CS ANALYTICAL

CONTAINING QUALITY

Flexible / IV Bag Package Systems

USP 1207 Container Closure Integrity Testing

Application of USP 1207 CCIT methods for flexible package systems present unique challenges and requires a custom solution

CS Analytical has developed a unique method for Flexible Package Systems to meet the requirements defined in USP 1207

Common Challenges with IV Bag Systems:

- **Polymeric material leads to expansion, permeation & outgassing**
- **Large volume presents limits placement into existing technologies**
- **Access ports & tubing connections limit traditional approaches**

Limiting Variables - High Voltage Leak Detection: In the case of large volume flexible systems, the primary limiting factor in the application of HVLD for routine testing is package size and availability of lab-scale solutions to accommodate such samples. Theoretically, as liquid filled packages, they would be candidates for HVLD testing. However, the physical limitations often rule out HVLD from a feasibility perspective.

Limiting Variables - Headspace Analysis: The large volume of IV bags are not conducive to placement into modern laser-based headspace analyzers, which are typically made to accommodate vials and other smaller-volume, rigid configurations.

Limiting Variables - Helium Leak Detection: With helium leak testing, a package is filled with helium gas and subjected to vacuum, where escaping helium is quantified. Due to the molecularly porous nature of flexible polymeric materials, and the small, light nature of helium, permeation through the materials makes helium leak testing difficult. This is exacerbated by large surface areas of large IV bag systems for gas to exchange while under vacuum.

Limiting Variables - Vacuum Decay: As with other pressure-based analyses, application of vacuum decay to large flexible systems is limited by package size, materials of construction, and clogging of defect pathways by the product. In addition, the molecularly porous surface area allows for gas trapped in and on package materials to outgas under vacuum, masking small defects.

The CS Analytical Solution

- **A comprehensive program that includes method setup, development, and validation. Typical limit of detection 10-35µm.**
- **The use of certified, laser-drilled positive controls ensure validation to a defined leak size at different package locations.**
- **A program that adheres to regulatory expectations and best practices for CCIT as outlined in USP 1207.**
- **A unique and proven method developed by the CS Analytical Team of USP 1207 Experts with over a decade of experience across a wide range of package systems.**
- **All work is performed in an FDA registered and inspected cGMP laboratory.**

Contact CS Analytical to Discuss Your IV Bag Testing Needs

engage@csanalytical.com