



PT-MT3 Electro-Magnetic Test Tablet

Operation Qualification (OQ)

V5.3

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Section 1.0 Scope Introduction

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Introduction

Objective

Operational qualification (OQ) is the process by which all functions of the Pharma Test PT-MT3 electro-magnetic test tablet 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 PT-MT3 electro-magnetic test tablet is composed of:

- The PT-MT3 instrument
- Supports to fit tablet hardness testers as per customer order

The PT-MT3 instrument represents a system for calibrating and qualifying the hardness range of Pharma Test and other brands of tablet hardness testers. The PT-MT3 instrument has an electronically controlled magnetically held “finger” made of stainless steel and a load cell attached to it. The finger is held in position by an electromagnet which is always powered with maximum current. The finger is equipped with an electronic load cell which can be calibrated to allow a maximum force of 500N.

The strike arm or jaw of the hardness tester makes contact with the load cell at the finger and tries to “break” the finger away from the electromagnet holding it in place. Depending on the force setting, the force required to make this break can be set stepplessly to maximum 500 N. The load cells have been calibrated against traceable standards to produce a useful series of equivalent tablet break points. The PT-MT3 can be supplied fully certified.

The system acts as a type of tablet simulator, which once broken can, unlike real tablets, be reset for the next test. At the end of a test it is possible to compare the force reading at the tested hardness tester and the actual setting at the PT-MT3. Both results should be within a specified tolerance and be stable over a number of repeated tests if the hardness tester works well. Also the testing time can be measured, this means the time when the strike arm or jaw of the hardness tester hits the load cell at the finger until breakpoint has been detected. This will allow qualifying instruments which run on a constant speed and force mode. In this case the time needed to break the magnetic finger should always be the same within minor tolerances.

Document History

Revision	Valid from	Author	Change	Remark
5.0	12.07.2012	PTAG	N	
5.1	13.08.2015	PTAG	N	PTB 420 added
5.2	27.10.2021	PTAG	R	Adj & Cal values harmonized
5.3	04.11.2024	PTAG	C	CAL-code section 5.8 corrected

Index Information - Change:

N = New Document

C = Correction

R = Revision

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 Equipment Description

In this section the equipment in this system, the required documentation and side installation requirements are identified.

Section 4.0 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 5.0 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 6.0 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

Enter the serial number of the PT-MT3. The serial number is printed on the type plate on the back of the instrument:

Part-No.	Instrument Description	Type	rec.	NA	miss.	Serial No.
29-18050	Electro-Magnetic Test Tablet	PT-MT3				

PT-MT3 Details

Voltage	115 V ☐ or 230/240 V ☐ 50/60 cycl.
Firmware Version	
Asset No. or Lab ID No.	

Section 3.0 Equipment Description

Section 3.1 Main Unit PT-MT3

These parts are included in the standard supply scope of the PTB 111E:

Part-No.	No.	Description	rec.	NA	miss.
290-0035	1	Calibration support			
10-60010	1	DAB stainl. steel cleaning oil, 1 bottle = 100ml.			
34-08500	1	IEC/EUR mains cord			
34-08511	1	US mains cord			
34-08512	1	GB mains cord			
34-08513	1	ARG/AUS/NZ mains cord			

Section 3.2 Optional Equipment - Supports

These supports are optional. Check if the received supply scope is according to the order confirmation, enter the received number of items and mark not ordered items as "NA":

Part-No.	No.	Support for	rec.	NA	miss.
29-18001		PTB 111E, 311E, PTB 411E, PTB 511E			
29-18001		PTB 301, PTB 302			
27-18001		PTBA 211E			
29-03510		PTB 420			
80-18001		WHT M, WHT ME			
		other: _____			

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

Section 4.0 Personnel Identification

Installation Engineer (1):

Name (print)

Initials

Signature

Date (MM/DD/YYYY)

Installation Engineer (2):
(optional)

Name (print)

Initials

Signature

Date (MM/DD/YYYY)

Released by:

Name (print)

Initials

Signature

Date (MM/DD/YYYY)

Performed by:

Signature

Date:

MM/DD/YYYY

Section 4.1 Required Qualification Equipment and Materials Identification

Part-No.	Description	Serial No.	rec.	N/A	miss.
28-00290	PTB-CAL15 - 5, 10, 15 kg calibration weight set				
10-61000	Digital stop watch				
xx-xxxxxx	Calibrated hardness tester				

