INSTRON®

The difference is measurable®

PHARMACEUTICAL PRODUCTS

Instron® - A Total Solution Provider

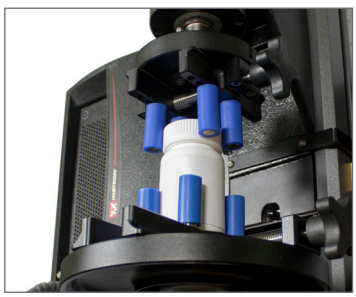
Reliability

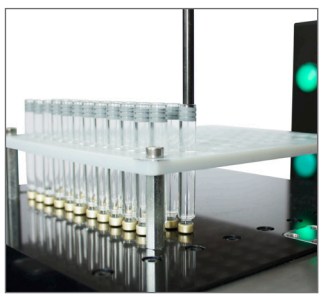
Expertise

FDA Compliance

Small-Footprint

Instron is the leading, global supplier of mechanical testing systems, suitable for tension, compression, flexure, peel, tear, friction, torsion, and fatigue tests. Mechanical testing of pharmaceutical products often consists of pill crush testing, hard and flexible package testing, syringe, auto-injector, and vial testing, as well as testing of drug delivery systems such as inhalers and transdermal patches. Mechanical testing of these products is especially important to guarantee properties such as adequate dosing, drug delivery time, integrity of packaging, and safety requirements of packaging such as child-proof opening mechanisms. If these mechanical characteristics are inappropriately quantified, this could lead to disastrous effects for a patient and pharmaceutical company producing the drug in use. For example, inadequately testing of pre-filled glass syringes to ISO 11040-4 could lead to adverse events associated with connectivity problems with needles and needleless Luer connectors or with general use such as cap tip removal via twisting or direct axial pull-off.





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Reliability

For over 75 years, Instron has designed and manufactured dependable materials testing systems. Instron's professional services team offers calibration and preventive maintenance to keep Instron systems running for years. Despite test system robustness, Instron systems maintain the precision to measure micron-size displacements and gram-level forces.

Expertise

Instron's Application Modules built into Bluehill Universal software provide pre-configured test methods for some of the most common ASTM and ISO pharmaceutical testing standards. Example pre-configured test methods include force measurements of breakaway, glide, cap removal, and needle penetration of syringes and auto-injectors.

FDA Compliance

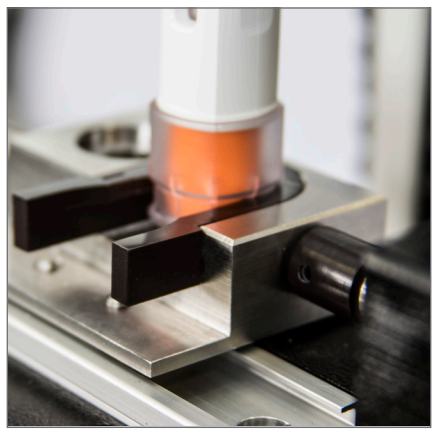
Instron offers validation assistance to laboratories that are required to meet U.S. Food and Drug Administration (FDA) guidelines, including installation qualification (IQ) and operational qualification (OQ). For over 10 years, Instron has partnered with Xybion Corporation, FDA compliance experts, to offer ComplianceBuilder software for meeting 21 CFR Part 11 compliance.

Small-Footprint

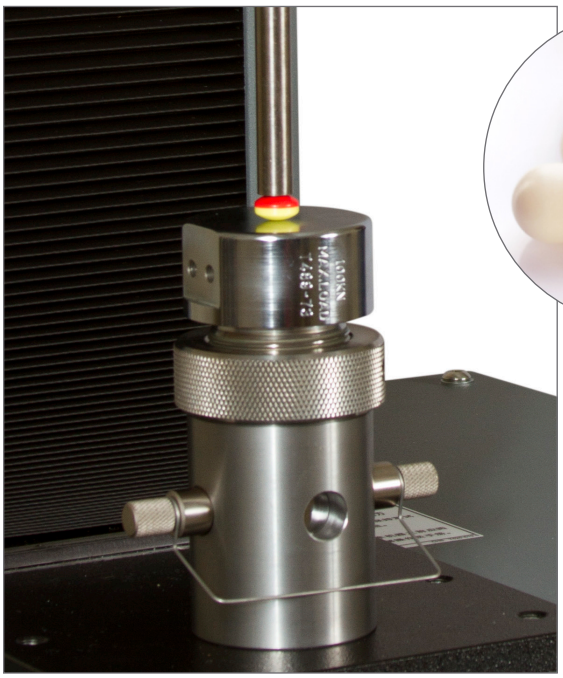
The small physical footprint of Instron's tabletop systems enable laboratories to save space, stay organized, and keep the laboratory clean. The small machine footprint includes both the test system and necessary software control, ideal for optimizing benchtop space in clean rooms in both research and quality laboratories.

