



Accelerated Aging Q&A

ASTM F1980-21 Revision

The Accelerated Aging protocol ASTM F1980 was updated in December 2021. Here, our technical experts address questions that medical device manufacturers and OEMs will be asking. Please consult with our Sales team to learn how the changes could impact your medical device and package system.

Environmental Testing at WESTPAK:

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



What is the background of the ASTM F1980 standard?

The ASTM F1980 standard was initially intended to simulate the aging process of packaging materials for expiration date claims. Based on the Arrhenius equation, the equivalent real-time aging duration could be accomplished in several months by exposing test samples to elevated temperatures. While the standard focused primarily on the materials used in the sterile barrier system (SBS), the standard was also used for the accelerated aging of products.

What were the general changes to the ASTM F1980 standard?

The F1980-21 revision strongly recommends a thorough understanding of the moisture degradation properties of all materials used in the medical device.

Accelerated aging studies are typically conducted by elevating the temperature without controlling humidity; this works well for SBS materials that do not have moisture degradation mechanisms. However, there is a potential to degrade the materials used in the product with low relative humidity (RH) levels encountered with uncontrolled humidity during accelerated aging.

Given the changes, do I need to start conducting Accelerated Aging with Controlled Humidity?

The need to use controlled humidity depends almost entirely on the materials used in your product and how moisture affects them. Fortunately, most SBS materials are moisture insensitive. However, product material degradation may occur during exposure to the low RH levels typically observed during accelerated aging with uncontrolled humidity.

We recommend relying on your material suppliers to provide the moisture degradation data for materials used in your product and packaging.

Environmental Testing Standards

ASTM F1980

ASTM D6653

ASTM D4332

ASTM F2825

ASTM D3103



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What humidity input should I use?

The manufacturer should determine if humidity should be controlled during accelerated aging with input from material suppliers. If unknown, a few options exist:

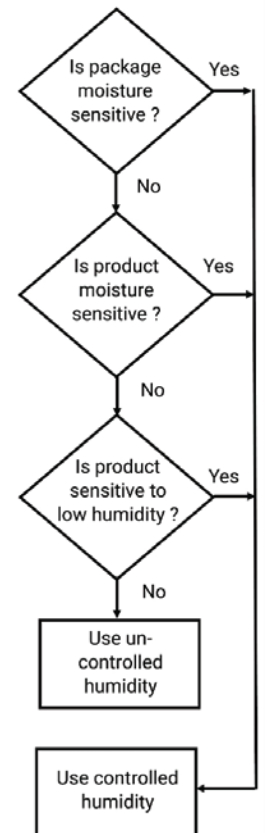
- 1) Business as usual; continue with current testing methods.
- 2) Determine a reasonable humidity input for aging. The standard's Appendix X3 notes, "When controlling humidity during an aging study, 45-55% RH should be targeted unless there is a specific warrant for using other humidity conditions."

What if I choose uncontrolled humidity?

The critical point of the revised standard is that the manufacturer should understand the product and packaging materials and if the accelerated aging conditions are influencing a potential failure mode in those materials.

Uncontrolled relative humidity (RH) is still acceptable and should continue to be used for most accelerated aging studies. Only after evaluating the materials used in the product should controlled humidity levels be considered. Even then, most materials will not be sensitive to elevated temperature and uncontrolled RH conditions. As per the standard, the evaluation and reasons for the decision should be documented.

Accelerated Aging Controlled Humidity Decision Flow Chart



What accelerated aging services does WESTPAK offer?

WESTPAK has over 100 environmental chambers providing a variety of customized temperature and humidity input possibilities. The most economical accelerated aging is conducted at elevated temperatures with uncontrolled RH. We currently have accelerated aging temperatures of +50°C, +55°C, and +60°C with humidity uncontrolled. Using one of these conditions enables the usage of our best economies of scale.

Do I still need to do Real Time Aging?

Yes, accelerated aging is used to specify an expiration date while conducting real-time stability studies in parallel. We recommend using a real-time aging facility such as WESTPAK's, where environmental conditions are monitored, exposure to light is minimized, and access is controlled.



"WESTPAK has a variety of accelerated aging temperature and RH conditions available for your needs. Please get in touch with our Sales team for availability and pricing."

Mark Escobedo,
Senior Sales Engineer