

PTB 500

Semi-Automated Tablet Testing System with Integrated Balance

The semi-automated tablet testing system PTB 500 is a dual test mode instrument to measure five different parameters of one sample. Hardness, diameter (or length), thickness, width and the weight of tablets can be determined here. The instrument features an integrated analytical balance and a sample carousel. The instrument is made in strict compliance with the EP <2.9.8> and USP <1217> Pharmacopoeia.



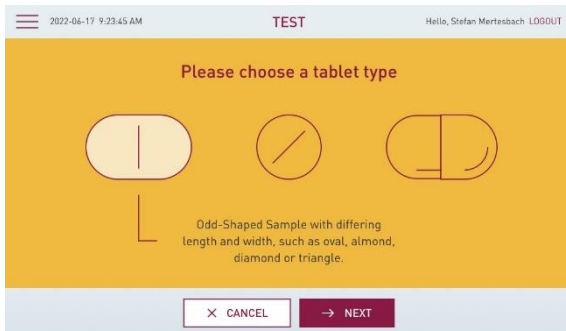
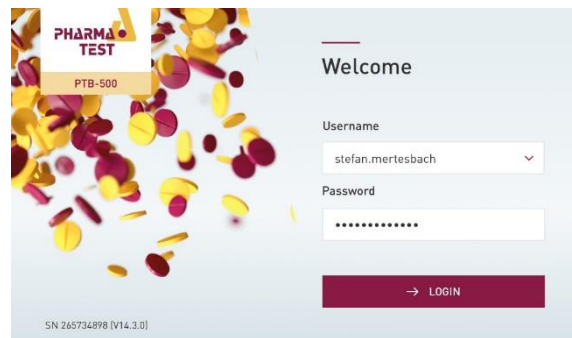
Measurement of 5 different parameters



PTB 500 features a carousel to transport the samples between the weight, thickness and combined width, diameter (or length) and the hardness testing station. It features an integrated Sartorius analytical balance to measure the weight of the individual samples. The measuring units can be selected from mm or Inch and KP (Kilopond), N (Newton) or Sc (Strong Cobb).

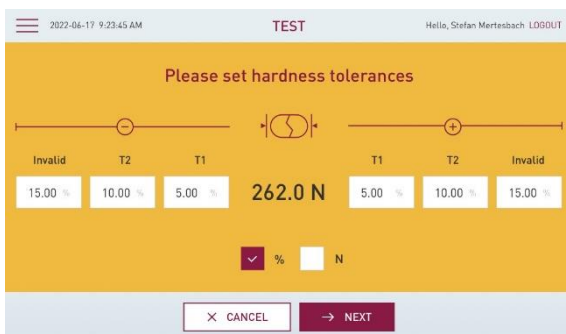
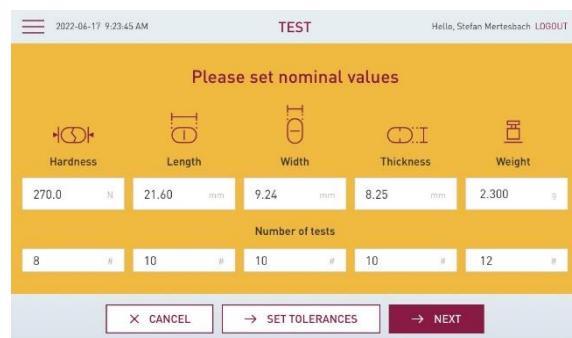
Running a Test

PTB 500 features a large, back-lit colour LCD. Navigate the menu using the touch screen or connect a standard keyboard and mouse. There are two ways to start a test with PTB 500 – start a quick test immediately after powering on the instrument without logging on or login to start a method-based test.



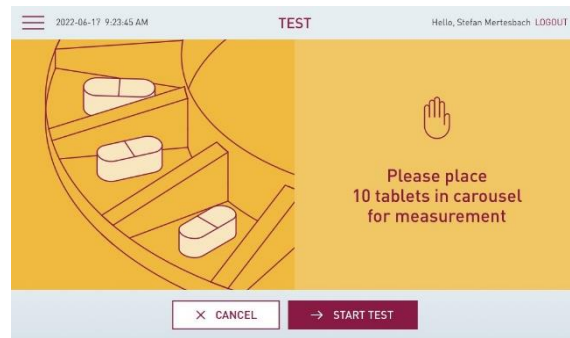
When running a test, you first choose the approximate tablet shape (round, oblong or capsule) and afterwards enter the nominal values or directly start a test without entering this information. Just enter the batch number and start the test.

