Installation Qualification (IQ)

PTB-M100 Portable
Tablet Hardness Testing Instrument

Version 1.3

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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	R	Added allen key to standard scope of delivery
1.2	31.07.2025	Pharma Test	R	Minor revision
1.3	11.08.2025	Pharma Test	R	Minor reorganization of IQ/OQ

Index Information – (Change):

N = New Document
C = Correction
R = Revision

Introduction

Objective

Installation Qualification (IQ) is used to verify that the Pharma Test Instrument/System (or components where applicable) has been installed according to the manufacturer's requirements. The results are documented and explained as passed (OK) or failed (NOK), compared to the requirements laid down in this form

Equipment

The Pharma Test PTB-M100 instrument is composed of:

- The PTB-M100 main instrument
- Standard supply scope
- Optional equipment and accessories according to customer order

PTB-M100 is a portable, manual hardness testing instrument for tablets. The instrument is made in strict compliance with the EP <2.9.8> and USP <1217> Pharmacopoeia. The force and break point are measured by a precise force sensor and the result is immediately displayed on the large color touchscreen.

Instructions for Documentation Completion

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

1. Complete all items on a form in full.
2. Document any deviation from defined protocols and expected results. Owner approval of protocol deviations must be documented before final approval signatures can be obtained.
3. 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:
4. Use your initials to confirm the entry
5. Enter the date of the additions (addendum)
6. Number the addendum pages numerically
7. Insert the addendum sheet behind the original page
8. 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. Write the correction on a separate addendum sheet
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

CAUTION: The following conditions 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

Installation Qualification Program

This document is divided into sections.

Section 1.0 Instrument Identification

In this section the instrument including details and serial number(s), as well as the required documentation are identified.

Section 2.0 Information User and Installation Place

This section the user of the equipment and installation place are defined

Section 3.0 Required Instruments, Substances and Standards

This section includes information about the equipment, tools and substances required to perform the Functional Qualification (OQ), as well as information of the place of installation.

Section 4.0 Documentation and Installation Procedure

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

Section 5.0 Results and Comments

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

Section 1.0 Instrument Identification

Check if the instrument/system according to the order confirmation has been received and enter the serial number and the type name. The serial number is printed on the type plate on the back of the instrument:

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

Instrument Details

Asset No. or Lab ID No.	

Section 1.1 Standard Scope of Delivery of PTB-M100

Part-No.	Nos	Description	Rec.	Miss.	NA
295-0400	1	Calibration support			
285-1771	1	Cleaning brush			
295-0600	1	Power supply and charger, USB, 5V, 2,4A incl. input clips EU, US, UK, AU			
34-01173	1	USB-A to USB-C cable, approx. 1m			
002-6003	1	Allen key, size 3			

Section 1.2 Optional Accessories

Part-No.	Description	Type	Serial No.	Rec.	Miss.	NA

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 1.3 Required Documentation and Information

Ordering Information

Customer Order Number	
Supplier Delivery-Note or Invoice Number	

Equipment Documentation

Part-No.	Description	Rec.	Miss.	NA
B-29-006x0	Operating manual			
IQ-29-006x0	Installation qualification			
OQ-29-006x0	Operation qualification			
NA	Instrument logbook			
QC-29-006x0	QC/DQ test report			
NA	Delivery note			

Section 1.4 Installation Requirements

NOTE: This instrument requires electrical installation with a quality, noise free ground (earth). All mains (line) supplies should be protected with an RCD (Residual Current Detector) which typically trips out when current leakage to ground (earth) of approx. 30mA is detected.

Electrical Conditions at Installation Site:

Voltage: 100/115V ☐ 230/240V ☐ Frequency: 60cycl. ☐ 50cycl. ☐

The Instrument must be installed on a level surface. The supporting bench must be able to support the weight of the Instrument, as well as other equipment installed on the same bench continuously.

NOTE: Pharma Test is not responsible for adequate site planning and installation. We are however, happy to advise if our help is requested.

Section 1.5 Operating Environment

Temperature:	15-40°C	Rel. humidity:	20-80%
Physical site:	Clean, dry and levelled bench	Weight support:	Approx. 50 kg/m²
Required bench space (width x depth x height):		30 **x** 10 **x** 10 cm	

Section 1.6 Clearance

A minimum of **10cm** of the rear and sides of the instrument is required.

