Operation Qualification (OQ)

PTB 330 Tablet Hardness Testing Instruments

Version 1.0

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Document History

Version	Valid from [dd.mm.yyyy]	Author	Change	Remark
1.0	15.10.2025	Pharma Test	N	First Release

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 330 tablet testing instrument is composed of:

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

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

Operation Qualification Program

This document is divided into sections.

Section 1.0 General Documentation Conventions

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

Section 2.0 Instrument Identification

This section identifies the main instrument and confirms that accessories and calibration tools as per the completed IQ are present.

Section 3.0 Operation Qualification Procedure

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

Section 4.0 Result and Comments

This section is used to document the results of the operation qualification and for comments regarding the qualification 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 (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 Date

Section 2.0 Instrument Identification

Check if the instrument/system and accessories according to the completed IQ are 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
29-06000	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

Asset No. or Lab ID No.	

Section 2.1 Calibration Tools, Standards and/or Substances Identification

Check if the required calibration tools, standards and/or substances according to the completed IQ are present.

OK	NA

Performed by: _____ Date: _____

Signature Date

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 Connect an External Printer

In case an external printer is to be used with the PTB 330 instrument, connect it to the printer port of the PTB 330.

OK	NOK	NA

Section 4.2 Connect an External Balance

In case an external balance is to be used with the PTB 330 instrument, connect it to the balance port of the PTB 330.

OK	NOK	NA

Section 4.3 Check Mains Connection

Check that the external power supply is connected to the 24 VDC power port on the backside of the instrument. Check that the mains cable is connected to the external power supply and to the mains.

OK	NOK	NA

Section 4.4 Start Up

Use the power switch on the backside of the instrument to turn it on.

No.	Description	OK	NOK	NA
4.4.1	Confirm that the PTB 330 turns on and that no error message appears.			
4.4.2	Confirm that the touch screen operates correctly.			

Performed by: _____ Date: _____

Signature Date

Section 4.5 Login and Enter Settings Menu

Login to the instrument as user "Admin". The default password is "PHARMATEST". Then enter the settings menu. Then enter locale settings.

OK	NOK	NA

Section 4.6 Perform Initial Settings – Language

Check the setting for "Language" and change it if necessary. Confirm your setting.

OK	NOK	NA

Section 4.7 Perform Initial Settings – Time/Date

Check the current time and date and the time and date formats and change them if necessary. Confirm your settings.

OK	NOK	NA

Section 4.8 Perform Initial Settings – Units

From the settings menu enter device settings. Check the units for hardness and length and change them if necessary. Confirm your settings.

OK	NOK	NA

Performed by: _____ Date: _____

Signature Date

Section 4.9 Perform Initial Settings – Break Parameters

The break parameters will be used for all quick tests and as defaults for new methods. It is recommended to leave these settings at the factory defaults, unless these prove to be problematic for your samples. Check the user manual for more details on the break parameters.

The factory defaults are:

Break detection: 3N

Max. distance: 2mm

Touch detection: 10N

Check the settings for break parameters and change them if necessary. Confirm your settings.

OK	NOK	NA

Section 4.10 Perform Initial Settings – Standby

After a period of inactivity equal to the set standby time the instrument will dim the display.

Check the setting for standby and change it if necessary. Confirm your setting.

OK	NOK	NA

Section 4.11 Perform Initial Settings – Output

By default, PTB 330 outputs test reports and any other report via the internal Printer. In case an external printer or a PT-Node is to be used instead, change the setting to external Printer. In case the test results should be transmitted as serial data to an external system, change the setting to RS232.

Check the setting for output and change it if necessary. Confirm your setting.

OK	NOK	NA

Section 4.12 Perform Initial Settings – Quick Test

Quick test is used to perform a test without creating a method with nominal values beforehand. By default, the quick test can be started directly from the start screen without requiring logging into the instrument. In case performing quick tests without logging in should be prohibited, set "QUICK TEST" to "no". Note that quick tests can still be performed, but via the main menu, after logging in to the instrument.

Check the setting for quick test and change it if necessary. Confirm your setting.

