

# ICH Stability Testing

## **For Pharmaceutical Products**

State-of-the-Art Testing Services Since 1986

**Ensure Product Integrity. Stay Compliant.** WESTPAK offers comprehensive ICH Stability Testing services that help pharmaceutical manufacturers meet global regulatory standards and confidently bring safe, effective products to market.

## What is ICH Stability Testing?

ICH Stability Testing is based on the International Council for Harmonisation's global guidelines Q1A (R2) Stability Testing of New Drug Substances and Products. These protocols evaluate how drug substances and pharmaceutical products respond to environmental factors like temperature, humidity, and light over time to ensure safety, efficacy and quality under various storage conditions. WESTPAK offers custom testing protocols tailored to unique pharmaceutical formulations and packaging systems.

## **Controlled Environment Conditions**

WESTPAK operates 2,600 square feet of validated chambers under strict ICH recommended conditions: +25°C / 60% RH – Long-term +30°C / 65% RH – Intermediate or Long-term +40°C / 75% RH – Accelerated Custom Conditions – Based on client requirements

Typical Testing Durations: Accelerated: Minimum 6 months Long-term: Minimum 12 months

## **CONTACT US**

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## **ICH Stability Testing**

#### **Expand Testing with WESTPAK**

At WESTPAK, we can conduct package validation, label qualification, and a variety of other test standards in accordance with industry standards.

Our comprehensive approach provides deeper insights into product performance, packaging durability, and labeling resilience; helping you maximize safety and market readiness. With over 20 stability chambers available, we're fully equipped to conduct this testing with precision and reliability.

WESTPAK's comprehensive ICH Stability Testing services confirm the quality, safety, and efficacy of pharmaceuticals in real-world conditions. Partner with us to ensure regulatory compliance and product quality.

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#### Why Partner with WESTPAK?

One of the other major benefits of ICH stability testing is that it plays a role in helping you to determine a drug's long-term efficacy.

WESTPAK has the stability chambers, facilities, experience, and package test capability that companies need to achieve compliance for their pharmaceutical products and packaging.

WESTPAK's custom storage conditions are also available to satisfy unique, proprietary requirements. Plus, our equipment undergoes regular validation protocols in addition to ongoing maintenance, calibration, and monitoring.

- 100,000+ sq. ft. of accredited testing space based in California
- ISO/IEC 17025 accredited (A2LA)
- ISTA certified laboratories
- Fully validated stability chambers
- Custom storage capabilities
- Reliable, independent third-party results

Contact us today to learn more about how we can help you stay in compliance with ICH stability guidelines and other important industry standards.





