

PT-LT100

Vacuum Leak Testing Instrument

The PT-LT100 leak tester is used to test for the integrity of packed strips, blisters and small sachets containing tablets, granules, 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.



Leak testing is widely applied in the pharmaceutical industry to check strips, blisters and bottles containing tablets, capsules, syrups and similar. It also finds application in the food industry, where it can be effectively used to check the airtightness of sweet packets, ready-to-eat pre-packed foods, confectionery packaging, packs of noodles or sauces. Samples are placed into the desiccator's housing, and the lid is placed in position. The pump starts to produce a vacuum inside the desiccators and the vacuum is held for a pre-set time.

The first thing to observe is that the tested package should keep its shape during this test; otherwise, the sealing is not correct. Secondly, as the package is immersed in a colored dye solution (normally Methylene Blue), the venting of the desiccators will allow any holes to be penetrated by the dye, and the contents of the flexible packaging will also be stained with the same coloring material. Similarly small bottles can also be tested. A sheet of paper will absorb any leaking fluid.

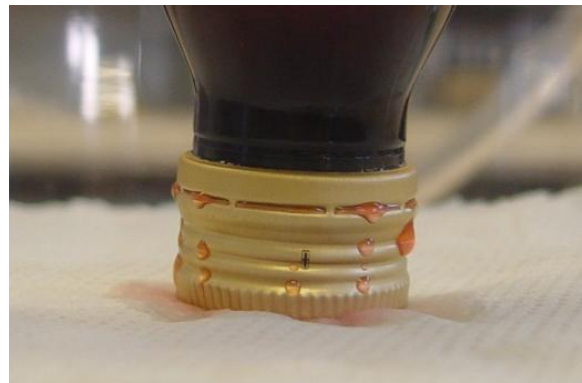
Operating Principle



Set vacuum level and holding time for your test. Up to four different vacuum levels and corresponding holding times can be programmed in a method. This way a product can be tested in a sequence of different vacuum levels, each with their own holding time. The instrument can be set to actively maintain the current vacuum level during the holding time. Besides visual inspection of the sample after test, it is also optionally possible to connect a balance to the instrument. This way the sample can be weighed before and after the test.

If the test is performed by immersing the sample in a liquid, the sample weight will increase in case it absorbs liquid through leaks.

If the sample is a container with liquid inside, the sample weight will decrease in case liquid is sucked out of the container through leaks.



Instrument Design

The instrument is made from high quality stainless steel which fully meets GLP requirements.

User Interface



PT-LT100 is operated by using a click wheel to navigate menus on the LCD screen and by functional keys to shortcut frequent operations. The display is backlit in changing colors that show the instrument status in a familiar traffic light system (green, yellow, red). Navigating the menu is quick and simple. The color-changing display makes it easy for the user to see when his input is required to proceed.

The instrument has a method and a user management system. Methods can be programmed, edited and stored directly on the instrument. Users can be created and assigned different user levels according to their roles (method or standard user, only one Admin).

Access to the instrument is protected by a login with username and password. Optionally a quick test menu can be accessed without logging in to the instrument first. This way tests can be performed with the instrument in case user access control and testing according to defined methods is not required.



Integrated Report Printer

PT-LT100 features an integrated report printer to document the test and calibration results. An integrated printer saves valuable bench space in your laboratory.

Cleaning and Maintenance

The integrated vacuum pump can be calibrated using an external vacuum meter. The air sucked in by the vacuum pump passed through a filter. The filter can be replaced easily without opening the instrument.

Data Storage and Export

A USB flash drive can be connected to the instrument to save and load methods in .csv-format. Printouts can be stored as text files. Results can be transmitted to external systems such as LIMS via a serial interface. Furthermore, instrument firmware updates can be installed, and factory settings be restored by using the flash drive without the need for any PC or programming tool.



Calibration

PT-LT100 features dedicated calibration programs for vacuum and timer function. The result can be documented by a print-out. The user is guided through each step of the calibration and a report is printed automatically.

The reports are saved on the instrument and can be printed later as well. A programmable qualification interval timer reminds the user to perform the instrument calibration once it is due. Each time the instrument is turned on it performs a quick self-check to ensure it is ready for operation. The result of the self-check can be documented via the integrated printer as well.

Available Desiccators

Desiccators with the following dimensions are available:

Part No.	Inner Diameter	Useable Inner Height	Volume	Material
26-02010	150mm	135mm	2,15l	Plastic
26-02030	200mm	175mm	4,35l	Plastic
26-02020	250mm	225mm	9,20l	Plastic
26-02040	380mm	283mm	18,5l	Glass

One desiccator is required to use the instrument.

