PTB 311E/311E-500/311E-800 Series of Automated Tablet Testing Instruments

Operation Qualification (OQ)

Version 6.3

For firmware version 4.02 and newer

Pharma Test Apparatebau AG
Siemensstrasse 5
D-63512 Hainburg / GERMANY

T: +49 6182/9532-600
F: +49 6182/9532-80
Email: info@pharma-test.de
Web: www.pharma-test.com

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Document History

Version	Valid from [dd.mm.yyyy]	Author	Change	Remark
5.2	08.09.2015	PTAG	N	New document format
5.3	27.07.2016	PTAG	C	Correction of misprint in section 5.7
5.4	25.10.2017	PTAG	R	PTB 311E-800 added
5.5	18.02.2020	PTAG	R	Section 4.21.2 PTB311-500 maximum force enlarged
5.6	15.10.2021	PTAG	R	Epson printer TM-U220D added
6.0	13.12.2022	PTAG	R	New features added (CAL functions and additional width measurement station)
6.1	17.05.2023	PTAG	R	Section 4.21.3 max hardness PTB311E-800 enlarged
6.2	06.10.2023	PTAG	R	Section 4.22 text correction
6.3	20.10.2023	PTAG	R	Expanded descriptions for sections 4.9, 4.10, 4.12, 4.16 and 4.17

Table 1: Document History

Index Explanation - Change:

N = New Document
C = Correction
R = Revision

Introduction

General

Operational qualification (OQ) is the process by which all functions of the Pharma Test instrument are being validated. For all tests performed, the results are recorded and the pass/ fail evaluation of all tests is determined by comparing the results with pre-determined acceptance limits. The procedure used to certify performance and any certified/accredited procedure that forms the test and certification of the equipment will be identified and/or included in the protocol.

Equipment

The Pharma Test PTB 311E/ 311E-500/ 311E-800 series tablet testing instrument is composed of:

- The PTB 311E, PTB311E-500 or PTB 311E-800 tester
- All required accessories
- Options supplied as specified by customer
- Options as per customer order

The PTB 311E/ 311E-500/ 311E-800 series automated tablet tester is used to test the hardness (tablet breaking force), thickness, width and diameter of solid dosage forms, such as tablets, sweets and catalysts. The PTB 311E/ 311E-500/ 311E-800 can be used in several configurations that satisfy USP/EP criteria including a printer to report the results. The instrument meets the USP <1217> and EP <2.9.8> monographs and is in strict compliance with the valid EEC norms for EMC and CE standards. It fulfills the DIN EN61010- ICE 1010 instrument safety requirements.

Instructions for Documentation Completion

All performers and reviewers must complete qualification forms using the following guidelines:

1. Write down your signature
2. Complete all items on a form in full.
3. Document any deviation from defined protocols and expected results. Owner approval of protocol deviations must be documented before final approval signatures can be obtained.
4. Write additional comments on an addendum sheet, when there is not enough space on a form to accommodate all comments. Follow these five steps when adding an addendum sheet:
    a. Write down your signature
    b. Write down the date of the additions
    c. Number the addendum pages numerically
    d. Insert the addendum sheet behind the original page
    e. Make all entries in permanent ink.

Correcting Entries

If you need to make corrections on a form, use the procedures described below:

Correcting Entries, sections and parts which are now required or available

It is possible that certain information or requirements are not available or necessary for the instrument to be qualified. This information may be a full section, a part of it or procedure. Mark this element clearly, so that it is understood that it is not necessary in this case.

To correct a long entry or information block on a form follow this procedure:

1. Draw a diagonal line, through the wrong, invalid or incorrect information
2. Enter the correction
3. Give a brief explanation of the change.
4. Sign it using your initial
5. Enter the date of the change

NOTE: All original entries must remain legible after any corrections have been made.