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 2.0 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 2.1 End User Information

Company Name: _____

Address: _____

_____

_____

Department/Bldg.: _____

Location/Bldg.: _____

Contact: _____

Telephone: _____

Fax: _____

E-Mail: _____

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 3.0 Required Calibration Tools for OQ

This section lists all calibration tools, standards and/or substances required to perform the operation qualification (OQ) of this instrument.

Part-No.	Description	Serial No.	Calibrated Until	OK	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)				

Section 3.1 Calibration Certificates for the Tools, Standards and Substances

PartNo.	Description	Calibration Date	Rec.	Miss.	NA
281-2890	Calibration certificate for PTB-CAL15 5, 10, 15 kg weight set				
281-2960	Calibration certificate for PT-MET50 (optional)				
281-2960	Calibration certificate for PT-MET100 (optional)				
281-2960	Calibration certificate for PT-MET150 (optional)				
281-2960	Calibration certificate for PT-MET200 (optional)				

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 4.0 Documentation and Installation Procedure

This Section describes the performance and documentation of the Installation Qualification of the instrument/system. Complete each section as described.

Full information about the use and operation of the instrument/system is available from the supplied Operating Manual

Section 4.1 Check Packaging Material

Check the packaging material the instrument/system has been delivered in for any defects or signs of mishandling during transport. In case any defects or signs are found, document them by pictures and check whether this has already been reported to the forwarder by the shipment's recipient.

OK	NOK	NA

Section 4.2 Unpacking

Unpack the instrument. Make sure that there are no more parts inside the packing material or box. Make sure that the instrument has not been damaged during transportation.

OK	NOK	NA

Section 4.3 Check for Completeness

All parts required for the standard operation of the instrument are listed at the supplied delivery note. Each part is labeled with its part-no. Please check the completeness of the delivery scope using the delivery-note (or invoice) attached.

Confirm that all items as per corresponding delivery note have been fully supplied.

OK	NOK	NA

In case any item is missing, please inform Pharma Test immediately. Please mention your purchase order no., the instrument serial number, the part number of the item that is missing, as well as the delivery note number. In case the missing part is essential for the operation of the instrument, you can only proceed with the Installation Qualification after the part has been received.

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 4.4 Assemble the Instrument

Install the instrument at its intended place of use and assemble the instrument with its components as per the supplied operating manual.

OK	NOK	NA

Section 4.5 Connect Mains

Check that the mains cable, external charger USB-C cable and the socket do not show any visible damage. Connect the mains cable to the charger and to the mains. Connect the USB-C cable to the USB-C port on the left side of the instrument and to the charger.

OK	NOK	NA

Section 4.6 Turn on the Instrument

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 4.7 Verify Firmware Version

After power on, the installed firmware version is displayed. Verify that the version displayed matches the version noted in the supplied QC protocol. Enter the firmware version on the last page of this document.

OK	NOK	NA

Section 4.8 Verify the Instrument Serial Number

Note the serial number displayed on the start screen of the instrument. Check that this serial number corresponds to the serial number printed on the type plate on the back of the instrument.

OK	NOK	NA

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 4.9 Check Charging of Battery

Confirm that the battery charge indicator shows that the instrument is now charging.

OK	NOK	NA

Section 4.10 Check Battery Operation

Disconnect the mains cable and confirm that the instrument works in battery mode. Confirm that the battery charge indicator changes to battery mode. Then re-connect the charger.

OK	NOK	NA

Section 4.11 Turn off the Instrument

Turn off the instrument using the power button on the backside of the instrument.

OK	NOK	NA

Section 4.12 Qualify the PTB-CAL15 5, 10, 15 kg Weight Set

Each instrument, which is used for the operation qualification (OQ) of this instrument has been tested and qualified at the factory. A certificate issued from an authorized laboratory is only supplied in case it has been ordered.

The PTB-CAL15 weight set is used to qualify the force sensor (load cell) of the instrument.

OK	NOK	NA

Section 4.13 Qualify the PT-MET Mechanical Tablets (optional)

Each PT-MET is supplied with a calibration certificate by the manufacturer. The PT-MET mechanical tablets can be used to qualify the break point detection of the instrument.

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 Installation Qualification (IQ) 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 Installation 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