INTERNATIONAL STANDARD

ISO 11608-3

First edition
2000-12-15

Pen-injectors for medical use —

Part 3: Finished cartridges — Requirements and test methods

Stylos-injecteurs à usage médical —
Partie 3: Cartouches prêtes à l'emploi — Exigences et méthodes d'essai

Reference number
ISO 11608-3:2000(E)

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Printed in Switzerland

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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 3.

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 part of ISO 11608 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11608-3 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*.

ISO 11608 consists of the following parts, under the general title *Pen-injectors for medical use*:

— *Part 1: Pen-injectors — Requirements and test methods*

— *Part 2: Needles — Requirements and test methods*

— *Part 3: Finished cartridges — Requirements and test methods*

Introduction

This part of ISO 11608 covers finished cartridges filled with medicinal products primarily intended for human use. It provides performance requirements regarding essential aspects so that variations of design are not unnecessarily restricted.

The devices described in this part of ISO 11608 are designed to be used with devices described in ISO 11608-1 and ISO 11608-2.

It is recognized that interchangeability of the components (pen-injector, needle and cartridge) is desirable for some medicinal products and to be avoided for other medicinal products, and that future designs may change the current concepts. Therefore ISO 11608-2 and ISO 11608-3 encourage interchangeability by establishing certain specific requirements for interchangeable needles (Type A) and interchangeable cartridges (Type A) respectively.

Performance requirements are imposed on both interchangeable (Type A) and non-interchangeable (non-Type A) cartridges. Additional dimensional requirements are imposed on interchangeable cartridges (Type A).

Information as to whether the components are interchangeable (Type A) or not will be given on the secondary container.

It is desirable that non-Type A cartridges do not fit pen-injectors intended for type A cartridges.

The sampling plans for inspection selected for this part of ISO 11608 are intended to verify, at a high confidence level, the manufacturer's ability to manufacture one “lot” of finished cartridges that conforms to the critical product attributes. The sampling plans for inspection do not replace the more general manufacturing quality systems that appear in standards on quality systems, e.g. the ISO 9000 series.

Regulatory authorities, pharmacopoeia and relevant trade associations should recognize the need for further testing, especially regarding compatibility between the medicinal products and cartridge as they are in contact for prolonged periods.

In some countries, national pharmacopoeia or government regulations exist and their requirements may take precedence over or complement this part of ISO 11608. In particular, materials in contact with the medicinal product shall comply with all relevant pharmacopoeia requirements.

Pen-injectors for medical use —

Part 3:
Finished cartridges — Requirements and test methods

1 Scope

This part of ISO 11608 specifies performance and test methods for multidose, single-chamber, pre-filled, finished cartridges used as primary containers in pen-injectors fulfilling the specifications of ISO 11608-1. Design and dimensions are specified for Type A cartridges.

This part of ISO 11608 is not applicable to multichamber cartridges, cartridges that are filled by the user, and cartridges intended for dental use.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 11608. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11608 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 3207, *Statistical interpretation of data — Determination of a statistical tolerance interval.*

ISO 11608-1:2000, *Pen-injectors for medical use — Part 1: Pen-injectors — Requirements and test methods*.

ISO 13926-1:1998, *Pen systems — Part 1: Glass cylinders for pen-injectors for medical use*.

3 Terms and definitions

For the purposes of this part of ISO 11608, the following terms and definitions apply.

The nomenclature of some of the cartridge components is illustrated in Figure 1.

3.1
cartridge
primary container for the medicinal product

3.2
unit container
package intended for customer use

3.3
cylinder
main body of the cartridge

3.4
plunger
component which seals one end of the cartridge and interfaces with the plunger rod of the delivery device

3.5
disc
component which seals the other end of the cartridge opposite from the plunger

3.6
cap
component which attaches the disc to the cartridge

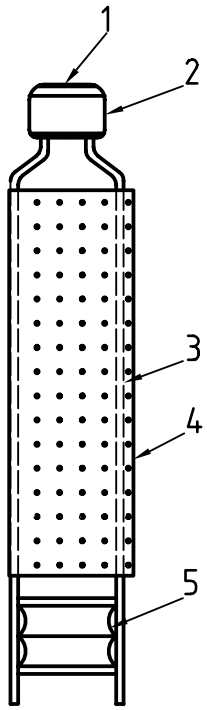
3.7
initiating force
force required to dislodge the plunger from its resting position

3.8
sustaining force
force required to maintain constant plunger velocity through the cylinder

3.9
plunger rod
delivery device mechanism which advances the plunger to deliver the medicinal product

3.10
label
identification of the contents of the cartridge

3.11
deliverable volume
contents of the cartridge which are accessible by utilizing the delivery device in accordance with the instructions for use



Key

1 Disc
2 Cap
3 Cylinder
4 Label
5 Plunger

Figure 1 — Type A finished cartridge

4 Requirements

4.1 Freedom from leakage

The cartridge shall be free from leakage at the plunger or the disc when tested in accordance with the method given in 5.5.