Conditions Requiring Re-Qualification or re-calibration

The following conditions may require re-qualification or calibration:

- When a system modification has been completed which affects the installation qualification
- When this system is being removed from where it was originally installed

Marking Elements That Are Not Applicable

Some elements may not apply to your system's configuration. The elements that are not required may be a procedure or part of a procedure and/or a form or part of a form. Mark each element carefully according to the instructions below, so that it will be clear that the element is unnecessary and that you have not skipped or forgotten the element.

1. Draw a diagonal line, through the element that is not required
2. Write down the letters "NA" (for "Not Applicable"), your initials, and the current date above the line
3. Include comments above the line or on the form to document the reason the element is not required
4. Where NA is indicated as an option, mark this field
5. Mark the section "rec." (for "received") if the part has been identified
6. Mark the section "miss." (for "missing") if the part has not been identified and needs to be sent immediately to finish the installation; in that case make sure that the missing part has been ordered by you and has been confirmed by us for shipment

The performer and reviewer must sign and date all forms as usual, even when part or all of the form is marked "NA".

NOTE: All original entries must remain legible after any corrections have been made.

Conditions Requiring Re-Qualification

The following conditions may require re-qualification or calibration:

- When a system modification has been completed which affects the installation qualification
- When this system is being removed from where it was originally installed
- When the software or firmware has been upgraded or changed
- A pre-determined period of time or use has passed
- After any minor service has been done
- After any parts have been replaced

Operation Qualification Program

This document is divided in sections.

Section 1.0 General Documentation Settings

In this section the general format setting of this document is described.

Section 2.0 Instrument Identification

This section includes the equipment description, part - and serial number

Section 3.0 Equipment Description

This section is used to enter the general information regarding the used calibration tools and validity

Section 4.0 Operation Qualification Procedure

This section contains the operation qualification procedure, test protocols and test results in a pass/fail format for each test.

Section 5.0 Result and Comments

This section is used to document the result of the operation qualification and for comments regarding the qualification procedure.

Section 1.0 General Documentation Settings

In this section the general format setting of this document is described.

Section 1.1 General Date Format of this Document

Please select the date format you want to use in this document.

Date Format	Selected	NA
dd.mm.yyyy		
dd/mm/yyyy		
mm.dd.yyyy		
mm/dd/yyyy		
Other:		

Table 2 General Date Format of this document (d=day, m=month, y=year)

Section 1.2 Personnel Identification

Performer (1):

Name (print) _____ Initials _____

Signature _____ Date (Section 1.1) _____

Performer (2):
(optional)

Name (print) _____ Initials _____

Signature _____ Date (Section 1.1) _____

Released by:

Name (print) _____ Initials _____

Signature _____ Date (Section 1.1) _____

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 2.0 Instrument Identification

Check if the instrument/system according to the completed IQ is present. Enter the serial number of the instrument. The serial number is printed on the type plate on the back of the instrument:

Part-No.	Instrument Description	Serial No.	OK	NA
29-02860	PTB 311E Automated Tablet Testing Instrument 300N			
29-02870	PTB 311E-500 Automated Tablet Testing Instrument 500N			
29-02875	PTB 311E-800 Automated Tablet Testing Instrument 800N			

Section 2.1 Instrument Identification – Thickness Jaws and Printer (Option)

Part-No.	Printer Type	OK	NA	Serial No.
29-2853x	Thickness testing jaw size = _____			NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 3.0 Equipment Description

Section 3.1 Explanation

- Not every single qualification tool in section 3.2 is necessary. Marking tools as "NA" is valid. To skip the mentioned section then by marking "NA" is valid, too.
- Tools which are not marked as "optional" are obligatory!
- One of the following combinations of calibration tools must be available for the hardness sections of the OQ:
  - **PT-MT3 with PT-MT support for PTB111/311/411/311-500/311-800 and printer:** This is the recommended procedure by Pharma Test. Using a PT-MT3, no calibration weight is needed anymore because the PT-MT3 fulfills the hardness calibration completely. Furthermore the force increase curve must be recorded to check the linearity up to the maximum hardness.
    - If the hardness calibration shows a discrepancy, the "Adjustment via PT-MT3" function on the Hardness Tester can be used for correction.
  - **PT-MT2 with PT-MT support for PTB111/311/411/311-500/311-800, static weights and printer:**
    - If an obsolete PT-MT2 is available, the usage is valid as long as the calibration is valid. Pharma Test recommends the load cell adjustment with at least 5kg, 10kg and 15kg static weights, too. Furthermore the force increase curve must be recorded to check the linearity up to the maximum hardness.
  - **Static weights and printer:** If no electro-magnetic test tablet is available, the Hardness calibration can be done only with static weights. In this case, the PTB311E should be calibrated at least to 15kg, the PTB311E-500 at least to 30kg and the PTB311E-800 at least to 50kg. Furthermore the force increase curve must be recorded to check the linearity up to the maximum hardness.

