

PTB 302

Manual Tablet Hardness Testing Instrument with Integrated Report Printer

The digital tablet hardness testing instrument PTB 302 features an integrated report printer. It is a single force mode hardness test apparatus adjusted for linear force increase while tablet hardness is tested. It offers a multiple point validation procedure for the built-in digital load cell. The instrument is made in strict compliance with the EP <2.9.8> and USP <1217> Pharmacopoeia.

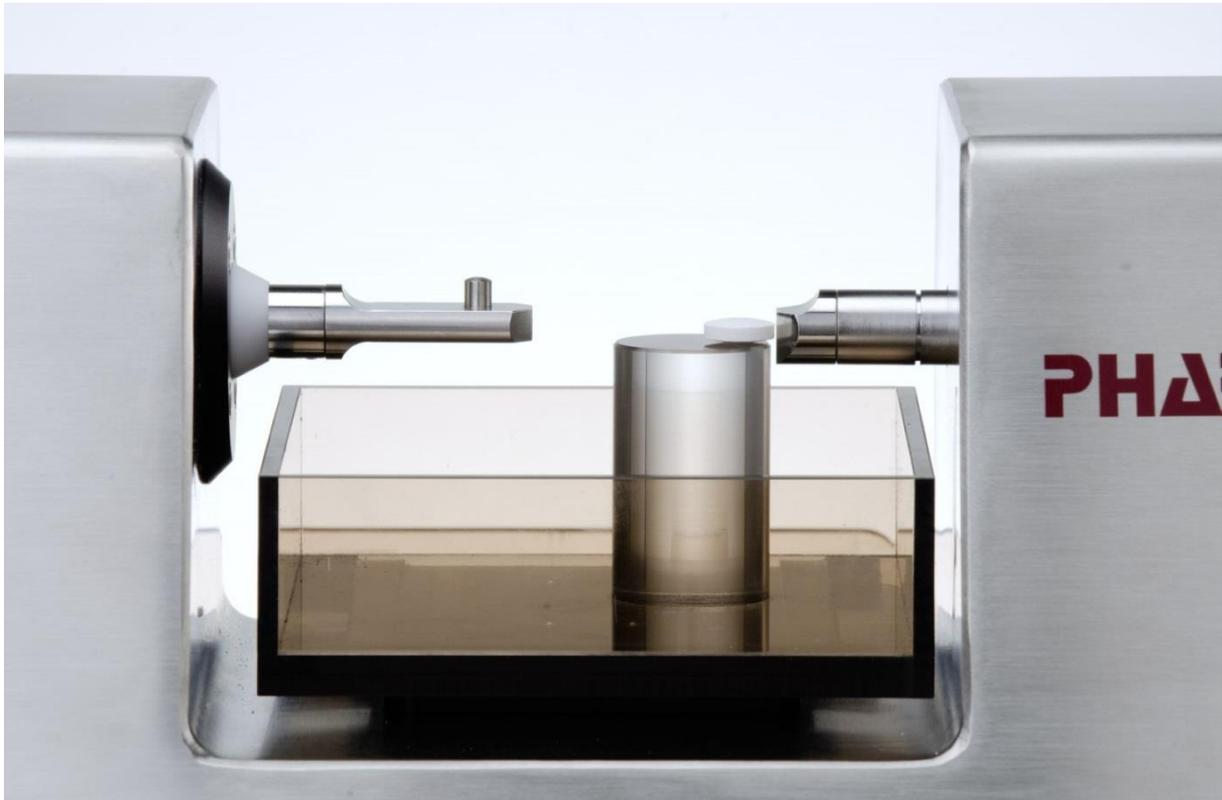


Test Procedure

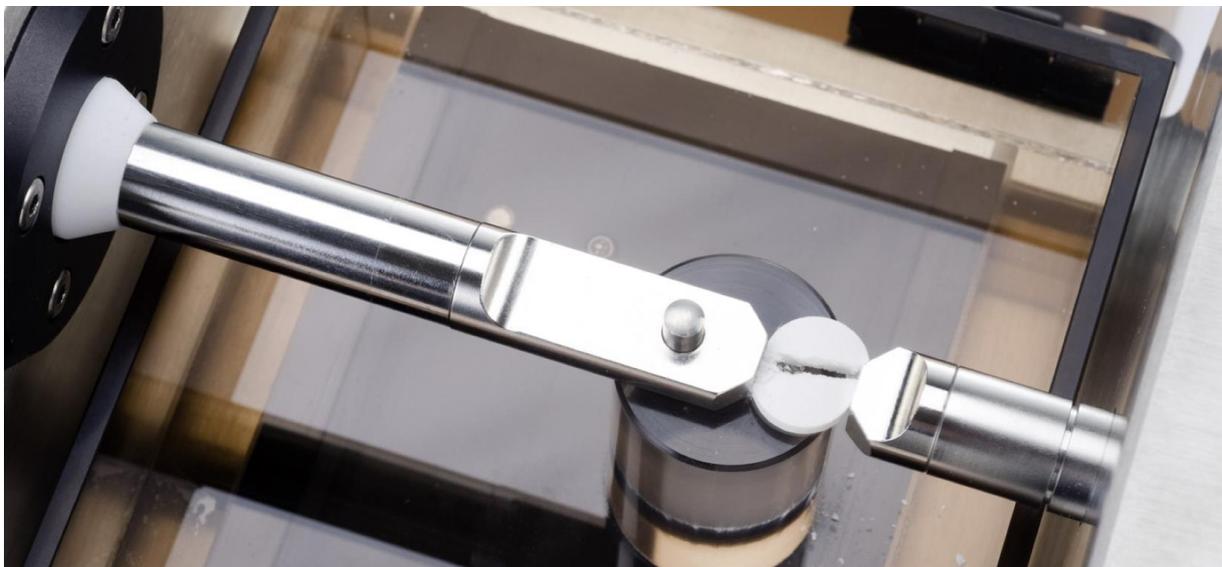
Select the unit to measure, KP (Kilopond), N (Newton) or Sc (Strong Cobb), now place the sample onto the sample dish and start the test. The driven jaw will run forward, touch and force the tablet until it breaks to measure the hardness (tablet breaking force). No change of tools is required; the design of the jaws does handle most kind of tablet shapes. The result is immediately displayed and printed via the integrated report printer. Repeat this until your series has been tested; get a full print-out including each individual result and an optional block of statistics including mean value and deviations of the test series. The flexibility and the reproducibility of the results have made this and other models, like the PTB 311E series become one of the most sold tablet hardness testing instruments worldwide. By using an integrated report printer, the bench space requirements to of this instrument are even lower than other instruments from the PTB series, since no additional external printer is required. Furthermore, the report printer requires less paper than a standard printer and by this helps to preserve our precious natural resources.

Operating Principle

Even in the existing USP and EP monographs there is no standard force setting or force increase mode established, but it is recommended to use a linear force increase rate of 20N/s. Different force settings usually cause problems when comparing results received by different supplier's instruments when testing the same tablet. The hardness result is directly influenced by the contact speed and force increase rate. Faster operated test jaw means lower reproducibility and often higher results.



