Operation Qualification (OQ)

PTB-M100 Portable
Tablet Hardness Testing Instrument

Version 1.2

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bsi. ISO 9001 Quality-management ISO 14001 Environmental-managment

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Document History

Version	Valid from	Author	Change	Remark
1.0	21.02.2025	Pharma Test	N	First release
1.1	07.03.2025	Pharma Test	C	Correction about setting the serial output for PT-Node in section 4.6
1.2	11.08.2025	Pharma Test	R	Minor reorganization of IQ/OQ

Index Information - Change:

N = New Document
C = Correction
R = Revision

Section 1.0 Scope Introduction

Objective

Operational qualification (OQ) is the process by which all functions of the Pharma Test PTB-M100 portable tablet hardness testing instrument are 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-M100 portable tablet hardness testing instrument is composed of:

- The PTB-M100 instrument
- The required standard accessories
- Optionally delivered accessories as per customer order

PTB-M100 is made in strict compliance with the EP <2.9.8> and USP <1217> Pharmacopoeia.

Instructions for Documentation Completion

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

Complete all items on a form in full.

Document any deviation from defined protocols and accepted results. Owner approval of protocol deviations must be documented before final approval signatures can be obtained.

Write additional comments on an addendum sheet when there is not enough space on a form to accommodate all comments. Follow these three steps when adding an addendum sheet:

1. Write down your initials
2. Write down the date of the additions
3. Number the addendum pages alphanumerically
4. Insert the addendum sheet behind the original page
5. Make all entries in permanent ink.

Correcting Entries

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

Correcting Short Entries

To correct a short entry (such as a single word or test result) on a form follow this procedure:

1. Draw a diagonal line, bottom left to upper right, through the miss-entered or incorrect information
2. Write down the correction to the upper right of the original entry
3. Give a brief explanation of the change
4. Write down your initial
5. Write down the date of the change

Correcting Long Entries

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

1. Draw a diagonal line, bottom left to upper right, through the miss-entered or incorrect information
2. Write the correction on a separate addendum sheet
3. Give a brief explanation of the change.
4. Write down your initial
5. Write down the date of the change
6. Number the addendum pages alphanumerically
7. Insert the addendum sheet behind the original page

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, bottom left to upper right corner, 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, check 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

CAUTION: The following conditions require re-qualification:

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

Re- calibration/ Re-certification Requirements

The following conditions require an Operation Qualification (OQ) re-calibration/re-certification:

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

Operation Qualification Program

This document is divided in sections.

Section 1.0 Scope Introduction

This section explains the purpose and use of this document and the general installation qualification procedure.

Section 2.0 Instrument Identification

This section has the purpose of identifying the instrument at hand, including parts and accessories, required documentation, and installation site requirements.

Section 3.0 Personnel Identification

In this section the user of the equipment, the equipment required for qualification is identified and the end user information is written down to complete the qualification.

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. Where accreditation is held for the calibration of the equipment being qualified, this procedure will be referenced. Where applicable, copies of these procedures are available from Pharma Test upon request.

Section 5.0 Result and Comments

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

Section 2.0 Instrument Identification

The completed IQ document is present. Enter the serial number of the PTB-M100. The serial number is printed on the type plate on the underside of the instrument:

Part-No.	Description	Type	Serial No.	Rec.	Miss.	NA
29-00600	Portable tablet hardness testing instrument	PTB-M100, 300N				
29-00650	Portable tablet hardness testing instrument	PTB-M100, 500N				

Instruments Details

Asset No. or Lab ID No.	

Section 2.1 Required Qualification Equipment and Materials Identification

Part-No.	Description	Serial No.	Rec.	Miss.	NA
28-00290	PTB-CAL15 5, 10, 15 kg weight set				
28-01050	PT-MET50 Mechanical Tablet, 50N (optional)				
28-01100	PT-MET100 Mechanical Tablet, 100N (optional)				
28-01150	PT-MET150 Mechanical Tablet, 150N (optional)				
28-01200	PT-MET200 Mechanical Tablet, 200N (optional)				

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 3.0 Personnel Identification

Installation Engineer (1):

Name (print)	Initials
Signature	Date (DD/MM/YYYY)

Installation Engineer (2): (optional)

Name (print)	Initials
Signature	Date (DD/MM/YYYY)

Installation Engineer (3): (optional)

Name (print)	Initials
Signature	Date (DD/MM/YYYY)

Approved by:

Name (print)	Initials
Signature	Date (DD/MM/YYYY)

Released by:

Name (print)	Initials
Signature	Date (DD/MM/YYYY)

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 3.2 End User Information

Company Name: _____

Address: _____

_____

_____

Department: _____

Location: _____

Contact: _____

Telephone: _____

Fax: _____

E-Mail: _____

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 4.0 Operation Qualification Procedure

For more detailed information on the general usage of the instrument refer to the instruction manual.

