

PTB 111EP – Manual Tablet Hardness Testing Instrument with Integrated Report Printer



The digital tablet hardness testing instrument **PTB 111EP** features an integrated report printer. It is a **dual force mode** hardness test apparatus as it can be used for either linear force or linear speed 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. Enter the nominal test information for hardness as well as a batch number via the PTB 111EP keyboard. 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).

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, date, time, serial number of the instrument, batch number of the product tested, 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

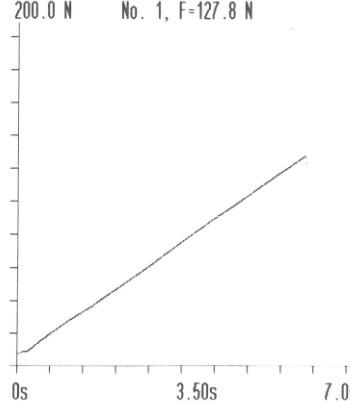
Even in the existing USP and EP monographs there is no standard force setting or force increase mode established, but it is recommended to use a linear force increase rate of 20N/s. Different force settings usually cause problems when comparing results received by different supplier's instruments when 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 instruments you may already use, select the force mode, linear force increase or linear speed increase and select the same or similar rate. 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.

Which Force Mode Should Be Selected?

For more than 18 years all Pharma Test hardness testing instruments offer the possibility to select either linear force or linear speed increase. 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 setting, otherwise the sample gets deformed only but does not break

Linear speed increase can also be used. Here the driving speed of the motor is kept linear. Actually if the touching force is kept low there is not too much difference in results between the two systems but it is very difficult to validate the linearity of the drive speed.

Example Print-Outs

<pre> *RECORD OF MEASUREMENT* ===== TABLET TESTING SYS PTB111E Ver.01.04.09 E Time 15:32:26 Date 02.05.13 S/N 018512 ===== Th. Value 300.0 N , 20.0 N/sec Product: _____ Batch: 000000000000 Job: _____ Method: _____ ===== Results [Unit: N] No. Force No. Force No. Force No. Force 1 73.2 2 60.9 3 66.1 4 76.6 5 65.6 6 48.6 7 76.2 8 80.5 ===== Statistics Xmax = 80.5 N Xmean = 68.46 N Xmin = 48.6 N Xabs = 10.41 N Xdif = 31.9 N Xrel = 15.21 % ===== Operator: ----- Name Signature ----- Released: ----- Name Signature </pre>	<pre> *RECORD OF MEASUREMENT* ===== TABLET TESTING SYS PTB111E Ver.01.04.09 E Time 15:36:09 Date 02.05.13 S/N 018512 ===== Th. Value 300.0 N , 20.0 N/sec Product: _____ Batch: 000000000000 Job: _____ Method: _____ ===== Results [Unit: N] No. Force No. Force No. Force 1 127.8 ===== 200.0 N No. 1, F=127.8 N -----  ----- Operator: ----- Name Signature ----- Released: ----- Name Signature </pre>	<pre> ** ADJUSTMENT REPORT ** ===== TABLET TESTING SYS PTB111E Ver.01.04.09 E Time 09:52:15 Date 04.04.13 S/N 018512 ===== Specification Setting (Cell Upright) ----- Act. Offset 15 12 - 52 Dig Tab. Detect. 96 48 - 999 Dig Hardn. Detect. 180 48 - 999 Dig Force Setting 20.0 5.0 - 200.0 N/s Max.H.Dist. 2.00 2.0 - 10.0 mm ----- Specification Setting (Cell Upright) ----- Zero-Value 0Kg 40 20 - 60 Dig Ref-Value 10Kg 1363 1240 - 1480 Dig Range 0Kg-10Kg 1323 1220 - 1460 Dig ----- Operator: ----- Name Signature ----- Released: ----- Name Signature </pre>
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Example Test Report

Example Test Report showing Force Increase Curve

Example Adjustment Report



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 tablets to calibrate the breakpoint detection of the whole 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 Pharmacopeia.



PT-MT3

The PTB 111EP 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-MT3 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. All results will be printed at the internal Thermo Printer. Using the RS232 COM port, all results can be transmitted to software running on a computer system.



PTB-CAL 30

Advantages

Some of the highlights the PTB 111EP offers are:

- 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 A4 format printer
- Select either linear force or linear speed increase (dual mode selection)
- Entry of time and date
- Enter a 12 digit batch number
- Automatic re-start facility to speed up the testing sequence
- Validation and calibration program for the measurement station
- Force curve print out
- Dual point adjustment of the load cell for the hardness test station
- Multiple point validation (calibration)
- Programmable print-out of force increase curve
- Data transfer via RS-232 interface
- Hardness testing in compliance with the EP <2.9.8> and USP <1217> Pharmacopoeia
- Test program for soft gelatine capsule testing by setting up a testing distance

Features

The main features of the PTB 111EP are:

- Fully USP <1217> and EP <2.9.8> compliant
- Dual force mode instrument with linear speed increase and linear force increase modes
- Steppless adjustment of the linear force or speed increase rate
- Integrated thermal printer
- Multiple point validation procedure built-in
- Programmable print-out of force increase curve
- Set to test tension strength of oblongs and caplets available

Standard Scope of Supply

The PTB 111EP comes ready to use with the following standard scope of supply:

- Standard jaw set size 4 to allow hardness test of 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:

- Tension test set to test break line force of shaped tablets
- 500N (PTB 111EP-500) extended force range
- Recommended spare part set
- Full range of certified validation tools available



Tension Strength Test Set to test tablets having a break-line

Technical Data

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 speed or linear force increase
Selectable Range	5.0 - 200 N/Second or 5.0 - 200 Millimeter/Minute
Accuracy	< 2% force or < 0.1% speed
Maximum Sample Size	45 mm
Drive Way Setting	1.0 - 30.0 mm to adapt sample size
Printer	Internal thermal printer
Interface	Serial RS232 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)
Force Detection Reproducibility	PT-MT3 Magnetic Tablet
Instrument Housing	Stainless Steel to meet GLP requirements
Bench Space Requirement	L 48cm x W 24cm x H 26cm
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.