Performed by: _____ Date: _____

Signature Date

OK	NOK	NA

Section 4.13 Perform Initial Settings – Auto Start

During a test run the auto mode can be activated. With auto mode active, the instrument automatically proceeds with the next step without waiting for the user to confirm. To give the operator enough time to insert and orientate samples, a delay in seconds can be set. By default, the delay is set to 2 seconds.

Check the setting for auto start and change it if necessary. Confirm your setting.

OK	NOK	NA

Section 4.14 Perform Initial Settings – Break Method

PTB 330 supports both linear force increase and constant speed break modes for the hardness measurement. The factory setting is linear force increase of 20 N/sec. This setting may need to be changed to obtain comparable hardness results to instruments operating with a different break method or break method parameter. See the user manual for more details.

Check the setting for break method and change it if necessary. Confirm your setting.

OK	NOK	NA

Section 4.15 Create a New User

From the main menu enter the user menu. Create a new user. Enter a username, a full name and a password. Confirm the password. Assign all rights to this user. Note the username and password in a secure manner.

OK	NOK	NA

Performed by: _____ Date: _____

Signature Date

Section 4.16 Change Administrator Password (optional)

It is strongly recommended to change the administrator password from the default password. In case you do not want to do this now, this section may be skipped. Otherwise change the password for the user "Admin" now and note the new password in a secure manner.

OK	NOK	NA

Section 4.17 Login as New User

Logout the administrator and login with the newly created user.

OK	NOK	NA

Section 4.18 Calibrate the Length Measurement

The instrument is supplied with a 3, 5 and 10mm reference block set but other reference blocks may be used instead. A three-point calibration should be performed with three measurements of each reference block. The reference blocks must be placed in the middle of the testing station, touching the testing station wall.

For reference blocks with a nominal size of ⩽10mm the tolerance is ±0,02mm. For reference blocks with a nominal size of >10mm and ⩽35mm the tolerance is ±0,05mm.

Enter the calibration menu and select length.

No.	Description	TARG	MEAS	OK	NA
4.15.1	Set the first calibration reference block.		NA		
4.15.2	Set the second calibration reference block.		NA		
4.15.3	Set the third calibration reference block.		NA		
4.15.4	Set the number of measurements.	3	NA		
4.15.5	Perform first measurement of first reference block.	Reference block ⩽10mm: = ±0.02mm; Reference block >10mm and ⩽35mm = ±0.05mm			
4.15.6	Perform second measurement of first reference block.				
4.15.7	Perform third measurement of first reference block.				
4.15.8	Perform first measurement of second reference block.				

Performed by: _____ Date: _____

Signature Date

No.	Description	TARG	MEAS	OK	NA
4.15.9	Perform second measurement of second reference block.				
4.15.10	Perform third measurement of second reference block.				
4.15.11	Perform first measurement of third reference block.				
4.15.12	Perform second measurement of third reference block.				
4.15.13	Perform third measurement of third reference block.				
4.15.14	Print the calibration report and attach it hereto. Then quit the length calibration.	NA	NA		

Section 4.19 Calibrate the Force Sensor (Load Cell)

Different reference weights are available from Pharma Test and may be used here. A three-point calibration should be performed with three measurements of each reference weight.

From the calibration menu select hardness.

No.	Description	TARG	MEAS	OK	NA
4.16.1	Set the first calibration reference weight.		NA		
4.16.2	Set the second calibration reference weight.		NA		
4.16.3	Set the third calibration reference weight.		NA		
4.16.4	Set the number of measurements.	3	NA		
4.16.5	Perform first measurement of first reference weight.	±0.1kg			
4.16.6	Perform second measurement of first reference weight.				
4.16.7	Perform third measurement of first reference weight.				
4.16.8	Perform first measurement of second reference weight.				
4.16.9	Perform second measurement of second reference weight.				
4.16.10	Perform third measurement of second reference weight.				

