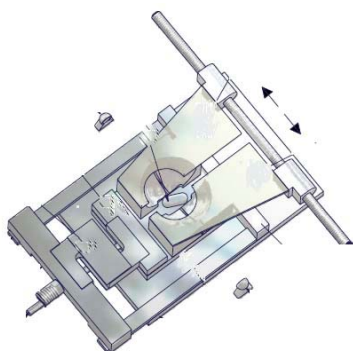


Semi Automated Tablet Testing Instrument 3in1 - Type PTB 320



The Semi Automated Tablet Testing Instrument **PTB 320** is a **dual test mode** apparatus as it can be used for either linear force or linear speed increase while Tablet Hardness is tested. Prior to the hardness of the tablet (sample) test it can measure the sample height and diameter (length).

Test Thickness, Diameter or Length and Hardness of the same Tablet using just one Instrument, the PTB 320. 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 alpha-numerical touch sensitive glass keyboard. Select the unit to measure, mm - IN, Kp, N or Sc. Place the sample into the unique sample positioning station for correct alignment inside the Thickness and Hardness test station. A Laser Beam is used for the touch free measurement of the sample thickness. Thereafter the sample is automatically moved towards the force jaw to measure diameter/length and finally its hardness. When finished the sample dish moves backwards to

drop the tested sample fragments into the collection shoot.

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



Semi Automated Tablet Testing Instrument 3in1 - Type PTB 320

The 3 results are immediately displayed and may be 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 report 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.

Testing Method File ...

In order to describe the testing procedure, linear force or speed increase, tolerance ranges for the 3 tests, number of samples to be tested a Method filing system is included, its filing capacity is close to unlimited. To start a test, call the valid Method and add product descriptive information, such as a batch number. When finished start the test.

Together with the Method filing system a user access and user rights control system is incorporated. Only authorised users can operate, qualify and calibrate the system.

Optional Equipment ...

The PTB 320 includes a RS232 interface to connect a Mettler or Sartorius Analytical **Precision Balance of 0.1 mg accuracy**. Using this option it is possible to test the individual weight of a sample prior to the test of its physical parameters of height, diameter and hardness. The samples have to be placed manually from the balance dish to the alignment position inside the PTB 320. Or the optionally available **Tablet Transport Magazine** may be used.



The Tablet Transport Magazine holds 10 samples, maximal diameter 25 mm. It is connected by a magnetic coupling to the drive inside the PTB 320. The transport belt moves forward to drop one sample directly into the alignment station inside of the PTB320.

When the test has been finished and the sample is released into the shoot the next sample is supplied automatically.

As the Tablet Transport Magazine can easily be removed from the PTB 320 it may be used to collect samples directly from a tablet press to be re-installed for testing. Actually its possible to use several magazines, one for each Tablet press.

Operating Principle...

The recently published monographs of the USP and EP Pharmacopoeia inform how a Tablet Hardness Tester should work but without establishing data of how to increase the applied force and when to detect a sample to be broken. 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 reproducibility and often higher results. In order to offer the possibility to select

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



Semi Automated Tablet Testing Instrument 3in1 - Type PTB 320

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. Another parameter you can adjust is the breaking detection signal, this is often useful to test softer samples.

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 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. But validation of this mode is reasonably difficult and requires specific equipment.

Calibration and Validation

An access controlled built-in calibration and validation program for all 3 stations is available. 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-MT3 magnetic tablet or different certified weights may be used. On the PT-MT3 select any force within 5 to 300N (500N) and run a test series, the resolution of the results of the PTB320 should be within 1.0N. The PT-MT3 instrument works like a tablet, it withstands force and then "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. Its also possible to use 3 different weights to qualify the correct load cell operation.

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 USB or Bluetooth interface, all results can be transmitted to a computer system.

The PTB 320 Tablet Test Instrument offers:

- 3 (or 4) test results from the same sample
- Use automatic re-start facility to speed up the testing sequence
- Use of a Tablet Transport Magazine for up to 10 samples
- Testing Method filing system
- User Access control and access right administration
- Documentation of all results using a separate Dot-Matrix or PCL Printer
- OQ, Calibration and Validation program for all 3 measurement stations
- Multiple point validation for the hardness test station
- Programmable print-out of force increase curve

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



Semi Automated Tablet Testing Instrument 3in1 - Type PTB 320

- Data transfer via USB or Bluetooth 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
- Use calibration and validation program and report results.

Technical Data

Display:	LC Display for No. of samples, thickness, diameter and hardness results
Keyboard:	Touch sensitive glass panel with alpha-numerical and function keys
Testing range thickness:	2.00 - 15.00 mm
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)
Force rate:	Adjustable for linear force increase or linear speed increase
Range:	5 - 150 mm/minute or 5 - 150 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-MT3 magnetic tablet at 50 - 85 and 130 N Different certified weights
Interface:	RS-232 serial port to connect a Mettler or Sartorius Balance USP Port Bluetooth
Instrument Housing :	Stainless steel to meet GLP requirements

Weights and Dimensions

Net weight:	14 kg
Gross weight:	19 kg
Packaging:	500 mm x 450 mm x 640 mm

Options

- Extended hardness range up to approx. 550N
- 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

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

