



Manual Ampoule Breakpoint Test Instrument, PTBA 211E

PTBA 211E, ampoule breakpoint tester acc. DIN/ISO 9187 standard

According to the DIN/ISO standards ampoule hardness has to be tested in order to control the quality during production. The PTBA 211E instrument meets the technical requirements mentioned in the ISO 9187 in all details.

Principle of Operation

The testing jaw is moved by means of a stepper motor into the neck of the ampoule to be tested. The instrument then increases the force in a linear mode until the sample breaks, usually at 10 mm/min. As soon as the ampoule is broken, the maximum force will be displayed and printed. The test jaw moves back to the home position ready for the next test. As the operator can enter an automatic re-start time, the next test will be performed immediately after a new sample has been placed onto the ampoule support.

A movable tray holds the ampoule support, a plexiglass (perspex) screen protects the operator.

Exchangeable ampoule supports allow the test of all kinds of ampoules from 1-30 ml.

Calibration and Validation



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.

Validation Report

| Specification | Comment | Result | Limits |
|--|-------------------------------|--------------|-------------------------|
| CALIBRATION REPORT | | | |
| AMPOULE-BREAKPOINT TESTER TYPE PTBA 211E | | | |
| Software Version : PTBA 211E Ver. 0.65E | | | |
| Instr. Serial NO. : 000736 Time: _ _ _ Date: _ _ _ | | | |
| Calibration | | | |
| Sero-Value 0kg : | Loadcell vertical | 00010 Digits | 5 - 15 Digits |
| Ref.-Value 10kg : | Loadcell vertical | 00109 Digits | 285 - 315 Digits |
| Range 0kg-10kg : | | 00299 Digits | 280 - 300 Digits |
| Validation | | | |
| Sero-Value 0kg : | Loadcell vertical | - - - kg | 0.1 - 0.4 kg |
| Ref.-Value 10kg : | Loadcell vertical | - - - kg | 10.1 - 10.4 kg |
| Range 0kg-10kg : | | - - - kg | 9.9 - 10.1 kg |
| Max. Force : | Hardness on block | - - - N | 300.0 - 360.0 N |
| Measured time : | to max. force | - - - Sec | 15.0 - 18.0 Sec |
| Act. Offset-Value : | vertical downward | 00004 Digits | 1 - 13 Digits |
| Touch detection : | | 00012 Digits | |
| Hardn. detection : | hardness decrease | 00013 Digits | |
| Act. force setting : | | 010.0 mm/Min | |
| Max. hardness path : | hardness test within 02.00 mm | | 2.0 - 10.00 mm |
| Opt. Startposition : | Start from home position | | (Select use CAL + 7 +1) |
| Diameter Calibration (Diff. steps: CO-Cl= 6666 +/-13 = OK) | | | |
| Sero-Value 10 mm : | Full range: >20667 | 21751 Steps | CO in No display = OK |
| Ref.-Value 20 mm : | Refer. 20mm: >20667 | 15096 Steps | Cl in No display = OK |
| Instrument calibrated AT: _ _ _ | | | |
| Calibration operator : _ _ _ O Factory: _ _ _ | | | |
| Signature _____ O PHARMA TEST (printed with keys <CAL>+<Print>) | | | |

The microprocessor controlled PTBA 211E instrument offers the following features:

- selectable force increase rate, 5-50 N/sec
- selectable speed increase rate, 5-50 mm/min (standard setting 10 mm/Min.)
- use automatic re-start facility to speed up the testing sequence
- documentation of all results using a separate Printer.
- OQ and Calibration program for all 3 measurement stations.
- ampoule testing in compliance with the DIN/ISO 9187 standard.
- programmable print-out of force increase curve
- built-in printer connection port to connect any Matrix or PCL printer
- built-in RS-232 interface

- calibration menu for the hardness test station
- reproducible results
- LED display and keyboard
- statistical calculation of results
- print-out of PQ result data
- exchangeable ampoule supports

Technical Data

| | |
|--|---|
| Display: | LED Display for No. of samples, thickness, diameter and hardness results |
| Keyboard: | numerical and function keys |
| Hardness: | 2.0 - approx. 330 N (Newton) |
| Accuracy: | better 1 N |
| Measuring units: | hardness selectable in either Newton (N), kilopond (kg) or Strong Cobb (Sc) |
| Force rate: | adjustable for linear force increase or linear speed increase |
| Range: | 5 - 50 mm/minute or 5 - 50 N/sec. |
| Number of tests previous to statistic: | 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 port printer port |

Weights and Dimensions

| | |
|---------------|--------------------------|
| Net weight: | 19 kg |
| Gross weight: | 24 kag |
| Packaging: | 450 mm x 450 mm x 650 mm |

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

Typical test report

PHARMA TEST AMPOULE-BREAKPOINT TESTER PTBA211 (V:0.65E) Page : 1

Manufacturer: _____ Ampoule size : _____

Batch : _____ Machine-No. : _____

Place : _____ Date : _____ Time : _____

Th.-Max: 050.0 N Th.-Min: _____ Setting : 010.0 mm/Min

Results

1=044.3 N, 2=043.9 N, 3=038.7 N, 4=041.3 N, 5=040.3 N,
6=035.7 N, 7=038.4 N, 8=047.9 N, 9=045.6 N, 10=042.6 N,

*** S T A T I S T I C S PTBA 211 ***

| | Hardness |
|------|----------|
| Xmax | 047.9 N |
| Xmin | 035.7 N |
| Xdif | 012.2 N |
| Xi/n | 041.9 N |
| Xabs | 003.7 N |
| Xrel | 008.9 % |

Signature