

Evaluating the Seal Strength of Flexible Barrier Materials in Medical Packaging

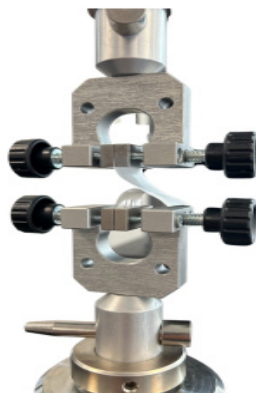
► Ensuring the integrity of packaging materials used for terminally sterilized medical devices is of utmost importance in the healthcare industry. Proper packaging safeguards the sterility of medical equipment and devices, preventing contamination and ensuring patient safety. Two essential standards in this domain are the French Pharmacopée (NF EN 868-5) and ASTM F88-15. This article focuses on ASTM F88-15, which defines the testing protocols for evaluating the seal strength of flexible barrier materials used in medical packaging.



Testing Methodology

ASTM F88-15 specifies the procedures for determining the seal strength of flexible barrier materials used in packaging. This test method is crucial in assessing the sealing quality of packaging materials and identifying their suitability for medical applications. The standard prescribes the removal of several test strips, each having a width of 15 mm, 25 mm, or 25,4 mm from the packaging to be analyzed.

To ensure accurate and repeatable results, a tensile test is performed using a Universal Testing machine. The samples are positioned as detailed in the standard, and a T-Peel measurement test is conducted on the cut-out strips until breakage occurs.



This test method aims to assess the quality of the sealing by measuring the maximum force applied and calculating the average hold during the test duration.

ASTM F88-15 specifies that 10% of the test's initial and final portions are excluded from the calculations.

It is recommended to conduct the test at speeds ranging from 200 to 300 mm/min. The choice of the testing speed may depend on the specific requirements of the packaging material and the equipment being tested.

Sample Holding Methods

The method for holding the samples can vary depending on the nature of the products to be tested. The choice of sample holding method is critical to ensure that the test accurately reflects the real-world conditions that the packaging materials will face in medical applications.

Results and Equipment

The key parameters to be measured during the testing are Peak Load, Max Load (Ultimate Tensile Strength), and Average Peel Force. These parameters provide critical insights into the seal strength of the flexible barrier materials and their suitability for medical packaging.

To perform these tests accurately, specialized equipment is required. The Nexygen Plus system is highlighted as the software that can automatically respect the rule of 10-90% for any specimen, which is essential for precise calculations of Average Peel Force.

The Nexygen Plus system works in conjunction with the LS1 machine, which offers various features, including:

Max Travel: 500 mm (800 mm on the LS5)

Resolution: 0.01 mm

Tensile-compression testing capabilities

Strength, deformation, and height control (with Nexygen Plus)

Dynamic compensation by force sensor

The YLC load cell is another crucial component, with features that include:

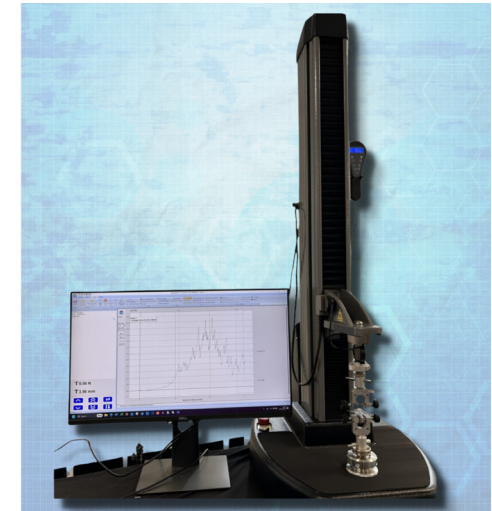
Capacity ranging from 5N to 1000N

Accuracy: 0.5% of value read

In addition to the equipment mentioned above, the Nexygen Plus Software plays a pivotal role in test data acquisition, analysis, and reporting.

It ensures that the results obtained are accurate, and it is instrumental in calculating the Average Peel Force.

Nexygen Plus stands out as a preferred system for medical peel testing, particularly due to its seamless execution of the 3 Seal Batch Test as prescribed by ASTM F88-15. This test is simplified with Nexygen Plus, offering comprehensive data, including the average seal force, to streamline the testing process.



Results and Equipment

ASTM F88-15 defines the standard test method for evaluating the seal strength of flexible barrier materials used in medical packaging. This testing protocol is critical for maintaining the sterility of medical devices and ensuring patient safety. By conducting tensile tests using Evaluating the Seal Strength of Flexible Barrier Materials in Medical Packaging Evaluating the Seal Strength of Flexible Barrier Materials in Medical Packaging a Universal Testing machine, healthcare professionals can accurately assess the quality of sealing in medical packaging materials. The choice of equipment, such as the LS1 machine and the Nexygen Plus system, is essential for achieving precise and reliable results in accordance with ASTM F88-15 standards. These tests are vital to maintaining the highest quality standards in the healthcare industry and ensuring the safety of patients.

Medical Field Standards:

French Pharmacopée:

Purpose: Defines quality and safety standards for pharmaceuticals and medical devices in France.

Relevance: Establishes criteria for materials and packaging used in the medical field to ensure compliance with French regulatory requirements.

NF EN 868-5:

Objective: Specifies testing protocols for packaging materials to ensure their suitability for sterilized medical devices.

Significance: Plays a crucial role in maintaining the integrity and sterility of medical packaging, adhering to European standards.

ASTM F 88:

Focus: Addresses peel testing methods for flexible barrier materials used in medical packaging.

Importance: Provides standardized procedures for evaluating the strength and integrity of seals, contributing to the reliability and safety of medical packaging worldwide.