Section 4.1 Turn on the Instrument

Check that the charger is connected to the mains and the USB-C cable to the PTB-M100. Press the power button on the backside of the instrument to turn it on. Confirm that the PTB-M100 turns on, that the start screen is displayed, and no error message appears.

OK	NOK	NA

Section 4.2 Connect Printer to PTB-M100 (optional)

In case a printer is available and to be used, connect it using the suitable serial cable to the PTB-M100 instrument and connect the printer to the mains. Switch on the printer.

OK	NOK	NA

Section 4.3 Connect PT-Node to PTB-M100 (optional)

In case a Pharma Test PT-Node network adapter is available and to be used, connect it using the supplied serial cable to the PTB-M100 instrument and connect the PT-Node to the mains.

OK	NOK	NA

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 4.4 Set Instrument Settings

Enter the settings menu. The default password is "PHARMATEST". Check each setting and note any changes from the default settings below.

In case a printer or a PT-Node is to be used, set "Serial output" to "Printer".

In case is the results are to be exported to an external system, set "Serial output" to "RS232".

Parameter	Default	Setting	OK	NOK	NA
Force unit	N (Newtons)				
Language	English				
Serial output	NA				
Date	NA				
Time	NA				
Date format	24h				
Standby time	5m				
Auto off time	10m				
Brightness	40%				

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 4.5 Calibrate the Load Cell (Force Sensor)

Enter the calibration menu. Set the calibration weights to 5, 10 and 15kg. Set the number of calibration measurements ("count") to 3. Use the supplied calibration support to place the calibration weights safely on the force sensor. Refer to the user manual for more details about this. Calibrate the force sensor using these weights and enter the values below. Then quit the calibration menu, print the calibration report and attach it hereto in case a printer is available.

No.	TARG	MEAS	OK	NOK	NA
1	4.9 – 5.1kg				
2	4.9 – 5.1kg				
3	4.9 – 5.1kg				
4	9.9 – 10.1kg				
5	9.9 – 10.1kg				
6	9.9 – 10.1kg				
7	14.9 – 15.1kg				
8	14.9 – 15.1kg				
9	14.9 – 15.1kg				

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 4.6 Perform Hardness Measurement Verification with PT-MET Mechanical Tablets (optional)

Perform a verification test using PT-MET mechanical tablets. Start a new test and enter a batch number. Use the type of PT-MET used as the batch number, i.e. "PT-MET50". Perform three tests for each type of PT-MET that is available. Confirm that each time a break is detected by the PTB-M100 and that the result is within the given range. Attach the printout of the result report to this document, in case a printer is available.

No.	Type	TARG	MEAS	OK	NOK	NA
1	PT-MET50	45-55N				
2	PT-MET50	45-55N				
3	PT-MET50	45-55N				
4	PT-MET100	90-110N				
5	PT-MET100	90-110N				
6	PT-MET100	90-110N				
7	PT-MET150	140-160N				
8	PT-MET150	140-160N				
9	PT-MET150	140-160N				
10	PT-MET200	190-210N				
11	PT-MET200	190-210N				
12	PT-MET200	190-210N				

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 4.7 Perform Hardness Measurement Verification with Customer Samples (optional)

Perform a verification test using a batch of tablets with known average hardness and standard deviation. Start a new test and enter a suitable batch number. Perform ten tests with tablets from this batch. Confirm that each time a break is detected by the PTB-M100. Compare the mean-value of the tablet hardness from the PTB-M100 result report with the mean hardness of the used tablets according to your experience. Attach the printout of the result report to this document. In case no printer is available not the individual test results and calculate the mean value.

Nominal value of customer sample

No.	Actual value	Sample broken	OK	NOK	NA
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

Nominal mean value	Actual mean value	OK	NOK	NA

Performed by: _____ Date: _____

Signature DD/MM/YYYY

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Section 5.0 Result and Comments

Type	PTB-M100	Serial Number	
Firmware Version			

The instrument has passed the Operation Qualification (OQ) 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 installation qualification must be repeated once the reason for failure has been eliminated.

Comments

This completes the Operation Qualification of the instrument.

Performed by: _____ Date: _____
Signature DD/MM/YYYY

Approved by: _____ Date: _____
Signature DD/MM/YYYY

Released by: _____ Date: _____
Signature DD/MM/YYYY