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Three Critical Items You Must Know to Plan and Start Accelerated Aging for Medical Devices

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Summary

Medical device manufacturers must provide adequate documentation that confirms their product and packaging will maintain efficacy and sterility during its shelf-life or expiration period. While this length of real-time aging testing can take years, manufacturers can utilize accelerated aging to get their products to market in a significantly shorter timeframe. However, before the accelerated aging planning process can begin, these three critical elements must be identified:

1. **Document the market's shelf-life storage requirements for the product,**
2. **Understand how the product and packaging may be affected by temperature and humidity,**
3. **Determine the test sample quantity.**

Once these three elements have been answered, the manufacturer is ready to begin the accelerated aging planning process.

Background and Introduction

In the United States, the Food and Drug Administration (FDA) requires medical device manufacturers to establish the product's expiration date before entering the market using real-time aging data, which would take years, time that manufacturers do not have with new product introductions.

Fortunately, the FDA allows accelerated aging data to establish a tentative expiration date for product labeling, provided the manufacturer also initiates shelf-life studies to determine the actual shelf life and supporting expiry date. After the real-time aging completes, test samples are compared to accelerated aging samples. Hopefully, the two sets compare favorably, thus confirming that accelerated aging's test results supported real-time testing.

Additionally, medical device developers and manufacturers must fully understand how handling, transportation, environmental conditions, and time affect product sterility and efficacy. A compromised sterile barrier system can potentially jeopardize the effectiveness and safety of the product.

Regulatory Requirements

Medical device manufacturers offering products for sale in the US must adhere to at least two test protocols affecting aging: ASTM F1980 and ISO 11607-1.

ASTM F1980-21, **Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices,** specifies the methodology for planning and conducting accelerated aging studies.

ISO 11607.1, **Packaging for Terminally Sterilized Medical Devices,** specifies the requirements for sterile products and packaging to ensure the safety of sterilized medical devices up to the point of use.

Both documents allow accelerated aging test results and data to be used temporarily until real-time or shelf-life studies have been completed.

Accelerated Aging Definition and Use

Accelerated aging, also called accelerated shelf-life, is an artificial representation of real-time. It is a test procedure that determines the effects of time by exposing samples to relatively high temperatures for a defined period. A test sample subjected to accelerated aging experiences the dynamic relationship between temperature and chemical reaction rate, where the reaction rate increases as the temperature rises. This testing is standard practice in various industries, including medical device manufacturing and food.

Three crucial things that must be known before accelerated aging can be planned or started:

The manufacturer must know and understand three crucial things before the accelerated aging planning and testing can begin.

1. Document the market's shelf-life storage requirements for the product

You must fully understand and document the shelf-life storage requirements for the medical device. The market's shelf-life is the period during which the device must remain suitable until its sterile package is opened at the point-of-use. The shelf-life storage requirements should identify the time (months) and environmental conditions the product would be exposed to during distribution, in a storage facility, and storage near its end point of use.

The total time (months) will be used as the Desired Real time (RT) factor in the Accelerated Aging Time formula.

2. Understand how the product and packaging may be affected by temperature and humidity

Per ASTM F1980-21, Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices, the Accelerated Aging Temperature (TAA) and humidity levels must be determined before calculating Accelerated Aging Time (AAT).

However, it's essential first to understand the effects that exposure to heat and humidity will have on the items to be tested. For example, would a lengthy exposure at +60°C degrade the product? Excessive heat has been known to harm certain plastics, adhesives, and components, often included in a medical device's construction.

Regarding relative humidity, if the product or packaging materials could be affected by moisture degradation, a 45% to 55% relative humidity level is suggested as a starting point (depending on the temperature chosen). Still, checking with your material provider or in-house material expert to understand your product and package's limits is essential. Note that controlled relative humidity may not be required to be controlled if the product is not affected by moisture degradation. Also, relative humidity is not included in the Arrhenius equation (defined below).

3. Determine the test sample quantity

Sample size determination must be completed before accelerated aging can begin, therefore, should be an input to accelerated aging test planning. First, what is the purpose of the testing and how will the test results be used? The answers to these questions will be helpful inputs in the sample size decision-making process.