4.2 Initiating force

The initiating force shall not exceed 40 N. For Type A, use the apparatus in 5.1 in accordance with the test method given in 5.6. For non-Type A, use an equivalent apparatus.

4.3 Sustaining force

The sustaining force shall not exceed 20 N. For Type A, use the apparatus in 5.1 in accordance with the test method given in 5.6. For non-Type A, use an equivalent apparatus.

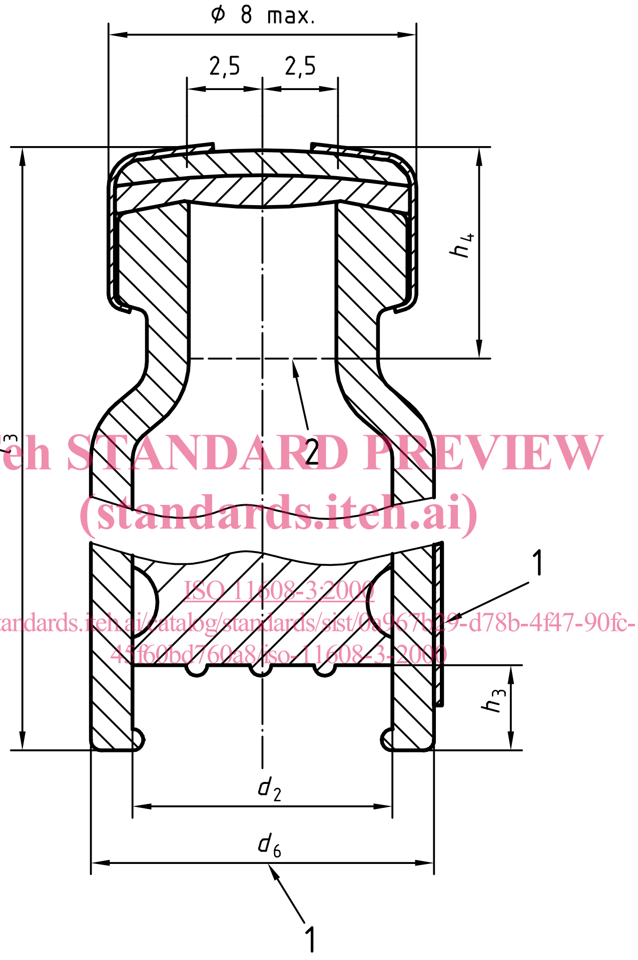
4.4 Dimensions

The dimensions of the cartridge shall be such that it fits and functions correctly with identified pen-injectors fulfilling the specifications of ISO 11608-1.

For Type A cartridges, the dimensions (shown in Figure 2) shall be in accordance with the dimensions given in Table 1 and as specified in row 1 or row 4 in Table 1 of ISO 13926-1:1998. Non-Type A cartridges shall have dimensions that make the cartridge different from those fulfilling the dimensional requirements given in row 1 or row 4 of Table 1 in ISO 13926-1:1998.

For Type A cartridges, the dimensions l_3 and h_4 shall be measured in accordance with the test method in 5.7.1 and 5.7.2, respectively. Dimensions d_6 and h_3 shall be measured in accordance with the test method in 5.7.3.

Dimensions in millimetres



Key

1 At label overlap

2 Meniscus limit

Figure 2 — Type A finished cartridge dimensions

4.5 Eccentricity

For Type A cartridges, the maximum eccentricity shall be determined in accordance with the test method in 5.8.

4.6 Visibility of the medicinal product

The contents of the cartridge shall remain visible over the length of the deliverable volume.

4.7 Meniscus

For Type A cartridges, the meniscus of the medicinal product in unpenetrated cartridges shall not extend below dimension h_4.

4.8 Resealability

Cartridges shall not leak from the septum penetration site after having been penetrated 1,5 times the typical number of doses for the medicinal product. Type A cartridges shall be tested in accordance with 5.10.

4.9 Cap

An example of an acceptable cap for a Type A cartridge is shown in ISO 11040-3.

4.10 Plunger and disc

An example of an acceptable Type A plunger and disc is shown in ISO 13926-2.

4.11 Material of the cylinder

If made of glass, the glass shall fulfil the requirements given in clause 4 of ISO 13926-1:1998.

4.12 Lubrication

If cartridge components are lubricated, the lubricant shall not, under normal or corrected-to-normal vision, be visible as droplets of fluid on the outside or inside surfaces of the components.

4.13 Dose accuracy

The dose accuracy of Type A cartridges shall meet the requirements given in 5.11.2 when tested in accordance with 5.11.1.

The dose accuracy of non-Type A cartridges shall meet the dose accuracy requirements in accordance with ISO 11608-1.

4.14 Deliverable volume and last-dose accuracy

The last-dose accuracy of Type A cartridges shall meet the requirements given in 5.13.2 when tested in accordance with 5.13.1.

The last-dose accuracy of non-Type A cartridges shall meet the dose accuracy requirements in accordance with ISO 11608-1.