TESTING MOISTURE EGRESS OF MEDICAL DEVICE PACKAGING.

Solutions for obtaining faster and more precise data on hard-to-test pharmaceutical and medical packaging.

In the pharmaceutical industry, where compliance processes are complex and lengthy, it's crucial to obtain accurate R&D data as quickly as possible. However, evaluating drug delivery systems like glass vials and saline pouches can be difficult and time-consuming. AMETEK MOCON offers an ideal solution in the form of the Capture Vessel Cartridge.

Certain drug delivery systems rely on a strong moisture barrier to maintain product integrity.

Irregular package size slows R&D of some drug delivery systems.

The standard USP 671 test for water vapor egress of pharmaceutical packaging outlines a gravimetric test method. While this method is accurate and can provide data on large numbers of samples at once, it's also time-consuming and subject to human error. Although USP 671 is required for compliance purposes, other methods are faster and better suited for early R&D.

Certain types of drug delivery systems, such as vials and saline pouches, rely heavily on tight seals and barrier materials that prevent moisture from escaping. However, these systems can be difficult to test. The small size and high barrier of pharmaceutical vials can result in months of almost undetectable egress values with the gravimetric method. For larger permeable pouches, the heavy weight leads to large test times due to balance capacity and sensitivity limits.

AMETEK MOCON® offers specialized test cartridges, such as the Capture Volume Cartridge, that simplify and speed up WVTR testing for medical packaging.

The Capture Vessel Cartridge is ideal for testing specialized medical packaging

IMPROVING WVTR EGRESS TESTING FOR MEDICAL DEVICE PACKAGING

APPLICATION NOTE

A custom solution for WVTR testing.

The Capture Vessel Cartridge is an impervious stainless steel cylinder that can be used with MOCON® package testing permeation analyzers, or attached to the PackRack® adaptor and used with several film permeation analyzers.

Testing small glass vials can present challenges due to extremely low egress values. Since glass is a non-permeable material, any gaps or leaks are likely restricted to the gasket or rubber stopper. The MOCON Capture Vessel Cartridge is available in a small 4.5 x 2" size, reducing the free purge volume. Labs can also place multiple vial samples into one cartridge, providing more overall water vapor, and a value that can then be divided by the total number of samples (Fig. 1). This helps with "per sample" sensitivity.

The large size of saline pouches creates the opposite problem. The Capture Vessel Cartridge is available in a size roomy enough for most saline pouches, and provides faster results than a gravimetric test; balances designed for heavy weights (500+ grams) don't have the needed sensitivity. Permeation analyzers also take continuous data, thus detecting a real-time egress rate as opposed to scheduled weight measurements (Fig. 2)

For both package styles, the Capture Vessel Cartridge is the ideal tool to aid in early R&D, where manufacturers need to prioritize fast and efficient data collection. Eliminating different package options early in the process means evaluating fewer samples using the traditional gravimetric method later on, saving manufacturers time and giving them better peace of mind.

Faster results for simpler R&D.

With highly specialized packaging and heavy regulations, healthcare manufacturers need a way to obtain precise WVTR egress data with quick turnaround times. MOCON Capture Vessel Cartridges, along with our highly accurate permeation analyzers, provide the ideal solution. Purpose-built and designed to be user-friendly, these cartridges enable medical packaging manufacturers to get packaging to market with the data confidence they require.

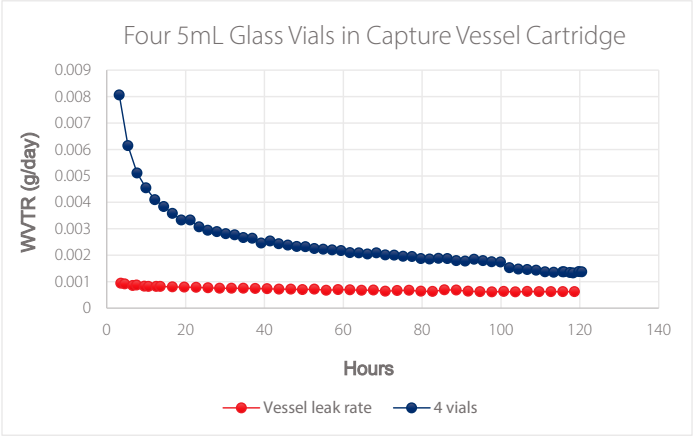

Fig. 1WVTR egress over time of multiple glass vials along with system leak rate

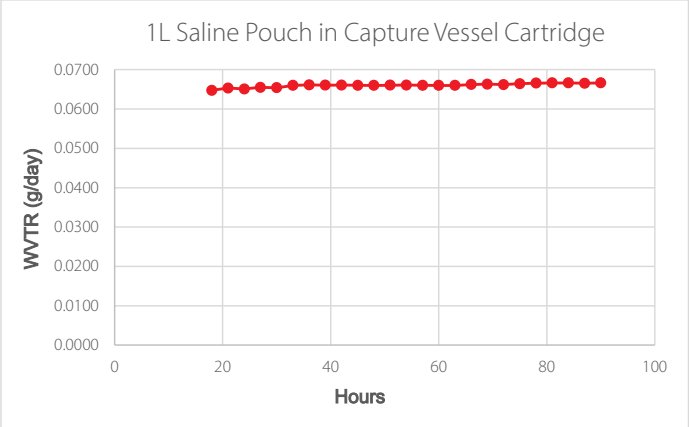

Fig. 2 WVTR egress over time for saline pouch

For more information on WVTR measurement for medical device packaging, visit our website or contact your AMETEK MOCON sales representative.

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