International Standard

ISO 13926-1

Cartridge systems —

Part 1:
Glass cylinders for cartridge-type needle-based injection systems (NIS) for medical use

Systèmes à cartouche —

Partie 1: Flacons en verre pour systèmes d'injection à aiguille (NIS) de type cartouche 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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

This fifth edition cancels and replaces the fourth edition (ISO 13926-1:2018), which has been technically revised.

The main changes are as follows:

— changing the title extending glass cylinders application to needle-based injection system general application;

— changing the scope extending glass cylinders application to needle-based injection system general application;

— updating the terms and definitions;

— updating Table 1 for dimension and introduction of designation using nominal volume (ml)/inner diameter (mm);

— changing the dimensions d_1, d_2 and d_3 in Table 1 from informative to normative;

— updating designation according to Table 1;

— adding Figure 2 and Table 2 for cartridges with vial flange configuration.

A list of all parts in the ISO 13926 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Primary packaging components made of glass materials are an integral part of medicinal products and thus, the principles of current Good Manufacturing Practices (cGMP) apply to the manufacturing of these components.

Principles of cGMP are described in, for example, ISO 15378 or GMP Guidelines[6],[7].

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Cartridge systems —

Part 1:
Glass cylinders for cartridge-type needle-based injection systems (NIS) for medical use

1 Scope

This document specifies the material, performance requirements and labelling, and gives recommendations for shape and dimensions of glass cylinders used in cartridge-type needle-based injection systems (NIS) for medical use, according to ISO 11608-3. This document applies to the glass cylinders as supplied by the manufacturer.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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*

ISO 8362-1, *Injection containers and accessories — Part 1: Injection vials made of glass tubing*

ISO 8536-2, *Infusion equipment for medical use — Part 2: Closures for infusion bottles*

ISO 11608-3, *Needle-based injection systems for medical use — Requirements and test methods — Part 3: Containers and integrated fluid paths*

ISO/DIS 13926-2:—[1)], *Cartridge systems — Part 2: Plunger stoppers for pen-injectors for medical use*

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

1) Under revision. Stage at the time of publication: ISO/DIS 13926-2:2026.

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3.1
cartridge
container for the medicinal product that is closed on one end with a *seal* (3.5) comprised of a combination of a disc, septum, or elastomeric closure with an aluminium cap, and on the other end with a *plunger stopper* (3.4)

[SOURCE: ISO 11608-3:2022, 3.1, modified — "seal comprised of" added]

3.2
customer
business entity which purchases cartridges and conducts further processing or filling as appropriate

3.3
manufacturer
business entity which performs or is otherwise responsible for the manufacturing of the cartridges for the customer

3.4
plunger stopper
component that seals one end of the *cartridge* (3.1) and moves within the container to cause or accommodate movement of the medicinal product

[SOURCE: ISO 11608-3:2022, 3.8, modified — cartridge instead of container]

3.5
seal
component of a *cartridge* (3.1), comprised of a combination of a disc, septum, or elastomeric closure with an aluminium cap that closes the end of the container through which the medicinal product is accessed

[SOURCE: ISO 11608-3:2022, 3.5, modified — "cartridge" instead of "container" and "comprised of a combination of a disc, septum, or elastomeric closure with an aluminium cap that closes" added]

4 Dimensions

The dimensions of the glass cylinders shall be as specified in Figure 1 and Figure 2 and in Table 1 and Table 2, in accordance with the designation type.

Glass cylinders are typically available in two different flange configurations: as shown in Figure 1 and Table 1 (cartridge flange), and Figure 2 and Table 2 (vial flange, in accordance with ISO 8362-1).

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