In order to offer the possibility to select an operating mode which will offer you similar results as the instrument you may already use, adjust the linear force increase rate to be the same or a similar rate as the instruments you are using as well. Also touch and detection force may be altered to suit the sample design specification. When the sample is touched the instrument switches to the selected mode and linear increasing rate.



Example Print-Out

Product: _____
Batch: _____
Date: _____
1 45.9 N
2 61.2 N
3 55.6 N
4 57.0 N
5 60.5 N
6 44.5 N
7 46.6 N
8 46.6 N
XMAX 61.20 N
XMIN 44.50 N
RANGE 16.70 N
SD 7.03 N
SREL 13.46 %
XM 52.24 N
NR 8
PTB 502 02.11/00
00000000000000000000000000000000

The report includes space for the user to enter a product name, a batch number and the date of the test.

The individual test results in the selected unit. The results are printed live as each sample is broken. Up to 250 samples can be tested in one run.

The following statistics can be printed optionally: maximum (XMAX), minimum (XMIN), range (RANGE), absolute standard deviation (SD), relative standard deviation (SREL), median (XM) and number of results (NR).

The report concludes with the instrument type and the installed firmware version.

Linear Force Increase

For more than 20 years all Pharma Test hardness testing instruments offer the possibility to select a linear force increase rate. Linear force increase is the recommended setting as it offers the most accurate control, as the rate of increase is directly controlled by the electronic load cell used to read the force. Also it is quite simple to validate the correct and linear operation as a tablet having a hardness of 100 Newton will be broken within 5 seconds if 20N/s had been set as force increase rate. The test of "soft" tablets often requires an increase of the standard force rate setting otherwise the sample gets deformed only but does not break. To select a linear speed increase mode is impossible using the PTB 302/502 hardness test instrument.