Section 3.2 Required Qualification Equipment and Calibration Tools

Part-No.	Description	Serial No.	Calibrated Until	OK	NA
10-61000	Stop watch				
004-3402	1 kg weight				
28-00290	5/10/15 kg weight				
28-00300	30 kg weight				
28-00500	50 kg weight				
29-18000	PT-MT2 magnetic test tablet or				
29-18050	PT-MT3 magnetic test tablet				
285-1755	10 mm calibration block				
002-0450	digital multimeter				
80-75109	Reference block 1-10.0 mm				
80-75111	Reference block 10-20.0 mm				
002-6035	Feeler gauge				

Mark NA when not required.

Section 3.3 Other Equipment Used – Not Calibrated

Part-No.	Description	Serial No.	OK	NA
29-18001	Support for PT-MT3 (used for PTB 111E, 311E, PTB 311E-500 and PTB 311E-800)	NA		

Mark NA when not required.

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.0 Operation Qualification Procedure

This section provides the operational procedure to qualify the instrument. Complete each subsection as described. For more detailed information on the general usage of the instrument refer to the instruction manual.

Section 4.1 Set/Check Mains Power Settings

No.	Description	TARG	OK	NA
4.1.1	Confirm that the main power setting of the instrument meets the requirement in the order document for his project	NA		
4.1.2	Confirm that the correct mains cable is attached.	NA		

Section 4.2 Start Up and Default Settings

Turn on the PTB 311E/ 311E-500/ 311E-800. The display will light up and initialization process will start automatically.

No.	Description	TARG	OK	NA
4.2.1	Confirm that the PTB 311E/ 311E-500/ 311E-800 turns on and that the initialization process runs through without reporting any errors.	NA		
4.2.2	Note the actual firmware version displayed on the start screen.			
4.2.3	Confirm that the LEDs light up, that all segments are fully visible and display the content correctly.	NA		
4.2.4	Login as Super User (Press **<CAL>** + **<0>** + **<1>** and the standard password 0000 0000).	NA		

Section 4.3 Verify Firmware Version

After the instrument is turned on the actual firmware version is displayed. Check that the version is the same as noted above and in the QC document for this instrument.

OK	NOK	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.4 Test Keys – <HARDNESS>-Key

Press <**HARDNESS**>. The LED display marked "HARDNESS" now shows a numerical value.

pass	fail	NA

Section 4.5 Test Keys – <DIAMETER / WIDTH>-Key

Press <**DIAMETER / WIDTH**>. The LED display marked "DIAMETER" now shows a numerical value. Press <**DIAMETER / WIDTH**> again. The LED display marked "WIDTH" now shows a numerical value.

pass	fail	NA

Section 4.6 Test Keys – < Test Keys – <THICKNESS>-Key

Press <**THICKNESS**>. The LED display marked "THICKNESS" now shows a numerical value.

pass	fail	NA

Section 4.7 Test Keys – Numerical Keys

Press the **<0>** numerical key, the "THICKNESS"-display shows "0" now. Press another three numerical keys. Check that the corresponding numbers appear on the "THICKNESS"-display and that the digits scroll one position after each number appears.

pass	fail	NA

Section 4.8 Test Keys – <*>-Key

Press <*****>. The "THICKNESS"-display shows "00.00".

pass	fail	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.9 Test Keys – <START>- and <STOP>-Keys

