**Container Closure Integrity Testing**

A critical step in understanding the biological safety and suitability of a container is the ability to characterize the materials and chemicals that have the potential to migrate through container closure system components and contaminate the drug product.

As the driving forces behind safety evaluation of materials and container closure systems in the US, the United States Pharmacopeia (USP) and Food and Drug Administration (FDA) enforce stringent requirements for Container Closure Integrity Testing (CCIT).

Historically, Dye Immersion and Microbial Immersion (both probabilistic tests) were the two leading methods for Container Closure Integrity Testing. Recently USP issued guidance to require deterministic methods to achieve more quantitative results for CCIT testing. While we do offer the traditional Dye Immersion and Microbial Challenge Testing for container closure systems, these methodologies are not considered quantitative. These tests are also destructive to the samples under test, and typically require a significant number of units for method development and validation.

Eurofins Lancaster Laboratories is committed to offering the most up-to-date methods for testing the closure systems for final drug product packaging and has invested in state-of-the-art instrumentation to meet these regulatory guidelines and verify the safety of your container closure system. In addition to the traditional Dye Ingress and Microbial Immersion methods, we also offer more sophisticated, quantitative methods such as Vacuum Decay, Pressure Decay, High Voltage Leak Detection, Oxygen Headspace and Helium Leak Detection. Each of these methods offers unique capabilities with ideal applications. We can help you determine which method is best for your project needs.

**Why Choose Eurofins Lancaster Laboratories?**
- We have more than 15 years of experience developing and executing methods for hundreds of container closure testing projects utilizing various container types.

**Vacuum Decay**
**Instrumentation:** VeriPac 455-M5 Vacuum Decay
**Description:** Measures leaks by vacuum decay based upon ASTM F2338. Performs leak testing with sensitivity to detect leaks down to approximately 5-10 microns. This option reduces the amount of valuable finished drug product required for stability testing as the testing is non-destructive to the sample, and therefore, the same sample can be used for other laboratory tests typically required during stability studies once the vacuum decay test has been performed.

**Best Application:** This technology is suitable for leak testing on container/closure systems such as syringes, vials, and pouches. Because this method is non-destructive to the sample under test, it is a great option for leak testing both before and during stability studies.

- We offer seven techniques for CCIT testing.
- Our techniques accommodate various packaging configurations.
- Our methods can minimize the number of samples required for testing.
Pressure Decay
**Instrumentation:** TM Electronics BT Integra Burst, Creep and Leak Tester
**Description:** Measures leaks by pressure decay based upon ASTM F2095.
**Best Application:** This technology accommodates both seal strength and package integrity testing for flexible packaging, such as bags and pouches.

High Voltage Leak Detection
**Instrumentation:** E-Scan 655 MicroCurrent High Voltage Leak Detector (HVLD)
**Description:** Detects package defects using an electrical current.
**Best Application:** This technology is suitable for use with liquid-filled parenteral drug product containers and syringes, where the packaging is far less conductive than the liquid inside.

Oxygen Headspace
**Instrumentation:** FMS-760 Oxygen Headspace Analyzer
**Description:** Uses Frequency Modulation Spectroscopy (FMS) to detect oxygen in the headspace of transparent rigid containers and measures rise or fall in the oxygen levels in the container's headspace to identify a potential leak. It can also be used to determine the rate of oxygen permeation into a sealed container over time.
**Best Application:** Because this method is non-destructive to the sample under test, it is a great option for leak testing parenteral containers both before and during stability studies.

Helium Leak Detection
**Instrumentation:** Helium Mass Spectrometer - Tracer Gas Detection, Vacuum Mode
**Description:** Quantitates the flow rate of helium from leaks in packaging after having been flooded with helium as a tracer gas. If a defect is present, the helium is then drawn out of the packaging through the defect by vacuum and detected using a mass spectrometer. This method is the most sensitive option, allowing for the detection of defects as small as 0.2 microns.
**Best Application:** This technology is suitable for package development to verify the package type is appropriate for the type of drug, as well as routine testing and stability for a wide variety of package types.