Example Test Report

TEST REPORT - RUN TEST

Department: Department
 Device-ID: ABC123
 Device: PT-LT100
 SN: 27777
 Version: 2.10 b6
 Date: 2025-02-25
 Time: 11:36:20
 User: Admin

 Method: method1
 Product: product1
 Batch: ABC123
 Analysis-ID: 22
 EP/USP: yes
 Diameter: 250 mm
 Time 1: 00:02:00
 Vacuum 1: 400 mbar
 Readjustment: yes
 Max. Runs: 1

Results in 1 Run:

.....Run: 1.....
 Trip vacuum 1: 399 mbar

 Start weight: 313.0000 g
 End weight: 313.1287 g
 Weight Incr.: 0.1287 g
 Weight Incr.: 0.0411 %

Test Result:
 Test passed

Printed: 2025-02-25 11:39:06

Operator name

Signature

Customer department
 Customer device-ID
 Instrument model name
 Instrument serial number
 Instrument firmware version
 Date of test start
 Time of test start
 User performing test
 Method name
 Product name
 Batch number for each test
 Analysis ID (automatically ascending)
 Text according to EP/USP or not
 Diameter of desiccator
 Vacuum hold time 1
 Vacuum level 1
 Maintain vacuum or not
 Total number of test runs

 Vacuum level at end of test
 Start weight (measuring weight is optional)
 End weight
 Absolute weight increase
 Relative weight increase

Test has passed

Date and time when the report was printed

Space to write operator name

Space to sign the report

PT-Node Network Adapter for Printing and Data Transfer



PT-Node is an adapter that connects up to two Pharma Test instruments simultaneously to a network using a wired LAN connection. This way you can print test results from the instrument via your web browser on any local or network printer. Furthermore, it is possible to transfer the test results from the instruments to external systems in the same network. PT-Node supports PT-LT100.

Advantages

- » Ensure the quality of your packaging process, save costs by detecting leaks early
- » Option to use an external balance instead of visual inspection
- » Graphical LCD screen showing actual and target settings
- » Integrated protocol printer reduces bench space requirements
- » Password protected access through user management system
- » Programmable qualification interval timer reminds the user to perform instrument calibration
- » Dedicated calibration programs and reports
- » Copy methods between instruments by using a common USB flash drive
- » Export test reports as text files
- » Transmit test result to external systems such as LIMS
- » IQ/OQ documents included free of charge

Features

- » Fully USP <1146> compliant
- » Test the integrity of strips, blisters, bottles and similar
- » User management system
- » Method management system
- » Integrated calibration programs
- » Connect USB flash drive to copy methods and store test reports
- » Integrated protocol printer

Standard Scope of Supply

PT-LT100 comes ready to use with the following standard scope of supply:

- » PT-LT100 instrument with integrated vacuum pump
- » Comprehensive documentation included (PDF, hardcopies optional):
 - User manual
 - DQ/QC instrument compliance test certificate
 - IQ documentation
 - OQ documentation
 - Instrument logbook

Options

In addition to the standard scope of supply, Pharma Test offers a broad range of accessories and options including:

- » PT-Node network adapter (part no. 24-00100)
- » Alternative external ticket printer (part no. 29-02200)
- » Full range of certified validation tools available

Technical Specifications

Parameter	Specification
Final vacuum level	100 to at least 920 mbar depending on ambient atmospheric pressure
Maintain vacuum level	Yes, adjustable in method
Maximum vacuum hold time	99 hrs. 59 min. 59 sec.
Number of vacuum levels	Up to 4 vacuum levels per test
Number of vacuum hold times	Up to 4 vacuum hold times per test
Number of test runs	Up to 9 runs per test run adjustable in method
Method management	Up to 256 test descriptions (methods) can be stored on the instrument
User management	Up to 32 users with selectable user right levels can be stored on the instrument
Result data storage	Store copies of result reports by connecting a USB flash drive
Display	LCD with color-changing backlight
Data entry	Keypad with function keys and click wheel
Interfaces	USB type A host port to USB type B device port to connect flash drives, for serial data export and firmware updates RS-232 printer port for optional balance or external printer
Instrument housing	Brushed stainless-steel housing
Power	100-240 Volt, 50/60 Hz
Instrument dimensions	Approx. 32 cm x 25 cm x 31 cm (width x depth x height)
Packaging dimensions	Approx. 61 cm x 42 cm x 33 cm (width x depth x height)
Net /gross weight	Approx. 7,0 / 13,5 kg
Certification	All components certified to USP / EP requirements
CE / EMC certification	All CE / EMC Certification provided
Validation	All IQ & OQ documents included

We reserve the right to make technical changes without any prior notice.