Leakage and Sealing Strength Tester
(Integrated Positive/Negative Pressure Method)
Model: ZFY-01

Product Description

ZFY-01 leakage and sealing strength tester adopts an integrated design of positive/negative pressure method, which meets the two testing methods of pressure and vacuum. It is suitable for packaging bags, bottle caps, vials/powder injection bottles, ampoules, microbial invasion, electronic Sealing and waterproof testing of components, lamps, mobile phones and other materials. It is an ideal testing instrument for food, plastic flexible packaging, wet wipes, pharmaceuticals, daily chemicals, and other industries.

Technical Characteristics

- The equipment is equipped with a 5-inch high-definition touch screen, controlled by a microcomputer, and equipped with a silent micro printer;
- "One-click" switching between positive pressure/negative pressure test, supporting setting of multi-stage pressure test;
- Intelligent pressurization, pressure maintenance, pressure compensation, timing, and pressure relief test processes are automatically completed;
- User hierarchical permission settings to meet GMP requirements, test record auditing, and tracking functions;

- Integrated design of 304# stainless steel and aviation plexiglass, making it easy to observe the test process. The circular structure container has better pressure bearing capacity.
- Pure copper safety valve to prevent overpressure (automatic pressure relief when the set pressure is exceeded) and safer to use;

Test Principle

The microbial intrusion test method, also known as the microbial challenge method, is a common seal integrity test method, which is usually performed at the same time as simulated filling. By following the simulated filling verification plan, the culture medium is simulated filled, and then the plugging and capping are performed. After the visual inspection is qualified, and after sterilization in a verified sterilization cabinet, the sealing surface of the container is immersed in high-concentration bacterial liquid. Make the culture medium in the sample container fully contact the inner surface of the seal. The neck of the sample and the outer surface of the seal should be completely immersed in the bacterial suspension. Take it out after soaking for a certain period of time. After regular culture, check whether there is microbial intrusion to determine whether the container is sealed. System integrity. At the same time, a positive control test needs to be done to confirm the growth-promoting ability of the culture medium. Vacuum or overpressure challenge conditions are often used during testing.

1. Test Methods

Pour the fresh bacterial suspension of Pswudomonas aeruginosa ATCC9027 into a stainless steel bucket.

1. Number 50 sterilized samples and completely invade them into the bacterial suspension. At the same time, place the bag flat so that the sterile culture medium in the bag fully contacts the inner surface of the welding part. The sample container remains in the bacterial suspension. Soak for 4 hours.

2. At the end of soaking, take another portion of the bacterial suspension and use a plate to count the concentration of the bacterial suspension.

3. Take out the sample from the bacterial suspension, wipe away the remaining bacterial suspension outside the sample container, and then disinfect the outer surface of the container with 70% isopropyl alcohol containing 0.5% peracetic acid.

4. Take two samples filled with culture medium and use them as positive controls. Disinfect their surfaces with 70% isopropyl alcohol containing 0.5% peracetic acid. Inoculate 10 to 100 CFU of Pseudomonas aeruginosa and perform a nutritional test on the culture medium according to step 8.2. .

5. Incubate the challenge test sample for 7 days, and observe and check the growth of microorganisms in the culture medium in the sample container. If there is growth, it is recorded as +, and if there is no growth, it is recorded as -. If bacteria grow in the sample container, follow the method in 8.2 to confirm that the growing bacteria is the challenge microorganism Pseudomonas aeruginosa; if all sample containers do not grow bacteria, take 10 samples and conduct a nutritional test of the culture medium according to 8.2.

6. After the test is completed, the bacterial suspension used in the challenge test shall be sterilized at 121°C for 30 minutes and then discarded.

2. Judgment Criteria

1. The challenge test of the sample will be valid only if the nutritional tests conducted in steps 2, 4, and 5 are all qualified.

2. At the beginning of the challenge test, the challenge bacterial suspension concentration (number of viable bacteria) must reach 1×106CFU/ml.

3. If bacteria grow during the challenge test, the number of samples growing bacteria must be recorded, and further investigation shall be carried out according to the following requirements.

4. Carefully check whether there are any defects in the seals of various parts of the container, causing microorganisms to infiltrate.

5. Defects in the sealing of the sample container will be observed and recorded in detail by taking photos.

6. If any container with bacterial growth in a challenge test is not due to obvious physical damage to the container seal, the test will be considered a failure.

The instrument complies with a number of national and international standards: GB/T 10440, GB/T 18454, GB/T 19741, GB/T 8368, YY/T0681, YY 0285, ASTM F1140, etc.

Technical Parameters

Project \ Model	ZFY-01 Leakage and Sealing Strength Tester
Sensor Range	0 ～ 200 Kpa (Positive pressure）; 0 ～-90KPA (Negative pressure）
	0 ～ 600 Kpa (Positive Pressure）; 0 ～ -90KPA (Negative Pressure) (Optional)
Air Pressure	0.4 MPa ～ 0.9 MPa（gas source provided by user）
Test Accuracy	±0.5％
Air Supply Interface	Φ6mm Polyurethane Pipe
Host Size	300 mm (L) × 310 mm (W) × 180 mm (H)
Transparent Pressure Tank (Stainless Steel/With Glass)	ϕ300mm×300mm（H） （Other sizes and materials can be customized）
Power Supply	AC 220V 50Hz
Net Weight	35 kg

Manufactured according to standards: GB/T 15171, GBT 27728, ASTM D3078, JJG646, 2015 National Pharmaceutical Packaging Material Standard, IEC60529:1989+a1:1999, GB4208, IPX8 test requirements specified in GB7000.1

Standard configuration: host computer, micro printer, stainless steel pressure vessel (can be customized as required), safety valve, pressure regulating valve, pressure gauge, sealing ring, air source pipe.

Optional parts: sample fixing bracket, test limit frame, test stainless steel mesh basket.

Note: The air source interface of this machine is a Φ8mm polyurethane pipe; the air source user must prepare it by himself.

For quotes and more information
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