Supplement Stability Testing Glossary

- **Accelerated Stability Study**: A stability test conducted under elevated temperature and humidity conditions to predict how a product will age over time. It helps estimate shelf-life more quickly than real-time studies.
- **Active Ingredient Potency Assay**: A test that measures the strength and concentration of an active ingredient to confirm it meets required specifications. It ensures the product delivers the intended effectiveness throughout its shelf-life.
- **Assay**: A laboratory test done to quantify the amount of a specific ingredient in a formula.
- **Batch**: A specific formula quantity produced under the same conditions during a single manufacturing cycle. It is expected to have uniform quality and characteristics throughout.
- **Chamber**: A temperature- and humidity-controlled appliance for storing samples during stability or shelf-life testing.
- **Degradation**: The breakdown of an ingredient or formulation over time during stability testing. It indicates how environmental factors affect product quality and potency.
- **Disintegration**: The process by which a dietary supplement tablet or capsule breaks apart into smaller pieces after ingestion. Disintegration testing measures how quickly the dosage form breaks down under specified conditions to help ensure the product releases its contents properly.
- **Elevated Stress Conditions**: Testing conditions that use higher-than-normal temperature, humidity, or light exposure to accelerate product degradation and identify potential stability issues.
- **Formula**: The specific combination of ingredients that make up a product.
- **ICH**: The International Council for Harmonization, which establishes global guidelines to ensure the safety, quality, and efficacy of pharmaceuticals and related products.
- **ICH Climate Zones**: Regions classified by the International Council for Harmonization (ICH) based on temperature and humidity conditions. These zones guide stability testing requirements to ensure products remain stable under the environmental conditions where they will be marketed and sold.
- **Intermediate Stability Study**: A stability test performed at conditions between real-time and accelerated studies. It helps evaluate product behavior when accelerated conditions cause unexpected changes or when additional data is needed.
- **Long-Term Stability Study**: A study performed under normal storage conditions to evaluate how a product maintains its quality, safety, and performance over its intended shelf-life. It provides the primary data used to establish expiration dating.
- **New Batch**: A newly manufactured lot of a formula produced under the same conditions but separate from previous batches.
- **Packaging Compatibility**: An assessment of how well a product interacts with testing to ensure compatibility between the product and its packaging, including evaluation of external packaging.
- **Photostability Study**: A test that evaluates how a product or ingredient responds to light exposure. It helps determine whether light causes degradation or affects the product's safety, quality, or appearance.
- **Pull Point**: Also referred to as a Time Point. A designated interval in a shelf-life or stability study when samples are pulled for testing to evaluate product quality over time.
  - *"Initial"* is also referred to as a time point for Time 0.
- **Real-Time Temperature**: The standard storage temperature used in real-time stability studies to evaluate how a product performs under normal, expected environmental conditions over time.
- **Shelf-Life Study**: Interchangeably used term with "stability study" or "stability project". A study that determines how long a product remains stable and maintains its intended quality, safety, and performance specifications under recommended storage conditions. It helps establish the product's expiration, use-by, and period-after-opening dates.

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