

# Leak and Seal Strength Tester (Integrated Positive/negative Pressure Method) HY-ZFY-01

## Özellikler :

### Detayl? Tan?m :

Technical features

Test Principle

Technical Parameters

### Technical features

1. The device is equipped with a 5-inch high-definition touch screen, controlled by a microcomputer, and equipped with a silent micro-printer;
2. Positive pressure/negative pressure test "one-button" switch, support setting multi-stage pressure test;
3. Intelligent pressurization, pressure maintenance, pressure supplementation, timing, and pressure relief test process are automatically completed;
4. User hierarchical permission setting, meeting GMP requirements, test record auditing, tracking functions;
5. Using a circular structure container, the air pressure is evenly distributed, and the pressure bearing capacity is better;
6. Pure copper safety valve to prevent overpressure (the pressure will be automatically relieved if it exceeds the set pressure) and it is safer to use;

### Test Principle

Microbial intrusion test, also known as microbial challenge, is a relatively common seal integrity test method, usually performed simultaneously with simulated filling. Carry out simulated filling of the culture medium according to the simulated filling verification scheme, and then carry out the plugging and capping, and the visual inspection is qualified. After the sterilization of the verified sterilization cabinet, the sealing surface of the container is immersed in the high-concentration bacterial solution. 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 soaked in the bacterial suspension. After soaking for a certain period of time, take it out. After regular culture, check whether there is microbial invasion to ensure that the container is sealed. system integrity.

At the same time, a positive control test is required to confirm the growth-promoting ability of the medium. Challenging conditions of vacuum or overpressure are often used in testing. The instrument conforms to many 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

Item	Leak and seal strength tester HY-ZFY-01
Sensor range	0 ? 100 KPa (positive pressure); 0 ? -100KPA (negative pressure)

0 ? 600 KPa (positive pressure); 0 ? -100KPA (negative pressure) (optional)	
Air source pressure	0.4 MPa ~ 0.9 MPa (gas source prepared by the user)
Test accuracy	±0.5%
Air source interface	φ6mm polyurethane tube
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

According to the standards: GB/T 15171, GBT 27728, ASTM D3078, JJG646, 2015 National Pharmaceutical Packaging Material Standard, IEC60529: 1989+a1:1999, GB4208, GB7000.1 stipulated in the standard manufacturing of IPX8 test requirements.

Standard configuration: host, micro-printer, stainless steel pressure vessel (can be customized according to demand), safety valve, pressure regulating valve, pressure gauge, sealing ring, air source connection.

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

Note: The gas source interface of this machine is a φ8mm polyurethane tube; the gas source is prepared by the user.