Secondly, the number of samples available for testing should be known. It's important to note that the purpose of testing may affect the selection of samples. For example, if the test results and data are submitted to the FDA as part of a 510(k) premarket submission demonstrating that the device is safe and effective, the test samples should be randomly pulled from production lots.

WESTPAK offers **Sample Size Calculators** on our website that you should find helpful.

Applying the Arrhenius Equation for Accelerated Aging

Accelerated aging planning can commence once the Three Critical Items above are understood and documented. ASTM F1980 incorporates the Accelerated Aging Factor (AAF) in the Arrhenius equation below to determine the Accelerated Aging Time (AAT).

$$\text{Accelerated Aging Time (AAT)} = \frac{\text{Desired Real Time (RT)}}{Q_{10}\,[(T_{AA}-T_{RT})/10]}$$

The four variables used in the above equation are as follows:

♦ Desired Real Time (RT)

The shelf-life or real-time duration in months that will be simulated through Accelerated Aging.

♦ Aging Factor (Q_{10})

The chemical reaction rate; the factor by which the rate of spoilage increases when temperature increases by 10°C. The aging factor is typically between 1.8 – 2.5, with 2.0 being the most common value; 2.0 means the rate of spoilage doubles every 10°C.

♦ Accelerated Aging Temperature (T_{AA})

The short-term storage temperature during the Accelerated Aging process. Commonly recommended temperatures are +50°C, +55°C, and +60°C dependent on product and package material.

♦ Ambient Temperature (T_{RT})

The Ambient Temperature is the temperature expected in the long-term storage environment, typically between +20°C to +25°C, with +25°C falling on the more conservative side and +23°C typically chosen.

The equation calculates the **Accelerated Aging Time (AAT)**, which is the length of time, in days, the accelerated aging test must run at the given Accelerated Aging Temperature (T_{AA}).

Example: Accelerated Aging Time (AAT)

$$\text{Accelerated Aging Time (AAT)} = \frac{\text{Desired Real Time (RT)}}{Q_{10}\,[(T_{AA}-T_{RT})/10]}$$

Variables

- ♦ Desired Real Time (RT): 12 months
- ♦ Ambient Temperature (TRT): +23°C
- ♦ Aging Factor (Q10): 2.0
- ♦ Accelerated Aging Temperature (TAA): +55°C

Result

- ♦ Accelerated Aging Time (AAT): 39.7 days (round up to 40 days)

Using the four factors above and WESTPAK's **Accelerated Aging Calculator** a sterile barrier system (SBS) that undergoes an Accelerated Aging test over the course of 40 days at +55°C, displays aging properties estimated to be the equivalent of a one-year-old real-time sample placed in ambient storage with a temperature averaging 23°C.

Evaluating a Product During and Post-Aging

During the Accelerated Aging process, the test laboratory will remove test samples and evaluate the product and package integrity at various aging time points, especially what is noted on the product expiry or shelf-life label. These evaluations may include the following:

- **Visual inspections (ASTM F1886)**
- **Sterile integrity testing**

Burst Testing (ASTM F2054)	Gross Leak Detection (Bubble) Testing (ASTM F2096)	Dye Penetration Testing (ASTM F1929 & ASTM F3039)	Seal Strength (Peel) Testing (ASTM F88)

Testing in Advance of Accelerated or Real-Time Aging

Conditioning and distribution testing is often performed on medical device products before accelerated or real-time aging. Distribution testing is transit simulation tests conducted in the test laboratory that evaluate how a package system performs when exposed to hazards commonly found in the distribution environment.

The package system that will undergo distribution testing must be subjected to conditioning before distribution testing. Conditioning at prescribed temperature and humidity levels for a specific time ensures that the package system materials will reach standard conditions and be ready for transit testing.

- Conditioning (ASTM D4332)
- Distribution Testing (ASTM D4169)

The Test Report

A comprehensive test report will be documented once all the testing has been completed. The report will include test sample descriptions, photos, test failure details, test standards utilized, the aging conditions, all equipment and instrumentation used, instrument calibration status, notes, and more.

The report will also detail post-aging evaluation results and whether the test has passed or failed per pre-established acceptance criteria.

The report and results can uncover the underlying issue of most performance problems and may recommend what to retest after the issues have been addressed.

