INTERNATIONAL STANDARD

ISO 11040-4

Second edition
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Prefilled syringes —

Part 4: Glass barrels for injectables

Seringues préremplies —

Partie 4: Cylindres en verre pour produits injectables

Reference number
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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
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Foreword

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The main task of technical committees is to prepare International Standards. 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.

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.

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

This second edition cancels and replaces the first edition (ISO 11040-4:1996) which has been technically revised.

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*

Introduction

For the parenteral use of liquid pharmaceutical products, at present ampoules and injection vials are mainly used. 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 to 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 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 referenced documents are indispensable for the application 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 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

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*

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