Installation Qualification (IQ)

PT-LT100
Leak Testing Instrument

Version 1.1

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Table of Contents

Document History

Version	Valid from	Author	Change	Remark
1.0	11.06.2025	Pharma Test	N	First release
1.1	31.07.2025	Pharma Test	R	Minor revision

Table 1: Document History

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 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

The PT-LT100 leak tester is used to test for the integrity of packed strips, blisters and small sachets containing tablets, granulates, liquids and so on. The instrument is used to test the quality of the packaging process and to check that the seals enclosing the product are perfectly intact. PT-LT100 is designed to find the smallest holes and imperfections in blister packs and other semi-rigid product packaging. It 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:

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), the completeness of the supply scope and optional accessories, as well as the required documentation are identified.

Section 2.0 Personnel Identification

In this section the personnel performing the installation qualification, the user of the equipment and place of installation are defined.

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

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

Instrument Details

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

Section 1.1 Standard Scope of Delivery

Part-No.	Nos	Description	Rec.	Miss.	NA
283-0420	5	Thermal paper rolls for internal printer			
101-2119	1	Silicon tube			
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			

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 1.2 Scope of Delivery – Desiccators

Desiccators are delivered as per customer order. At least one desiccator is required to use the instrument. A suitable desiccator may also be supplied locally:

Part-No.	Description	Serial No.	Rec.	Miss.	NA
26-02010	Desiccator, plastic, 150mm Ø				
26-02030	Desiccator, plastic, 200mm Ø				
26-02020	Desiccator, plastic, 250mm Ø				
26-02040	Desiccator, glass, 380mm Ø				

Section 1.3 Scope of Delivery - Optional Accessories – Balance

A balance can be connected to the PT-LT100 instrument. A suitable balance may also be supplied locally:

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

Section 1.4 Scope of Delivery - Optional Accessories – External Printer

PT-LT100 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

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 1.5 Required Documentation and Information

Ordering Information

Customer Order Number	
Supplier Delivery-Note or Invoice Number	

Equipment Documentation

Part-No.	Description	Rec.	Miss.	NA
B-26-03000	Operating manual			
IQ-26-03000	Installation qualification			
OQ-26-03000	Operation qualification			
NA	Instrument logbook			
QC-26-03000	QC/DQ test report			
NA	Delivery note			

Section 1.6 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 1.7 Operating Environment

Temperature:	15-40°C	Rel. humidity:	20-80%
Physical site:	Clean, dry and levelled bench	Weight support:	Approx. 30 kg/m²
Required bench space (width x depth x height):		32 **x** 25 **x** 31 cm without desiccator	

Section 1.8 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.	Rec.	Miss.	NA
10-61000	Stopwatch				
382-0350	Vacuum gauge, digital or				
382-0300	Vacuum gauge, analog				

Section 3.1 Certificates for the Tools, Standards and Substances

PartNo.	Description	Calibration Date	Rec.	Miss.	NA
101-3200	Calibration certificate for stopwatch				
382-0310	Calibration certificate for vacuum gauge, digital				
382-0360	Calibration certificate for vacuum gauge, analog				

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 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 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

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 4.6 Turn on the Instrument

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

OK	NOK	NA

Section 4.7 Verify the 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 Turn off the Instrument

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

OK	NOK	NA

Section 4.10 Qualify the Stopwatch

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 stopwatch is used to qualify the timer of the instrument.

OK	NOK	NA

Section 4.11 Qualify the vacuum gauge

The vacuum gauge used to qualify the vacuum function of the instrument and the desiccators.

OK	NOK	NA

Performed by: _____ Date: _____

Signature DD/MM/YYYY

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Section 5.0 Result and Comments

Type	PT-LT100	Serial Number	
Mains Voltage		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