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MEDICAL ENGINEERING TECHNOLOGIES

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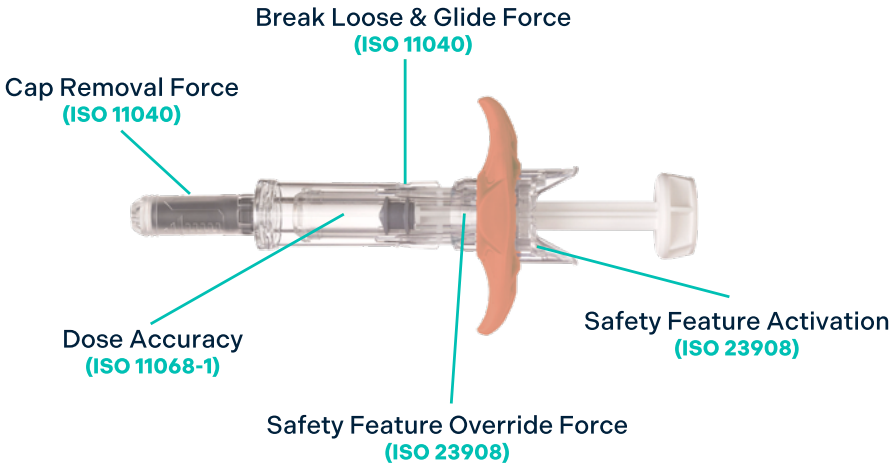
Pre-filled Syringe Testing Factsheet



Testing Stardards

- ISO 10993
- ISO 11040
- ISO 11608
- ISO 11607
- ASTM D4169
- ISO 7886
- ISO 8537
- ISO 80369
- ISO 23908

Types of Pre-filled Syringes

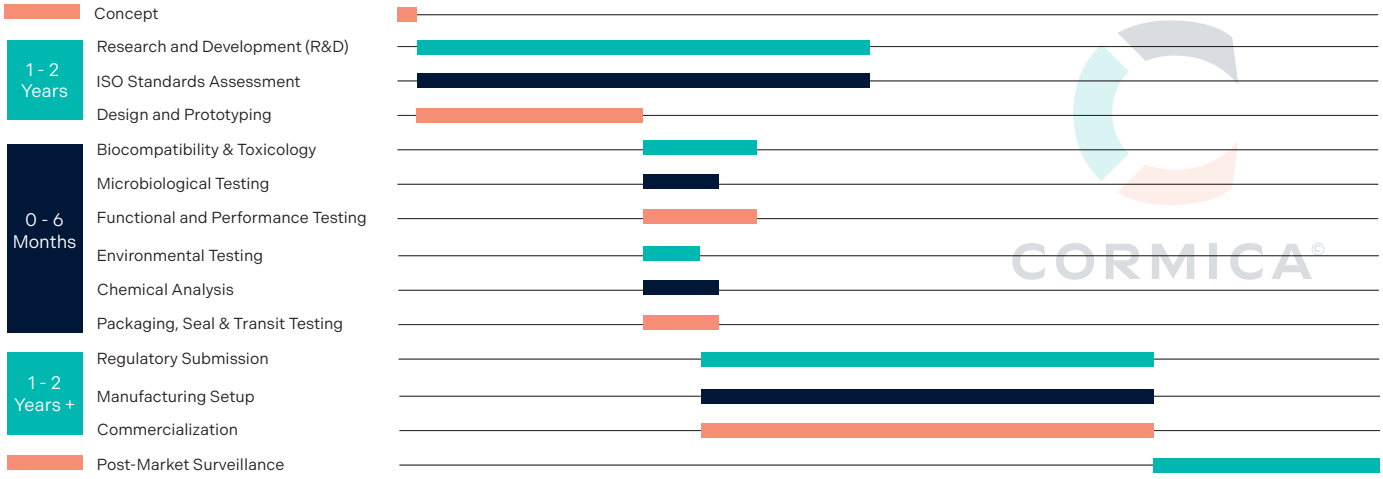
- Single-Chamber
- Dual-Chamber
- Safety Syringes
- Tamper-Evident
- Specialty
- Biologics
- Preloaded Syringes for Autoinjectors
- Pre-filled Flush Syringes

Historically liquid pharmaceutical products for injection, known as parenteral products, were typically supplied in primary containers like ampoules and vials. These containers necessitated the transfer of the liquid into a hypodermic syringe and the attachment of the appropriate injection needle before it could be used.