Calibration and Validation

The current USP Pharmacopeia requires the force sensor of a tablet hardness testing instrument to be calibrated periodically over the complete measuring range (or the range used for measuring samples) with a precision of 1N. All Pharma Test tablet hardness testing instrument can be statically calibrated over the complete measuring range by the use of different traceable counterweights. All instruments support the checking of at least three different points during calibration to prove the linearity of the force sensor.



Furthermore, Pharma Test offers the PT-MT3 magnetic tablet to calibrate the breakpoint detection of the entire tablet hardness testing instrument (force sensor and mechanics of the instrument). All Pharma Test tablet hardness testing instruments are fully compliant to the requirements of the current USP/EP Pharmacopeia. The PTB 302/502 offers a built-in calibration and validation program for the hardness test station. To validate the hardness test station the PT-MT3 magnetic tablet or different certified weights are used. Use the PT-MT to qualify the correct breakpoint detection, the PT-MT3 instrument works like a tablet, it withstands force and after "breaks".

For the two point adjustment (zero and reference) of the load cell inside the hardness station a certified reference weight of 10 kg is used. For validation purposes the use 5 up to 30kg certified weights is recommended. All adjustment and calibration results can be printed and countersigned. To prove the linearity of the instrument, the operator can program a print-out of the force curve recorded during a test. This will show the linear increase of the adjusted force mode. Also different weights, like the CAL-15 and CAL-30 which includes 5, 10, 15kg and also 30kg or the PTB-CAL30 using 2 additional 10kg weights for total 50kg, may be placed onto the load cell or the PT-MT3 shall be used to validate the linearity and breaking detection reproducibility. All results will be printed at the internal Thermo Printer. Using the RS-232 COM port, all results can be transmitted to software running on a computer system.



Advantages

- » No external printer required, this reduces the necessary bench space
- » Documentation of all results using an integrated report printer
- » Report printer uses less paper compared to a standard format printer
- » Automatic re-start facility to speed up the testing sequence
- » Validation and calibration program for the measurement station
- » Dual point adjustment of the load cell for the hardness test station
- » Multiple point validation (calibration)
- » Data transfer via RS-232 interface
- » Hardness testing in compliance with the EP <2.9.8> and USP <1217> Pharmacopoeia

Features

- » Fully USP <1217> and EP <2.9.8> compliant
- » Single force mode instrument
- » Integrated thermal printer
- » Multiple point validation procedure built-in
- » Adjustable linear force increase rate setting

Standard Scope of Supply

The PTB 302/502 comes ready to use with the following standard scope of supply:

- » Standard jaw to allow hardness test of nearly all size and shape samples
- » Broken sample collector
- » 10 rolls of printer paper
- » Comprehensive documentation folder including:
 - » User manual
 - » QC/DQ testing certificate
 - » IQ documentation
 - » OQ documentation
 - » Conformity Declaration
 - » CE/EMC Declaration
 - » Instrument logbook

Options

In addition to the standard scope of supply Pharma Test offers a broad range of accessories and options including:

- » Ampoule Test Support
- » Max. force rat up to 500N (PTB 502)
- » Recommended spare part set
- » Full range of certified validation tools available

Technical Specifications

Parameter	Specification
Display	LED Display showing number of tests and hardness result
Data Entry	Numerical and Functional keys
Standard Force Range	5.0 to approximately 300N
Accuracy	< 1N
Resolution	0.074N (300N model) - 0.1482N (500N model)
Force Settings	Linear force increase
Selectable Range	5.0 - 200 N/Second
Accuracy	< 2% force
Maximum Sample Size	40 mm (Option 70mm)
Printer	Internal thermal printer
Interface	Serial RS-232 COM port
Calibration Guidance	Built-in calibration procedures the digital load cell
Adjustments	Two point adjustment - zero and 10kg
Calibrations	Multiple point for load cell precision using certified weights (CAL15/30/50)
Force Detection Reproducibility	PT-MT3 Magnetic Tablet
Instrument Housing	Stainless Steel to meet GLP requirements
Bench Space Requirement	530 x 240 x 180 mm (Length x Width x Height)
Certification	All components certified to USP / EP requirements
CE / EMC Certification	All CE / EMC Certification provided
Validation	All IQ & OQ documents included

We reserve the right to make technical changes without any prior notice.