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Bubble Emissions Test - Medistri

Bubble Emissions Test

Bubble leak testing is an important method in the medical packaging industry to detect critical leaks within packaging. This test is particularly useful for validating the integrity of packages and bags, which is necessary to maintain a sterile environment for the contents. This test involves submerging the package or bag in water and applying a small amount of pressure to the package. The presence of a continuous stream of bubbles indicates a leak and therefore a breach of the sterile barrier.

Used to detect gross leaks in packaging, bubble leak testing is a highly accurate testing method used throughout the medical packaging industry. It is particularly useful for checking the integrity of packaging and pouches that need to provide a sterile environment for their contents.

Bubble leak testing is often referred to as ASTM F2096, the official title for a certain kind of bubble test, and it is accepted as a standard testing method for detecting leaks in packaging using internalized pressure. It is also known as a submersion leak test, bubble emission test or underwater immersion leak test. ASTM F2096 is a standard set by ASTM International, a globally recognized leader in the development and delivery of voluntary consensus standards for a wide range of industries.

Bubble Emission Tests are a cost-effective way to determine whether packaging or equipment has a leak, which is particularly crucial in the healthcare industry. The test also helps to ensure that the contents of a product remain protected from the outside environment, maintaining sterility, which is vital for medical devices.

An ASTM F2096 test submerges a packet or pouch under at least one inch of water. A low pressure is supplied to the packaging in a controlled flow and the packaging is closely monitored for any signs of escaping air.

A continuous flow of bubbles indicates a leak and shows that any sterile barriers have been breached. To comply with standards, a bubble leak test must be able to detect leaks from holes of 250 μ m (0.010 in.) or 250-microns.

ASTM F2096 is a globally recognized standard method for detecting gross leaks in packaging using the bubble leak testing approach. This test is particularly useful for checking the integrity of packaging and pouches that need to provide a sterile environment for their contents.

It's important to note that this test method is considered destructive due to the requirement of an entry into the package to supply internal air pressure. This means that the packages tested with this method cannot be reused or returned to the production line.

Despite some limitations, including its destructive nature and potential inapplicability to certain materials, ASTM F2096 remains a fundamental method for maintaining packaging integrity and, consequently, product safety.

Should you fully validate your packaging system or should you simply test one particular characteristic of your sterile barrier system, Medistri laboratory is accredited and highly experienced for the most common tests.

To learn more about Medistri's Bubble Emissions Test, visit on our website here or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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