Installation Qualification (IQ)

PTB 330 Tablet Hardness Testing Instrument

Version 1.0

Pharma Test Apparatebau AG
Siemensstr. 5
63512 HAINBURG
GERMANY
T: +49 6182 9532-600
F: +49 6182 9532-650
info@pharma-test.de
www.pharma-test.com

bsi. ISO 9001 Quality-management ISO 14001 Environmental-managment
Certificate No FS 529019/0388D

Table of Contents

Document History

Version	Valid from [dd.mm.yyyy]	Author	Change	Remark
1.0	14.10.2025	Pharma Test	N	First Release

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 330 tablet testing instrument is composed of:

- The PTB 330 tablet hardness testing instrument
- All required accessories
- Options supplied as specified by customer

The PTB 330 series of automated tablet testers is used to test the hardness (tablet breaking force), thickness, width, diameter and weight of solid dosage forms, such as tablets, sweets and catalysts. PTB 330 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. 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:
    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.

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

Installation Qualification Program

This document is divided in sections.

Section 1.0 General Documentation Conventions

In this section the general formatting conventions of this document are described.

Section 2.0 Instrument Identification

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

Section 3.0 Required Calibration Tools for OQ

This section includes information about the calibration tools, substances and standards required to perform the Operations Qualification (OQ) and the corresponding calibration certificates.

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 Documentation and Installation Procedure

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

Section 6.0 Results and Comments

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

Section 1.0 General Documentation Conventions

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

Section 1.2 Personnel Identification

Performer (1):

Name (print) _____ Initials _____

Signature _____ Date _____

Performer (2):
(optional)

Name (print) _____ Initials _____

Signature _____ Date _____

Released by:

Name (print) _____ Initials _____

Signature _____ Date _____

Performed by: _____ Date: _____

Signature Date

Section 1.3 End User Information

Company name: _____

Address: _____

_____

_____

Department/Building: _____

Location/Building: _____

Contact: _____

Telephone: _____

E-Mail: _____

Performed by: _____ Date: _____

Signature Date

Section 2.0 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.	Instrument Description	Serial No.	Rec.	Miss.	NA
29-06000	PTB 330 tablet hardness testing instrument 300N				
29-06050	PTB 330 tablet hardness testing instrument 500N				
29-06100	PTB 330 tablet hardness testing instrument 1,000N				

Instrument Details

Instrument voltage	24 VDC
External power supply voltage	100-240 Volt, 50/60 Hz
Asset no. or lab ID no.	

Performed by: _____ Date: _____

Signature Date

Section 2.1 Standard Scope of Delivery

Part-No.	Nos	Description	Rec.	Miss.	NA
288-1100	1	Waste container			
288-1000	1	Sample support, flat			
283-0420	5	Thermal paper rolls for internal printer			
285-1785-3	1	3, 5, 10mm reference block set			
285-1771	1	Cleaning brush			
10-60010	1	Stainless steel caring oil			
34-08400	1	Power supply, external			
34-08500	1	Mains cable, EUR or			
34-08510	1	Mains cable, CH or			
34-08511	1	Mains cable, US or			
34-08512	1	Mains cable, GB or			
34-08513	1	Mains cable, AR/AUS/NZ or			
34-08514	1	Mains cable, IN/ZA or			
34-08515	1	Mains cable, BR			

Section 2.2 Scope of Delivery - Optional Accessories

Part-No.	Nos	Description	Rec.	Miss.	NA
288-1005		Sample support with oblong groove			
288-1050		Sample support according to customer specifications			
288-1200		Calibration support with felt			
288-1210		Calibration support for weights			

Performed by: _____ Date: _____

Signature Date

Section 2.3 Scope of Delivery - Optional Accessories – Balance

A balance can be connected to the PTB 330 instrument. A suitable balance may also be supplied locally:

Part-No.	Model	Serial No.	Rec.	Miss.	NA

Section 2.4 Scope of Delivery - Optional Accessories – External Printer

PTB 330 features an internal printer. An external printer can be used instead. A suitable external printer may also be supplied locally:

Part-No.	Model	Serial No.	Rec.	Miss.	NA

Section 2.5 Required Documentation and Information

Ordering Information

Customer Order Number	
Supplier Delivery-Note or Invoice Number	

Performed by: _____ Date: _____

Signature Date

Section 3.0 Equipment Documentation

Part-No.	Description	Rec.	Miss.	NA
B-29-06000	Operating Manual			
IQ-29-06000	Installation Qualification			
OQ-29-06000	Operation Qualification			
NA	Instrument Log Book			
QC-29-06000	QC/DQ Test Report			
NA	Delivery Note			

