INTERNATIONAL STANDARD

ISO 13926-2

Second edition
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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

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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.

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;

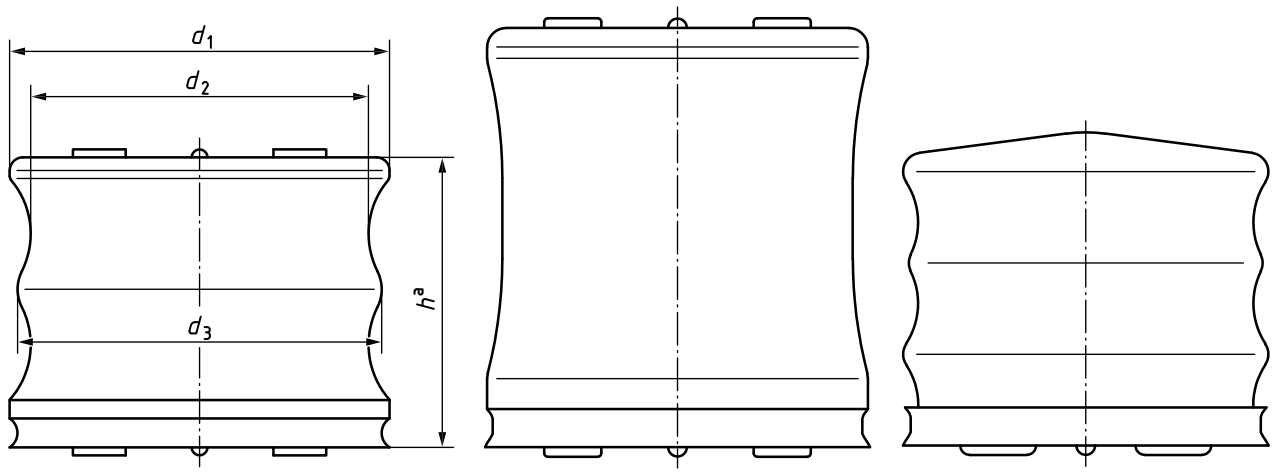
— Type A2: plunger stoppers without ribs;

— Type A3: plunger stoppers with ribs and dome.

4 Shape and dimensions

4.1 Shape and dimensions of plunger stoppers shall be as shown in Figure 1 and as given in Table 1.

Dimensions in millimetres



a) Type A1 **b) Type A2** **c) Type A3**

Key

d_1, d_2, d_3 diameters of plunger stoppers

h height of plunger stoppers

a The height shall be agreed between manufacturer and user.

Figure 1 — Shape and dimensions of plunger stoppers for pen-injectors for medical use

Table 1 — Dimensions of plunger stoppers for pen-injectors for medical use

Dimensions in millimetres

Nominal inner diameter of the glass cylinder[a]	Diameter		
	d_1 min.	d_3 min.	d_2 max.
6,85 ± 0,1	7,1	6,9	6,6
8,65 ± 0,1	9,0	8,8	8,3
9,25 ± 0,1	9,5	9,3	8,8
9,65 ± 0,1	9,9	9,7	9,2
12,00 ± 0,15	12,4	12,1	11,7
11,85 ± 0,15	12,25	11,95	11,55
16,05 ± 0,15	16,5	16,15	15,7

a Values in accordance with ISO 13926-1.

The height shall be agreed between the manufacturer and the user.

4.2 In order to avoid adhesion of the plunger stoppers to each other, there shall be spacers. The height of the spacers shall not exceed 0,3 mm.

The shape of the spacers should be agreed between manufacturer and cartridge assembler.

4.3 If not otherwise specified, general dimensional tolerances shall be in accordance with ISO 3302.

5 Designation

Plunger stoppers can be designated according to their type; see Clause 3 and Figure 1. The designation shall be expressed as the word “plunger”, followed by a reference to this part of ISO 13926, followed by the inner diameter of the glass cylinder d_2, followed by the letter designating the type.

EXAMPLE Designation of a plunger stopper Type A1 complying with the requirements in this part of ISO 13926 for a glass cylinder with an inner diameter of 6,85 mm:

Plunger ISO 13926-2 – 6,85 – A1

6 Material

The elastomeric material used shall meet the requirements specified in Clause 7.

Plunger stoppers shall be made from the elastomeric formulation originally tested and approved by the end-user. The manufacturer of the plunger stoppers shall ensure the conformance of each delivery with the type sample and the compliance with previously agreed functional and compendial requirements.

The elastomeric material shall withstand two sterilization cycles when autoclaving in saturated steam at (121 ± 2) °C for 30 min without impairment of its function under the conditions of normal use. In case of other sterilization methods, e.g. irradiation, the suitability of the material has to be evaluated.

7 Requirements

7.1 General

The requirements specified in 7.2 to 7.4 represent minimum requirements which refer to the condition of the elastomeric plunger stoppers on receipt by the user.

7.2 Physical requirements

7.2.1 Hardness

The hardness agreed between manufacturer and user shall not differ from the nominal value by more than ±5 Shore A when tested in accordance with ISO 7619-1 on special test specimen. Alternatively, the hardness can be tested on the plunger stoppers in accordance with ISO 48. If tested in accordance with ISO 48, the microhardness shall not differ by more than ±5 IRHD from the type sample.

The manufacturer should provide suitable test specimens upon request.

7.2.2 Freedom from leakage

The cartridges shall be free from leakage at the plunger when tested in accordance with the method given in Annex A.

7.2.3 Initiating and sustaining forces

The initiating and sustaining forces are influenced by all components of the container closure systems and process parameters, e.g. siliconization. The testing of complete systems is described in ISO 11608-3. The results depend on the configuration and the pre-treatment (dry, kind of liquid, storage time, etc.)