International Standard

ISO 11040-8

Second edition
2026-06

Prefilled syringes —

Part 8: Requirements and test methods for finished prefilled syringes

Seringues préremplies —

Partie 8: Exigences et méthodes d'essai pour les seringues préremplies prêtes à l'emploi

Reference number
ISO 11040-8:2026(en)

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Published 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.

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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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The document 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 11040-8:2016), which has been technically revised.

The main changes are as follows.

— The entire document has been revised for consistent use of terms and language.

— A basic statistical approach for design verification testing of functional performance requirements has been included in the Clause and in 6.1.

— Single terms and definitions (see Clause 3) have been revised, deleted or included.

— The definition of intended use (see 4.1) has been revised for clarity.

— Break-loose and extrusion forces (see 6.2) has been revised; it has been clarified to perform testing with the finished prefilled syringe as intended for use. A new Annex A, with the respective test method, has been introduced.

— The former subclause for burst resistance was removed; parts of its contents have been included in the revised subclause for liquid leakage resistance (see 6.10).

— Flange breakage resistance (see 6.3) has been revised to include specification limits and a test method reference. It was clarified to perform testing with the finished prefilled syringe, with further instructions. Front end breakage resistance requirements have been deleted.

— Front end closure pull-off forces and torques (see 6.4) have been revised to clarify test methods and specification limits.

— Connectivity with small-bore connectors (see 6.5) was clarified to perform testing with the finished prefilled syringe as intended for use.

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— Residual volume (see 6.6) was clarified to perform testing with the finished prefilled syringe as intended for use. A new Annex B, with the respective test method, has been introduced.

— Needle penetration force (see 6.7) and needle pull-out force (6.8) were revised to clarify test methods and specification limits.

— Liquid leakage resistance (see 6.10) was combined with parts of the contents of former subclause for burst resistance and revised. A new Annex C, with the respective test methods, has been introduced.

— A new subclause for administration time with defined constant test force (see 6.12) has been included. A new Annex D, with the respective test method, has been introduced.

— A new subclause for unintended plunger stopper movement of finished prefilled syringes (see 6.13) has been introduced.

— Where applicable, references to pharmacopoeias have been included in the subclauses to pharmaceutical requirements (see Clause 7).

A list of all parts in the ISO 11040 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

Historically, injectable (parenteral) liquid pharmaceutical products have been mainly provided in primary containers (i.e. ampoules and vials) which required the liquid to be transferred into a hypodermic syringe and combined with the appropriate injection needle before administration. This procedure is not only time-consuming, but also presents a multitude of possibilities for contamination and use errors.

Over the past decades, the presentation of liquid pharmaceutical products in prefilled syringes for single use, many with staked needles, has become more prevalent. The simplicity of use that is provided not only benefits their use in the clinical setting, but also enables these to be used by lay users in a home setting.

The standardization of the requirements for prefilled syringes has been addressed by ISO/TC 76 in two ways:

— the specifications of the components of the prefilled syringe prior to filling are included in the previous parts of the ISO 11040 series;

— the requirements for the final prefilled syringe, presented to the user as a finished product, are addressed in this document.

Finished prefilled syringes can require marketing authorization as a medicinal product, in some regions as a combination product or as a medical device, depending on their contents and the intended use. The syringe plays a dual role in the finished product — as a container closure system and as a delivery device. Safety, functional performance and usability need to be considered, also in case of intended use in combination with pre-attached, co-packaged or cross-referenced additional components and/or devices. This document addresses the syringe and its contents as a system, with the intent to ensure the successful application for its intended use. In this context, the minimal configuration of a finished prefilled syringe is the syringe barrel filled with the intended contents (i.e. the injectable product) and closed with a front end closure and a plunger stopper (sealing the back end). Additional components (e.g. either attachment of a needle for single use or assembly of a plunger rod or both) may need to be added by the manufacturer or user to make it ready for administration by manual injection according to its intended use. Alternatively, such a finished prefilled syringe may be combined by the manufacturer or user with a device for administration by a needle-based injection system according to its intended use.

