Operation Qualification (OQ)

PT-LT100
Leak Testing Instrument

Version 1.2

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Document History

Version	Valid from	Author	Change	Remark
1.0	16.06.2025	Pharma Test	N	First release
1.1	31.07.2025	Pharma Test	R	Minor revision
1.2	06.02.2026	Pharma Test	C	Corrections to air pressure data. Table for use at different altitudes.

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 PT-LT100 leak 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 PT-LT100 instrument is composed of:

- The PT-LT100 main instrument
- Standard supply scope
- One or more desiccators
- Optional equipment and accessories according to customer order

PT-LT100 is fully compliant with the current USP <1146> monograph.

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 PT-LT100. The serial number is printed on the type plate on the back of the instrument:

Part-No.	Description	Type	Serial No.	Rec.	Miss.	NA
29-03000	Leak testing instrument	PT-LT100				

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
10-61000	Stopwatch				
382-0350	Vacuum gauge, digital or				
382-0300	Vacuum gauge, analog				

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)

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: _____

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 Connect a Desiccator

Connect a desiccator to the instrument. If more than one desiccator is available, select the smallest one. Make sure it is properly connected and that the lid is closed tightly.

If no desiccator has been supplied with the instrument, a suitable desiccator can be supplied locally. A desiccator must be available to complete this OQ. Refer to the user manual for more information on how to connect the desiccator.

OK	NOK	NA

Section 4.2 Turn on the Instrument

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. Use the power switch on the backside of the instrument to turn it on. Confirm that the screen lights up.

OK	NOK	NA

Section 4.3 Perform Self-Test

Press the click wheel to start the self-test. Confirm that the self-test runs passes without any error. The self-test takes approx. 1 minute to complete (the exact time depends on the size of desiccator used).

OK	NOK	NA

Section 4.4 Check Buttons and Click Wheel

Verify that all buttons and the click wheel work well.

OK	NOK	NA

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 4.5 Log In to the Instrument

From the main menu select "Select user". From the list of users select "ADMIN". Enter the default password: "ADMIN" and select "Continue".

OK	NOK	NA

Section 4.6 Create a New User

From the main menu select "Edit user". Then select "Add new user". Enter a name for the new user and select "Continue". Enter a password for the new user and select "Continue". Confirm the new password by entering the same password again and select "Continue". You will get a confirmation message that the password has been set. Select "Continue". Otherwise retry entering the password and make sure you enter it exactly the same twice. Note down this user password. Change the user permissions to "Method user" and select "Continue". On the next screen, select "Continue" again to create the new user.

OK	NOK	NA

Section 4.7 Change Administrator Password

From the main menu, select "Edit password". Change the default administrator password to your personal password. You need to enter the new password a second time to confirm the change.

Make sure to note down your password and to secure this information.

OK	NOK	NA

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 4.8 Set General Settings

From the main menu select "Settings". The settings menu offers the possibility to load and save files from and to a USB flash drive, to adjust date, time and PQ interval, to display the actual run time and to set the install date. Furthermore, the option to perform a quick test without login can be deactivated here. You can select to show the password during entering or to hide the characters. You can enter a department and a device ID. These will be included on the printouts. The instrument language can be selected here as well. Additional language files can be installed using the load files function. Refer to the user manual for more information about this. The info displays information about the instrument such as model, serial number, firmware version and more. The last menu item leads to the device settings menu, this will be used later.

Now, set date and time in the relevant menu and change any of the settings mentioned above as per your requirements.

OK	NOK	NA

Section 4.9 Set and Restart PQ Interval

From the settings menu, select "PQ interval". Select "Set PQ interval". Set the PQ interval in months to the desired setting and select "Continue". Pharma Test recommends performing a performance qualification (PQ) every six months. Confirm that you want to start the PQ interval from today by selecting "Continue" on the following screen. Once the set PQ interval has elapsed, the instrument will remind the operator that the PQ is due. Note however, that use of the instrument will in no way be limited even in case the PQ is overdue. It is a reminder only.

