INTERNATIONAL STANDARD

ISO 13926-1

Third edition
2004-11-01

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

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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 13926-1 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This third edition cancels and replaces the second edition (ISO 13926-1:1998), which has undergone a minor revision, correcting dimensions d_5 in Table 1 and the uppermost angle in Figure 1.

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

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

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

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 used with pen-injectors in accordance with ISO 11608-1. It is applicable to primary packs in direct contact with the drug.

NOTE Aluminium caps for insulin pen-injector systems are covered by ISO 11040-3.

Pen systems —

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

1 Scope

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

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

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 720, *Glass — Hydrolytic resistance of glass grains at 121 °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*

3 Dimensions

The dimensions of the glass cylinders shall be as shown in Figure 1 and as given in Table 1.

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

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 same height as the neck length (h_1);

— the stated tolerances of the neck opening are maintained;

— the diameter of the neck opening at the inner end may be a maximum of 0,3 mm smaller than at the top.