Package Tightness Tester HY-LT-01

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Main features

Based on standards to meet user needs

1.Based on the test principle of "ASTM F2338 Standard Test Method for Non-destructive Detection of Leaks in Packages by Vacuum Decay Method" approved by the US FDA, using reliable vacuum decay detection components imported from the United States, the detection limit can reach 1 micron , and trace gas verification can also be carried out at the same time.
2.Based on <1207.1> PACKAGE INTEGRITY TESTING IN THE PRODUCT LIFE CYCLE—TEST METHOD SELECTION AND VALIDATION, "Technical Guidelines for Sealability Research of Chemical Drug Injection Packaging System (Trial)", "Technical Requirements for Quality and Efficacy Consistency Evaluation of Chemical Drug Injection Generic Drugs ?, providing the equipment method suitability verification report.
3.Provide installation, operation and performance qualification (IQ/OQ/PQ) verification documents.
4.Non-destructive testing, using a non-destructive testing method to test the airtightness of the sample package, the sample will not be damaged after the test.

Optimized hardware design, fully upgraded performance.

1.The whole machine is made of stainless steel cylinder (food grade, meeting FDA material requirements), and the rounded corner design of the whole machine is easy to clean.
2.The test chamber is easy to replace, and it only takes 0.5 seconds to replace the chamber, which solves the problem of cumbersome chamber replacement on the market.
3.Conform to ASTM F2338 requirements, designed with three-color display signal lights, real-time display of instrument working status.
4.Original imported vacuum attenuation detection components 0-+50°C temperature compensation to avoid external environmental influences.
5.Comply with ASTM F2338 requirements, built-in high-precision flowmeter, can automatically set the flow rate arbitrarily, and solve the problem of complicated flow setting in the market.
6.1-inch medical-grade touch screen, high resolution based on T5CPU, with high reliability.
7.Using oil-containing vacuum pump, it can work continuously, and the vacuum is as low as 0.003mbar.

Smart software meets regulatory requirements, is easy to use, and improves efficiency in an all-round way

1.The software conforms to the GMP audit trail system and meets the requirements of the US FDA 21 CFR PART 11 electronic records and electronic signatures.
2.Three-level password authority management system, set different operation authority

according to different operators.
3.The software comes with one-key water removal and one-key preheating functions to eliminate background noise and improve detection accuracy and efficiency.
4.Automatic detection mode, only need to place the sample to carry out air tightness detection, improve the test efficiency.
5.The test data is automatically processed and stored by the software and exported in the form of a file through the USB port.

Multiple cooperation supports personalized service customization

1.Cooperate with well-known domestic testing institutions to provide packaging sealing testing and method applicability verification services, laser drilling services.
2.Cooperate with American LenoxLASER company to provide positive bottle laser drilling service.
3.To meet the needs of users, we can provide cavity designs for various samples.
4.Double method detection system of vacuum decay method and pressure decay method can be customized.

Test Principle

Package Tightness Tester HY-LT-01 is based on the principle of ASTM F2338 vacuum decay method. The vacuum decay test is a non-destructive, quantitative measurement method. During the test, the test sample is placed in a test chamber closely matched with the leak test system (the test chamber is specially designed according to the sample, the smaller the gap between the test chamber and the sample, the higher the test resolution),
The test chamber is evacuated by the external vacuum pump of the test system. After reaching the vacuum degree, the system automatically stops vacuuming. After a period of equilibration, the absolute pressure sensor and vacuum sensor in the system monitor the pressure rise (that is, the vacuum decay value) within a predetermined time. If the pressure rise exceeds the predetermined value, it indicates that the sample leaks.

Technical Parameter

Technical indicators	Parameter
Testing method	Vacuum decay method, pressure decay method (optional)
Pressure range	0.05?1000mBar.abs
Pressure Sensor Accuracy	±0.25%S.P.
Pressure Sensor Response Time	<20ms
Vacuum decay detection element	Imported from USA, Assembled in China
Detection limit	1?m ?0.009sccm ?1.5×10-5Pa.m3/s
Sensitivity(Resolution)	0.2?m
Detection scope	1?m?missing rubber stopper
Preheat time	30min
External dimensions	350mm (L) × 300mm (W) × 360mm (H)
Supply voltage	AC100V?240V, 50/60Hz
Power	Host power ? 100W, vacuum pump power 200W
Weight	About 25kg
Instrument configuration	1 host, 1 vacuum pump, 2 sets of test chambers
Instrument selection	Two-stage high-performance rotary vane pump (Germany), positive bottle (China), test chamber customization

Part Name	Model	Material	QTY	Remark 1	Remark 2

Chamber of air tightness detector	Soft bag (500ml or less)	304	1 set	Including negative body material 6061, hardware brand MiSUMi (Japan), plastic parts brand elesa (Italy), gas circuit joint brand SMC (Japan), seal brand Hansheng (Taiwan)	Can make PTI, ATC, when the test cavity.
Chamber of air tightness detector	Hard bottle (500ml or less)	304	1 set		
Chamber of air tightness detector	Hard bottle (500ml or less)	Plexiglass	1 set		
Chamber of air tightness detector	500ml or more		1 set		
Negative body	500ml or less	6061	1 pc		

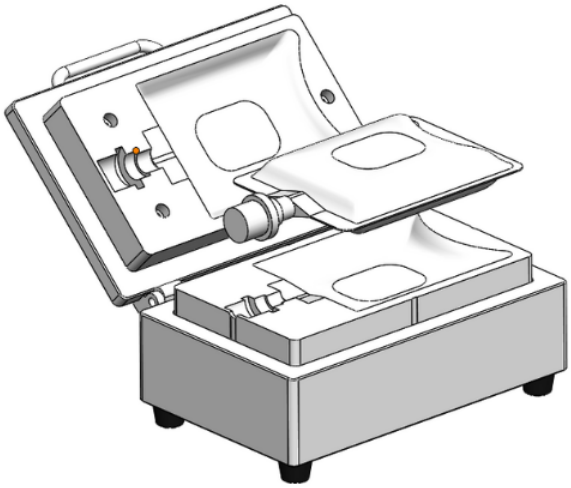
Explanation of nouns

Leakage: Leakage is the inadvertent escape or entry of a substance (solid, liquid, or gas) through a breach in a package wall or through a gap between package components. Leakage can also refer to material entering or escaping from damaged packaging.

Sealing tester cavity customization

1. Details

2. Description of drawings



Attachment 1 - Soft bag test cavity

Attachment 2 - Stainless steel cavity

Attached picture 3 - Plexiglass cavity