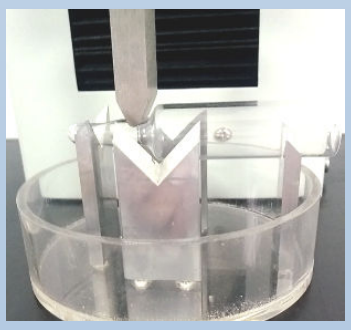
CELL INSTRUMENTS

Material Testing Solutions

BST-01
Ampoule Breaking Tester

Quantifying ampoule break force to guarantee dose integrity



www.pharmacopoeiatest.com
www.ampouletest.com

Decades of Innovation in Material Testing

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Background & Importance

Ampoules provide sterile, hermetically sealed delivery of injectable drugs.

Testing ampoule break strength ensures that pharmaceutical ampoules can be opened safely with a predictable force, preventing patient injury, glass contamination, dosage loss, and regulatory non-compliance. Break-force data guide manufacturing QC, formulation selection, user training, and automation integration, ultimately protecting product integrity and end-user safety.

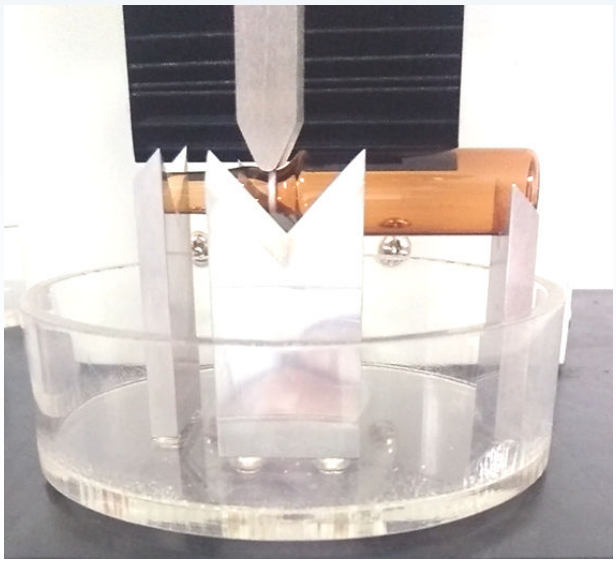
Application

The ampoule neck's breaking force must be low enough for caregivers to open safely, yet high enough to prevent accidental shards or contamination. Quantitative testing per ISO 9187 and GB 2637 ensures both patient safety and regulatory compliance.

An Ampoule Breaking Strength Tester is a precision instrument designed to measure the force required to break the neck of a glass ampoule.

Test Process

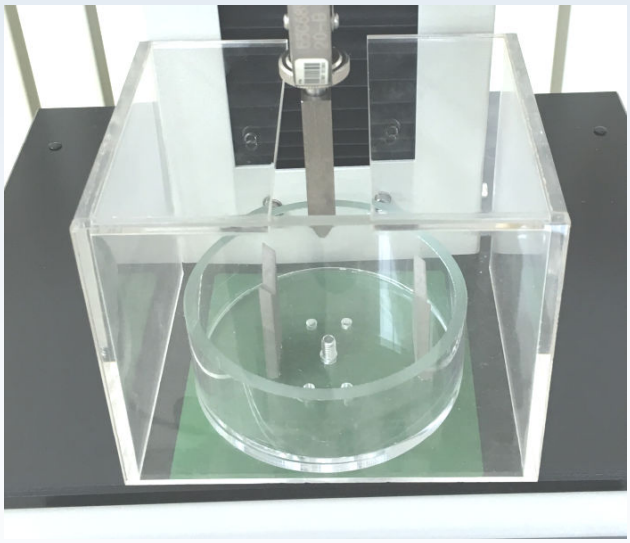
1. Fixture Selection: Choose a set of metal bars according to ampoule volume.
2. Mount ampoule (1, 2, 3, 5, 10, 20, 25, 30mL capacity).
3. Speed Setting: Default 10 mm/min and adjustable
4. Breaking: Start the test, and the tester punch descends until neck fracture; high-precision load cell records peak
5. Data Handling: The Embedded screen program shows the maximum, minimum, and average break