A method-based test includes the option as well to choose the tablet shape and to enter the nominal values first but also offers the option to “learn” the parameters instead of entering the nominal values.

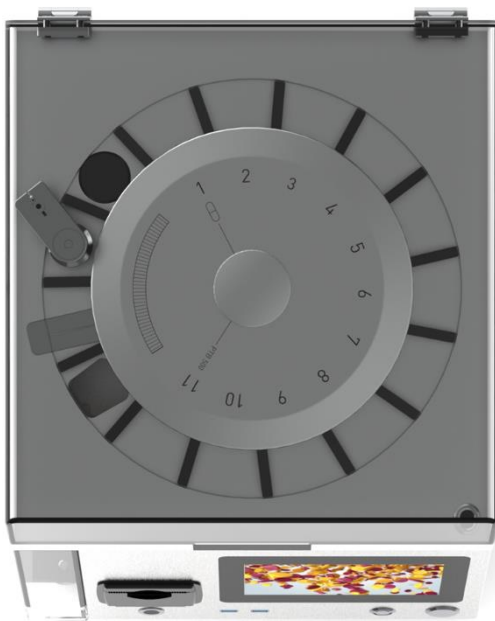


For this several tablets can be tested one after the other and the instrument will calculate the mean values of each parameter and propose these in a newly created method. The values can then be changed from there by the user as well. You can also define acceptance criteria by entering tolerances.

Place the tablets into the carousel of the instrument. The instrument gives clear instructions including pictures to the user at every step and will ask you to insert additional samples in case more are required than carousel chambers are available.



Test Procedure



The samples are automatically transported to the test stations by the rotating carousel. First the weight is measured by the integrated Sartorius analytical balance. Then the thickness is measured and third comes the combined diameter (or length) and hardness testing station. It is also possible to measure the width of the sample. In this case the operator is prompted to position the sample accordingly in the test station.

Now for the diameter (or length) and hardness measurement the force jaw will move forward, touch the tablet at its highest point to measure the diameter and immediately its hardness (tablet breaking force).

Finally, the broken sample is discarded into the waste container.

The on-screen menu will lead the user through the test at all times. The five results are immediately displayed and can be printed directly or transferred to a LIMS system. The results are saved to the internal database of the instrument and can be always reviewed.

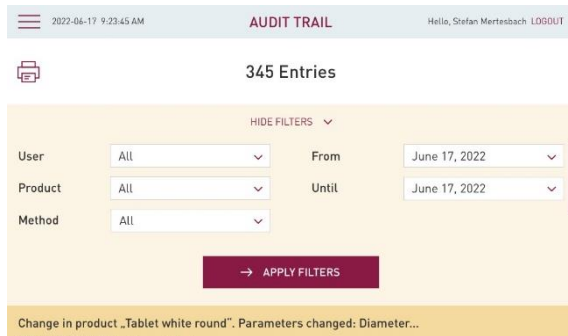
#	WEIGHT	THICKNESS	WIDTH	LENGTH	HARDNESS
1	2.299 g	8.24 mm	9.24 mm	21.67 mm	262.1 N
2	2.320 g	8.25 mm	9.25 mm	21.64 mm	285.5 N +T1
3	2.310 g	8.26 mm	9.23 mm	21.60 mm	275.1 N
4	2.260 g	8.21 mm	9.24 mm	21.59 mm	232.1 N -T1
5	2.309 g	8.22 mm	9.25 mm	21.58 mm	271.8 N
6	2.289 g	8.24 mm	9.25 mm	21.54 mm	297.5 N +T2
7	2.288 g	8.24 mm	9.25 mm	21.55 mm	297.5 N +T2

When printing via either a printer directly connected by USB or a network printer three options are available: print the data including each individual result as well as product information, date, time, user, instrument serial number, statistics can be added to this information of just print the breaking curve of the last broken tablet.

It is always possible to activate or de-activate separate testing stations. This way it is possible to just test the hardness of a tablet without measuring any other parameters. For this, deactivate the other parameters like thickness by leaving the field for the nominal value and number of samples empty.

