

PTB-M

Manual Tablet Hardness Testing Instrument

PTB-M is a manual hardness testing instrument for tablets. The instrument is made in strict compliance with the EP <2.9.8> and USP <1217> Pharmacopoeia. PTB-M is very easy to use. Simply place the sample on the testing platform and rotate the knob manually. The jaw will move and force will be applied to the sample. The force is monitored electronically and displayed at the moment of breakage.



Test Procedure

The hardness value is displayed on the four digit LED display in either Newton (N), Kilopond (Kp), StrongCobb (Sc) or Pounds (Lb). The units can be changed by the press on one button on the instruments control panel. The instrument is battery operated. A power adapter may also be used and is included in the standard supply scope. The results can be documented by connecting a PT-RP80 report printer to the serial printer port of the PTB-M.

Calibration and Validation



Using the certified PTB-CAL15 weight set, calibration of PTB-M can be carried out on site and requires only a few minutes. 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. The PTB-M 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 counterweights 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.



Example Test Report

Hardness Tester PTB-M 300N
 COMPANY NAME:Pharma Test
 LOCATION:QC Lab
 INST. SR. NO.:20378 2.81
 MODEL NO:PTB-M
 CAL. DATE:06/06/15
 CAL. DUE DATE:06/09/15

TEST DATE: 06/06/15 15:42

PRODUCT: _____

BATCH : _____

TEST DETAILS

UNIT: N

SR. NO.	HARDNESS
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1	30.1
2	30.2
3	30.0
4	29.9
5	30.1
6	30.0
7	30.1
8	30.1
9	30.2
10	30.1

MAX : 30.2 MIN : 29.9

MEAN: 30.1

PERFORMED BY: _____

APPROVED BY : _____



Advantages

- » Compact, portable instrument
- » Features the same high quality force sensor as other Pharma Test hardness testers
- » Very easy to use, immediate results
- » Entry of time and date
- » Can be operated by 9V battery or using supplied power adapter
- » Select result display unit from Newton (N), Kilopond (Kp), StrongCobb (Sc) and Pounds (Lb)
- » Documentation of all results using the optional PT-RP80 report printer
- » Easy to calibrate

Features

- Fully USP <1217> and EP <2.9.8> compliant
- Hardness Range: 5 N to approx. 300 N (500N optional)
- Accuracy: 0.1 N
- Resolution: 0.1 N/0.01 Kp
- Test tablet sizes of up to 28mm diameter
- Includes a 4 digit LED display and indicator for selected unit
- Connect PT-RP80 report printer to document the results (optional)
- Calibration program included

Standard Scope of Supply

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

- » Removable broken sample container and cleaning brush
- » Power adapter
- » 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-M500) extended force range
- » PT-RP80 report printer to document results
- » Recommended spare part set
- » Full range of certified validation tools available

Technical Specifications

Parameter	Specification
Display	LED Display, 4 digits showing hardness result
Data Entry	Functional keys
Standard Force Range	5.0 to approximately 300N (500N optional)
Accuracy	0.1N
Maximum Sample Size	28 mm diameter
Printer	Printer port to connect PT-RP80 report printer
Interface	RS-232 COM port
Calibration Guidance	Built-in calibration procedure for 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	PT-MT3 Magnetic Tablet and suitable support
Reproducibility	
Bench Space Requirement	275cm x 90 x 100 mm (Length x Width x Height) without external printer
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.