

Hardness

Background: Hardness Testing

Together with friability, hardness (or breaking force) is a defining physical characteristic for a tablet. High hardness values may indicate for example, longer disintegration and dissolution times, compromising the speed of drug delivery.

On the other hand, if hardness is too low, then friability may be also high, giving rise to poor product stability and compromised dose uniformity.

By examining correlations between hardness, disintegration, dissolution and friability, a dosage form with optimum characteristics can be produced.

Chapters Ph. Eur. 2.9.8 **Resistance to Crushing of Tablets** and USP Chapter <1217> **Tablet Breaking Force** describe standardised methods for the assessment of tablet hardness.



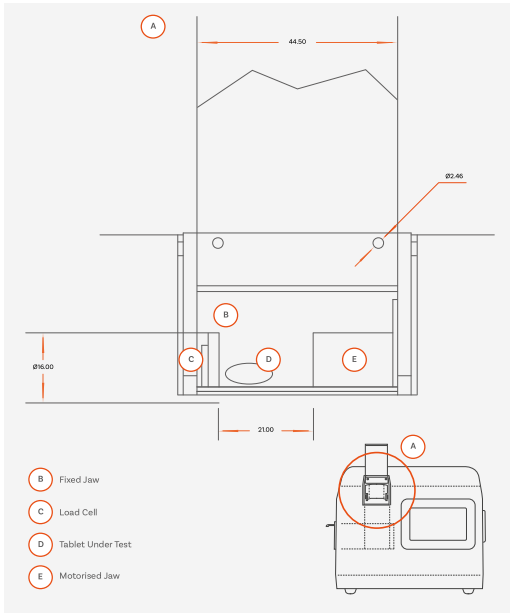
Hardness

Test Apparatus & Method

A tablet is placed between two platens (jaws), one of which is attached to a force gauge with load cell and the other to a motor which provides the mechanical drive.

The motorised jaw drives forward pressing the tablet against the fixed jaw until the tablet breaks. The motorised jaw then retracts and the load force required to break the tablet is recorded.

The units of force normally employed to quantify breaking force are Kiloponds (Kilogram-Force) or Newtons.



Hardness: TBF 100i

Rapid, no-fuss tablet hardness testers

Combining the economy of a simple, easy to use hardness tester with the accuracy of microprocessor-controlled data collection, the compact TBF 100i hardness tester delivers precise tablet hardness and diameter measurements. Tablet thickness and weight can also be recorded (optional).

Offering high tablet throughput, the intuitive touchscreen user interface of the TBF 100i streamlines test set-up procedures for users, whilst the built-in data processor provides analysts with tablet breaking force statistical analyses at the touch of a button.



Ph. Eur. and USP Compliant



Choice of breaking force measurement units



Intuitive touchscreen control to simplify operation



Force application: constant speed



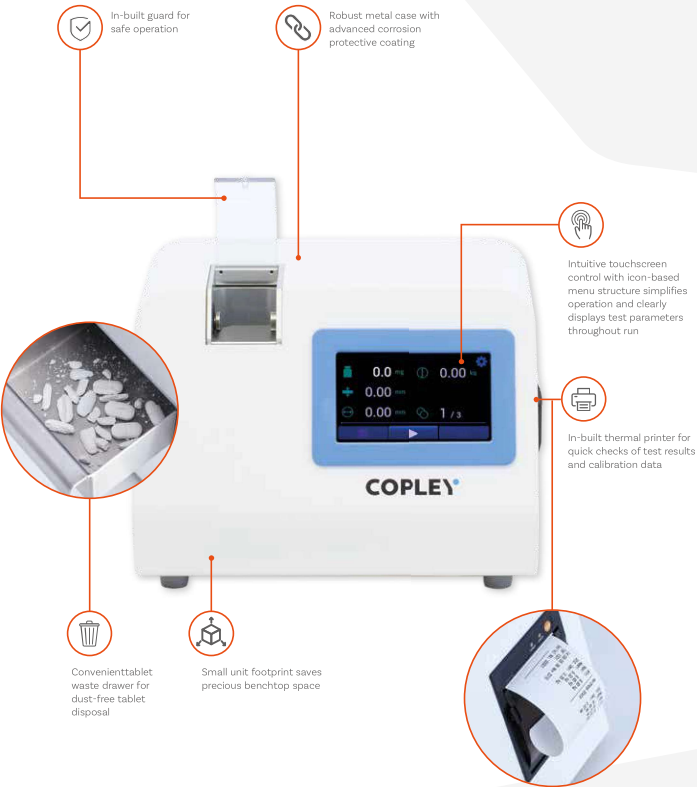
Option: Manual or automated entry of tablet weight & thickness data



Extensive data reporting output options



TBF 100i: Key Features



TBF 100i: Touchscreen User Interface



- A Before testing (batch mode enabled)
- B After test completion (batch mode enabled). Progress bar indicates test run complete.
- C Tablet hardness statistics
- D Settings menu (I)
- E Settings menu (II)
- F Test speed setting screen
- G TBFi interface settings menu
- H Calibration menu

Key Features:

- **Intuitive menu structure** enables users to locate features quickly and easily
- **Easy-set** user-configurable **test parameters**:
 - Rate of force application (mm/min)
 - Force measurement unit (N, kp, kgf, or lbs)
 - Tablet Batch size
- **Key tablet measurements clearly displayed on-screen to user**
 - Tablet weight (if applicable)
 - Tablet thickness (if applicable)
 - Tablet diameter (if enabled)
 - Tablet hardness
- **Batch progress displayed during batch testing run** provides clear indication on throughput status
- Resistive touchscreen interface can be **operated with gloves on**
- Hygienic **wipe-clean** screen
- High productivity - **easy system set-up and operation** minimises training burden



TBF 100i with calibration rig

Reporting

Extensive data output options are available as standard, including direct printing from the TBF 100i and direct reporting to a PC.