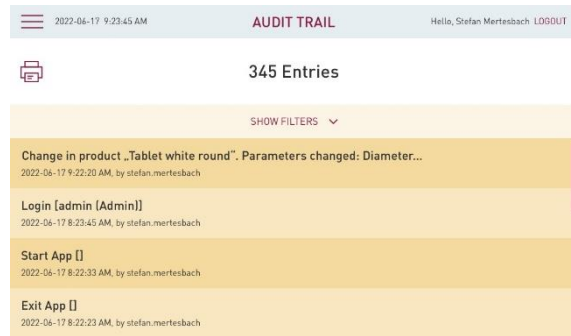
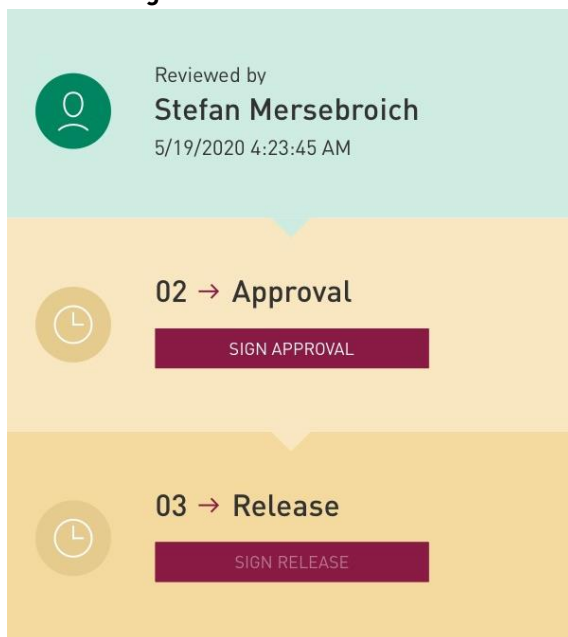
Audit Trail

PTB 500 features an audit trail that displays all events according to 21 CFR Part 11 requirements. The events can be displayed on the instrument itself and be printed for examples as PDF for documentation purposes.

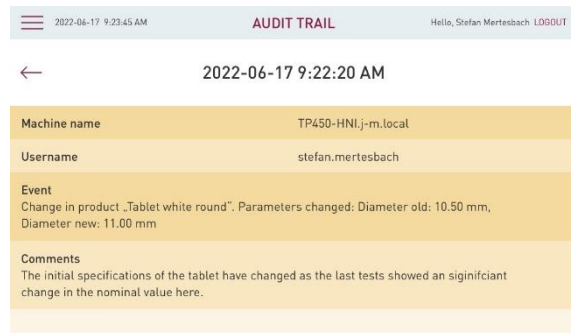


For each event a detailed description is available with mention of the related user, method and product and which value has been changed from what to what.

Electronic Signatures



The events of the audit trail can be filtered by user, product, method and date of the event.



PTB 500 features a three-step approval process with electronic signatures according to 21 CFR Part 11 requirements. After creating or changing a method the user has to confirm the changes with his login information. The method is assigned the reviewed status. A second user has then sign in with his information approve the change. Finally, a third user releases the new or updated method. Only released methods can be used to run tests.

For use in unregulated environments this three-step approval process can be deactivated but once this is enabled all changes have to go through this process to comply with the data integrity requirements of 21 CFR Part 11.



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. The instrument offers also the option to test capsules with the help of a special procedure, which allows the instrument to just touch the sample, compressing, but without breaking it.

Which Force Mode Should Be Selected?

Since more than 10 years ago all Pharma Test tablet hardness testing instruments offer the possibility to select either linear force or linear speed increase. Linear force increase 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 with, for example 100N hardness, will be broken within 5 seconds, when 20N/s had been set as force increase rate. Linear speed increase can also be used; here the driving speed of the stepper motor is kept linear.

Actually, as long as the touching force is kept low, there is not too much difference in the results between the two modes, but validation of this mode is reasonably difficult and requires specific equipment. In general results obtained with the linear speed increase mode are less reproducible than the ones with linear force increase mode. Therefore, Pharma Test recommends using linear force increase. We will continue to offer both modes of operation to offer the possibility of comparing results of different instruments by setting the same parameters of operation.

