Helium Leak Detection

One Technology...Many applications
CCI for container closure development
CCI analysis at cryo storage conditions
The most sensitive flow based leak test

THE TECHNOLOGY

Helium leak detection (HeLD) is routinely used and widely accepted for applications that require the utmost leak sensitivity. Helium gas in an element with the second smallest atomic mass, is inert(non-reactive), is naturally rare in the atmosphere, and is non-flammable. Due to its low atomic mass this gas penetrates through the smallest cracks and micro-holes; being rare in the atmosphere eliminates background helium "noise" resulting in an extremely high signal-to-noise ratio thereby greatly increasing test sensitivity; being inert (non-reactive) ensures that the helium gas will not negatively affect the components being tested; and being non-flammable gives confidence that it is the safest tracer gas to use in a lab or production setting.

A custom-tuned spectrometer quantitatively measures the amount of helium escaping a package under vacuum. Leakage is quantified to levels well below Maximum Allowable Leakage Limits (MALL) of most all product-package systems, ideal for package development qualification and validation. Custom designed and easy to change test fixtures enable a wide range of applications. HeLD is currently used to fulfill test requirements and procedures in FDA guidance, EU Annex 1, ASTM F2391, and USP <1207>.

BENEFIT

- Helium enables the discovery of extremely small microleaks that other leak testing methods cannot detect.
- Using a high vacuum technique, the leak test limits can be set down as low as 1 x 10-10 mbar-L/sec, a sensitivity level allowing unique comparisons between packaging components, materials, formats, and production parameters.

PRODUCT OVERVIEW

The Seal Integrity Monitoring System (SIMS) 1915+, is the optimal solution for helium-based leak detection for a variety of pharmaceuticals, biologics, and medical device product package systems. Common applications include vials, syringes, cartridges and blister cards. For parenteral products, common applications for helium include leak testing the rubber stopper on a vial or the plunger on a syringe or cartridge assembly.

Using helium as the tracer gas, packages can be quantitatively tested to levels far exceeding the vacuum bubble and dye penetration test methods. This quantitative approach allows direct comparison across various packaging materials and formats, production line settings and stability storage conditions, supporting the entire lifecycle.

This SIMS 1915+ will enable the quantitative analysis of packages at a sensitivity level as low as 1 x 10-10 mbar/L/sec. and provides relevant data sets in place of a simple pass/fail criteria while enabling testing to be performed at room temperature.

Each SIMS 1915+ Helium Leak Testing instrument is custom built to client specific standards and package configurations. We specialize in the engineering and development of custom test fixtures tailored to the component to be tested, which ensures precision and accuracy to meet your study goals, package configurations and quality monitoring needs.

Helium Fill Device

Headspace Analyzer Module (HSAM)

Test Chamber for Vials

SPECIFICATIONS

	SIMS 1915+
TEST METHOD	Helium Pre-fill or 100% Flow
APPLICATION	Testing and evaluation during package design and development, tooling qualification, production line setup and on-going product quality monitoring.
PACKAGE TYPE	Cold form blister cards, foil pouches, parenteral vials, cartridges, pre-filled syringes, bottles, combination product systems and medical device products.
TEST CONFIGURATION	Console frame assembly with stainless steel working surface, including an articulating arm for mounting of computer monitor and keyboard.
OPERATOR INTERFACE	Customer supplied Window 10/11 (Pro) PC interface
MINIMUM DETECTABLE LEAK RATE	1 x 10^{-10} mbar L/sec.
CFR SECURITY CAPABILITY	Data Acquisition & Analysis Module running ETHOS-HLD 21 CFR Part 11 Compliant Data Integrity Software.
SYSTEM DIMENSIONS	25.5" (764mm) W x 30.25" (508mm) D x 38.5" (1153mm) H
DIMENSIONS WITH MONITOR ARM	44.0" (111.8cm)/63.0" (160.0cm) Additional width and height
WEIGHT	258 lbs. (117.3 kg.)
POWER	100-240 VAC: 50/60 cycles
OPTIONS	Validation Qualification Package (IQ/OQ/PQ)
TEST METHOD	◦ ASTM F2391, Vacuum & Sniffer Modes Recommended in USP <1207> ◦ FDA Recognized Standard - Standard Test Method for Measuring Package and Seal Integrity Using Helium as the Tracer Gas
BACKING PUMP	Oil Free (No Exhaust) Backing Pump
MAX INLET PRESSURE	1.3 kPA
OPERATING TEMPERATURE	10-40° C