Section 4.2 End User Information

Company Name: _____

Address: _____

Department: _____

Location: _____

Contact: _____

Telephone: _____

E-Mail: _____

Performed by: _____ Date: _____

Signature

MM/DD/YYYY

Section 5.0 Operation Qualification Procedure

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

Section 5.1 Turn on the Instrument

Turn on the instrument using the power switch on the rear left side of the instrument. All displays will light up.

pass	fail	N/A

Section 5.2 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.

pass	fail	N/A

Section 5.3 Test Keys

Check that all keys function correctly.

pass	fail	N/A

Section 5.4 Select Force Result Units

Press <CAL> to enter the setup menu. Press <4> to switch between the possible units. Select „N“ (= Newton) as unit.

pass	fail	N/A

Section 5.5 Enter Actual Date

Press <CAL>, <5> and then <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	N/A

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

Section 5.6 Enter Actual Time

Press <CAL>-, <5> and then <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	N/A

Section 5.7 Enter Calibration Interval

Press <CAL>, <5> and then <2>. The calibration validity date is displayed. Press <START> to change the calibration interval. "Ci" "xx" are displayed to indicate the interval time. Press <.> to select the interval time from "1" – "3" – "6" – "12" – "24" months or set it to "OFF". Confirm the entry by pressing <*> or cancel the edit by pressing <STOP>. Press any key to continue.

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

pass	fail	N/A

Section 5.8 Check the Load Cell Offset

Press <CAL> and then <2> to display the load cell offset.

Nominal Value (D)	Actual Value (D)	pass	fail	N/A
12 – 52				

Section 5.9 Calibrate the Load Cell – 5kg Weight

Place the finger upright in the calibration support (part no. 290-0035). Start the calibration program of the PT-MT3.

Nominal Value (kp)	Actual Value (kp)	pass	fail	N/A
4.95 – 5.05				

Section 5.10 Calibrate the Load Cell – 10kg Weight

The finger is still placed in upright position in the calibration support.

Nominal Value (kp)	Actual Value (kp)	pass	fail	N/A
9.95 – 10.05				

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

Section 5.11 Calibrate the Load Cell – 15kg Weight

The finger is still placed in upright position in the calibration support.

Nominal Value (kp)	Actual Value (kp)	pass	fail	N/A
14.95 – 15.05				

Section 5.12 Calibrate the Break Point Detection and Reproducibility

Remove the finger from the calibration support. Insert the finger into the support for the hardness testing instrument used. Set the hardness testing instrument to the force mode of 20N/sec. Leave all other settings at the default.

Set the PT-MT3 to mode A. Enter the nominal values. Perform 10 tests each. Print out the result report and attach it hereto. Note the results in the table below.

Nominal Value (N)	Xmax		Xmin		Xmean		OK	NOK	NA
	TARG	ACT	TARG	ACT	TARG	ACT			
30	27.5 – 32.5		27.5 – 32.5		27.5 – 32.5				
100	97 - 103		97 - 103		97 - 103				
200	196 - 204		196 - 204		196 - 204				
300	295 - 305		295 - 305		295 - 305				

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

Section 5.13 Calibrate the Break Time

Enter the nominal value. Perform 10 tests. Use the stop watch and measure the time from making the contact with the load cell until the break is detected. Print out the results report and attach it hereto. Note the results in the table below.

Nominal Value (N)	TARG (sec.)	ACT (sec.)	OK	NOK	NA
100	4.5 – 5.5				
	4.5 – 5.5				
	4.5 – 5.5				
	4.5 – 5.5				
	4.5 – 5.5				
	4.5 – 5.5				
	4.5 – 5.5				
	4.5 – 5.5				
	4.5 – 5.5				
	4.5 – 5.5				

Section 5.14 Calibrate the Break Time Detection

Set the PT-MT3 to mode B.

Enter the nominal value. Perform 10 tests. Print out the results report and attach it hereto. Note the results for time in the table below.

Nominal Value (sec.)	Xmax		Xmin		Xmean		OK	NOK	NA
	TARG	ACT	TARG	ACT	TARG	ACT			
5	4.9 – 5.1		4.9 – 5.1		4.9 – 5.1				

Note the results for force in the table below.

Nominal Value (sec.)	Xabs		OK	NOK	NA
	TARG	ACT			
5	0.0 – 1.0				

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

