WESTPAK
TESTING. OWNERSHIP. INTEGRITY.

Accelerated Aging Services

Accelerated Aging determines the effects of time rapidly by exposing test samples to elevated temperatures. The technique is standard practice in the medical device and other industries. Most importantly, it is recognized by regulators worldwide as a valid method to accurately predict the effects of Real-Time shelf-life and establish expiration claims before Real-Time Aging has concluded.

Environmental Testing at WESTPAK:

- ✓ Accelerated Aging
- ✓ Altitude
- ✓ Environmental
- ✓ Conditioning
- ✓ ICH Stability
- ✓ Real-Time Aging / Shelf Life
- ✓ Temperature & Humidity
- ✓ Temperature
- ✓ Stability
- ✓ Thermal Cycling
- ✓ Thermal Shock

What is Accelerated Aging?

The Accelerated Aging process is based on the relationship between temperature and chemical reaction rate, in which reaction rate increases as temperature rises. The method uses higher temperatures to accelerate the aging process by representing Real-Time Aging artificially.

For example, a sterile barrier system (SBS) subjected to 40 days of Accelerated Aging at +55°C will exhibit aging properties similar to Real-Time samples stored for one (1) year, assuming an ambient storage temperature of +23°C.

Manufacturers can utilize Accelerated Aging results as a justification to get the product to market faster and establish the required expiration claims.

How Is Accelerated Aging Performed?

ASTM F1980 “Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices” is the protocol that helps to define the aging parameters.

WESTPAK’s laboratories utilize environmental chambers with temperatures set at +50°C, +55°C, or +60°C, and uncontrolled relative humidity (RH), to conduct most of the Accelerated Aging. However, the customer can request different temperature and humidity levels as may be required.

Accelerated Aging simulates the Real-Time shelf-life environment; ambient storage temperatures between +20°C and +25°C are typically assumed. +20°C will generate the shortest Accelerated Aging duration due to the most significant temperature difference.

Is Humidity Used with Accelerated Aging?

Accelerated Aging is typically performed with uncontrolled RH because most SBS materials are not moisture sensitive. However, ASTM F1980-21, the current revision, recommends that the use of humidity during Accelerated Aging be considered for all materials; findings and decision rationale should be documented.

Environmental Testing Standards

ASTM F1980

ASTM D6653

ASTM D4332

ASTM F2825

ASTM D3103

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Accelerated Aging Services

Environmental Chambers Are Utilized for Accelerated Aging

- Of the 100+ environmental chambers available, 12 are shared and individually set for +50°C, +55°C, or +60°C.
- Temperatures lower and higher than those in shared chambers can be used.
- Chambers range in size from walk-in (2,600 ft3) to small (4 ft3).

How Are the Variables for Aging Studies Determined?

The following are considered:

- Customer and product requirements,
- How test results will be used,
- Sample material specifications,
- Quantity and size of samples,
- Shelf-life parameters,
- Real-Time Aging duration.

WESTPAK uses the Arrhenius equation to calculate Accelerated Aging Time (AAT) based on the relationship between temperature and the chemical reaction rate.

Should Relative Humidity (RH) be Controlled During Accelerated Aging?

- The need to use controlled RH depends almost entirely on the materials used in the product and how moisture affects them.
- Use of high humidity (>60% RH) or low (<30% RH) during Accelerated Aging may result in unnatural effects on materials, especially polymers.
- Aging studies with and without humidity may be necessary to determine the effects and provide justification.

How Does Real-Time Aging or Shelf-Life Apply?

- Accelerated Aging results are used to test shelf-life claims and document expiration dates by accelerating real-world shelf-life aging conditions.
- Real-Time and Accelerated Aging studies must be performed in parallel to completion for the claimed shelf life of the product. Ultimately, after the Real-Time exposure, samples are withdrawn, studied, and compared with Accelerated Aging samples and data.

"Accelerated Aging is used for both product and package. First, make sure you know the temperature sensitivities of each, then develop the test plan around the lowest temperature."

Mark Escobedo
Senior Sales Engineer