Peel strength testing of syringes, needles, and other pharmaceutical packaging is important to ensure the package is strong enough to protect the sterility of the product while also ensuring the package is easy for the patient to open.

Compressive testing on parenteral vials to quantify residual seal force.

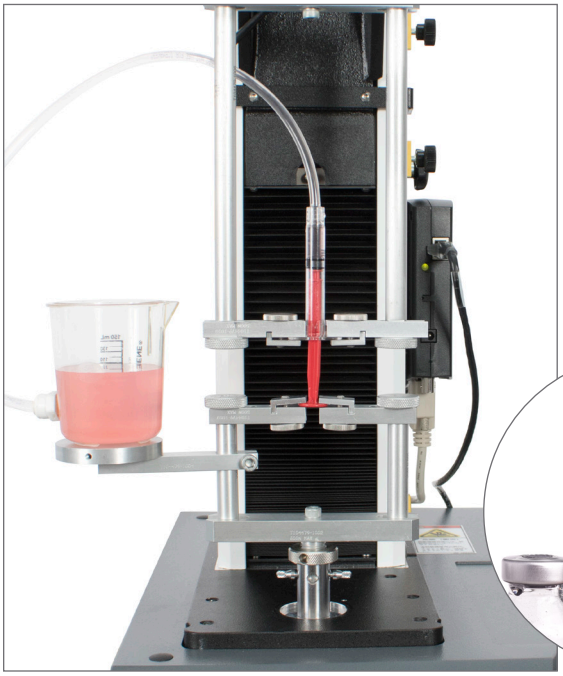


Quantifying cap removal force to ISO 11608-5 ensure the quality of the cap to pen connection while simultaneously ensures patients can easily remove the cap of an auto-injector pen.



A lower compression platen and upper flat probe is used to perform pill crush testing to ensure the pill can withstand a minimum compressive load.

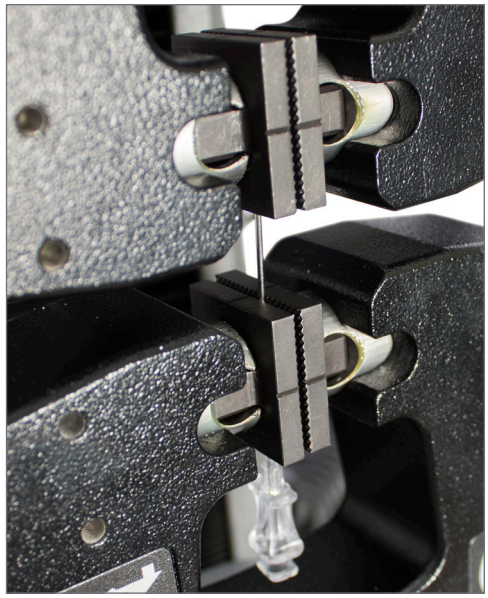
A 5940 single column machine with the torsion add-on applies compressive or tensile loading on a child-proof medicine bottle while simultaneously twisting the cap off.



Test fixture designed to meet the requirements of ISO 7886-1 Annex G for sterile, single-use hypodermic syringes.

ISO 11608-5 requires needle-based injection systems to be tested for cap removal, activation force and displacement of the injector, injector timing, and measurement of the ejected fluid.

Quantifying torsional properties of syringe caps and luer locks is conducted to ISO 80369-7, ISO 594-1 and ISO 594-2.



Tensile test to determine the union strength between the needle hub and needle to ISO 11070.

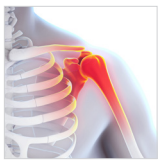
Instron's instruments and technologies are used for various types of tests across many diverse medical sectors. The flexibility of Instron systems to adapt to numerous applications make our systems truly universal.

Designed from the ground up for touch, Instron's static testing software, Bluehill Universal, is easy-to-use, increases testing efficiency, and contains modular features that enable users to run the most complex tests.

With ISO 9001 accreditation, our goal is to provide the best ownership experience by delivering the highest quality products, expert support, and world-class service. Instron Connect provides users with a powerful communication platform via a secure connection between the Instron system at your facility and Instron's global technical support engineers. With Instron Connect, users receive faster remote technical support, reduce risk with schedule verification and preventive maintenance reminders, and are effortlessly able to keep up to date with the latest software features.

Medical Sectors

Visit our website to learn more about the different medical sectors we support: go.instron.com/bio



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