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Performing Stability Studies

With Reliable, User-Friendly Percival Scientific Stability Chambers

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Introduction to Stability Studies

A stability study is a scientific process used to determine how a product changes over time when exposed to specific environmental conditions. These studies help researchers understand how long a product remains safe, effective and within specification throughout its determined shelf life.

Stability studies are commonly used in many industries:

- Pharmaceuticals (solid oral dosage, liquids, injectables, topicals)
- Biologicals (products such as vaccines, monoclonal antibodies, proteins and other biologic materials may require additional stability considerations as outlined in ICH Q5C)
- Medical devices
- Food and beverage products
- Nutraceuticals and dietary supplements
- Agricultural products
- Chemicals and specialty materials
- Other nondurable consumer goods

By monitoring products under controlled temperature, humidity and light conditions, scientists and quality personnel can predict long-term changes and establish storage recommendations and expiration dates.

Many companies outsource stability studies to third-party laboratories or research organizations. Purchasing your own Percival Scientific stability chamber(s) may prove to be cost effective and become a vital research tool for continuous product and packaging improvements.

It is imperative to consider following the International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use and its guidelines for stability studies, which are considered the global standard. Other considerations, such as applicable geographic locations along with their climate zones and the type of material being studied, are also important.

Why Perform Stability Testing?

Stability testing helps organizations understand their products better and ensure safety for consumers by:

Determining Shelf Life – Manufacturers need evidence to support expiration dates and recommended use periods.

Meeting Regulatory Requirements – Regulatory agencies such as the FDA, EMA, WHO, state regulatory bodies (e.g., medical cannabis regulators), and major distributors and retailers require stability data for many products before approval or sale.

Verifying Product Quality – Stability studies ensure products continue to meet specifications throughout their lifecycle.

Supporting Product Development – Researchers use stability data to compare formulations, packaging options and storage conditions.

Reducing Risk – Understanding how products degrade helps prevent quality failures, recalls and customer complaints.

Key Components of a Stability Study

Every stability study includes four basic elements:

1. **The Product Being Tested** – The material being evaluated may include:
   - Drug products
   - Drug substances (APIs)
   - Biological samples
   - Cell cultures
   - Food products
   - Beverages
   - Cannabis products
   - Dietary supplements
   - Paper goods
   - Medical devices
   - Other nondurable consumer goods

Studies require multiple units of product from one or more batches (three is typical). Determine the number of units based on the prescribed storage conditions, testing time points and testing parameters.



2. **Storage Conditions** – Samples are placed in environmental chambers that maintain specific conditions such as:

   Temperature

   - 25°C to 40°C for long-term, intermediate and accelerated studies (more on that to come)
   - Refrigeration (5°C) or frozen (-20°C or below) storage conditions may be necessary

   Relative humidity

   - 60% to 75% RH, but may differ based on location-specific zones
   - Uncontrolled in colder temperatures

   Light exposure (for photostability research)

   CO_2 concentration (when applicable)

Studies require the multiple units stated above to be stored together under the same storage conditions. These controlled environments allow for standardization of exposure. Testing of multiple units, such as in triplicate, increases the confidence in the data being generated. Understanding variation both between and within batches is likely important to help determine the total number of samples and tests in the study protocol.

Storage conditions may vary depending on the intended market and climatic zone. Regulatory agencies recognize that products distributed globally may be exposed to significantly different temperature and humidity conditions. Stability protocols should be designed to reflect the environmental conditions likely to occur during distribution and storage in target markets.

3. **Time Points (T)** – Samples are tested at predetermined intervals. Common time points include:

   - Initial time point (T=0)
   - 1 month
   - 2 months
   - 3 months
   - 6 months
   - 9 months
   - 12 months
   - 24 months

Study duration depends on the product being tested and on regulatory requirements. The duration for a long-term study should include the expected shelf life, while an accelerated study may be much shorter based on the coefficient determined to indicate the rate of degradation, change or contamination. Such a coefficient can be determined with the help of a stress or forced degradation study.



