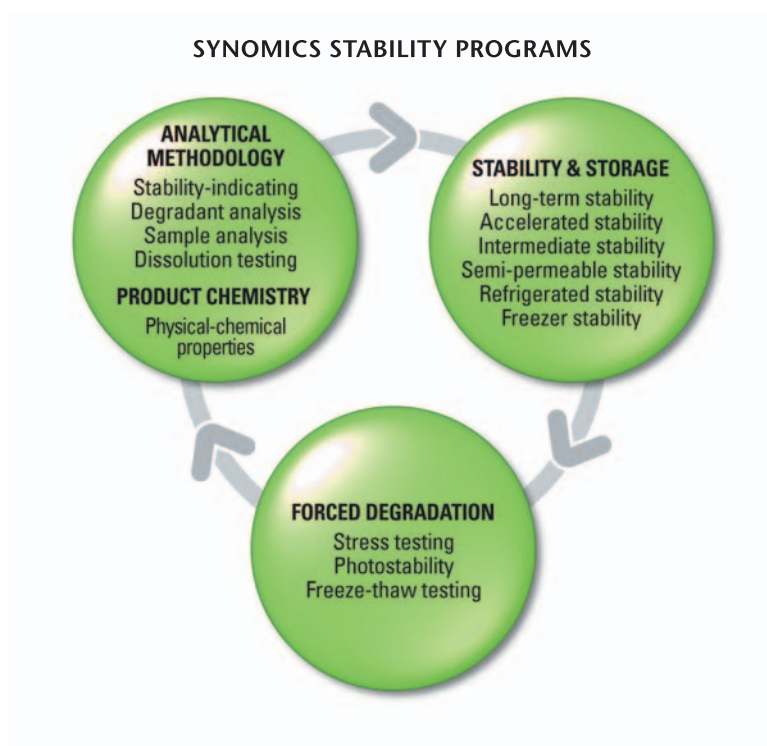


Stability and Storage Programs

The objective of stability and storage testing is to provide evidence on how the integrity of a material varies with time under the influence of a variety of environmental factors such as temperature, humidity and light, and to establish a shelf life for the product with recommended storage conditions.



Synomics Pharma Services provides the full complement of stability and storage tests to meet ICH guidelines ranging from accelerated stability through long-term stability and storage, typically 36-months in duration. Data for long-term testing should be

at least 12-months in duration at the time of regulatory submission, and should be continued for a period to cover the time that the product is expected to remain within its specification.

Accelerated studies are designed to increase the rate of chemical degradation or physical change of a product by using exaggerated storage conditions as part of the formal stability studies. When significant change is observed at the accelerated storage condition, a 12-month study at an intermediate storage condition is usually warranted.

Stress testing (or forced degradation) is the method employed to develop and demonstrate the specificity of stability-indicating methods and, if necessary, to determine degradation pathways for degradation products derived from the active ingredient(s). Stress testing can involve temperature (in 10°C increments above that for accelerated testing), humidity ($\geq 75\%$ RH), oxidation, hydrolysis across a wide range of pH values, and photostability.

It is important to establish that the intrinsic photostability characteristics of a new product do not result in unacceptable change after the product is exposed to light. Synomics Pharma Services offers photostability testing to meet the requirements of ICH Q1B – Option 1 for new drug substances and products. Typically, UV light doses range between 1 and 3 times the ICH standard.

Synomics Pharma Services develops and validates the stability-indicating analytical procedures that are utilized for samples pulled from stability studies at the predetermined time points. A stability-indicating assay must be able to detect the loss of an active ingredient and differentiate between the active ingredient and degradation products if the latter are observed.

In addition, stability tests can typically include an impurities assay, dissolution test, appearance, hardness, pH, viscosity and moisture content. Synomics Pharma Services also offers other physical-chemical properties tests that can be included as appropriate.

CONTRACT STABILITY SERVICES

Synomics Pharma Services offers contract stability studies to meet the requirements of FDA 21 CFR 211, ICH Q1A(R) and ICH Q1B - Option 1. Services include:

- Long-term stability
- Accelerated stability
- Intermediate stability
- Semi-permeable stability
- Refrigerated stability
- Freezer stability
- Stress testing (forced degradation)
- Photostability - Option 1
- Freeze-thaw cycling
- Raw material testing
- Placebo and excipient testing
- Analytical services
- Identification of impurities and degradants
- Dissolution testing
- Physical-chemical properties

INSTRUMENTATION AND TECHNOLOGY

Stability & Storage Programs

FDA/ICH validated chambers at:

- 25°C ± 2°C/60% ± 5% RH
- 30°C ± 2°C/65% ± 5% RH
- 40°C ± 2°C/75% ± 5% RH
- 40°C ± 2°C/≤25% RH

(specialized conditions also available such as 5°C ± 3°C and -20°C ± 5°C)

Analytical Methods Support

- HPLC (PDA)
- GC (FID, FPD, μ ECD, NPD, TCD, Tekmar Headspace)
- GC/MS
- LC/MS
- LC/MS/MS

REGULATORY COMPLIANCE

Synomics Pharma Services maintains the highest standards of regulatory compliance in facilities, validated instrumentation and quality systems to meet both GLP and GMP requirements for FDA, EPA and ICH. Our facility maintains active licenses for DEA Schedule II and IV controlled substances and for radioactive materials use.

CONTACT INFORMATION

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