OK	NOK	NA

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 4.10 Set Device Settings

From the settings menu select "Device settings". From here you can perform calibration of the instrument, select which vacuum unit to be used and select types of balance and printer connected to the instrument.

By default, the instrument is set to use mbar for the vacuum unit and this document assumes this setting for the subsequent calibration of the instrument. We recommend changing this setting later, after the OQ has been completed, in case you want to use mmHg instead of mbar.

Optionally a balance can be connected to the instrument and the type of balance can be set here. Refer to the user manual for information on supported balances and how to use them together with PT-LT100. In case an external balance is to be used with this instrument, select the corresponding type now.

By default, the instrument is equipped with an internal printer, and it is setup to use this internal printer. So, this setting only needs to be changed in case an alternative, external printer is to be used. Refer to the user manual for more information about supported external printers. In case an external printer is to be used with this instrument, select the corresponding type now.

OK	NOK	NA

Section 4.11 Perform Valve Opening Test

It is possible to manually open the solenoid valves of the instrument thereby releasing any vacuum. To manually open the solenoid valves, press the <Esc> key. You will hear a clicking sound when the valves open. Confirm that you can hear the valves opening.

OK	NOK	NA

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 4.12 Calibrate Vacuum Accuracy

Make sure that a desiccator is still connected to the instrument and that the lid is closed tightly.

To perform the upcoming test, find out what sea level you are at. In the first column, you will find the relevant ranges in meters above sea level. (m ASL) Only fill in the range that applies to you.

From the device settings menu select “PT-LT calibration”. Then select “Calibrate vacuum”.

Description	m ASL	TARG (mbar)	MEAS	OK	NA
Set the nominal vacuum to 920 mbar and the hold time to 10 seconds.	0-100	920	NA		
Select “Continue”. Use the vacuum gauge to check the actual real vacuum. Enter the real vacuum.		870-930			
Confirm that during this test a vacuum of 920 mbar was reached. After vacuum release wait for at least 60 seconds.		NA	NA		
Set the nominal vacuum to 900 mbar and the hold time to 10 seconds.	101-500	900	NA		
Select “Continue”. Use the vacuum gauge to check the actual real vacuum. Enter the real vacuum.		850-910			
Confirm that during this test a vacuum of 900 mbar was reached. After vacuum release wait for at least 60 seconds.		NA	NA		
Set the nominal vacuum to 840 mbar and the hold time to 10 seconds.	501-1000	840	NA		
Select “Continue”. Use the vacuum gauge to check the actual real vacuum. Enter the real vacuum.		790-850			

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Description	m ASL	TARG (mbar)	MEAS	OK	NA
Confirm that during this test a vacuum of 840 mbar was reached. After vacuum release wait for at least 60 seconds.		NA	NA		
Set the nominal vacuum to 780 mbar and the hold time to 10 seconds.	1001-1500	780	NA		
Select "Continue". Use the vacuum gauge to check the actual real vacuum. Enter the real vacuum.		720-790			
Confirm that during this test a vacuum of 780 mbar was reached. After vacuum release wait for at least 60 seconds.		NA	NA		
Set the nominal vacuum to 730 mbar and the hold time to 10 seconds.	1501-2000	730	NA		
Select "Continue". Use the vacuum gauge to check the actual real vacuum. Enter the real vacuum.		680-740			
Confirm that during this test a vacuum of 730 mbar was reached. After vacuum release wait for at least 60 seconds.		NA	NA		

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Description	m ASL	TARG (mbar)	MEAS	OK	NA
Set the nominal vacuum to 680 mbar and the hold time to 10 seconds.	2001-2500	680	NA		
Select "Continue". Use the vacuum gauge to check the actual real vacuum. Enter the real vacuum.		630-690			
Confirm that during this test a vacuum of 680 mbar was reached. After vacuum release wait for at least 60 seconds.		NA	NA		
Print the calibration report and attach it to this document.		NA	NA		

Section 4.13 Calibrate the Desiccators

Make sure that a desiccator is still connected to the instrument and that the lid is closed tightly. Note which type of desiccator is currently connected to the instrument and start the calibration from the corresponding section below. Perform this calibration for all types of desiccators supplied and/or to be used. Mark the remaining desiccators not supplied and/or not to be used as "NA".