4. **Testing Parameters** – Researchers evaluate characteristics that indicate product quality, such as:

   Chemical tests

   - Potency
   - Purity or impurities (degradation products)
   - pH
   - Moisture content
   - Leaching contaminants (e.g., heavy metals from packaging)

   Physical tests

   - Appearance
   - Color
   - Dissolution
   - Odor
   - Taste

   Microbiological tests

   - Microbial contaminants
   - Sterility
   - Water activity



Types of Stability Studies

The ICH provides globally recognized guidance for stability testing of pharmaceutical products. While these guidelines were developed for drug substances and drug products, the principles are frequently applied to biologics, nutraceuticals, cannabis products, food products, agricultural products and other nondurable consumer goods. Key guidance documents include ICH Q1A(R2) (Stability Testing of New Drug Substances and Products), ICH Q1B (Photostability Testing), ICH Q1D (Bracketing and Matrixing Designs), ICH Q1E (Evaluation of Stability Data) and ICH Q5C (Stability Testing of Biotechnological/Biological Products).

Within ICH Q1A(R2), the following stability study types are commonly utilized:

Long-Term Stability Testing – Evaluates products under recommended storage conditions for the expected shelf life:

- **Purpose:** establish expiration dates and storage instructions
- **Conditions:** 25°C / 60% RH

Intermediate Stability Testing – Often performed when accelerated conditions cause unexpected changes:

- **Purpose:** provide additional data between long-term and accelerated conditions
- **Conditions:** 30°C / 65% RH

Accelerated Stability Testing – Exposes products to elevated temperatures and humidity levels:

- **Purpose:** predict long-term stability in a shorter period.
- **Conditions:** 40°C / 75% RH (e.g., storing samples at 40°C and 75% RH may reveal degradation patterns faster than room-temperature storage)

An accelerated study may be performed in conjunction with a long-term study. The data and determinations made from the accelerated study can then be validated with the long-term study data and determinations.

Products that require refrigerated or frozen storage conditions have their own guidance for stability study conditions. Review ICH Q1A(R2) for the exact conditions.

The ICH Q1B guidelines define photostability as the stability of the material when exposed to sunlight or artificial light equivalents.

Photostability Testing – Evaluates how exposure to light affects a product:

- **Purpose:** determine whether protective packaging or light-sensitive storage instructions are necessary.
- **Conditions:** constant temperature and humidity with two ICH Q1B options for light exposure. Some lighting systems can lead to faster testing times than others. Percival Scientific's photostability chambers can meet the light exposure requirements in less than 24 hours, while competitors usually require 2-4 days. Review ICH Q1B for specific guidelines, but consult the manufacturer of the photostability chamber for specifics about the chamber's capabilities compared to ICH.

Stress/Forced Degradation Testing – Deliberately degrading a product or material in a short amount of time using severe environmental conditions (high heat, high humidity, photolysis/ultraviolet light, oxidation, hydrolysis) to determine the possible effects of time, humidity, light and other factors without waiting for a long-term or accelerated stability study. The data gathered from these studies can help determine which testing parameters to consider in future stability studies. Data collected can be modeled to help determine the expected relationship between long-term, intermediate, accelerated and forced degradation studies.

Freeze-Thaw Testing – Repeatedly freezes and thaws products:

- **Purpose:** evaluate stability during shipping, storage and handling.

In-Use Testing – Tests stability of a product under real-world, opened and stored-over-time conditions:

- **Purpose:** evaluate products that may be susceptible to spoilage or require different storage once opened.

In-use stability studies are also of key importance and differ from other stability tests by storing and testing the same opened container(s) to mimic typical real-world use.

How to Design a Basic Stability Study for In-House Use

Developing a stability study protocol is the initial phase to implementing stability testing at your facility. Create a protocol by following these steps:

1. Define Your Objective

   A clearly defined objective guides the entire study. Start by answering:

   - What product are you studying?
   - What information do you need?
   - Are you establishing shelf life?
     - If so, what is the anticipated shelf life of the product?
     - Are specific ingredients in the product going to limit shelf life?
     - Is it possible to add preservatives to lengthen shelf life?
   - Are you comparing formulations?
   - Are you evaluating packaging?

