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Bubble Leak Testing Services - Medistri

Bubble Leak Testing Services

? What is Bubble Leak Testing?

👉 Bubble Leak testing is a method of detecting leaks in sealed packaging by visually inspecting them against changes in pressure. This process is used to assess the integrity of packaging's seal and the integrity of the sterile barrier before and during releasing the final products on the markets.

? Who needs to perform Bubble Leak Testing on its products?

👉 There are several industries that require Bubble Leak testing such as:

- Pharmaceutical Industry
- Food & Beverages Industry
- Automotive Industry
- Aerospace Industry
- Military Industry
- Medical Device Industry

? Why do perform Bubble Leak Testing?

👉 Many defects can lead to leakage during the manufacturing and packaging of the product. That is why this test allows us to detect defects in the packaging before final production and shipment to the customer. This test allows us to test multiple forms of packaging, whether they are in a protective atmosphere or even in a vacuum.

? How do you perform Bubble Leak Testing?

👉 Medistri uses its specialised equipment to perform Bubble Leak Testing as follows:

- 1 - The packaging is immersed under water in a specialised test chamber.
- 2 - Medistri increases or decreases the pressure in the chamber to visualise the reaction of the product.
- 3 - The pressure change in the equipment is done at a predetermined velocity.
- 4 - The packaging is observed throughout the procedure. The observation is made by a steady stream of air bubbles that form if there is a failure zone on the product's seal.
- 5 - If a steady stream of bubbles is observed, it would indicate a breach of the sterile barrier.

? What are the regulatory standards for performing Bubble Leak Testing?

👉 For the pharmaceutical industry, Medistri's laboratory routinely performs Bubble Leak Tests following ASTM F2096 "Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurisation Bubble Test". Bubble Leak testing can also be performed according to:

- ASTM D3078
- ASTM D4169
- ASTM D4991
- ASTM D5094

? What are the advantages of using the Bubble Leak testing method?

👉 The advantages of Bubble Leak Testing for Sterile Barrier Integrity are:

- Using immersion leak method is the most effective seal integrity testing method.
- Testing is reliable and can be performed multiple times on multiple samples.
- It shows a practical representation of package leakage.
- It allows for a visual inspection of the product and its specific leak.
- It allows testing for different packaging types and sizes.

? Are there other packaging test that can be performed to measure sterile barrier integrity?

👉 Yes - There are a variety of sterile barrier integrity tests. Such as:

- Visual inspection Test
- Peel Strength Test
- Burst Test
- Dye Penetration Test
- Creep Test
- Bubble Emission Test

📞 To learn more about our bubble leak testing services, visit our website www.medistri.swiss or contact our team directly at contact@medistri.swiss or here.

- The Medistri team

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