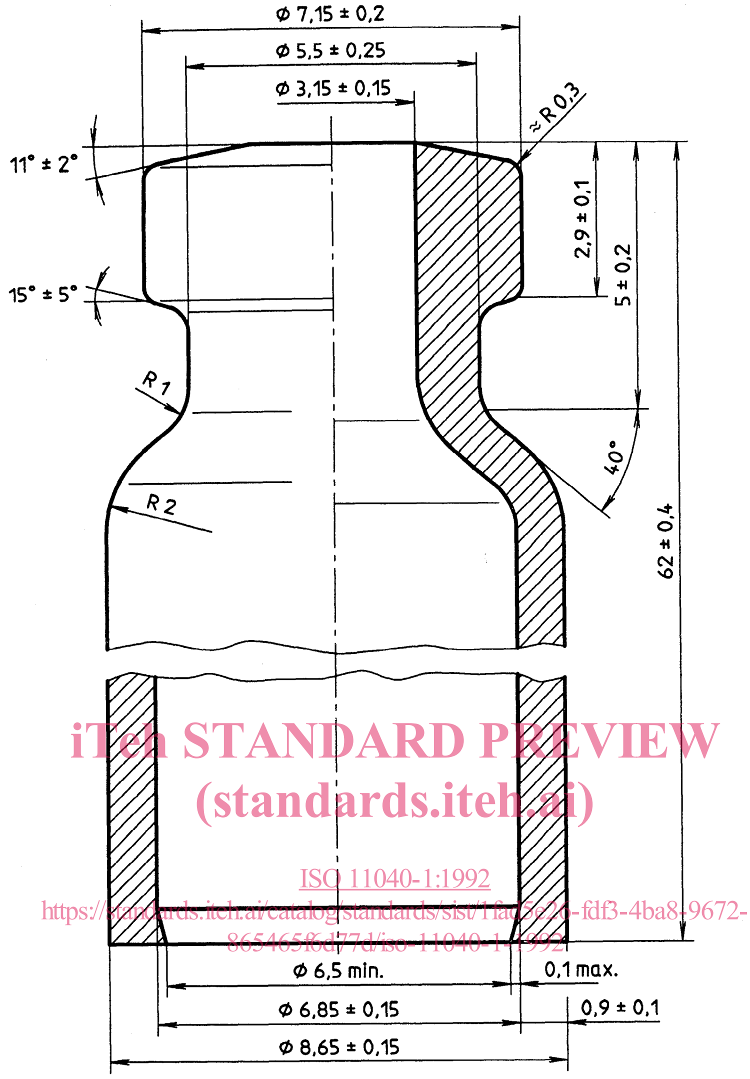

Figure 1 — Dimensions of glass cylinder for dental local anaesthetic cartridges

4 Material

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

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

5 Performance

5.1 Glass cylinders made of glass tubing should have a sealing surface which is flat and free from ripples or undulations which would affect the sealing performance of the closure.

5.2 Glass cylinders should not contain seed or bubbles to an extent which will interfere the visual examination of the contents.

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

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

— the truncated cone 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 the top (3,15 mm ± 0,15 mm).

6 Requirements

6.1 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 of the ISO 4802 - HC 1 hydrolytic resistance container class.

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

6.2 Annealing quality

If glass cylinder is annealed, the maximum residual stress shall not produce an optical retardation exceeding 40 nm per millimetre of glass thickness.

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

7 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 (only if the cylinder is printed) or date of production.

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Descriptors: medical equipment, anaesthetic equipment, dental equipment, syringes, glassware, containers, specifications, dimensions, designation, marking.

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