Press <**START**> twice. The force jaw now starts to move forward. Press <**STOP**> while the force jaw is still moving forward before touches the opposite load cell block. The force jaw will stop moving and return to the home position. Press <**STOP**> again, the display shows "no dAtA". Press **<STOP>** again.

pass	fail	NA

Section 4.10 Test Keys – <AUTO>-Key

Press <**AUTO**> twice. The "HARDNESS"-display shows the numbers "0.2" for the default setting of 0.2 seconds or the last setting which is currently saved on the instrument. Enter the numbers "2" and "0" (= auto delay of 2.0 seconds). The display now shows "2.0".

pass	fail	NA

Section 4.11 Test Keys – <CAL>-Key

Press <**CAL**> + <**2**> + <**2**> to select the hardness force increase mode of the PTB 311E/311E-500/311E-800. The factory setting is 20N/second linear force increase. Press the <**.**> to choose the correct force mode: "dFo".

Press <**START**> to enter "20.00" if it is not shown already. Confirm this setting with <*****> to save this value and exit the menu.

pass	fail	NA

Section 4.12 Select Force Result Units

Login as Superuser. Press <**CAL**> + <**2**> + <**0**>. Press <**.**> to toggle between the force result units. The red diode switches between the possible units of "N", "Kp" and "Sc". Select „N" (= Newton) as unit.

pass	fail	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Enter Actual Date

Login as Superuser. Press <**CAL**> + <**1**> + <**0**>. The actual date is displayed. Press <**START**> to edit the date. Enter the date in the following format: "DDMMYY" by using the numerical keys. Confirm the entry by pressing <*****> or cancel the edit by pressing <**STOP**>.

pass	fail	NA

Section 4.13 Enter Actual Time

Login as Superuser. Press <**CAL**> + <**1**> + <**1**>. The actual time is displayed. Press <**START**> to edit the date. Enter the date in the following format: "HHMMSS" by using the numerical keys. Confirm the entry by pressing <*****> or cancel the edit by pressing <**STOP**>.

pass	fail	NA

Section 4.14 Enter Calibration Interval

Login as Superuser. Press <**CAL**> + <**1**> + <**2**>. The calibration validity date is displayed. Press <**.**> to change the calibration interval. Select the new calibration interval from 1, 2, 3, 6, 12 or 24 moths or "off" by pressing <**.**> to toggle between the settings. Confirm the entry with <*****> or cancel with <**STOP**>.

If the calibration interval time is elapsed, the message "CAL INT" is displayed.

pass	fail	NA

Section 4.15 Enter Batch Number

The batch number may be entered before each test start. Press <**START**> and enter a maximum of 12 digits for the batch number. Start a test by pressing <**START**> again after entering a batch number. After one or more tests are finished, press <**STOP**> to stop a currently running test and press <**STOP**> a second time to end the test series. If a printer is connected, a printout with the results, statistics, batch number, time and date is produced. The entered batch number will be re-used for subsequent tests until a new batch number is entered.

pass	fail	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.16 Check Load Cell Offset

Press <**CAL**> + <**5**> + <**2**>. The load cell offset value in digits is shown on the "WIDTH/DIAMETER"-display. The offset value in the selected force result unit is shown in the "HARDNESS"-display. Note the value in digits below. Press <**STOP**> to exit this menu.

Nominal Value (Digits)	Actual Value (Digits)	pass	fail	NA
12 – 52				

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.17 Calibrate the Load Cell (DMS)

Optional: See Section 3.1

Remove the load cell (DMS) outside of the instrument in an upright position. To perform the calibration of each weight, press <**CAL**> + <**5**> + <**2**> to enter the nominal weight to test and confirm with <*****>. Put the nominal weight on the load cell and confirm with <**START**>. Now the calibration process starts. Remove the weight afterwards and continue with the next weight or stop the calibration by pressing two times <**STOP**>.