LOW TEMPERATURE ADD-ON TEST SYSTEMS FOR COLD TEMP CCI APPLICATIONS

Complex drug and biologic formulations have resulted in life science companies continuous drive toward deeper cold storage in an effort to maintain product quality attributes. These products, often cell or gene therapies, or proteinaceous in nature,often require storage at temperatures below -20 C and are involved in storage and distribution environments at ultra cold temperatures.

While the products demanding such intense cold storage may be complex, oftentimes, the package systems in which the products are placed are rather traditional in nature, such as a screw or crimp top vial. However, at these temperatures, many of the materials used in these package systems that are responsible for maintaining package integrity are not typically assessed at these temperatures. When exposed to deep-cold or ultra-cold temperatures, physical changes to elastomeric components in particular can occur as materials reach or exceed their glass transition state, creating leaks at low temperatures that would otherwise not be observed while at room temperature. This type of leakage is typically observed at primary seal areas, such as that between an elastomeric closure and glass vial being used below -60C. Having a means to test container closure integrity while at these low temperatures enables manufacturers to gain insight into optimal package choice and design, as well as assembly parameters, to minimize leakage and demonstrate robust understanding of a package system's performance in accordance with USP <1207>.

COLD STORAGE TESTING -0°C TO -160°C

SIMS 1915+ WITH LOW-TEMPERATOR ADD-ON SYSTEMS

To meet this market need for evaluating leaks at cold temperatures, PTI offers several low temperature add-on units for the SIMS leak detectors. The LT 80, LT 85 and LT 150 add-on low temperature units are available as upgrades to existing installed SIMS units or as a complete package.

APPLICATIONS

Vials

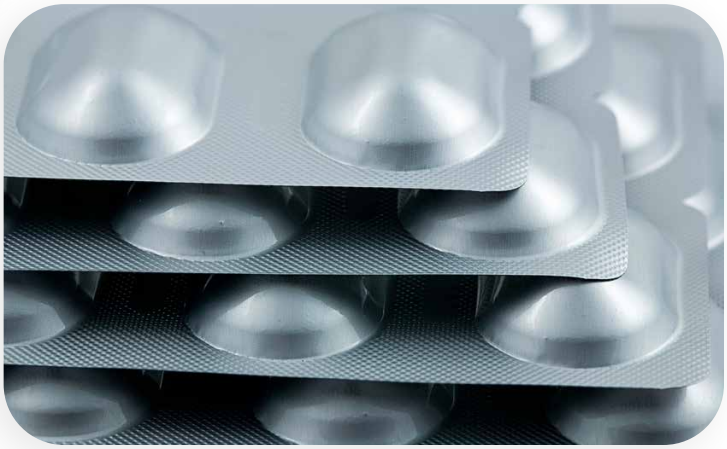
One of the most common package configurations for a variety of pharmaceutical and biotechnology products. Helium is the most ideal and sensitive method for component qualification for empty components as well as product filled vials.

Pre-Filled Syringes

The use of PFS systems has become more prevalent with the introduction of new and unique biological products. Helium test methods can be designed and developed that enable highly effective test programs for these unique package systems.

Bottles

Similar to vial package systems, bottles, whether composed of plastic materials or glass, continue to be one of the most widely used package systems and Helium remains the gold standard for quality testing purposes.



Blister Cards

Regardless of the cavity size and count, Helium remains the optimal test method for the qualification of the material components of CFF blister cards and has a long and trusted history for production line quality control verification.

Foil Pouches

The use of foil for pharmaceutical package systems remains in wide-spread use and Helium test methods continue to be a viable and highly sensitive approach to meeting strict regulatory requirements.

Combination Product Systems

Multi-chamber systems that require unique test requirements are ideally suited for the use of Helium leak testing to ensure all components meet the strict leak rate requirements.

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8 Skyline Drive | Hawthorne, NY 10532 USA
Tel: 914.337.2005
info@pti-ccit.com
www.pti-ccit.com
www.heliumleak.com