Stability 201 Guide

Commonly asked questions about "stability" or "shelf-life" projects/studies for cosmetics and OTC drugs.

Stability testing is the process of confirming that a product will remain safe and effective over its entire shelf life. This 201-level guide covers the basic concepts, testing methods, and regulatory requirements involved in ensuring cosmetic and OTC drug stability.

What is OTC drug stability testing?

Evaluates how the quality of a product over time under the influence of environmental factors like temperature, humidity, and light. Results are used to set the product's expiration date and recommend storage conditions. For OTC drug products sold in the U.S., expiration dates are required by the FDA and must be supported by stability data.

Key attributes to test

Stability testing involves monitoring critical product characteristics that could change over time.

Common tests include evaluating:

- **Physical properties**: Appearance, color, odor, viscosity, and pH.
- **Chemical properties**: The potency of the active ingredients and the formation of impurities or degradation products.
- **Microbiological properties**: The effectiveness of preservatives and microbial limits, which is especially important for non-sterile liquids.
- **Package Compatibility**: The integrity of the packaging and its compatibility with the product.

Types of stability studies

1. *Real-time (long-term) stability*

Purpose: To confirm the proposed shelf life by testing the product under expected storage conditions.

Conditions: Storage at controlled room temperature, which is typically 25°C ± 2°C with 60% ± 5% Relative Humidity (RH) for the U.S.

Testing frequency: Common intervals include 0, 3, 6, 12, 24 and 36 months.

2. *Accelerated stability*

Purpose: To quickly predict the product's shelf life by using exaggerated stress conditions.

Conditions: High temperature and humidity, such as 40°C ± 2°C with 75% ± 5% RH for the U.S.

Testing frequency: Typically tested at 0,1, 2, 3, and 6 months.

Use for market launch: The FDA allows companies to use accelerated stability data to project an initial expiration date for a new product, but this must be confirmed by a concurrent real-time study.

3. *Intermediate stability*

Purpose: Used when a product fails accelerated testing. Data help bridge the gap between accelerated and real-time results.

Conditions: Intermediate conditions, such as 30°C ± 2°C with 65% ± 5% RH.

Testing frequency: Common intervals include 0, 3, 6, 12, 24 and 36 months.

4. *Photostability*

Purpose: Determine whether a product remains stable when exposed to light and to identify degradation caused by UV or visible light. Important for products with light-sensitive ingredients or transparent packaging.

Conditions: Light-exposure testing per ICH Q1B (Option 2), typically using a broad-spectrum light source (300–800 nm) at ~200 W/m^2 with a total exposure of at least 1.2 million lux-hours. Samples are tested in final packaging alongside a protected dark control.

Testing frequency: Generally a short-duration stress test conducted once per study. Total light-exposure duration is typically completed within 7-10 business days.

How to perform cosmetics/OTC stability testing

1. *Create a stability protocol*

Before testing, develop a written plan that includes:

- *Product to be tested.*
- *Number of batches and sample sizes.*
- *Specific tests and acceptance criteria.*
- *Testing methods (which must be validated).*
- *Storage conditions and time points.*
- *Description of the container and closure system.*

2. *Select samples*

Use samples from at least three batches for initial stability studies.

Use the final, market-ready container-closure system. Test the smallest container size, as it is often the most susceptible to environmental factors.

3. *Conduct initial tests (Time Zero)*

Before stability storage testing, perform all planned tests on the initial samples as part of routine test to establish a baseline for all critical attributes, such as potency, color, specific gravity, appearance, pH, odor and viscosity.

4. *Place samples in storage*

Store the samples in controlled environmental chambers set to the appropriate conditions for real-time, accelerated, and intermediate studies.

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