No.	Description	TARG	MEAS	pass	fail	NA
4.17.1	Calibrate the load cell using a 1 kg weight (only PTB 311E).	0.90 – 1.10 kp				
4.17.2	Calibrate the load cell using a 5 kg weight.	4.90 – 5.10 kp				
4.17.3	Calibrate the load cell using a 10 kg weight (if applicable).	9.90 – 10.10 kp				
4.17.4	Calibrate the load cell using a 15 kg weight (if applicable).	14.90 – 15.10 kp				
4.17.5	Calibrate the load cell using a 30 kg weight (if applicable).	29.90 – 30.10 kp				
4.17.6	Calibrate the load cell using a 50 kg weight (only PTB 311E-800).	49.90 – 50.10 kp				
4.17.7	Print out the calibration report and attach it hereto. Press <CAL> + <5> + <0>.	NA	NA			
4.17.8	Install the DMS into the holder inside the instrument in its operating position.	NA	NA			
4.17.9	Measure the distance between the sample dish and the force plate. Use the feeler gauge and adjust. Check the parallel position of the sample dish and the force plate.	0.3 – 0.5mm				

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.18 Calibrate the Break Point Reproducibility with a PT-MT2

Optional: See Section 3.1

If a PT-MT3 is used, skip this section and proceed with section 4.20.

The load cell is mounted and aligned correctly inside the instrument. The pressure jaw tip is mounted, the sample holder plate dismounted. The PT-MT2 and the calibration support are inserted. The PT-MT2 is switched on for at least 20 minutes. Hardness measurement is activated, Diameter and Thickness measurement deactivated. Measurement will be done in automatic mode, repeat time 3 seconds. Perform 50 measurements. Press <**START**>. The jaw moves forwards onto the PT-MT2 and raises the force until a break is detected. The maximum value will be displayed and printed.

Performed by: _____ Date: _____

Section 1.2 Section 1.1

No.	Description	TARG	MEAS	OK	NA
4.18.1	Adjust the PT-MT2 to position <**1**>. Perform 20 tests manually to establish the magnetic field. The results are not documented.	NA			
4.18.2	Perform 50 tests, print the results and attach the report hereto.	Xmean= 47.0–52.0 N			
4.18.3	Confirm the result for Xmax.	<52.0N			
4.18.4	Confirm the result for Xmin.	>47.0N			
4.18.5	Calculate the absolute standard deviation (Xabs) for the results.	0.0 – 0.9N			
4.18.6	Adjust the PT-MT2 to position <**2**>. Perform 20 tests manually to establish the magnetic field. The results are not documented.	NA			
4.18.7	Perform 50 tests, print the results and attach the report hereto.	Xmean= 80.0–86.0 N			
4.18.8	Confirm the result for Xmax.	<86.0N			
4.18.9	Confirm the result for Xmin.	>80.0N			
4.18.10	Calculate the absolute standard deviation (Xabs) for the results.	0.0 – 0.9N			
4.18.11	Adjust the PT-MT2 to position <**3**>. Perform 20 tests manually to establish the magnetic field. The results are not documented.	NA			
4.18.12	Perform 50 tests, print the results and attach the report hereto.	Xmean=126 .0– 134.0 N			
4.18.13	Confirm the result for Xmax.	<134.0N			
4.18.14	Confirm the result for Xmin.	>126.0N			
4.18.15	Calculate the absolute standard deviation (Xabs) for the results.	0.0 – 0.9N			

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.19 Calibrate the Break Point Reproducibility with a PT-MT3

Optional: See Section 3.1

If a PT-MT2 was used, skip this section and proceed with section 4.21. The load cell is mounted and aligned correctly inside the instrument. The pressure jaw tip is mounted, the sample holder plate dismounted. The PT-MT3 and the calibration support are inserted. The PT-MT3 is switched on for at least 20 minutes. Hardness measurement is activated, Diameter and Thickness measurement deactivated. Measurement will be done in automatic mode, repeat time 3 seconds. Perform 50 measurements. Press <**START**>. The jaw moves downwards onto the PT-MT3 and raises the force until a break is detected. The maximum value will be displayed and printed.

