

# ICH Stability Testing Requirements for Pharmaceutical and Supplement Products Explained

*ICH stability chambers with continuous monitoring for long-term, intermediate, and accelerated studies supporting FDA submissions and retailer qualification*

IRVINE, CA, UNITED STATES, March 20, 2026 /EINPresswire.com/ -- Qalitek Laboratories, an ISO 17025-accredited third-party testing laboratory with ICH-qualified stability testing capabilities serving dietary supplement brands and pharmaceutical drug developers across North America, today explained the stability testing requirements that brands need to understand when establishing shelf-life claims for dietary supplements and preparing stability data packages for pharmaceutical regulatory submissions.



Stability testing determines how the quality of a drug substance, drug product, or dietary supplement changes over time under the influence of environmental factors including temperature, humidity, and light. For pharmaceutical products, ICH Q1A(R2) establishes the internationally recognized framework for stability study design, storage conditions, testing intervals, and the data package required for regulatory submissions to FDA, EMA, and other ICH member regulatory authorities.

ICH Q1A(R2) defines four climatic zones with corresponding long-term storage conditions. Zone II "the standard for pharmaceutical products intended for global markets" specifies 25 degrees C / 60% RH for long-term stability. Accelerated stability studies are conducted at 40 degrees C / 75% RH, with intermediate stability at 30 degrees C / 65% RH. Testing intervals are specified at 0, 3, 6, 9, 12, 18, 24, and 36 months.

"Stability data is one of the most frequently misunderstood requirements in both pharmaceutical development and supplement manufacturing," said Nour Abochama, Vice

President of Operations at Qalitek Laboratories. "For pharmaceutical IND submissions, FDA expects stability data that demonstrates the drug substance and product are stable under the proposed storage conditions for the duration of the clinical trial. For supplement brands, the question is whether the shelf-life claim on the label is supported by actual stability data " or whether it's an estimate. Those are very different things from a regulatory and liability perspective."

For dietary supplement brands, stability testing serves multiple purposes. Retailer qualification programs at major retailers including Whole Foods Market and Target increasingly require stability data for supplement products. Amazon's compliance programs for certain supplement categories reference stability testing as a documentation requirement. FDA's cGMP regulations under 21 CFR Part 111 require supplement manufacturers to establish specifications for finished products, which should include stability-based expiration dating.

Qalitek's stability chambers are ICH-qualified and continuously monitored with automated data logging, maintaining temperature within plus or minus 2 degrees C and humidity within plus or minus 5% RH of target conditions. The laboratory offers stability programs at all ICH-specified conditions: long-term (25 degrees C / 60% RH), intermediate (30 degrees C / 65% RH), accelerated (40 degrees C / 75% RH), and refrigerated (5 degrees C plus or minus 3 degrees C). Photostability testing per ICH Q1B is available for products with light-sensitive ingredients.

Testing at each stability time point is conducted using the analytical methods specified in the stability protocol, which typically include identity testing, potency/assay, degradation product analysis, physical appearance, dissolution for solid dosage forms, and microbiology. For dietary supplements, the stability protocol is developed based on the product's dosage form, ingredient profile, and the shelf-life claim being substantiated.

"The stability programs we design for pharmaceutical clients are built around their regulatory timeline " IND filing date, NDA submission target, or ANDA approval timeline," said Nour Abochama. "We work backward from the submission date to determine when stability studies need to be initiated, what time points need to be available at submission, and what the ongoing stability commitment will look like post-approval. That timeline planning is as important as the testing itself."

## RESOURCES

Full article: <https://qalitek.com/services/supplement-shelf-life-stability-testing/>

## ABOUT QALITEK LABORATORIES

Qalitek Laboratories is an ISO 17025-accredited third-party analytical testing laboratory with facilities in Irvine and San Diego, California. The laboratory provides certificate of analysis (COA) testing, heavy metal analysis by ICP-MS, microbiology testing per USP <61> and <62>, preservative efficacy testing, stability studies under ICH guidelines, and regulatory compliance support for dietary supplement brands, cosmetic companies, and consumer goods manufacturers. Turnaround times start at 48 hours for standard panels. Testing programs meet

21 CFR Part 111, California Proposition 65, Amazon supplement compliance requirements, and Health Canada NHP Directorate standards.

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