PTBA 211E

Ampoule Breakpoint Testing Instrument

The PTBA 211E ampoule breakpoint tester is design and manufactured in compliance to the EN-ISO <9187-1/2:2010> standard. According to the DIN/ISO standards Ampoule Breakpoint has to be tested in order to control the quality during production of empty ampoules and prior to the filling process.

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The result is immediately displayed and printed to a connected dot-matrix or suitable PCL5 type Laser-Jet or a Dot-Matrix printer. Repeat this until your series has been tested, get a full print-out including each individual result, date, time, serial number of the instrument, batch number of the product tested, mean value and deviations of the test series.

Operating Principle

The testing jaw is moved by means of a stepper motor into the neck of the ampoule to be tested. The ampoule is placed onto a DIN/ISO compliant support. As soon as the jaw meets the ampoule the instrument increases the force in a linear speed mode until the sample breaks, the usual force rate is 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 Plexiglas (Perspex) screen protects the operator. A built-in lamp illuminates the handling area to ease the correct positioning of the ampoule at the support. Exchangeable ampoule supports allow the test of all kinds of ampoules from 1-30ml.

Calibration and Qualification

All Pharma Test hardness testing instruments can be statically qualified over the complete measuring range by the use of different traceable counterweights. All instruments support the checking of at least three different points during qualification to prove the linearity of the force sensor. Furthermore, Pharma Test offers the PT-MT3 magnetic tablet/ampoule to calibrate the breakpoint detection of the whole ampoule breakpoint testing instrument (force sensor and mechanics of the instrument).

PT-MT 3

The PTBA 211E offers a built-in calibration and qualification program for the hardness test station. To validate/qualify the hardness test station the PT-MT3 magnetic tablet/ampoule or different certified counterweights are used. Use the PT-MT3 to qualify the correct breakpoint detection, the PT-MT3 instrument works like an ampoule, 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 of the PT-MT3 or 5 up to 30kg certified counterweights is recommend-ded. 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 CAL-15 and CAL-30 which includes 5, 10, 15kg and also 30/50kg may be placed onto the load cell to validate the linearity. All results will be printed or using the RS-232 COM port, all results can be transmitted to PC software running on a computer system.

Validation Report

CALIBRATION REPORT AMPOULE-BREAKPOINT TESTER TYPE PTBA 211E
Software Version : PTBA 211E Ver. 0.65E
Instr. Serial No.: 000736 Time: __ : __ Date: __ . __ . __

Specification	Comment	Result	Limits
Hardness	**Calibration**		
Zero-Value 0kg:	Loadcell vertical	00010 Digits	5 - 15 Digits
Ref.-Value 10kg:	Loadcell vertical	00309 Digits	285 - 315 Digits
Range 0kg-10kg :		00299 Digits	280 - 300 Digits
Hardness	**Validation**		
Zero-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	3 - 13 Digits
Touch detection :		00012 Digits	
Hardn. detection :	hardness decrease	00033 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: C0-C1= 6666 +-13 = OK)**		
Zero-Value 10 mm:	Full range: >20667	21751 Steps	C0 in No display = OK
Ref.-Value 20 mm:	Refer.20mm: <20667	15096 Steps	C1 in No display = OK

Instrument calibrated AT: ____ . ____ . ____

Calibration operator : _____ O Factory: _____

_____ O PHARMA TEST
Signature (printed with keys <CAL>+<Print>)

PTB-CAL 15

Advantages

» Entry of time and date
» Enter a 12 digit batch number
» Automatic re-start facility to speed up the testing sequence
» Documentation of all results using a separate Dot-Matrix or PCL5 printer
» 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)
» Programmable print-out of force increase curve
» Data transfer via RS-232 interface
» Breakpoint testing of empty ampoules in compliance with the EN ISO <9187-1/2:2010>
» Speed increase rate factory setting: 10mm/min.
» Force increase rate 20-200 N/s can be set alternatively

Features

» Dual force mode instrument with linear speed increase and linear force increase modes
» Multiple point validation procedure built-in
» Programmable print-out of force increase curve

Standard Scope of Supply

The PTBA 211E comes ready to use with the following standard scope of supply:

» Standard Jaw set to allow breakpoint test of all size of ampoules up to 30ml
» Broken Sample collector and protection shield
» 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 (PTBA 211E-500) extended force range
» Dot-Matrix or PCL5 Laser Printer
» Recommended spare part set
» Full range of certified validation tools available

Technical Data

Parameter	Specification
Display	LED Display showing number of tests and breakpoint result
Data Entry	Numerical and Functional keys
Standard Force Range	5.0 to approximately 300N (optional 500N)
Accuracy	< 1N
Resolution	0.074N (300N model) - 0.1482N (500N model)
Force Settings	Linear speed or linear force increase (standard setting: 10 mm/Min)
Selectable Range	5.0 - 200 N/Second or Millimeter/Minute
Accuracy	< 2% force or < 0.1% speed
Printer	Parallel Interface to connect Dot-Matrix or PCL 5 Printer
Interface	RS232 COM port
Calibration Guidance	Built-in calibration procedures the digital load cell
Adjustments	Two point adjustment - zero and 10kg
Calibrations	Multiple point for load cell precision using certified weights (PT-CAL15/30 and PT-CAL 50)
Force Detection Reproducibility	PT-MT3 Magnetic Tablet and suitable support
Instrument Housing	Stainless Steel (312) to meet GLP requirements
Bench Space Requirement	L 30cm x W 30cm x H 48cm (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.