Advanced Features

The BST-01 Ampoule Breaking Tester automates ISO 9187 and GB 2637 protocols, delivering repeatable breaking - force data with industrial-grade stability, PLC control, and an intuitive HMI touchscreen. Offering interchangeable fixtures (1–30 mL), adjustable speeds, sample protection, and optional software connectivity, it streamlines QC and R&D workflows across glass, plastic, and composite ampoule formats.

- PLC Control & HMI Touchscreen: Intuitive menus, robust automation.
- Stepper Motor & Ball-Lead Screw: Precise displacement control for consistent break speed.
- Interchangeable Fixtures: Accommodates 1–30 mL ampoules and related medical packaging.
- Protective Cover & Collection Tube: Ensures operator safety from glass shards or fragments.
- Adjustable Speed & Auto Return: Tailor tests for different need and improve throughput.
- Microprinter: On-demand hardcopy of break values.
- RS-232 & Software (Optional.): Seamless report and export.
- IQ/OQ/PQ documentation.



Specifications

Test Range	0~200N (customizable)
Speed	1~500mm/min
Resolution	0.1N
Accuracy	0.5% F.S.
Power	AC 110~220V 50/60Hz

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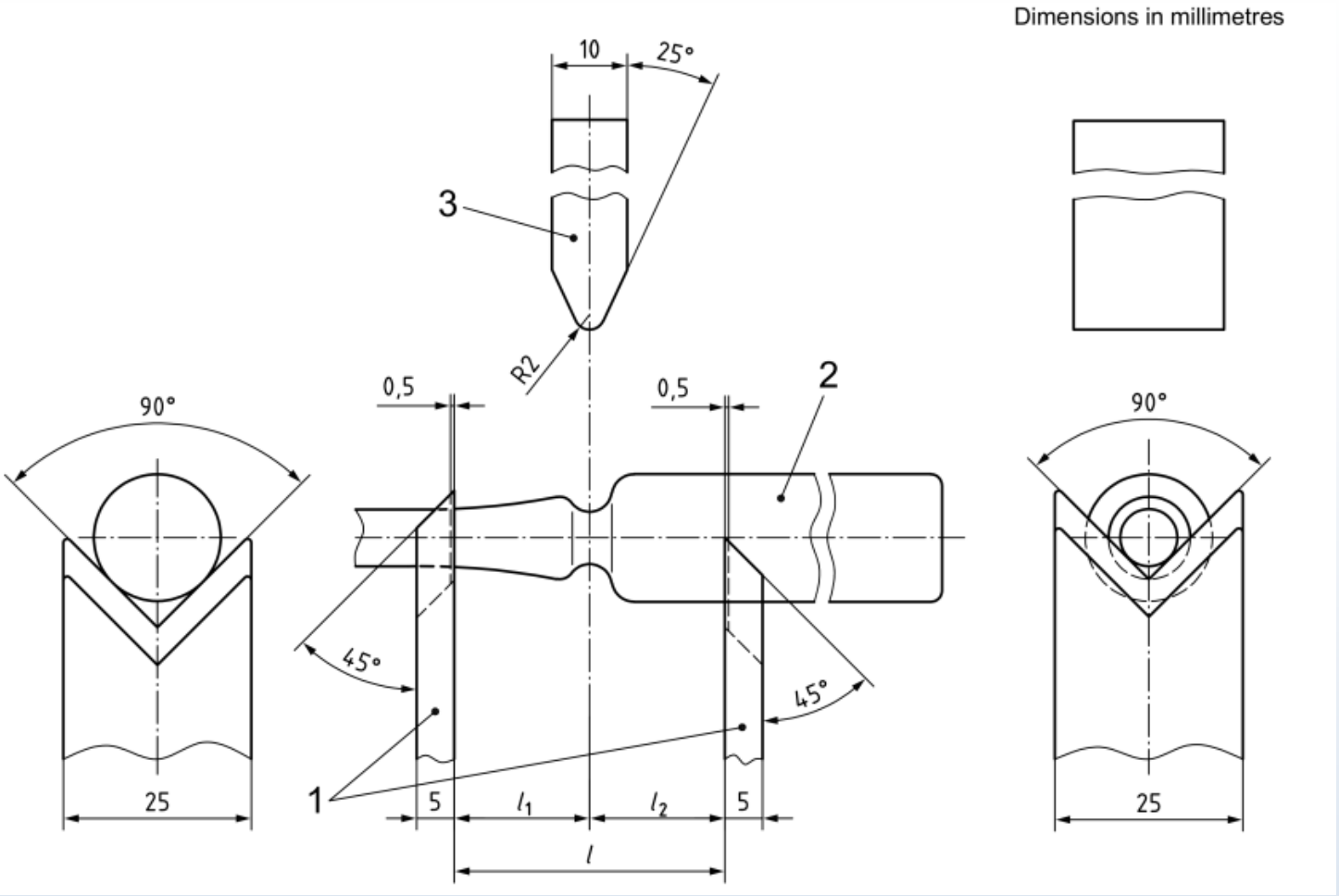
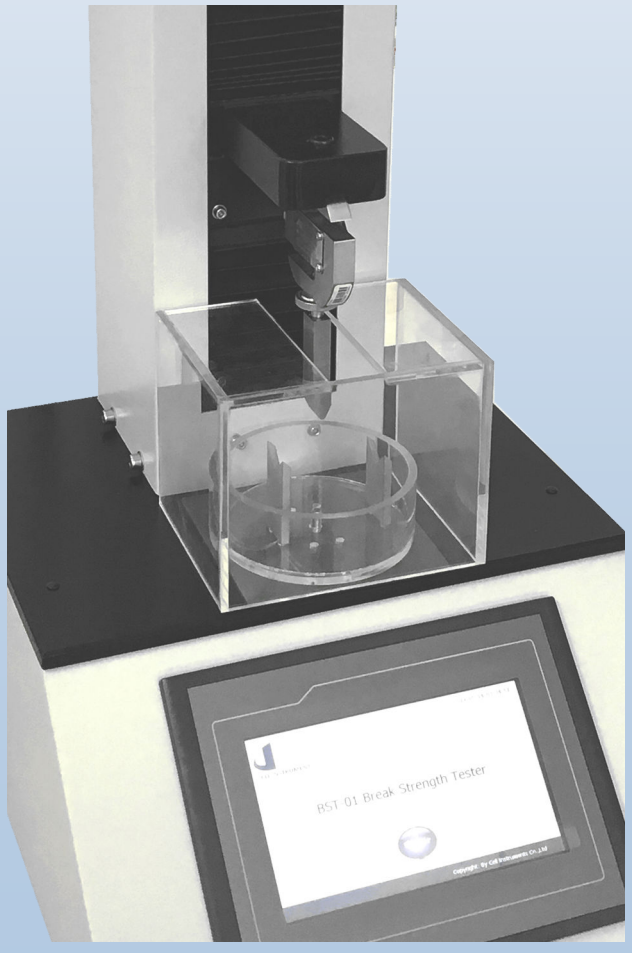
Dimensions in millimetres



Test set-up for determining the force for breaking ampoules



Jigs and Cover

Cell Instruments Co., Ltd.
No. 5577 Gongyebei Rd, Licheng District, Jinan, 250109, P.R.C.
Web. www.celtec.cn
www.packqc.com
www.qualitester.com
www.cnceltec.com (Chinese)
Email: info@celtec.cn
Phone: +86 18560013985 (Mobile/WeChat)