Micro Leak Testing
Container Closure Integrity Testing

The most sensitive
The most reliable

VeriPac 455
a PTI technology

VeriPac 455 is a non-destructive inspection system for highly sensitive micro leak detection of empty & pre-filled syringes, liquid filled & lyophilized vials and other liquid filled packaging.

The VeriPac 455 is a deterministic, quantitative inspection technology that can be incorporated into protocols at any point in the handling process as it is non-destructive, non-invasive and requires no sample preparation. Applications for this technology include stability studies, clinical trial studies, quality assurance testing and production statistical process control (SPC). The VeriPac 455 is capable of detecting leak rates as low as 0.05 cc/min. Results have proven to be superior and more reliable than the dye ingress test.

The VeriPac 455 core technology is based on the ASTM vacuum decay leak test method (F2338-09) recognized by the FDA as a consensus standard for package integrity testing. This test method was developed using VeriPac leak test instruments. The VeriPac 455 features patented dual vacuum transducer technology, PERMA-Vac, that offers increased test sensitivity and produces repeatable, reliable results. The VeriPac 455 also incorporates significant advances in internet connectivity and networking capabilities that facilitate remote operation, system monitoring and MES integration capability.

BENEFITS

- Non-destructive, non-subjective, no sample preparation
- Defect detection down to 0.01 cc/min
- Highest level of sensitivity, repeatability and accuracy
- Results proven superior to dye ingress
- Deterministic, quantitative test method
- Supports sustainable packaging and zero waste initiatives
- ASTM test method and FDA standard

TECHNOLOGY

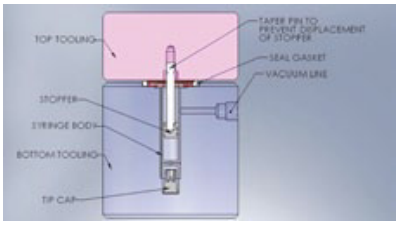
The VeriPac 455 leak tester connects to a test chamber that is specially designed to contain the package to be tested. The package is placed inside the test chamber to which vacuum is applied. The dual transducer technology is used to monitor the test chamber for both the level of vacuum as well as the change in vacuum over a predetermined test time. The changes in absolute and differential vacuum indicate the presence of leaks and defects within the 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.

TECHNOLOGY (CONT.)

Test systems can be designed for manual or automatic operation. This inspection method is suitable for laboratory offline testing and QA/QC statistical process control. The test cycle takes only a few seconds, results are non-subjective and testing is non-destructive to both product and package.

INSPECTION CRITERIA

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



Test chamber for syringe

SPECIFICATIONS

Application	**MICRO LEAK DETECTION**	
Package Type	• Empty & pre-filled syringes • Liquid filled & lyophilized vials (glass or plastic) • Filled & sealed bottles, FFS bottles • Non-porous pouches • BPC (Bulk Pharmaceutical Chemical) containers	**CONTAINER CLOSURE INTEGRITY TESTING** • API (Active Pharmaceutical Ingredient) containers • BFS containers • Ophthalmic dropper tip bottles containing liquid materials • Glass or plastic ampoules containing liquid materials • Lidded (nonporous trays or cups) containing liquid materials
Test Configuration	Offline laboratory and Production line applications	
Test System*	Dual Transducer PERMA-Vac Technology*	
Technology*	Differential Vacuum Decay	
Operator Interface	10" Color Touch Screen	
Recognized Test Method	ASTM F2338-09, referenced in USP <1207>	
Test Parameter Storage	Up to 20 products (ETHOS 21 CFR, Part 11 software provides unlimited product storage)	
Base Unit Test Sensitivity**	Down to 0.01 cc/min (Approximate hole size 1 micron)	
Application Sensitivity***	0.034 cc/min (Approximate hole size 2 micron)	
Test Results/Resolution	Pass/Fail Result in mBar and Pascal units	
CFR Security Capability	Yes (21 CFR, Part 11) PTI ETHOS Software	
Remote Internet Access	Yes	
Manufacturing Execution Systems (MES) Integration	Yes	
Data Collection	Collects test data for view on HMI touch screen and electronic data collection	
Test Chamber Tooling	Manual or automatic	
ASTM Test Method	ASTM F2338-09 based on VeriPac leak testers – www.astm.org	
Test Instrument Enclosure	Stainless Steel	
Dimensions	14.5" W – 22" D – 12" H	
Weight	40 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	
Articles/Publications	• PDA Journal of Pharmaceutical Science and Technology: Vacuum Decay Container/Closure Integrity Testing Technology. Part 1. ASTM F2338-09 Precision and Bias Studies http://journal.pda.org/cgi/content/abstract/63/5/472 • PDA Journal of Pharmaceutical Science and Technology: Vacuum Decay Container/Closure Integrity Testing Technology. Part 2. Comparison to Dye Ingress Tests http://journal.pda.org/cgi/content/abstract/63/5/489	