Stability Management for Pharma & BioPharma Products

Nelson Labs is a global provider of microbiological testing, analytical chemistry, and advisory services, supporting pharma and biopharma companies. We have over 35 years of experience solving challenges that are not typically addressed in routine testing. We have the capabilities and expertise to support drug product stability for CMC from IND to commercialization. We are US FDA registered, cGMP compliant, and ISO17025 accredited and have laboratories located throughout North America and Europe.

The following are some of the services Nelson Labs offers to support ICH stability testing for drug products and drug substances:

Stability Storage per ICH Q1A Conditions

- -20°C ± 5°C
- 5°C ± 3°C
- Long-Term Stability: 25°C ± 2°C / 60% RH ± 5% RH
- Intermediate Stability: 30°C ± 2°C / 65% RH ± 5% RH
- Accelerated Stability: 40°C ± 2°C / 75% RH ± 5% RH
- Other Customized Storage Conditions
- Photostability, ICH Option 2

Note: Nelson Labs offers protocol development, method development, method feasibility, verification/validation, and suitability for all compendial procedures.

R&D and Marketed-Product Release & Stability Testing

- Universal & Specific Release Tests
  - Identification
  - Assay & Related Substances
  - Particulate Matter
  - pH
  - Osmolality
  - CCIT
  - BET
  - Sterility
  - Volume Content
  - KF (for Lyophilized Products)
  - Reconstitution Time & Clarity of Solution
  - Appearance and Color
  - E&L

Contact us today!

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US FDA registered and third-party accredited to ISO 17025 standards

