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VeriPac 355

a PTI technology

Micro Leak Testing

Container Closure Integrity Testing

VeriPac 355 is a non-destructive micro leak detection system for container closure integrity and package integrity testing for a wide range of products and packaging formats. This system is specifically designed to test containers for gas leaks for dry products (lyophilized vials, powder filled) as well test for liquid leaks (non-protein based liquid filled vials, prefilled syringes). The VeriPac 355 can be incorporated into protocols at any point in the handling process as it is non-destructive and requires no sample preparation. With the capability to detect leak rates as low as 0.2 cc/min, depending on packaging specifications, the VeriPac 355 is the optimal non-destructive quantitative test method for many pharmaceutical, medical device and food applications.

The VeriPac 355 core technology is based on the ASTM vacuum decay leak test method (F2338-24) recognized by the FDA as a consensus standard for package integrity testing. This test method was developed using VeriPac leak test instruments.

Benefits

- Non-destructive, non-subjective, no sample preparation
- Deterministic, quantitative test method
- 5 µ Defect detection down to 5 microns
- High level of sensitivity, repeatability and accuracy
- Short cycle time provides operator with PASS/FAIL result
- Small footprint and modular portable design
- ASTM test method and FDA standard

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Inspection Criteria

- Measures seal integrity of entire container or package
- Tests for gas leaks for dry products (lyophilized vials, powder filled)
- Tests for liquid leaks (liquid filled vials, prefilled syringes)
- Measures and verifies container closure system integrity

Technology

The VeriPac 355 leak tester connects to a test chamber that is specially designed to contain the package to be tested. The package is placed inside the test chamber to which vacuum is applied. The high resolution absolute transducer technology is used to monitor the test chamber for both the level of vacuum as well as the change in vacuum over a predetermined test time and is capable of detecting gross and micro leaks. The test cycle takes only a few seconds, results are non-subjective and testing is non-destructive to both product and package.

The sensitivity of a test is a function of the sensitivity of the transducer, the package design, the package test fixture and critical test parameters of time and pressure. Test systems can be designed for manual or semi-automatic operation. This inspection method is suitable for laboratory offline testing and QA/QC statistical process control.

Specifications

APPLICATION	◦ Micro Leak Detection ◦ Container Closure Integrity Testing
PACKAGE TYPE	◦ Empty & prefilled syringes ◦ Liquid filled & lyophilized vials ◦ Filled & sealed bottles & cups ◦ Ampoules ◦ Non-porous pouches ◦ BPC (Bulk Pharmaceutical Chemical) containers ◦ API (Active Pharmaceutical Ingredient containers ◦ BFS containers ◦ Ophthalmic dropper bottles ◦ Porous lidded trays
TEST CONFIGURATION	◦ Offline laboratory ◦ Production line applications
TEST SYSTEM*	High resolution absolute transducer
TECHNOLOGY*	Vacuum Decay
RECOGNIZED TEST METHOD	ASTM F2338-24, referenced in USP <1207>
OPERATOR INTERFACE	Touch screen
TEST PARAMETER STORAGE	Up to 20 products
TEST SENSITIVITY**	Down to 0.2 ccm (approximate hole size 5 micron)
TEST RESULTS/RESOLUTION	*PASS/FAIL* result in mBar
SECURITY PASSWORD	Yes
REMOTE INTERNET ACCESS	Yes
DATA COLLECTION	Collects test data for view on HMI touch screen and electronic data collection
TEST CHAMBER	Manual or semi-automatic
TEST INSTRUMENT ENCLOSURE	Stainless Steel
TESTER DIMENSIONS	12” W – 18.5” D – 10” H
WEIGHT	33 lbs.
POWER	100-240 VAC; 50/60 cycles
AIR	90 psi required only for automatic test chamber
OPTIONS	◦ Validation Qualification Package (IQ/OQ/PQ) ◦ Microcalibrator Flowmeter
CERTIFICATIONS	CE

*U.S. Patents 5,513,516 6,513,366
**Test results may vary according to application and package specifications.