



QUESTIONS TO ASK YOUR LABORATORY PARTNER

STABILITY STORAGE AND TESTING

Effective stability programs require more than controlled storage. Every attribute with a specification needs analytical data demonstrating it remains within limits throughout shelf life, and that data must come from methods that are truly stability-indicating, validated to regulatory standards, and capable of detecting changes the program design may not have anticipated. The questions below provide a framework for evaluating whether a laboratory's method development experience, operational practices, and capacity for long-term program management match what your program requires.

Evaluation Questions

Infrastructure and Environmental Controls

- What ICH-compliant storage conditions do you offer?
- Do you provide specialized temperature ranges, including refrigerated (2 to 8 degrees C), frozen (-20 degrees C), ultralow (-80 degrees C), or cryogenic (below -130 degrees C)?
- How do you monitor and document temperature and humidity excursions?
- What redundancy systems protect samples during equipment failures?
- How do you manage capacity across long-term and commercial-scale programs?
- If your program includes controlled substances:* Are you DEA-licensed for the schedule that corresponds to the compound to be tested, and at which facilities does that licensing apply?

Analytical Capabilities

- Do you develop stability-indicating methods in-house, or do you require client-provided methods?
- What analytical techniques are available for degradant detection and identification?
- Can you perform physicochemical attribute testing (dissolution, pH, particle size, appearance) within the same facility as stability storage?
- Do you offer microbiological testing relevant to stability programs, including preservative efficacy, bioburden, and sterility?
- How do you approach container closure integrity testing and extractables and leachables analysis?
- Do you conduct photostability and forced degradation studies per ICH guidelines?

Method Development and Validation

- What is your approach to forced degradation studies, and how do those results inform method development?
- How do you demonstrate a method is stability-indicating?
- How do you handle method failures or unexpected degradants identified during active stability studies?
- What is your typical timeline for method development and validation of a new molecule?
- Do you support method transfers, and how do you maintain data continuity if methods are revised during a program?

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Regulatory and Quality Systems

- Are you FDA-registered and inspected? What does your inspection history look like?
- How are stability study protocols developed, and what documentation do clients receive?
- How do you investigate and report out-of-specification (OOS) results?

Program Design and Phase Appropriateness

- Can you support stability programs from IND-enabling studies through commercial manufacturing?
- How does your study design approach differ between early development and NDA submissions?
- What storage conditions can you accommodate, and how do you work with clients to align study design with a molecule's degradation profile and intended markets?

Communication and Partnership

- Who will serve as our primary project management / technical contact, and will we have direct access to the scientists running our studies?
- How do you communicate proactively about emerging issues, including degradation trends, capacity constraints, or unexpected results?
- Can you provide interim updates and trend data during active study periods?
- How do you handle program continuity across a multi-year study if key scientific staff change?

Choosing the Right Stability Partner

Stability lab selection tends to get less attention than it deserves early in a program, when the NDA feels distant, and timelines feel flexible. The questions in this checklist are designed for that earlier stage, when the evaluation is still straightforward, and the relationship being established has the most room to be set up well.

How a lab describes its approach to method development, mid-study challenges, and program continuity over time tells you as much as its equipment list does.

Element's Stability Storage and Testing Capabilities

Element provides integrated stability storage and testing through our FDA-registered and inspected, ISO 17025-accredited laboratory network across North America. Our capabilities span ICH-compliant storage, method development and validation, comprehensive analytical chemistry, microbiological testing, and container closure integrity, available within the same laboratory network. Stability storage and testing capabilities are available at Element Santa Fe Springs, Element Ann Arbor, and Element Toronto.

Questions About Your Stability Program?

Connect with our pharmaceutical testing experts to discuss your program needs and timeline.

Click or scan the QR code to start the conversation.