This document includes requirements for the design verification of the finished prefilled syringe's functional performance requirements in accordance with its design specifications. The test methods and other aspects of testing described in this document are intended to verify the design at a confidence level of 95 %. They are not intended to stipulate acceptance criteria for lot release (e.g. acceptable quality limits, probability content, probability or other) in the context of manufacturing processes. Finished prefilled syringes based on customised components can still be tested in accordance with this document. Testing at component, sub-assembly, or in-process level can be sufficient for design verification of specific requirements if the influence of processing on the finished prefilled syringe can be ruled out.

There are other international and national standards and guidance publications and, in some countries, national regulations that are applicable to medical devices and medicinal products and combinations thereof. Their requirements might supersede or complement this document. Developers and manufacturers of finished prefilled syringes are encouraged to investigate and determine whether there are any other requirements relevant to the safety and functional performance or marketability of their products.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

In this document the following verbal forms are used.

— "Shall" indicates requirements.

— "Should" indicates recommendations.

— "May" indicates permissions.

— "Can" indicates possibility or capability.

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Prefilled syringes —

Part 8: Requirements and test methods for finished prefilled syringes

1 Scope

This document is applicable to aseptically processed or terminally sterilized finished prefilled syringes (intended for single use only) based on syringe barrel components addressed in ISO 11040-4 or ISO 11040-6, together with a plunger stopper (sealing the back end) based on components addressed in ISO 11040-5 and a front end closure for parenteral preparations with focus on quality, functional performance and safety requirements, as well as relevant test methods.

Finished prefilled syringes which have undergone an additional preparation step by the user before injection (e.g. diluent-containing syringes that have been emptied for reconstitution and in which the reconstituted injectable product has been aspirated after reconstitution) are excluded from the scope of this document.

NOTE 1 This document can also be used as a guidance for other types, designs and/or sizes of finished prefilled syringes, for example dual chamber prefilled syringes.

NOTE 2 For finished prefilled syringes that are used in needle-based injection systems, see also ISO 11608 (all parts) [1].

NOTE 3 Attention is drawn to applicable national or regional regulations and pharmacopoeias, such as Ph.Eur. [2], USP [3] or JP [4].

NOTE 4 Finished prefilled syringes for parenteral preparations which are medical devices or which, according to the principal mode of action of the product (i.e. the means by which the product achieves its principal intended action), are borderline between medical devices and medicinal products fall within the scope of this document, even if they are not always regulated as medicinal products.

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 11040-4, *Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling*

ISO 11040-4:2024, *Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling*

ISO 11040-5, *Prefilled syringes — Part 5: Plunger stoppers for injectables*

ISO 11040-6:2019, *Prefilled syringes — Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling*

ISO 11040-6, *Prefilled syringes — Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling*

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ISO 23908, *Sharps injury protection — Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration — Requirements and test methods*

ISO 80369-1, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ISO 80369-20, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

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/

3.1
finished prefilled syringe
prefilled container closure system for parenteral preparations as marketed, including, for example, filling with the intended contents and assembly of additional components, aseptic processing or terminal sterilization as applicable, and final packaging by the *manufacturer* (3.2)

3.2
manufacturer
natural or legal person holding the licence (e.g. marketing authorisation or other as applicable) for the injectable product with responsibility for the design, development, manufacture, packaging and labelling of a *finished prefilled syringe* (3.1), before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party

3.3
needle-based injection system
injection system intended for parenteral administration of medicinal products using a needle or cannula and a multi-dose or single-dose container

[SOURCE: ISO 11608-1:2022 [5], 3.15]

3.4
user
patient or health care giver (e.g. clinical personnel, doctor, lay person) who handles (e.g. prepares, applies, disposes of) the *finished prefilled syringe* (3.1)

4 User requirements

4.1 Definition of intended use

The manufacturer shall define the intended use of the finished prefilled syringe. Aspects to be considered shall include the following:

— intended medical indication and criticality of administration, e.g. in emergency situations;

— patient population including their health status and the user profile;

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