Contact us

Medical Devices Packaging Validation

What Is Packaging Validation for Medical Devices?

Packaging validation is an important step in our medical device testing which ensures the safety and durability of the packaging for medical devices. Packaging validation includes **sterilisation control**, **sealing testing**, as well as intense testing of the **robustness of packaging.** Our packaging validation ensures that **storage and transportation packaging** comply with regulatory standards.

Applus+ Laboratories offers packaging validation as part of our **batch release testing services.** This is to make sure that medical devices are well packaged and can withstand differing storage and transportation conditions. We offer packaging validation along with:

- Biocompatibility testing
- Cleaning validation
- Material and Chemical Characterisation
- Stability validation

What Packaging Validation Services Do We Offer?

We offer **comprehensive packaging validation services** to test packaging solutions. These services are major test methods according to **NF EN ISO 11607-1 standard** and are critical for the certification of packaging for medical devices.

Visual Inspection of Seals According to ASTM F1886

We provide visual inspection of seals according to ASTM 1886 standard. This involves the **close examination of seals** in order to spot any potential sealing defects that might be visible to the naked eye at a **distance of 30 to 45 cm.** In order to pass, a seal must

not exhibit any defects such as holes, inclusions, channels, or pores that could affect its integrity. The seal should not show any signs of **delamination** or **detachment of the paper.**

Manual Peeling and Seal Strength Tests

We conduct rigorous testing methods for evaluating the manual peeling and seal strength of medical packaging materials. We perform these tests **according to the NF EN 868-5 standard.**

- **Seal Peelability NF EN 868-5 Annex E**
  Seal peelability testing involves a visual inspection of the seal for **imperfections** or **inadequate coverage.** This also includes observing that there is **no paper cleavage outside the sealing area** which needs to be **at least 6 mm.**
- **Strength of Sealings NF EN 868-5 Annex D**
  Sealing strength assessments are performed with a resistance test using a **tensile machine.** A **punch knife** and **press** are used to cut perpendicularly to the weld from the pouches. For steam sterilisation processes, the acceptance criterion is that **the value must not be less than 1.5 N/15mm.** For other sterilisation processes, the value must not be less than 1.2 N/15mm.

Integrity Testing by Dye Penetration ASTM F1929 / ASTM F3039

We perform **dye** penetration tests on both porous and non-porous packaging materials in order to detect leaks. This involves **introducing coloured solution** within the packaging to visibly signal where there might be **holes or cracks** in the sealing that emit leaks. The sealing should not allow for any passage of liquid.

Integrity Testing by Bubble Test ASTM F2096

We conduct this method to validate that the packaging is **perfectly leak-tight**, both at the welds and at the faces of the materials. This integrity testing consists of detecting any leaks in sterile barrier systems by applying pressure inside the packaging.

Natural and Accelerated Ageing Tests

We provide **crucial natural and accelerated** aging tests to determine the lifespan and expiry dates of medical devices. These dates are typically 2 to 3 to 5 years and we test both the accelerated and natural tests **simultaneously according to the ASTM F1980 standard** to validate the packaging's integrity post-aging. **This process uses Arrhenius' law** to establish time/temperature equivalence. Passing this test can greatly speed up a manufacturer's time to market.

Transport Tests Simulation

We **perform transport test simulation** is a critical validation process used to ensure that medical packaging can **withstand being transported.** We mainly test according to two standards: the ASTM D4169 standard and the International Safety Transport Association (ISTA) programme.

First, we define the **test sequence representative of the distribution circuit**, then we apply the various mechanical stresses associated with transport: climatic environment, drop, compression, vibration, altitude. At the end of the tests, a **full validation of the packaging is performed** to validate its integrity and the maintenance of sterility. The medical devices are returned to the customer for verification of the devices after transport tests.

What Are the Advantages of Packaging Validation?

Packaging validation is essential for making sure the packaging material for your medical devices is secure and **conforms to regulatory requirements.** Packaging validation has important advantages for clients since means that your product is **fully certified and able to enter the marketplace.** These advantages include the following:

- **Performance and Reliability**
  Our packaging validation ensures the **integrity of your medical device's packaging** under various environmental and logistical conditions throughout its lifecycle. This is critically important to ensure that when patients receive the product, it **functions exactly as intended**, without any issues caused by packaging faults.
- **Patient Safety**
  Effective packaging validation tests the packaging's ability to **prevent contamination and physical damage**, thereby protecting the medical device from failures that **could pose a safety hazard** to patients. Particular attention is given to the strength of the seals and barrier properties to **eliminate risks of leaks and contamination penetration.**
- **Compliance with Regulatory Requirements**
  By adhering to strict regulatory standards, our packaging validation process not only ensures compliance with legislation but also **enhances consumer confidence.** Demonstrating that product packaging can effectively protect it throughout its lifecycle bolsters consumer confidence in its safety and efficacy.
- **Risk Minimisation**
  Packaging validation identifies risks such as **packaging degradation**, **breaches in sterile barriers**, and the **potential for physical damage** during transport. By identifying these issues, necessary adjustments can be made to enhance packaging robustness, ensuring that the product withstands the rigours of transportation and storage without **compromising safety or performance.**
- **Market Access**
  Adhering to international packaging standards broadens the market access of your

product. Certified reliable packaging allows for the **safe transportation and storage of your medical device** in various regions, thereby expanding your global presence and market potential.

Why Choose Applus+ Laboratories for Packaging Validation?

Choosing Applus+ Laboratories for your package validation aligns you with **a distinguished leader in medical device testing.** Our services, compliant with ASTM and ISO standards, are specifically crafted to guarantee the structural integrity and safety of your medical device packaging.

At Applus+ Laboratories, we offer packaging validation testing combined with **exceptional client service**, making us the ideal partner for your packaging needs. We support the full spectrum of your project, from development to market entry:

- Our team delivers **development testing and insightful recommendations** for enhancing packaging designs, ensuring your packaging meets high-quality standards.
- We conduct thorough **lifecycle testing of packaging** to ensure it preserves product integrity across various conditions and over time.
- We provide **qualification services** for both your product and its packaging, performing detailed evaluations to ensure your packaging solutions are **robust and effective.**
- Our **Contract Manufacturing Organisation (CMO) services** also include comprehensive support for packaging operations.

With operations **across multiple countries**, Applus+ Laboratories brings our leading-edge packaging validation testing services to clients worldwide, ensuring accessibility to superior testing solutions wherever you are located.

Choose Applus+ Laboratories as your trusted advisor and partner in medical device packaging testing. Our commitment to **providing high-quality services** and **expert guidance** is designed to streamline your path to market while navigating the complexities of packaging validation with confidence and precision.