

# Prefilled Syringe Testing

Prefilled syringes are used for many therapeutic biologic formulations, and are a good option for ophthalmic injections that require very low volumes of the drug product. They are useful for biologics and other expensive drug products because the overfill volume for the syringe is much lower than the volume required for products filled into vials. Another advantage of a prefilled syringe is their ease of use. They are suitable for self-delivery by the patient and reduce the risk of contamination when compared to the multiple steps required for withdrawing a dose from a vial. They are, however, challenging to manufacture with respect to filling, sealing, inspecting, and conducting testing that is specific to the primary packaging. STEMart provides manufacturers of prefilled syringe with the leading programme for comprehensive design validation testing, including all aspects of the relevant ISO syringe standards plus usability studies and measurement of bio-availability.

## Applicable Standards Related to Prefilled Syringe

- ISO 10993 Biological Evaluation of Medical Devices
- ISO 7886 Sterile Hypodermic Syringes for Single Use
- ISO 8537 Sterile Single-Use Syringes, With or Without Needle, for Insulin
- ISO 11040 Pre-Filled Syringes
- ISO 11608 Needle-Based Injection Systems for Medical Use - Requirements and Test Methods
- ISO 80369 Small-Bore Connectors for Liquids and Gases in Healthcare Applications
- ISO 11607 Packaging for Terminally Sterilized Medical Devices
- ASTM D4169 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- USP 40 - F35
- BS 3221 Oral Delivery Syringe Testing

## Test Capabilities for Prefilled Syringe

- Dose Accuracy Testing
- Break-Loose Force Testing: Measure the force required to initiate movement of the plunger in the syringe barrel.

- Glide Force Testing: Measure the force required to continuously move the plunger through the barrel of the syringe.
- Separation Force Testing: Measure the force required to remove the needle from the syringe.
- Unscrewing Torque Testing: Measure the force required to remove needles that are screwed onto the syringe.
- Ease of Assembly
- Resistance to Overriding
- Stress Cracking
- Validation of Graduation Markings
- Dead Space
- Corning Needle Test
- Mechanism Safety Examination
- Performance Test According to ISO 11040 and ISO 11608
- [Biocompatibility Testing](#)
- [Extractables & Leachables](#)
- [Impurities Identification](#)
- [Container Closure Integrity Test](#)
- [Stability Testing](#)

**STEMart** provides a wide range of testing service for syringe/formulation combination to help manufacturer complete full performance and safety validation required for FDA submission and EC registration. If you want to learn more detail about our testing services, or would like to consult with the experts at STEMart, please feel free to [contact us](#).