

High Voltage Discharge Leak Tester

Leak-HV



Solve the leakage problem of various drug packaging



The deflated heads, bubble heads, pointed heads, flat heads, and micropores produced during the sealing of ampoule bottles. Some micropores below 15um are difficult to observe and pose a risk of leakage.



One of the reasons for leakage is the matching problem between the rubber stopper and the aluminum-plastic cover of large infusion bottles, or the insufficient density of the rubber stopper.



The coordination of the cartridge, piston, rubber gasket and aluminum cap affects the sealing of the cartridge, which poses a great threat to the stability of the packaged drugs.



Glass bottles may have cracks, bubbles and micropores during processing and transportation. Some micropores below 15um are difficult to observe, posing a risk of leakage.

Application areas

Meet a variety of samples and achieve the best cost-effectiveness

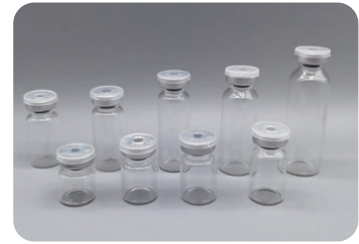
Mainly used in the sealing test of glass infusion bottles, BFS, eye drop bottles, vials, ampoules, prefilled needles and other pharmaceutical packaging industries.



BFS



Eye drop bottle



Vials



Ampoules



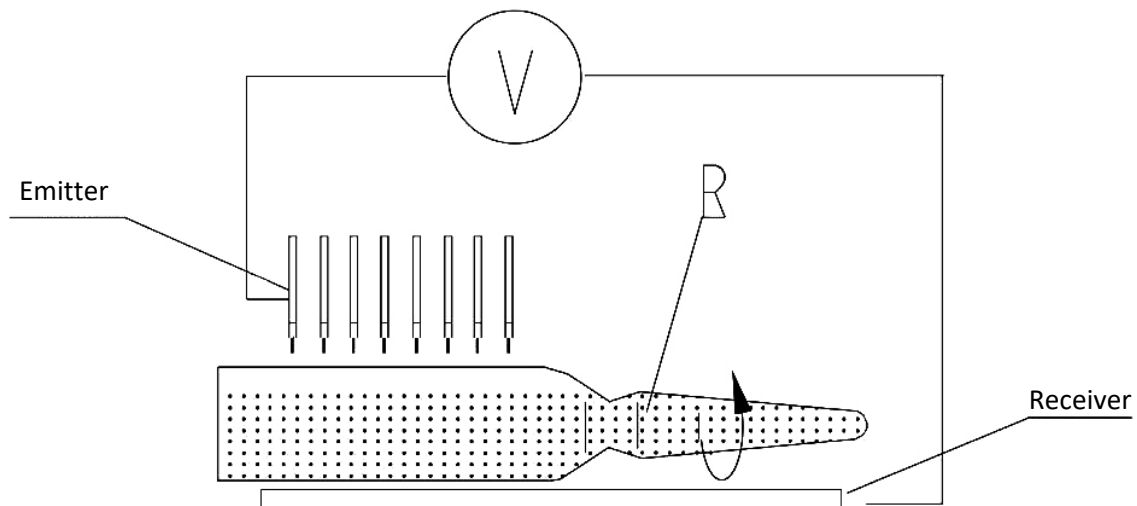
Glass infusion bottles



Prefilled syringes

High voltage discharge test principle

The emitter and the receiver are connected on both sides of the sample, and the set detection high voltage provided by the detection power supply is guided to the emitter. When detecting a non-leaking sample, the capacitance between the two electrodes is large (due to the partition of the bottle wall, the electrodes cannot contact the liquid medicine, so the capacitance is generated), and the induced micro-current is small; when detecting a leaking sample (there are leaks and damage at the bottle mouth, bottle bottom, and bottle body), the capacitance between the insulating bottle wall and the electrode disappears, and a loop is formed between the transmitter and the receiver. At this time, the detected micro-current is large. As long as the size of the micro-current is compared, it can be determined whether the sample is leaking. Compare the maximum value of the current value of each drug with the set upper limit. If it is greater than or equal to the set upper limit, the system will judge it as unqualified, otherwise it is qualified.



Technical advantages

- The test efficiency is extremely high, and the sample scanning test can be completed in a few seconds.
- The test results are non-subjective judgments, no manual participation is required, and the data accuracy and objectivity are guaranteed.
- Roller electrode, one-button start, automatic detection.
- Suitable for detecting tiny leaks, and can also identify samples with large leaks, and give qualified and unqualified judgments.
- Multiple modules can be quickly switched, suitable for packaging tests of different capacities and dosage forms.
- Double grounding, triple protection of safety, emergency, and detection door, safety is intuitive and visible.
- The maximum current is 20mA, which has less impact on the sample.
- It has full password protection function, divided into four levels of authority management, and each operator has a unique login name and password combination to enter the instrument operation.
- Unlimited storage of users, unlimited test data storage.
- Comprehensive audit tracking system, meet FDA 21CFR PART11 electronic record and electronic signature requirements.
- Meet GMP requirements for local data storage, automatic processing, statistical test data functions, and export in a format that cannot be modified or deleted to ensure permanent preservation of test results.
- The Windows operating system is intuitive and reliable, and the comparison curve of the test process is clear.
- It has error alarm function and power-off memory capability to ensure the integrity of data in abnormal power-off situations.
- The instrument is equipped with RS232 serial port and USB interface, supports data LAN transmission, and has ISP online upgrade function to meet customer personalized requirements.

Instrument parameters

Indicator	Parameters
Test method Packaging	High voltage discharge method
material Contents	Glass or plastic products made of non-conductive materials
Substance	Non-flammable, non-conductive packaging, liquid power failure(conductivity greater than 1ms/cm, or actual test), liquid volume greater than 30%
Range	0-20mA
Test voltage	0-20KV
Detection sensitivity	1-3um
Host size	670mm X 560mm X 980mm (length, width and height)(bottle)
Weight	About 90Kg
Environmental temperature	20℃~30℃
Relative humidity Working	< 70%RH, no condensation
Power	220V 50Hz

Standard

USP 1207.2 Package integrity leak test technology

Instrument configuration

Host, control software, computer, measuring head