

Manual Tablet Testing Instrument 3-in-1 - Type PTB 311E



The Manual Tablet Testing Instrument **PTB 311E** 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 and the diameter, height station.

Test Thickness, Diameter or Length and Hardness of the same Tablet using just one Instrument, the PTB 311E. The instrument is made in strict compliance with the EP <2.9.8> and USP <1217> Pharmacopoeia.

Enter the nominal test information for Thickness, Diameter or Length and Hardness via the PTB 311E keyboard. Select the unit to measure, mm - IN - kp, N or Sc, now place the sample upright into the Thickness Test Holder and start the test. The driven jaw will now run forward and touch the tablets highest point to measure the thickness, thereafter it reverses back so that the sample falls into horizontal position to test diameter and hardness.

The 3 results are immediately displayed and printed to a connected Dot-Matrix or suitable PCL Type Laser- or DeskJet printer. Repeat this until your series has been tested, get a full print including each individual result, mean value and deviations.

In case you need to test hardness "only", no problem; zero Thickness and Diameter station and do hardness test only. This flexibility and the reproducibility of the results have made the PTB311E series to become one of the most sold hardness testers.

Operating Principle...

Even in the existing monographs from USP and EP is no standard force setting or force increase mode established. This usually is causing problems comparing results received of different suppliers instruments of the same tablet. The hardness result is directly influenced

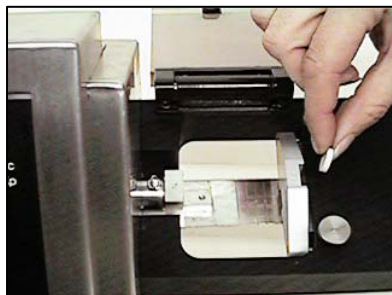
PHARMA TEST AG
Siemensstrasse 5
D-63512 Hainburg (GER)



+49 6182 9532-600
+49 6182 9532-650
email@pharma-test.de
www.pharma-test.com



Manual Tablet Testing Instrument 3-in-1 - Type PTB 311E



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, we allow to select the force mode, linear force increase or linear speed increase as we do for the rate. The only parameter we do not alter is the force touching the sample which is for all Pharma Test Hardness Test Instruments very low as if you would try to break by hand. When touched we start to increase.

Which force mode to select ?

Since more than 10 years all PHARMA TEST Hardness Test instruments offer the possibility to select either linear Force or Speed increase.

Linear force increase certainly offers the most accurate control, as the rate of increase is directly controlled by the electronically load cell used to read the force. Also it is quite simple to validate the correct and linear operation as a Tablet of 100 Newton hardness will be broken within 5 seconds if 20N/s had been set.

Linear speed increase can also be used. Here the driving speed of the stepper motor is kept linear. Actually if the touching force is kept low there is not too much difference in results between the 2 systems.

Calibration and Validation



Built-in calibration and validation program for all 3 stations. For thickness and diameter certified reference blocks, 1-20 mm, are used for both validation and calibration. To validate the hardness test station the PT-MT magnetic tablet or different certified weights are used. Use the PT-MT to qualify the correct breakpoint detection, select a force, for example 50, 85 or 130 N and run a test series, the resolution of the results should be within 1.0N. The PT-MT instrument works like a tablet, it withstands force and than “breaks”. For the 2 point calibration of the

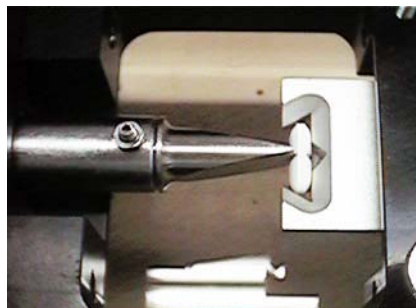
hardness station a certified reference weight of 10 kg is used. All calibration and validation results can be printed and countersigned. The PT-MT3 will be used to qualify both, breakpoint detection as well as correctness of the set force increase rate.

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 PTB-CAL3 which includes 5, 10, and 15kg, may be placed onto the load cell or the PT-MT3 to validate the linearity. Using the standard RS-232 interface, all results can be transmitted to a computer system.

