pti science of quality

Container Closure Integrity Testing of

INTRAVENOUS BAGS

Overview

CCI is defined as whether the container is maintaining a **sterile barrier**. Intravenous (IV) bags are crucial in delivering fluids or medication quickly. Leaking parenteral packages are considered extremely **high risk** as they deliver fluid directly into the bloodstream and have a high potential for microbial growth, requiring the need for **sensitive and reliable** CCI testing.

VeriPac VACUUM DECAY TECHNOLOGY

Vacuum Decay technology is an ASTM Standard "Test Method for Non-destructive Detection of Leaks in Packages by Vacuum Decay Method (F2338). This technology is also a physical test method that is recommended by UPS 1207 and is an FDA consensus standard that can be used for CCI testing for high risk package applications with fast, repeatable and reliable test results that provide quantitative and deterministic quality assurance. This technology can be used on a wide variety of package formats, product classes and product combinations.

Life Science CCI Services

Testing, Training & Consulting Services
Test Method Development Support
Validation Support and Deployment

Our expertise and services ensure your products meet the highest standards of performance and regulatory compliance

IV BAG INSPECTION - FACTORS

Leak Location

IV Bag and Polymer

- Type
- Thickness
- Layers

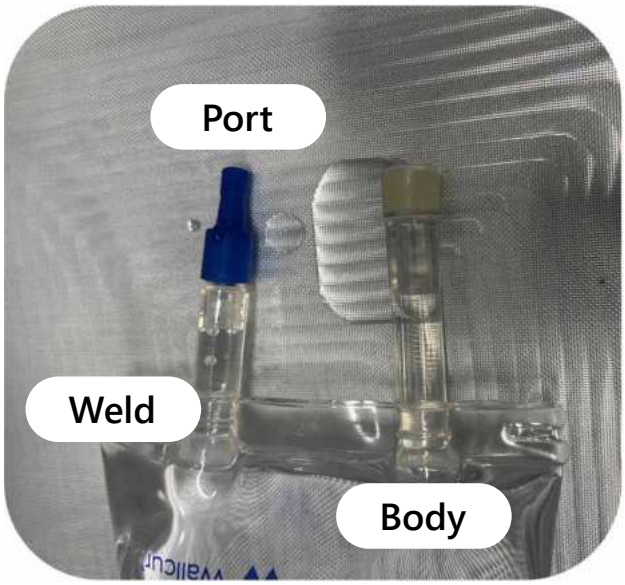
Volume & Fill Level

Additional Challenges

- Seams, Joints
- Barbs and assemblies

Test Method Considerations

- Air Flow vs. Liquid Flow
- Validation Probable Leak Conditions and Locations



IV BAG TESTING SOLUTIONS

IV bags can be evaluated effectively using VeriPac vacuum decay technology. The VeriPac leak detection instrument is connected to a manually operated test chamber containing the IV bag. PTI offers a range of test chamber configurations depending on IV bag dimensions, profile (thin vs. thick) and fill volume. Both standard and customized solutions are available to achieve the optimal inspection solution for each IV bag application.

The test method involves drawing vacuum on the IV bag in the test chamber and monitoring for any changes in vacuum level. If the package is defective, air or liquid will leak from the package into the chamber, causing a change in pressure. Non-defective packages do not leak any pressure into the chamber, holding the chamber vacuum level constant.

Benefits:

- VeriPac solutions leak test the entire IV bag including weld and port regions that are subject to damage and stress
- Test chambers are designed to accommodate various IV bag profiles, fill volume and thickness
- Reliable and consistent leak detection down to 20 microns

VeriPac vacuum decay technology for IV bags is conducted at deep vacuum. When liquid contents are present, a deep vacuum can be achieved, vaporizing liquids that may be at the defect site. Positive controlled samples (leaks) are generated to test for leak sensitivity. To verify and calibrate test results, a microcalibrator flowmeter is used as part of the testing protocol.