This process not only consumed a significant amount of time but also introduced numerous opportunities for contamination and errors during use. This increased use of prefilled syringes offers a straightforward user experience, making them not only advantageous in clinical settings but also accessible for use by individuals at home.

Every new syringe / formulation combination requires full performance and safety validation for FDA submission and EC registration. The key parameters to be assessed will be based on the design requirements agreed early in the design phase. These can include: Dose Accuracy, Extractables & Leachables, Maintenance of Sterility and Functional Attributes.

Pre-Filled Syringe Testing Approx. Duration



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ISO 11040

Prefilled syringes require marketing authorisation as a drug, combination or a medical device depending on the content and intended use. The prefilled syringe has a dual role as it acts as a container closure system and a delivery device. Safety, performance and usability are critical aspects that need to be assessed. **ISO 11040-8** addresses the syringe and its contents as a single system, ensuring the devices meets it's intended purpose.

There are eight individual parts to the **ISO 11040** series of standards, these are:

- **ISO 11040-1:2015** - Prefilled syringes - Part 1: Glass Cylinders for Dental Local Anaesthetic Cartridges: This part of the series covers the specifications for glass cylinders for dental local anaesthetic cartridges.
- **ISO 11040-2:2011** - Prefilled syringes - Part 2: Plunger Stoppers for Dental Local Anaesthetic Cartridges: This part focuses on the specifications for plunger stoppers used in dental local anaesthetic cartridges.
- **ISO 11040-3:2012** - Prefilled syringes - Part 3: Seals for Dental Local Anaesthetic Cartridges: This part focuses on the specifications of seals for dental local anaesthetic cartridges.
- **ISO 11040-4:2012** - Prefilled syringes - Part 4: Glass Barrels for Injectables and Sterilised Subassembled Syringes Ready for Filling: This part specifically addresses the requirements for glass barrels for injection preparations and sterilised subassemblies ready for filling.
- **ISO 11040-5:2012** - Prefilled syringes - Part 5: Plunger Stoppers for Injectables: This part of the series covers the specifications of plunger stoppers for glass barrels.
- **ISO 11040-6:2018** - Prefilled syringes - Part 6: Plastic Barrels for Injectables and Sterilised Subassembled Syringes Ready for Filling: This part provides guidance materials, dimensions and performance requirements for polymer barrels.
- **ISO 11040-7:2015** - Prefilled syringes - Part 7: Packaging Systems for Sterilised Subassembled Syringes Ready for Filling: This part specifies the packaging system used to deliver syringes ready for filling in tubs and nests.
- **ISO 11040-8:2016** - Prefilled syringes - Part 8: Requirements and Test Methods for Finished Prefilled Syringes: This part provides the requirements for the final prefilled syringe as presented to the end-user.

ISO 11608-1

ISO 11608-1 details the requirements and test methods for single use needle-based injection systems (NISs), used to deliver medicinal product through a needle or soft cannula. These NISs can be prefilled, user-filles, replaceable or non-replaceable. This standard only applies to prefilled syringes where they are incorporated into the NIS, stand-alone prefilled syringes are covered by **ISO 11040-8**. The requirements of **ISO 11608-1** only apply to stand-alone prefilled syringes if a mechanism impacts the delivery functions.

ISO 23908

ISO 23908 details the requirements and test methods for evaluating the performance of sharps injury protection features of medical devices containing single use hypodermic needles. These sharps injury protection features can either be active or passive in design and are designed to prevent or reduce the potential for disease transmission from post-use sharps injuries. **ISO 23908** is designed to be a broad standard covering a wide variety of medical devices, it provides general requirements for design, testing and labelling instead of specific physical and doctorial design requirements.