Performed by: _____ Date: _____

Section 1.2 Section 1.1

No.	Description	TARG	MEAS	OK	NA
4.19.1	Set the PT-MT3 to 50N and start it.	NA			
4.19.2	Perform 50 tests at 50N, print the results and attach the report hereto. The printouts of the PT-MT3 will be also attached.	Xmean= 48.0 - 52.0 N			
4.19.3	Confirm the result for Xmax.	<52.0N			
4.19.4	Confirm the result for Xmin.	>48.0N			
4.19.5	Calculate the absolute standard deviation (Xabs) for the results.	0.0-0.9N			
4.19.6	If the instrument is a PTB311E-500 or a PTB311E-800, skip the following tests 4.20.7 – 4.20.10 and proceed with 4.20.11	NA			
4.19.7	Perform 50 tests at 150N, print the results and attach the report hereto. The printouts of the PT-MT3 will be also attached.	Xmean= 147.0 - 153.0 N			
4.19.8	Confirm the result for Xmax.	<153.0N			
4.19.9	Confirm the result for Xmin.	>147.0N			
4.19.10	Calculate the absolute standard deviation (Xabs) for the results.	0.0-0.9N			
4.19.11	Perform 50 tests at 250N, print the results and attach the report hereto. The printouts of the PT-MT3 will be also attached.	Xmean= 246.0 - 254.0 N			
4.19.12	Confirm the result for Xmax.	<254.0N			
4.19.13	Confirm the result for Xmin.	>246.0N			
4.19.14	Calculate the absolute standard deviation (Xabs) for the results.	0.0-0.9N			
4.19.15	If the instrument a PTB311E, finish section 4.20 now and proceed with section 4.21	NA			
4.19.16	Perform 50 tests at 450N, print the results and attach the report hereto. The printouts of the PT-MT3 will be also attached.	Xmean= 445.0 - 455.0 N			

Performed by: _____ Date: _____

Section 1.2 Section 1.1

No.	Description	TARG	MEAS	OK	NA
4.19.17	Confirm the result for Xmax.	<455.0N			
4.19.18	Confirm the result for Xmin.	>445.0N			
4.19.19	Calculate the absolute standard deviation (Xabs) for the results.	0.0-0.9N			

Section 4.20 Test Maximum Force

Activate the printout of the force increase curve by setting **<CAL> + <5> + <1>** and connect a printer to the instrument. Start a test with the testing compartment empty. The force jaw moves forward and touches the opposite load cell block. Stop the time from the moment of touching until the force jaw starts to move back again. When the force jaws moves back the maximum force has been reached. The shown error **"E156"** is normal at this step of operation.

Note the time and the hardness result which is either displayed or printed below.

PTB 311E only

		Nominal Hardness Value (N)	Actual Hardness Value (N)	pass	fail	NA
4.21.1	Set the PTB 311E to 300N	300 – 330				
		Nominal Time (seconds)	**Actual Time (seconds)**	**pass**	**fail**	**NA**
		14 – 17				

PTB 311E-500 only

		Nominal Hardness Value (N)	Actual Hardness Value (N)	pass	fail	NA
4.21.2	Set the PTB 311E-500 to 500N	500 – 660				
		Nominal Time (seconds)	**Actual Time (seconds)**	**pass**	**fail**	**NA**
		24 – 34				

PTB 311E-800 only

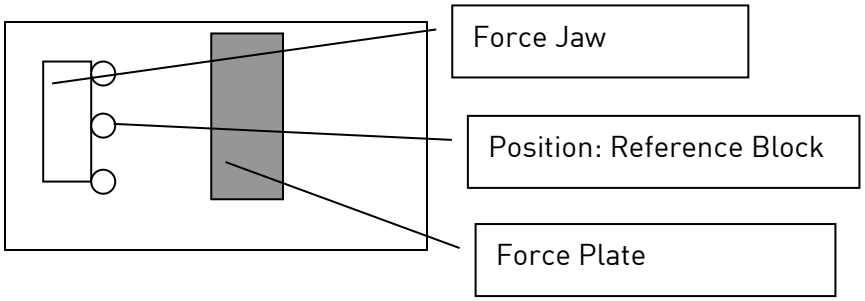
		Nominal Hardness Value (N)	Actual Hardness Value (N)	pass	fail	NA
4.21.3	Set the PTB 311E-800 to 800N	800 – 940				
		Nominal Time (seconds)	**Actual Time (seconds)**	**pass**	**fail**	**NA**
		39 – 48				