Working with Us

WESTPAK strives to be your ultimate test services partner and works diligently as a team to earn your trust. Our **ISTA-certified laboratories and ISO 17025 accredited testing** back our Quality Management System (QMS). The outstanding customer service we provide to all customers is recognized throughout the industry.

Are you ready to get started with accelerated aging? **Request a quote or ask a question** now or contact us directly.

We look forward to the possibility of working with you on your upcoming tests.

About WESTPAK

As a third-party, independent test laboratory that specializes in product and package testing solutions, our facilities are ISO/IEC 17025 accredited by the American Association for Laboratory Accreditation (A2LA) as well as the International Safe Transit Association (ISTA). Learn more about our range of **Service offerings**.

John Baumwoll

John Baumwoll has served as Production Manager at WESTPAK, Inc.'s accredited testing laboratory in San Diego, California, since graduating in 2010 from Cal Poly, San Luis Obispo, with a bachelor's degree in Industrial Technology with a minor in Packaging.

In nearly 13 years, John and his production team have increased production volume while maintaining consistently high-quality levels for customers from Medical Device, Pharmaceuticals, Aerospace, Defense, Computers & Electronics, Cold Chain, Consumer Goods, and others.

John is a member of ASTM Committees D10 on Packaging and F02 on Primary Barrier Packaging. He is an active Cal Poly Packaging Advisory Board member and represents WESTPAK at ASTM conferences twice annually.

John's passions and interests include providing customers with the highest level of safety, quality, and customer service. He enjoys helping customers improve their products, Packaging, and efficiency, ultimately improving people's lives.

During his free time, John enjoys San Diego's coastline and traveling, scuba diving, hiking, exploring, and enjoying nature.

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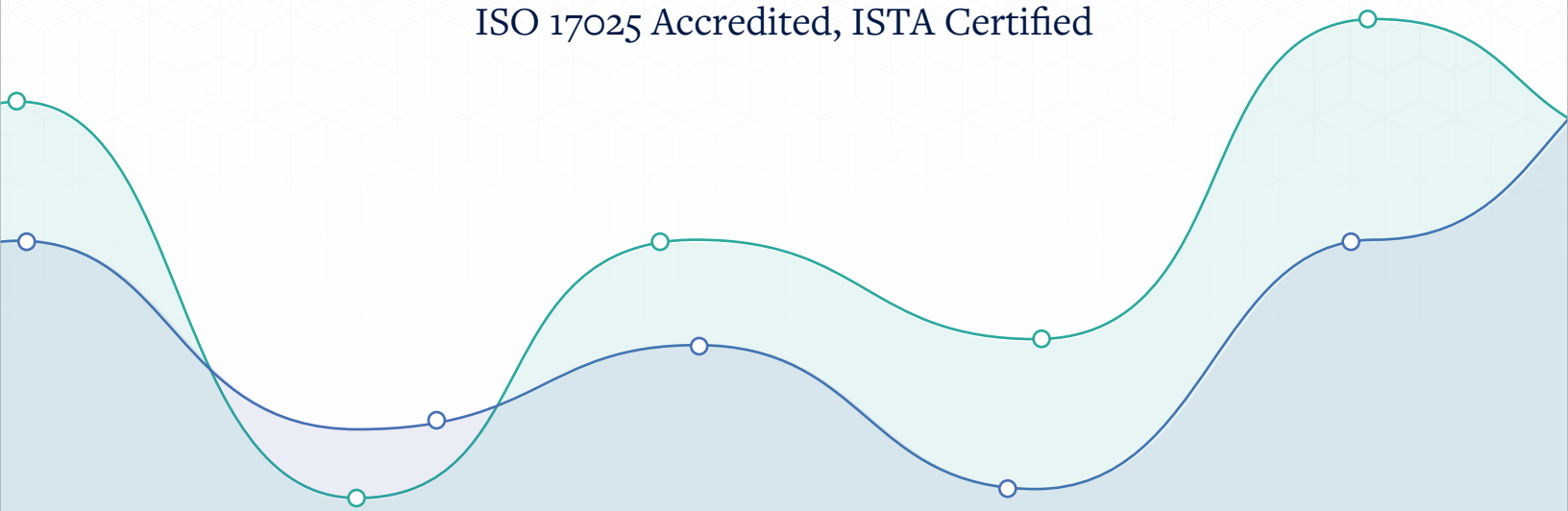

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