2. Select Storage Conditions

   - Choose environmental conditions that reflect:
   - Expected storage environments
   - Regulatory requirements
   - Transportation conditions
   - Real-world use scenarios
   - Environmental chambers that maintain stable, uniform conditions throughout stability studies are essential. Significant fluctuations in temperature, humidity and light exposure can render a stability study inconclusive, wasting time and cost.

3. Determine Sampling Time Points

   Plan when samples will be removed and tested. A typical beginner study for a product with a predicted one-year shelf life might include:

   - Time Point 0
   - Month 1
   - Month 3
   - Month 6
   - Month 9
   - Month 12
   - Month 15

   More complex studies may require additional intervals.

4. Define Acceptance Criteria

   Predetermined criteria prevent bias and support regulatory compliance. Determine what constitutes a passing result before the study begins.

   Examples:

   - Potency remains within 90–110% of the label claim
   - No visible color change
   - pH remains within specification
   - Microbial levels remain below 10 CFU/g

5. Monitor, Test and Record Data

   Thorough documentation is essential for data integrity and audits. Throughout the study:

   - Verify chamber conditions regularly
     - Ensure stability chambers with humidifiers have a continuous supply of manufacturer-specified water
   - Document deviations
   - Record all test results
   - Maintain traceable records

6. Analyze Results

   - Look for trends over time, such as:
   - Loss of potency
   - Physical changes, such as color, flocculation, clumping, etc.
   - Moisture uptake
   - Increased degradation products
   - Increased microbial levels

Statistical analysis can be used to estimate shelf life and identify significant changes. Regression analysis and other statistical tools described in ICH Q1E (Evaluation of Stability Data) can be used to establish expiration dates, identify trends and determine whether observed changes are statistically significant. Accelerated stability studies can provide preliminary shelf-life estimates that can later be confirmed through real-time, long-term studies.

These data may be used to determine storage conditions (e.g., store below 25°C), storage container type (e.g., amber glass to protect from light), packaging selection and shelf life, among other factors.

Common Challenges in Stability Studies

Unfortunately, since stability studies are performed over time, and usually a very long time at that, challenges may arise. Some examples include:

Temperature Excursions – Unexpected temperature fluctuations can impact study results.

Equipment Reliability – Environmental chambers must provide accurate and consistent control throughout the study. Percival Scientific stability chambers are tested in-house prior to shipping to ensure strict adherence to set temperature and humidity specifications. Consider the need for backup power supply options.

Sample Management – Large studies often involve hundreds or thousands of samples that must be tracked carefully. Having the space to reliably store that many samples at once can be challenging, but Percival Scientific can design and build walk-in stability chambers to meet this need.

Regulatory Compliance – Studies must follow applicable guidelines and maintain complete documentation.

Consider Percival Scientific When Choosing Your Next Stability Chamber

Environmental chambers play a critical role in stability testing. When selecting a chamber, consider the following:

- Temperature range
- Humidity control capabilities
- Optional lighting systems
- Additive gas (CO_2) needs
- Forced degradation capabilities
- Uniformity and stability performance
- Data logging options
- Regulatory compliance support
- Capacity requirements
- Alarm and monitoring systems
- Reliable environmental control helps ensure accurate and repeatable results throughout the study.
- Percival Scientific designs environmental chambers used by researchers, manufacturers and quality teams worldwide.

Our stability-testing solutions provide:

- Precise temperature and humidity control
- 24-hour photostability testing capabilities
- Reliable long-term operation
- Customizable chamber configurations
- Advanced monitoring and control systems
- Support for pharmaceutical, biotechnology, agricultural and research applications

Whether you're running a simple product evaluation or a regulated stability program, maintaining consistent environmental conditions is essential for generating reliable data.

Stability studies are a foundational part of product development and quality assurance. By exposing products to controlled environmental conditions and monitoring changes over time, organizations can determine shelf life, verify product quality and meet regulatory expectations.

Available Percival Scientific solutions:

- RX-3600E
- RX-3000L
- RX-3000, RX-3600
- Custom walk-in stability rooms

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