Cincinnati Sub-Zero

Ensuring Product Integrity: The Role of Stability Chambers in Controlled Environment Testing

Weiss Technik North America, Inc. 12011 Mosteller Road . Cincinnati, OH 45241 . (513) 326-5252

www.cszproducts.com

What is a Stability Chamber?

A stability chamber creates a precisely controlled environment that maintains specific temperature and humidity conditions to test product stability over time. These chambers range in size from small reach-in units to large walk-in chambers and are used for applications such as real-time stability testing, accelerated stability testing, and forced degradation testing. Stability chambers are essential in the life sciences industry, ensuring products are tested under precise and controlled environmental conditions. These chambers validate the performance of products before full-scale production, guaranteeing that life-saving products reach patients safely and promptly.

Uses of Stability Chambers

Stability chambers are used in a wide range of industries and applications, including pharmaceutical products and packaging, medical products and packaging, biopharmaceuticals, nutraceuticals, research and universities, personal care products, consumer products, food products, flavors and fragrances, medical electronics and test kits, surgical instruments, and tissue storage.

Industry Standards Requiring Stability Chambers

Stability chambers are used for various tests, including real-time stability testing, expiration date/shelf life testing, accelerated stability testing, forced degradation testing, and package/transport testing.

Stability chambers must comply with various industry standards. Below are some of the test standards where stability chambers are often used.

- ICH Q1A – FDA Harmonized Guideline for Stability Testing of New Drug Substances & Products
- ASTM F1980 - Accelerated Aging for Sterile Packaging for Medical Devices
- ISO 11607 - Validation Testing - Packaging for Terminally Sterilized Medical Devices
- IEC 60601 - 1 3rd edition - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ASTM D4169 - Standard Practice for Performance Testing of Shipping Containers and Systems
- ISTA 3A - Packaged-Products for Parcel Delivery System Shipment 150 lb or Less
- ISTA 7E - Thermal Controlled Transport Packaging for Parcel Delivery System Shipment
- Other test standards

Two of the most common test standards are shown below.

ICH Q1A - Harmonized test standard Stability Testing of Drug products & packaging

The below is a summary of the FDA guidance document which highlights test/storage conditions. It is important to note that the ± values refer to uniformity. See the section below on the differences between temperature control and uniformity.

2.1.7.1 & 2.2.7.1	Storage Conditions for Drug Substances or Products	General Case Long Term	25°C, ±2°C/60% RH ±5% RH or	12 months
		Intermediate	30°C, ±2°C/65% RH ±5% RH	6 months
		Accelerated	40°C, ±2°C/75% RH ±5% RH	6 months
2.1.7.2 & 2.2.7.4	Drug Substances or Products for Storage in a Refrigerator	Long Term	5°C, ±3°C	12 months
		Accelerated	25°C, ±2°C/60% RH ±5% RH	6 months
2.1.7.3 & 2.2.75	Drug Substances or Products for Storage in a Freezer	Long Term	-20°C, ±5°C	12 months
2.2.7.3	Drug products packaged in Semi-Permeable Containers	Long Term	25°C, ±2°C/40% RH ±5% RH or 30°C, ±2°C/35% RH ±5% RH	12 months
		Intermediate	30°C, ±2°C/65% RH ±5% RH	6 months

ASTM F1980 - Accelerated Aging for Sterile Packaging for Medical Devices

This test specification is used to determine the long-term effects of distribution, handling, and storage when devices are included in the protective packaging. Long-term temperature and /or humidity testing for Accelerating Aging is used to determine shelf life. By increasing the temperature, test time can be reduced. See example chart below.