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 using 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. The PTB x30 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 thickness, width and diameter (length) station, certified reference blocks are used for both calibration and adjustment. Weight sets are used to calibrate and adjust the force sensor (load cell) of the instrument over the complete measuring range. 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 PTB-CAL15 and PTB-CAL30 weight sets which include 5, 10, 15kg and 30kg (PTB-CAL30) using two additional 10kg weights for total 50kg, may be placed onto the load cell or the PT-MT3 and can be used to validate the linearity. Using the RS232 COM port, a Matrix or PCL5 printer can be added, and all results can be transmitted to software running on a computer system.



Advantages

- » Select either linear force or linear speed increase (dual mode selection)
- » Stepless adjustment of the force or speed increasing rate
- » Sophisticated user-management
- » Sophisticated method and user management with fingerprint sensor system included
- » Entry of time and date
- » Test start functionality to start testing with minimal preparation
- » Automatic re-start facility to speed up the testing sequence
- » Directly connectable to LIMS or other network options
- » 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) up to 30 or 50kg
- » Programmable print-out of force increase curve
- » Serial data transfer via RS-232 interface
- » Test program for soft gelatin capsule testing by setting up a testing distance

Features

- » Tablet hardness testing in full compliance to USP <1217> and EP <2.9.8> Pharmacopeia
- » 5 results of the same sample: thickness, width, diameter (length), hardness and weight (via connected external analytical balance)
- » Dual force mode instrument with linear speed increase and linear force increases modes
- » Statistical calculations of mean value, absolute and relative standard deviations, minimum and maximum result
- » Networking capabilities
- » Multiple point validation procedure built-in
- » Programmable print-out of force increase curve
- » Graphical user interface with clear operator instructions
- » Set to test tension strength of oblongs and caplets available



Standard Scope of Supply

The PTB 500 comes ready to use with the following standard scope of supply:

- » Broken sample collector
- » 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:

- » 500N (PTB 500-500) and 1,000N (PTB 500-1000) extended force range
- » Recommended spare part set
- » Full range of certified validation tools available
- » Different splints for tablet guidance in test station via exchangeable bottom plates

Technical Specifications

Parameter	Specification
Number of testing stations	5 (Hardness, Thickness, Width, Diameter/Length, Weight)
Hardness testing range	PTB 500: 2.0 – 300.0 N ± 10 N PTB 500-500: 5.0 – 500.0 N ± 50 N PTB 500-1000: 10.0 – 1,000.0 N ± 50 N
Hardness accuracy	Better than 1N
Hardness resolution	0.1N
Thickness testing range	2.00 – xx.00 mm
Thickness accuracy	Better than ±0.02 mm
Width & diameter testing range	2.00 – xx.00 mm
Width & diameter accuracy	Better than ±0.02 mm
Thickness, width & diameter resolution	0.01mm
Weight measurement	By internal Sartorius balance cell
Weight testing range	0.0001g – 200.0000g
Weight accuracy	0.1mg
Measuring units	Thickness, diameter and width selectable between millimeter (mm) and inches (IN); Hardness selectable between Newton (N), Kilopond (kp) and Strong Cobb (Sc)
Force mode	Selectable: linear force increases or linear speed increase
Force rate	5 – 250 N/sec. (linear force increase); 5 - 250mm/Min. (linear speed increase)
Display	7", high resolution color LCD, backlit
Data entry	Touch screen, USB keyboard and/or mouse supported
Instrument firmware compliance	21 CFR Part 11 compliant user management and result database, electronic signatures, integrated audit trail
Method storage	Integrated database
User management	Integrated database
Result storage	Integrated database
Interface	USB, LAN
Printer	Built-in thermal printer (optional), connect standard USB or LAN printers
Instrument Housing	Stainless steel (304) to meet GLP requirements
Power	115/230 Volt AC, 50/60 Hz
Installation Requirements	Ambient Temperature 15-35 °C Relative Humidity 15-80 %rH Desk with at least 50 kg working load. All around the instrument at least 10 cm free distance to walls or other equipment. Free access to the mains power plug and switch.
Instrument Dimensions	Approx. 500 x 500 x 400 mm (Length x Width x Height)
Packaging Dimensions	Approx. 650 x 660 x 440 mm (Length x Width x Height)
Net / Gross Weight	Approx. 25 kg / 30 kg (without optional accessories)
Certification	All components certified to USP / EP requirements
CE / EMC Certification	All CE / EMC Certification provided
Validation	All IQ & OQ documents included

Features are subject to change due to ongoing development. We reserve the right to make technical changes without any prior notice.