The PTB 311E Tablet Test Instrument offers:

- 3 test results from the same sample
- Use automatic re-start facility to speed up the testing sequence
- Documentation of all results using a separate Matrix or PCL Printer
- OQ and Calibration program for all 3 measurement stations
- Dual Point Calibration for all 3 test stations
- Multiple Point Validation for all 3 test stations
- Programmable print-out of force increase curve
- Data transfer via RS-232 interface
- Switch any station on or off at any time
- Adjustable force control for hardness testing, select either linear force or linear speed increase
- Select units to measure thickness/diameter or length either mm or inches
- Hardness testing in compliance with the EP <2.9.8> and USP <1217> Pharmacopoeia
- Test program for soft gelatine capsule testing
- Only hardness testing instrument in the market which offers unique adjustment facilities of force increase and breaking detection force rates to meet any upcoming monograph.
- Use calibration and validation program and report results.

Testing Tension Strength of Oblong and Caplets



The specially designed sample holder and force jaw is suitable to be used in the PTB 311 Testing Instrument. It is designed to test the tension strength at the break line of shaped and also round tablets

Technical Data

Display:	LED Display for No. of samples, thickness, diameter and hardness results
Keyboard:	Numerical and function keys
Testing range thickness:	2.00 - 15.00 mm (using different jaws)
Accuracy:	Better 0.05 mm, typically 0.02 mm
Diameter:	2.00 - 40.00 mm
Accuracy:	Better 0.05 mm, typically 0.02 mm
Hardness:	2.0 - approx. 330 N (Newton)
Accuracy:	better 1N
Measuring units:	Thickness and diameter selectable in either mm (Millimetre) or IN (Inches)
Hardness Result:	Print-out and display selectable in either Newton (N), kilopond (kp) or Strong Cobb (Sc)

Manual Tablet Testing Instrument 3-in-1 - Type PTB 311E

Force rate:	Adjustable for linear force increase or linear speed increase
Range:	1 - 200.0 mm/minute or 5.00 - 99.99 N/sec.
Number of tests for statistics:	Up to 250
Calibration Procedure:	Needs 10 mm reference block and 10 kg reference weight (certified)
Validation breaking detection:	PT-MT magnetic tablet
Validation force setting:	PT-MT3 magnetic tablet
Validation linearity of the load cell:	PTB-CAL3 certified weight 5, 10, 15 kg
Validation thickness, diameter:	Certified reference blocks 2 - 40 mm
Interface:	RS-232 serial port Parallel printer port for DOT Matrix or PCL Printer Connection
Instrument Housing :	Stainless steel to meet GLP requirements

Weights and Dimensions

Net weight:	10 kg
Gross weight:	15 kg
Packaging:	450 mm x 450 mm x 640 mm

Options

- Extended hardness range up to approx. 550N
- Oblong tension strength test jaws for different shapes
- PTB32 software to enter manually individual weight of sample previous to hardness test and get calculated batch statistics.

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

Manual Tablet Testing Instrument 3-in-1 - Type PTB 311E

Typical Test Report includes Statistics

* Tablet Testing System PTB 311E * Ver. 0.773E Page : 1

Product :	Date :
Batch :	Time :
Job :	Operator :
Method :	Comment :

Th.value :	Thickness 03.00 mm	Diameter 09.00 mm	Hardness 110.0 N	Setting 20.00 N/Sec
------------	-----------------------	----------------------	---------------------	------------------------

No.	Thickness	Diameter	Hardness
1	02.93 mm	08.11 mm	106.7 N
2	02.94 mm	08.11 mm	108.6 N
3	02.95 mm	08.09 mm	092.8 N
4	02.97 mm	08.12 mm	113.6 N
5	02.98 mm	08.11 mm	095.8 N
6	02.97 mm	08.11 mm	098.7 N
7	02.95 mm	08.11 mm	097.1 N
8	02.99 mm	08.12 mm	095.8 N
9	03.13 mm	08.21 mm	124.8 N
10	03.32 mm	08.44 mm	092.8 N

* S T A T I S T I C S PTB 311E * Ver. 0.773E

	Thickness	Diameter	Hardness
Xmax	03.32 mm	08.44 mm	124.8 N
Xmin	02.93 mm	08.09 mm	092.8 N
Xdif	00.39 mm	00.35 mm	032.0 N
Xi/n	03.01 mm	08.15 mm	102.7 N
Xabs	00.12 mm	00.11 mm	010.5 N
Xrel	04.04 %	01.30 %	010.2 %

Signature