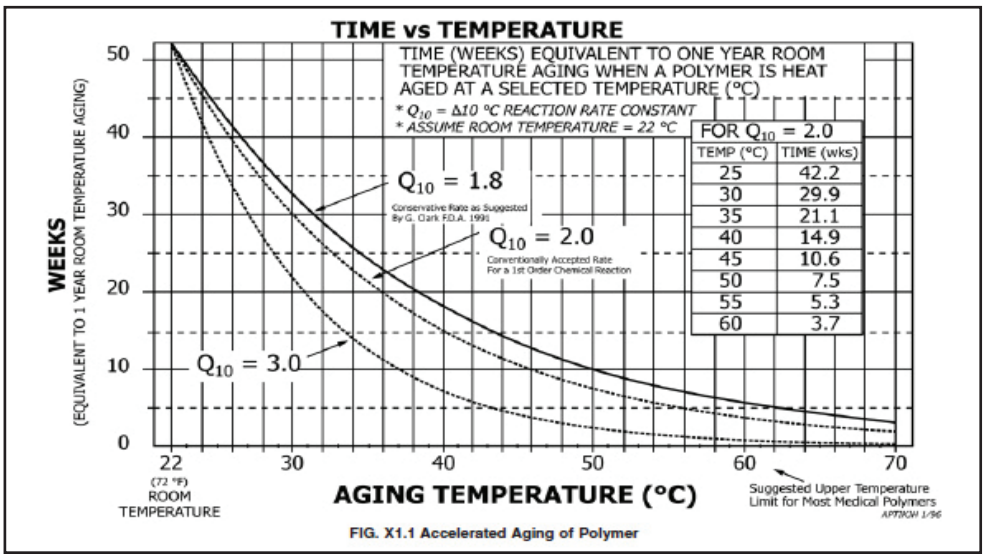

FIG. X1.1 Accelerated Aging of Polymer

In the medical device industry, products must comply with FDA and other regulatory requirements. Manufacturers face significant challenges in design validation, documentation, and product testing while striving to bring new products to market quickly and stay ahead of the competition. All medical device equipment utilizing electronics must meet the IEC 60601-1 standard, which governs safety and performance testing requirements and requires the use of stability test chambers.

Key Features of Stability Chambers

When selecting a stability chamber, several important features should be considered, such as GMP compliance, high accuracy sensors (RTDs and capacitive humidity sensors), 21 CFR Part 11 compliant touchscreen control, software and hardware safety limits for product protection, temperature uniformity, reliability and ease of maintenance, compact design and mobility, low noise level, and energy efficiency.

Differences Between Temperature Control and Uniformity

In the realm of stability chambers, two critical parameters often discussed are temperature control and temperature uniformity. These terms refer to different aspects of maintaining the desired environmental conditions within the chamber.

Temperature Control

Temperature control refers to the ability of the stability chamber to maintain the set-point temperature at a specific location within the chamber. This is typically measured at a single control sensor location and is indicated on the controller screen. For instance, a stability chamber might have a temperature control specification of ±0.3°C, meaning that the temperature at the control sensor location will deviate by no more than 0.3°C from the set-point.

Temperature Uniformity

Temperature uniformity, on the other hand, measures the variation in temperature across multiple points within the chamber. This is measured to ensure that the temperature is consistent throughout the usable volume of the chamber, which is crucial for the validity of stability tests. It is calculated using the difference between the highest and lowest temperatures measured within the workspace. Like temperature control, it is specified in a deviation from setpoint. If the chamber has a setpoint of 60°C, and the uniformity it ±2°C, then the range is acceptable from 62°C to 58°C.

Factors Affecting Temperature Uniformity

Several factors can affect temperature uniformity, including the design of the chamber, the placement of samples, and the type of sensors used. For instance, validations sensors such as RTDs and thermocouples have different accuracies, which can impact the overall uniformity. The inaccuracy of validation sensors, such as RTDs (±0.2°C) and thermocouples (±0.5–1.0°C), should be considered when calculating total uniformity.

Understanding the difference between temperature control and uniformity is crucial for selecting and validating stability chambers. While temperature control ensures that the set-point temperature is maintained at a specific location, temperature uniformity ensures that this temperature is consistent throughout the chamber. Both parameters are important for the reliability and accuracy of stability testing.

Stability Chambers for Product Testing

CSZ stability chambers include reach-in and walk-in models. Our versatile reach-in chambers are available in single, double and triple door units, offering additional storage and testing capacity without requiring the investment of a full walk-in chamber.

- GMP compliant design
- Temperatures range from 2°C to 70°C and 20% to 90% RH
- Constant operation at 5°C is possible without defrosting
- Stainless steel interior for easy cleaning and decontamination
- Touch screen operator interface - Program, Control and Monitor your testing
- Analog output to connect with monitoring systems
- Patented sterile steam system humidification for contamination-free operation
- Compact size with casters allows for easy fit through doorways
- Uni-Flow airflow design provides precise temperature uniformity
- Energy efficient, low power draw
- Meets ICH Q1A guidelines
- Quiet operation
- Six shelves per door
- Lockable door
- Integrated humidity water tank

Stability chambers are essential for ensuring the safety and efficacy of life science products. CSZ stability chambers offer industry-leading temperature and humidity uniformity that meet industry standards and support regulatory compliance. By choosing the right stability chamber, companies can ensure that their products are tested under optimal conditions, leading to consistent product quality, successful validation and market approval. Please contact us for further information.