Dietary Supplement Stability 201 Guide

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 dietary supplements stability.

Types of stability studies

1. Real-Time (Long-Term) Stability
Purpose: Confirms the proposed shelf life by testing the supplement under expected storage conditions.
Conditions: Storage at controlled room temperature, which is typically 25°C ± 2°C with 60% ± 5% Relative Humidity (RH) in U.S. markets.
Testing frequency: Common intervals include 0, 3, 6, 12, 24, and 36 months.

2. Accelerated Stability Testing
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 in U.S. markets.
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/m² 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 dietary supplement 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, appearance, odor, and liquid-specific properties (viscosity and pH).

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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