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.21 Check the Length Measurement Stations and the parallelism of the station assembly

Different Reference Blocks are used to calibrate the thickness station. Each block is placed at 3 positions within the test department as shown below. The results have to be at each position within the target, if a test fails the test stations must be adjusted and calibrated again. For all tests the hardness parameter is set to 0.0N.



4.22.1 Place a 3 mm reference block into the station and start the test as follows:
Thickness = 03.00 mm, Diameter = 03.00 mm, Width = 03.00 mm

Description	TARG	MEAS Thickness	MEAS Diameter	MEAS Width	OK	NA
Test at Pos. 1	2.98 -3.02 mm					
Test at Pos. 2						
Test at Pos. 3						

4.22.2 Place a 5 mm reference block into the station and start the test as follows:
Thickness = 5.00 mm, Diameter = 5.00 mm, Width = 5.00 mm

Description	TARG	MEAS Thickness	MEAS Diameter	MEAS Width	OK	NA
Test at Pos. 1	4.98 -5.02 mm					
Test at Pos. 2						
Test at Pos. 3						

4.22.3 Place a 10 mm reference block into the station and start the test as follows:
Thickness = 10.00 mm, Diameter = 10.00 mm, Width = 10.00 mm

Description	TARG	MEAS Thickness	MEAS Diameter	MEAS Width	OK	NA
Test at Pos. 1	9.98-10.02mm					
Test at Pos. 2						
Test at Pos. 3						

4.22.4 Attach the original printout to this document.

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.23 Test Tablet Measurement

Use a batch of tablets with known average thickness, average width, average diameter and average hardness to test the correct operation of the instrument.

Enter the average values of this batch as nominal values on the PTB 311E/ 311E-500 /PTB 311E-800. Test one up to ten tablets of this batch and note the results below. Check that each sample was broken by the PTB 311E/ 311E-500 /PTB 311E-800 and that the shown results are plausible.

In case a printer is connected to the instrument, press <**PRINT**> to print out the test report and attach it to this document.

* Please note that comparable results will only be achievable if the force mode and force rate setting of the instrument used so far are equal to the settings of the PTB 311E/ 311E-500 /PTB 311E-800.

Description	Thickness	Width	Diameter	Hardness	Results		
Nominal Values					**OK**	**NOK**	**NA**
Meas. 1st Sample							
Meas. 2nd Sample							
Meas. 3rd Sample							
Meas. 4th Sample							
Meas. 5th Sample							
Meas. 6th Sample							
Meas. 7th Sample							
Meas. 8th Sample							
Meas. 9th Sample							
Meas. 10th Sample							

Section 4.24 Attach Reports

Attach to this document all the test reports which are available. Check that the reports were printed correctly.

pass	fail	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Pharma Test Apparatebau AG
Siemensstraße 5
D-63512 Hainburg/Germany

Telephone +49 6182 9532-600
Telefax +49 6182 9532-80
+49 6182 9532-650
info@pharma-test.de
www.pharma-test.com

Section 5.0 Result and Comments

Instrument Type		Serial Number	
Mains Voltage		Firmware Version	

Addendum Sheet/s attached to this document Yes ☐ No ☐

If yes, how many:

The instrument has passed the operation qualification procedure. Yes ☐ No ☐

Check "yes", if all tests have passed. In case one or more tests failed, check "no" and document the reason for the failure on this report. In this case the applicable sections of the operation qualification have to be repeated once the reason for failure has been eliminated

Comments

This completes the operation qualification of the tested instrument.

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Released by: _____ Date: _____

Section 1.2 Section 1.1