Section 4.13.1 Desiccator 150mm (part no. 26-02010)

From the device settings menu select "PT-LT calibration". Then select "Calibrate vacuum".

Description	TARG (mbar)	MEAS	OK	NA
Set the nominal vacuum to 600 mbar and the hold time to 2 minutes.	600	NA		
Select "Continue". Use the vacuum gauge to check the actual real vacuum. Enter the real vacuum.	525-675			
Confirm that during this test a vacuum 600 mbar was reached.	NA	NA		
After vacuum release wait for at least 60 seconds and then use the vacuum gauge to check the zero-vacuum value.	0-5			
Print the calibration report and attach it to this document.	NA	NA		

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 4.13.2 Desiccator 200mm (part no. 26-02030)

From the device settings menu select “PT-LT calibration”. Then select “Calibrate vacuum”.

Description	TARG (mbar)	MEAS	OK	NA
Set the nominal vacuum to 600 mbar and the hold time to 10 seconds.	600	NA		
Select “Continue”. Use the vacuum gauge to check the actual real vacuum. Enter the real vacuum.	570-630			
Confirm that during this test a vacuum 600 mbar was reached.	NA	NA		
After vacuum release wait for at least 60 seconds and then use the vacuum gauge to check the zero-vacuum value.	0-5			
Print the calibration report and attach it to this document.	NA	NA		

Section 4.13.3 Desiccator 250mm (part no. 26-02020)

From the device settings menu select “PT-LT calibration”. Then select “Calibrate vacuum”.

Description	TARG (mbar)	MEAS	OK	NA
Set the nominal vacuum to 600 mbar and the hold time to 10 seconds.	600	NA		
Select “Continue”. Use the vacuum gauge to check the actual real vacuum. Enter the real vacuum.	570-630			
Confirm that during this test a vacuum 600 mbar was reached.	NA	NA		
After vacuum release wait for at least 60 seconds and then use the vacuum gauge to check the zero-vacuum value.	0-5			
Print the calibration report and attach it to this document.	NA	NA		

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 4.13.4 Desiccator 380mm, Glass (part no. 26-02040)

From the device settings menu select "PT-LT calibration". Then select "Calibrate vacuum".

Description	TARG (mbar)	MEAS	OK	NA
Set the nominal vacuum to 600 mbar and the hold time to 10 seconds.	600	NA		
Select "Continue". Use the vacuum gauge to check the actual real vacuum. Enter the real vacuum.	580-620			
Confirm that during this test a vacuum 600 mbar was reached.	NA	NA		
After vacuum release wait for at least 60 seconds and then use the vacuum gauge to check the zero-vacuum value.	0-5			
Print the calibration report and attach it to this document.	NA	NA		

Section 4.14 Calibrate the Timer Function

This test is to confirm that the integrated timer of the instrument is working. From the PT-LT calibration menu select "Calibrate timer".

Description	TARG (sec)	MEAS	OK	NA
Set the timer to 60 seconds and start the calibration. Use the stopwatch. Enter the real time measured.	59-61			
Print the calibration report and attach it to this document.	NA	NA		

Performed by: _____ Date: _____

Signature DD/MM/YYYY

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Section 5.0 Result and Comments

The instrument has passed the operation qualification 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 in this report. In this case the operation qualification must be repeated once the reason for failure has been eliminated.

Comments

This completes the operation qualification of the PT-LT100 leak testing instrument.

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

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

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