Reported parameters

- **Individual Tablet Results**
 - Diameter (if enabled)
 - Hardness
 - Weight (if applicable)
 - Thickness (if applicable)
- **Tablet Batch Statistics**
 - Batch minimum, maximum, mean and standard deviation of:
 - Diameter
 - Hardness
 - Weight
 - Thickness
- **Calibration Data**
 - Calibration date
 - Temperature calibrated at (°C)



Compliance & Maintenance



- ✓ Certificate of compliance to Ph. Eur./USP provided as standard
- ✓ Comprehensive IQ/OQ/PQ documentation packages and toolkits available
- ✓ Passcode-protected static calibration routine
- ✓ Optional calibration rig available
- ✓ Latest calibration information stored and available to export/print

Choose your Tablet Hardness Tester



TBF 100i

Cat. Number
2532



TH3/200

Cat. Number
7801



TH3/500

Cat. Number
7802

Pharmacopoeial Compliance
Ph. Eur. 2.9.8
USP <1217>

Tablet Measurements
Breaking force • Diameter
Weight* • Thickness*

Statistics Reporting
Yes

Max. Tablet Diameter
36 mm

Force Range
0-490 N

Batch Testing
Yes

Portable
No

Unit Dimensions (w x d x h)
283 x 237 x 208 mm

Pharmacopoeial Compliance
Ph. Eur. 2.9.8
USP <1217>

Tablet Measurements
Breaking force

Statistics Reporting
No

Max. Tablet Diameter
30 mm

Force Range
0-200 N (+/- 0.04 N)

Batch Testing
No

Portable
Yes

Unit Dimensions (w x d x h)
82 x 380 x 90 mm

Pharmacopoeial Compliance
Ph. Eur. 2.9.8
USP <1217>

Tablet Measurements
Breaking force

Statistics Reporting
No

Max. Tablet Diameter
30 mm

Force Range
0-500 N (+/- 0.1N)

Batch Testing
No

Portable
Yes

Unit Dimensions (w x d x h)
82 x 380 x 90 mm

*Optional with balance and/or thickness gauge

TBF 100i: Technical Specifications	
User Interface	Resistive touchscreen
Max. Tablet Diameter	36 mm
Force Range	0 - 490 N
Force Application	Constant speed 1 - 50 mm/min
Hardness Units	N, kp, kgf, lbs
Testing Throughput	~ 5-8 tablets per minute* <small>*depending on hardness/diameter of tablet under test</small>
Fracture Detect Percentage	Adjustable between 30% - 90%
Data Output	RS 232 USB type B (for communications with a PC) In-built thermal printer
Waste Drawer	Integrated

TBF 100i			
Cat. No.	Description	Cat. No.	Description
2532	Tablet Hardness Tester Model TBF 100i	2505	IQ/OQ/PQ Documentation Pack
2503	Calibration Rig	2511	Re-Calibration Certificate
2504	Set of Calibration Weights for TBF 100i (4 x 10 kg, 2 x 5 Kg)	2506	Pack of 10 Paper Rolls
2510	Other Qualification tools		
2512	Re-calibration of Qualification Tools		



TBF 100i with open guard

Choose your TBF 100i Accessories

Tablet Weight & Thickness

With the addition of a balance and/or Mitutoyo micrometer for measuring thickness, the TBF 100i becomes a complete system for measuring the hardness, diameter, weight and thickness of tablets. This configuration is a highly efficient, cost-effective alternative to more sophisticated commercial systems for measuring these critical tablet parameters.

Alternatively, tablet weight and thickness can be entered into the TBF 100i system manually.



Mitutoyo Measuring Gauge



Sartorius Balance Model Quintix 224-1 CEU



TBF 100i Accessories

Cat. No.	Description
2507	Sartorius Balance Model Quintix 224-1 CEU (including cable)
2508	Mitutoyo Thickness Measuring Gauge

Hardness: TH3 Tester

Ideal for use in the production area for a quick check of compression force, the TH3 is a portable and simple-to-use tablet hardness tester.

Using a multi-turn, low-friction hand wheel to apply the load, the TH3 is available with two load ranges, which can apply up to 200 N or 500 N (TH3/200 and TH3/500 respectively). The resulting breaking force is displayed clearly on the LCD with a wide choice of data output options.

With easy calibration verification, this tester offers easy and convenient tablet hardness testing in busy production environments.

TH3: Key Highlights



Reporting

The TH3 is provided with RS-232, Mitutoyo and analogue data output as standard. All displayed readings including breaking force in Newtons, grams, pounds or ounces, can be transmitted to external devices, including PCs and printers.

TH3 Series

Cat. No.	Description
7801	Tablet Hardness Tester Model TH3/200
7802	Tablet Hardness Tester Model TH3/500
7803	Re-Calibration Certificate
7804	Calibration Verification Hanger & Weight
4902	Mini Processor for TH3 Tester
9005	Compact Printer (Force Gauge)