Performed by: _____ Date: _____

Signature Date

No.	Description	TARG	MEAS	OK	NA
4.16.11	Perform first measurement of third reference weight.				
4.16.12	Perform second measurement of third reference weight.				
4.16.13	Perform third measurement of third reference weight.				
4.16.14	Print the calibration report and attach it hereto. Then quit the hardness calibration.	NA	NA		

Section 4.20 Perform Hardness Measurement Verification with PT-MET (optional)

Pharma Test offers PT-MET mechanical test tablets for daily verification of tablet hardness testers. These are available with nominal hardness values of 50, 100, 150 and 200N. You can use PT-MET here to perform a verification test to show the plausibility or the hardness measurement procedure. If no PT-MET are available skip this section and mark test relating to PT-MET which are not available as "NA".

Enter the methods menu from the main menu. Start a new test using the existing method "PT-MET". Enter a batch number, for example "OQ" and proceed. Place the PT-MET in the test station and follow the onscreen instructions. Repeat this process for all available PT-MET and enter the results below.

No.	Description	TARG	MEAS	OK	NA
4.17.1	Perform first measurement with PT-MET50.	45-55N			
4.17.2	Perform second measurement with PT-MET50.	45-55N			
4.17.3	Perform third measurement with PT-MET50.	45-55N			
4.17.4	Print out the test report and attach it hereto.	NA	NA		
4.17.5	Perform first measurement with PT-MET100.	90-110N			
4.17.6	Perform second measurement with PT-MET100.	90-110N			
4.17.7	Perform third measurement with PT-MET100.	90-110N			
4.17.8	Print out the test report and attach it hereto.	NA	NA		

Performed by: _____ Date: _____

Signature Date

No.	Description	TARG	MEAS	OK	NA
4.17.9	Perform first measurement with PT-MET150.	140-160N			
4.17.10	Perform second measurement with PT-MET150.	140-160N			
4.17.11	Perform third measurement with PT-MET150.	140-160N			
4.17.12	Print out the test report and attach it hereto.	NA	NA		
4.17.13	Perform first measurement with PT-MET200.	190-210			
4.17.14	Perform second measurement with PT-MET200.	190-210			
4.17.15	Perform third measurement with PT-MET200.	190-210			
4.17.16	Print out the test report and attach it hereto.	NA	NA		

Performed by: _____ Date: _____

Signature Date

Section 4.21 Perform Tablet Test Tablet Measurement Verification with Customer Samples (optional)

This test is intended to show the plausibility of the hardness measurement procedure using actual tablets. Use a batch of tablets with known average weight, average thickness, average width, average diameter and average hardness.

NOTE: comparable hardness results will only be achievable if the break method and break method parameters of the instrument used so far are equal to the settings of this PTB 330.

Enter the methods menu.

Create a new method with an appropriate name. You may enter a comment for this method.

Select the basic sample shape according to your tablets. Selecting "Oblong" here is preferred to activate the width measurement.

Deactivate "EP uniformity of mass" and "USP dietary supplement". Set number of tests to 10 for each available measurement. In case less than 10 tablets are available reduce this number accordingly. Set number of weight tests to 0 in case no balance is connected to the instrument.

Set the nominal values for each available measurement to the average values of this batch of tablets.

Deactivate all tolerances.

Leave the test parameters at their default values.

Leave the break method and break method parameters at their default setting and value, unless you want to compare the hardness test results with another instrument, using different settings.

Save the new method.

Test the tablets using this newly created method and note the results below. Check that each sample was broken by the PTB 330 instrument and that the results displayed are plausible.

Print out the test report and attach it to this document.

Performed by: _____ Date: _____

Signature Date

Description	Weight	Thickness	Width	Diameter	Hardness	Results		
NV						OK	NOK	NA
Sample 1								
Sample 2								
Sample 3								
Sample 4								
Sample 5								
Sample 6								
Sample 7								
Sample 8								
Sample 9								
Sample 10								

Performed by: _____ Date: _____

Signature Date

Notes:

Performed by: _____ Date: _____

Signature Date

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Section 5.0 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 operation qualification of the tested instrument.

Performed by: _____ Date: _____

Signature Date

Released by: _____ Date: _____

Signature Date