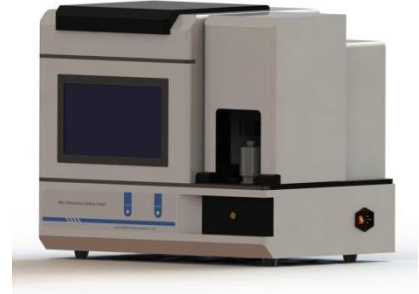


Product Name: Micro Leakage Sealing Tester

Product model: NDL-V301

Product Introduction:

This instrument is designed for non-destructive micro-leak testing of various empty/prefilled syringes, injection bottles (glass/plastic), filled and sealed bottles, other rigid packaging containers, and electrical components. Based on vacuum decay and pressure decay testing principles, it utilizes advanced mechanical design and rigorous, scientific calculation methods to ensure rapid testing, high accuracy, and high stability. Customization of non-standard software and test fixtures is also possible.



Product Features:

Dual test principle, innovative mechanical design

- Adopting the dual testing principles of vacuum decay method and pressure decay method, it can conduct qualitative and quantitative non-destructive testing of the sealing of packaging;
- The test parameters can be preset according to the sample specifications, and the test plan can be automatically stored to achieve one-click operation of the test process;
- Scientific and rigorous structural design, the whole machine adopts an integrated structure, reasonable layout and convenient operation;
- The test gas circuit adopts an integrated valve island design without any external gas pipes and gas circuits, ensuring the overall sealing of the test system;
- The test chamber adopts a fully automatic pneumatic clamping method, the double-rod cylinder seals the pressure evenly and has good test stability;
- Innovative mechanical design, automatic placement, automatic clamping of the test cavity, automatic completion of the test process, and automatic release of the test cavity after the test. The entire test process requires no human intervention, ensuring the accuracy and objectivity of the test data.
- The test chamber is connected to the host by pneumatic clamping, and test chambers of different specifications are automatically locked, making replacement and maintenance convenient;
- The whole machine adopts 304 stainless steel shell, which meets the cleanliness requirements of the pharmacopoeia;

Ultra-high test accuracy to ensure data repeatability

- It has excellent test adaptability and can detect both tiny leaks and large leaks in samples, and automatically give a pass/fail judgment;
- Use non-destructive testing methods to conduct non-destructive testing of samples for leakage to ensure data accuracy and objectivity;
- Adopting internationally renowned imported brands of micro-differential pressure, pressure sensors, and

pneumatic components with stable and reliable performance;

- Adopting internationally renowned imported brand external high-precision micro flow meter to optimize and improve the measurement and verification methods (optional);
- Precision pressure testing system, greatly improving test accuracy;
- Equipped with multiple pressure overload and electrical safety protection to ensure the safety of the instrument and operators;

Industrial-grade full-touch operating system, safe and convenient

- Built-in industrial-grade touch-screen computer, Windows system operation, real-time viewing of test data and test curves;
- The flat software operation interface has simple and intuitive steps, smooth control, and is easy to learn;
- Equipped with Chinese and English bilingual operation interface to meet different language requirements;
- Equipped with high-precision and high-speed sampling chips to ensure the accuracy, real-time and repeatability of test results;
- One-button operation, fully intelligent system control, and automated test process;
- Vacuum, test and penetration time are adjustable and stored in the database to ensure consistency of test conditions;
- The test curve is displayed in real time and the data is intelligently counted, making it easy to quickly view the test results;
- The instrument has the functions of automatic determination of test results, storage of test data, and traceability of test data;
- It has user hierarchical authority management function, customized authority control, password login, and convenient user management;
- Comply with GMP requirements for data integrity and traceability, and meet the needs of the pharmaceutical industry (optional);
- The system is embedded with universal data interfaces such as USB and Ethernet ports, which facilitates external access, data transmission and remote system upgrades.
- Equipped with the remote upgrade function of the test system, which is convenient for users to maintain and upgrade in the future;
- Supports quick query of historical data and is equipped with a micro printer, so the test results can be directly output and printed;
- Supports ZELKTEST laboratory data sharing system to centrally manage test results and test reports (optional).

Test principle:

The host system is sealed and connected to a dedicated test chamber corresponding to the sample to be tested. The sample is placed in the test chamber, sealed, and then evacuated. This creates a pressure differential between the inside and outside of the sample, allowing gas to enter the test chamber and the host system through the leak. The

host system uses the pressure change measured by the analysis sensor to calculate the sample's pressure decay value, equivalent pore diameter, standard flow rate, and other results, thereby determining whether the sample is leak-proof. The pressure decay method operates on the opposite principle.

Reference standards:

ASTM F2338, YY/T 0681.18, USP<1207>, "Guidelines for Sealing of Sterile Pharmaceutical Packaging Systems", etc.

Technical indicators:

Item	Data
Pressure range	-101 kPa ~ 300 kPa
Detection method	Vacuum decay method/pressure decay method
Test Unit	kPa / mbar / psi/Pa
Differential pressure sensor accuracy	±0.075%
Resolution	0.01pa
Measuring range	≥0.01ccm (about 1um)
Testing time	15 to 40 seconds
Test cavity	Fully automatic pneumatic clamping (size and type are customized according to the sample)
Control method	11.6-inch industrial-grade touch all-in-one computer
Control system	Windows 10 and above operating systems
Audit Trail	support
Software Features	Level 10 and above management authority settings comply with relevant provisions of the National Pharmacopoeia
Data storage	Unlimited storage
Data transmission	USB, RS232, 485, RJ45, wireless WIFI, USB flash drive export
keyboard and mouse	2.4G wireless keyboard and mouse
Reporting method	Micro printer/A4 report
External air source	Vacuum pump, compressed air
Air source pressure	≥0.5MPa (gas source to be provided by the user)
Air source interface	φ6mm polyurethane tube
Appearance material	304 stainless steel
Dimensions	Main unit: 340(L)×480(W)×320mm(H)
power supply	220VAC±10% 50Hz



Link Testing
Only for Flexible Packaging

net weight

About 20kg

Product Configuration:

Standard configuration: host, keyboard, mouse, micro printer, vacuum pump, $\Phi 6$ mm polyurethane tube

Customized parts: Test chamber customized according to sample specifications, negative standard reference samples, positive standard reference samples

Optional accessories: micro flow meter, air compressor, non-standard test chamber, negative bottle, positive bottle

Note: The air source interface of this machine is a $\Phi 6$ mm polyurethane tube, and the air source is prepared by the user.