Manual Tablet Testing Instrument, PTB 311E (double test mode: linear force or speed)

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 Pharmacopoeia.

Enter the nominal test informations for Thickness, Diemater 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, meanvalue 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 reproduceability of the results have made the PTB311E series to become one of the most sold hardness testers.

Operating Principle

There is no monograph or standard established yet which informs how a Tablet Hardness Tester has to work. This often causes problems comparing results received of different suppliers instruments of the same tablet. The hardness result is directly influenced by the **contact speed** and **force increase** rate. Faster operated test jaw means lower reproduciablity 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

Pharma Test Apparatebau GmbH
Siemensstraße 5 Tel:+49-6182-9532-600 Email:email@pharma-test.de
D-63512 Hainburg/Germany Fax:+49-6182-9532-650 Internet:www.pharma-test.de

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 tp select either linear Force ob Speed increase.

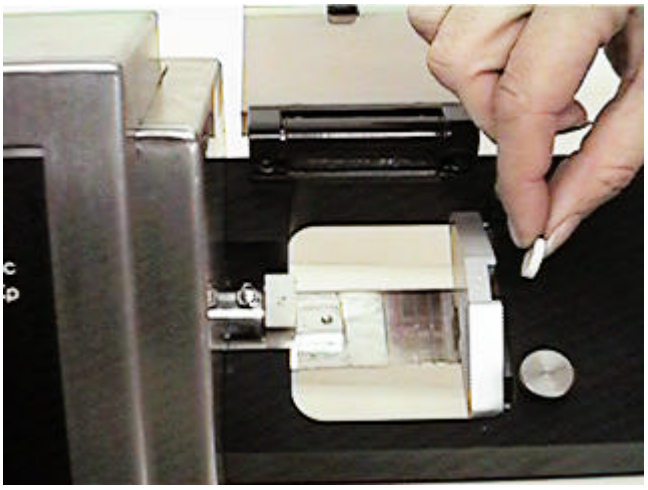
Linear force increase certainly offers the most accurate control, as the rate of increase is directly controlled by the electronical load cell used to read the force. Also it quite simple to validate the correct and linear operation as a Tablet of 100 Newton hardness will be broken within 5 seconds if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

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 diamater certified reference blocks, 1-20 mm, are used for both validation and calibration. To validate the hardness test station the **PT-MT2** magnetic tablet is used. Select a force of 50, 85 or 130 N and run a test series, the resolution of the results should be within 1.0N. The PT-MT2 instrument works like a tablet, it withstands force and than “breakes”. 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.

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. Using the standard RS-232 interface, all results can be transmitted to a computer system.



Place the Tablet or Oblong into the Thickness Jaw. Surely the coorect thickness will be measured, no matter of shape and size of sample due to the desing of the Jaw.

After Thickness has been measured the sample is turned automatically into the horicontal position to test Diameter and Hardness

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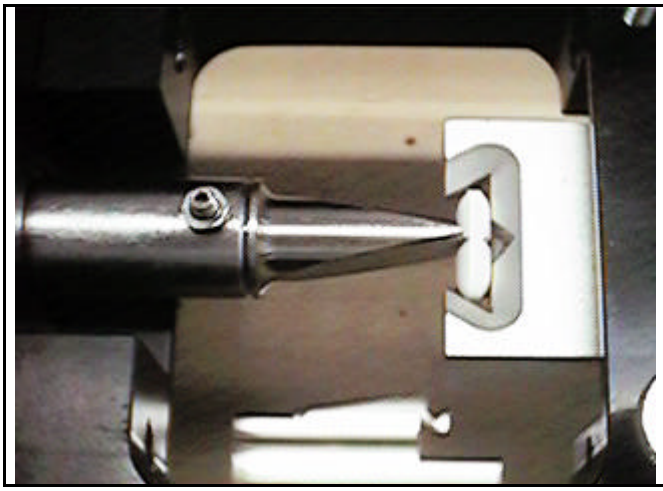
The PTB 311E Tablet Test Instrument offers:

- 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.
- 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 and German DAB Pharmacopoeia.
- Test program for soft gelatine capsule testing
- Only hardness testing instrument in the market which offers unique adjustement facilities of force increase 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 or PTB 411 Testin 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)
Accurracy:	better 0.05 mm, typically 0.02 mm
Diameter:	2.00 - 40.00 mm
	better 0.05 mm, typically 0.02 mm
Hardness:	2.0 - approx. 330 N (Newton)
Accuracy:	better 1N
Measuring units: (Inches)	thickness and diameter selectable in either mm (Millimetre)or IN
	hardness selectable in either Newton (N), kilopond (kp) or Strong Cobb (Sc)
Force rate:	adjustable for linear force increase or linear speed increase

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Range:	5 - 50 mm/minute or 5 - 50 N/sec.
Number of tests for statistics	up to 250
Calibration Procedure:	needs 10 mm reference block and 10 kg reference weight (certified)
Validation:	PT-MT2 magnetic tablet at 50 - 85 and 130 N
Interface:	RS-232 serial port parallel printer port
Instrument Housing :	stainless steel to meet GLP requirements

Options

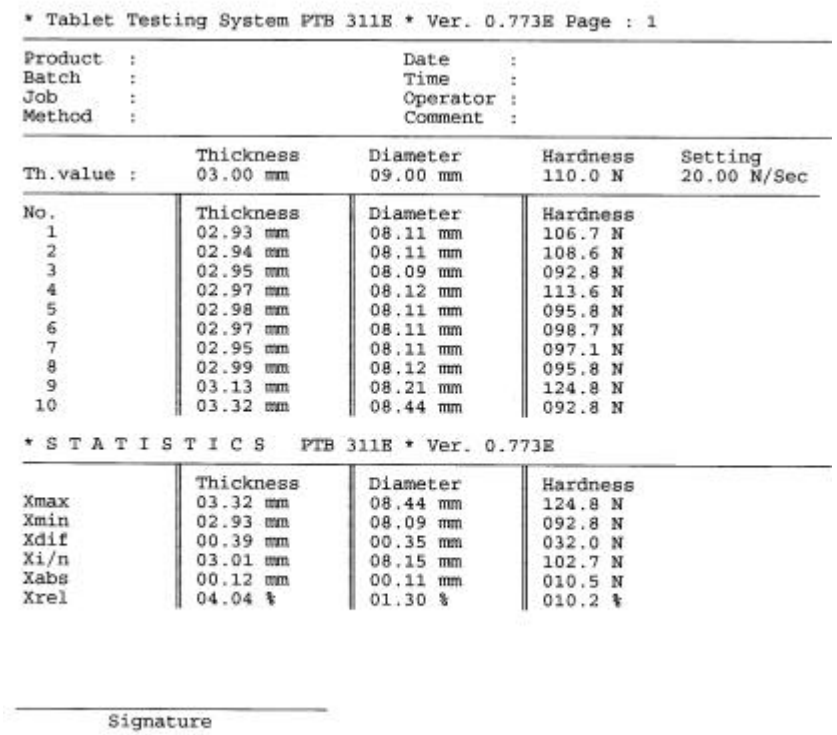
Extended hardness range up to approx. 550N.
Oblong tension strength test jaws for different shapes.
PTB32 software to enter manually individual weight of sample previous to hardness test and get calculated batch statistics.

Weights and Dimensions

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

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

Typical Test Report includes Statistics



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

	Thickness	Diameter	Hardness	Setting
Th.value :	03.00 mm	09.00 mm	110.0 N	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

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