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VeriPac 465

VACUUM DECAY

Product Overview

The VeriPac 465 performs leak detection based on the basic principles of physics and does not require the use of trace gasses or sample preparation to perform the test. The VeriPac 465 core technology is based on the ASTM vacuum decay leak test method (F2338) recognized by the FDA as a consensus standard for package integrity testing. This test method was developed using VeriPac leak test instruments. The VeriPac 465 combines technological innovation and practical adjustments to patented dual vacuum transducer technology, PERMA-VAC, to make it the most sensitive and versatile vacuum-based leak detection technology to date. Through the introduction of unique test cycles, pneumatic controls and processing algorithms, the VeriPac 465 is establishing itself as the foremost vacuum-based leak test for parenteral products.

Technology

The VeriPac 465 advances in high vacuum testing has redefined what is achievable with a vacuum-based leak detection technology. The next generation PERMA-VAC technology addresses vacuum leak detection at the very core of the physical test measurement, controlling the test system volume and maximizing the Signal-to-Noise Ratio (SNR) between good and defective samples. VeriPac 465 technology reduces the baseline measurement for good samples and amplifies the test result for defective samples. This technology is geared towards detecting leaks in the MALL range for parenteral packaging and can also be applied to flexible and semi flexible package formats. The VeriPac 465 leak tester connects to a test chamber that is specially designed for the package or container. 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.

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.

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
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 based on VeriPac leak testers, 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
MES INTEGRATION	Yes
DATA COLLECTION	Collects test data for view on HMI touch screen and electronic data collection
TEST CHAMBER TOOLING	Manual or automatic
TEST INSTRUMENT ENCLOSURE	Stainless Steel
DIMENSIONS/WEIGHT	14.5" W x 22" D x 12" H | 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
CERTIFICATIONS	CE

* U.S. Patents 5,513,516 6,513,366 8,544,315 | Test results may vary according to application and package specifications.
**The base unit test sensitivity that can be compared with competitive vacuum based test equipment sensitivity claims.
***The detection sensitivity of standard applications that provides a detection capability with at least a 4-Sigma Signal-Noise separation in real-world operating environments.