Section 3.1 Installation Requirements

NOTE: This instrument requires electrical installation with a quality, noise-free ground (earth). In this case, as in all electrical installations where liquid handling is an integral part of the instrument function, 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 3.2 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):		45 **x** 30 **x** 25 cm	

Section 3.3 Clearance

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

Performed by: _____ Date: _____

Signature Date

Section 4.0 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
412-0245	10g weight to qualify an external balance (optional)				
412-0240	20g weight to qualify an external balance (optional)				
412-0209	50g weight to qualify an external balance (optional)				
28-00290	PTB-CAL15 5, 10, 15 kg weight set to qualify the force sensor				
28-00300	30kg weight to qualify the force sensor (optional)				
285-1785-3	Reference block set 3, 5, 10mm to qualify the length measurements				
80-75109	Reference block set 1-10.0mm to qualify the length measurements (optional)				
80-75111	Reference block set 10-20.0mm to qualify the length measurements (optional)				
28-01050	PT-MET50 Mechanical Tablet, 50N to verify the hardness measurement procedure (optional)				
28-01100	PT-MET100 Mechanical Tablet, 100N to verify the hardness measurement procedure (optional)				
28-01150	PT-MET150 Mechanical Tablet, 150N to verify the hardness measurement procedure (optional)				
28-01200	PT-MET200 Mechanical Tablet, 200N to verify the hardness measurement procedure (optional)				

Tests using optional items may be skipped. Mark "NA" when not used. Check the OQ document for more details about optional tests.

Performed by: _____ Date: _____

Signature Date

Section 4.1 Calibration Certificates for the Tools, Standards and Substances

Part-No.	Description	Calibration Date	Rec.	Miss.	NA
412-0211	Calibration certificate for 10g weight				
412-0211	Calibration certificate for 20g weight				
412-0211	Calibration certificate for 50g weight				
281-2890	Calibration certificate for PTB-CAL15				
281-2830	Calibration certificate for 30kg weight				
320-1785-3	Calibration certificate for reference block set 3, 5, 10mm				
801-2800	Calibration certificate for reference block set 1-10.0mm				
801-2802	Calibration certificate for reference block set 10-20.0mm				
281-2960	Factory calibration certificate for PT-MET50				
281-2960	Factory calibration certificate for PT-MET100				
281-2960	Factory calibration certificate for PT-MET150				
281-2960	Factory calibration certificate for PT-MET200				

Section 4.2 Other Equipment Used – Not Calibrated

Part-No.	Description	Serial No.	OK	NA
002-6003	Allen key, size 3	NA		
288-1200	Calibration support with felt	NA		
288-1210	Calibration support for weights	NA		

Performed by: _____ Date: _____

Signature Date

Section 5.0 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 5.1 Check Packaging Material

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

OK	NOK	NA

Section 5.2 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 5.3 Check for Completeness

All parts required for the standard operation of the instrument are listed on the delivery note supplied. 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 the 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 Date

Section 5.4 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 5.5 Connect Mains

Keep the power switch on the backside of the instrument at off. Check that the mains cable, external power supply cable and the socket do not show any visible damage. Connect the external power supply to the 24 VDC power port on the backside of the instrument. Connect the mains cable to the external power supply and to the mains.

OK	NOK	NA

Section 5.6 Turn on the Instrument

Use the power switch on the backside of the instrument to turn it on. Confirm that the screen lights up, that all pixels light up and the content is shown correctly.

OK	NOK	NA

Section 5.7 Verify Firmware Version

After power on, the installed firmware versions are displayed. Verify that the versions displayed match the versions noted in the supplied QC protocol.

No.	Description	Version	OK	NA
4.7.1	Note the actual terminal board firmware (leftmost) version displayed on the start screen.			
4.7.2	Note the actual interface board firmware (middle) version.			
4.7.3	Note the actual measuring board firmware (rightmost) version.			
4.7.4	Check that the versions are the same as noted in the QC document for this instrument.	NA		

Performed by: _____ Date: _____

Signature Date

Section 5.8 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

Section 5.9 Turn off the Instrument

Turn off the instrument using the power switch on the rear left side of the instrument.

OK	NOK	NA

Notes

Performed by: _____ Date: _____

Signature Date

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 6.0 Result and Comments

Instrument type	PTB 330	Serial number	

Have any additional sheets been attached to this document?	YES	NO

If yes, how many sheets have been attached?	Nos

The instrument has passed the installation qualification procedure.	YES	NO

Check yes when all tests have passed. In case one or more tests failed check no and document the reason for the failure in this report. In this case the applicable sections of the installation qualification must be repeated once the reason for failure has been eliminated.

Comments

This completes the installation qualification of the tested instrument.

Performed by: _____ Date: _____

Signature Date

Released by: _____ Date: _____

Signature Date