INTERNATIONAL STANDARD

ISO 13926-2

Second edition
2011-04-01

Pen systems —

Part 2: Plunger stoppers for pen-injectors for medical use

Systèmes de stylos-injecteurs —

Partie 2: Bouchons-pistons pour stylos-injecteurs à usage médical

Reference number
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Contents

Page

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.

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 13926-2 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 13926-2:1999), which has been technically revised by

— aligning this International Standard with the ISO 8871 series;

— separating requirements on plunger stoppers (this part of ISO 13926) and seals; the latter are now completely covered by ISO 13926-3;

— revising Table 1 on dimensions of plunger stoppers;

— revising the requirements on material, hardness, freedom from leakage, initiating and sustaining forces;

— adding requirements on resistance to ageing.

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: Plunger stoppers for pen-injectors for medical use*

— *Part 3: Seals for pen-injectors for medical use*

Introduction

Primary packaging components made of elastomeric materials are an integral part of medicinal products. As such, the principles of current Good Manufacturing Practices (cGMP) are applicable to the manufacturing of these components.

Principles of cGMP are described in ISO 15378 and in GMP Guidelines published by the European Community[4] and the United States of America[5].

Pen systems —

Part 2:
Plunger stoppers for pen-injectors for medical use

1 Scope

This part of ISO 13926 specifies the shape, dimensions, material, performance requirements and labelling of plunger stoppers for pen-injectors for medical use.

NOTE The potency, purity, stability and safety of a medicinal product during its manufacture and storage can be affected significantly by the nature and performance of the primary packaging.

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 48, *Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD)* [alternative normative reference to ISO 7619-1]

ISO 3302 (all parts), *Rubber — Tolerances for products*

ISO 7619-1, *Rubber, vulcanized or thermoplastic — Determination of indentation hardness — Part 1: Durometer method (Shore hardness)* [alternative normative reference to ISO 48]

ISO 8871-1, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates*

ISO 8871-4, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods*

ISO 13926-1, *Pen systems — Part 1: Glass cylinders for pen-injectors for medical use*

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

3 Classification

Plunger stoppers shall be classified as follows:

— Type A1: plunger stoppers with ribs;

— Type A2: plunger stoppers without ribs;

— Type A3: plunger stoppers with ribs and dome.