Stability 301 Guide

Provides an overview of ICH Climatic Zones, scheduled time points, and the key parameters customers can select to evaluate during a stability study.

Where are your products being sold?

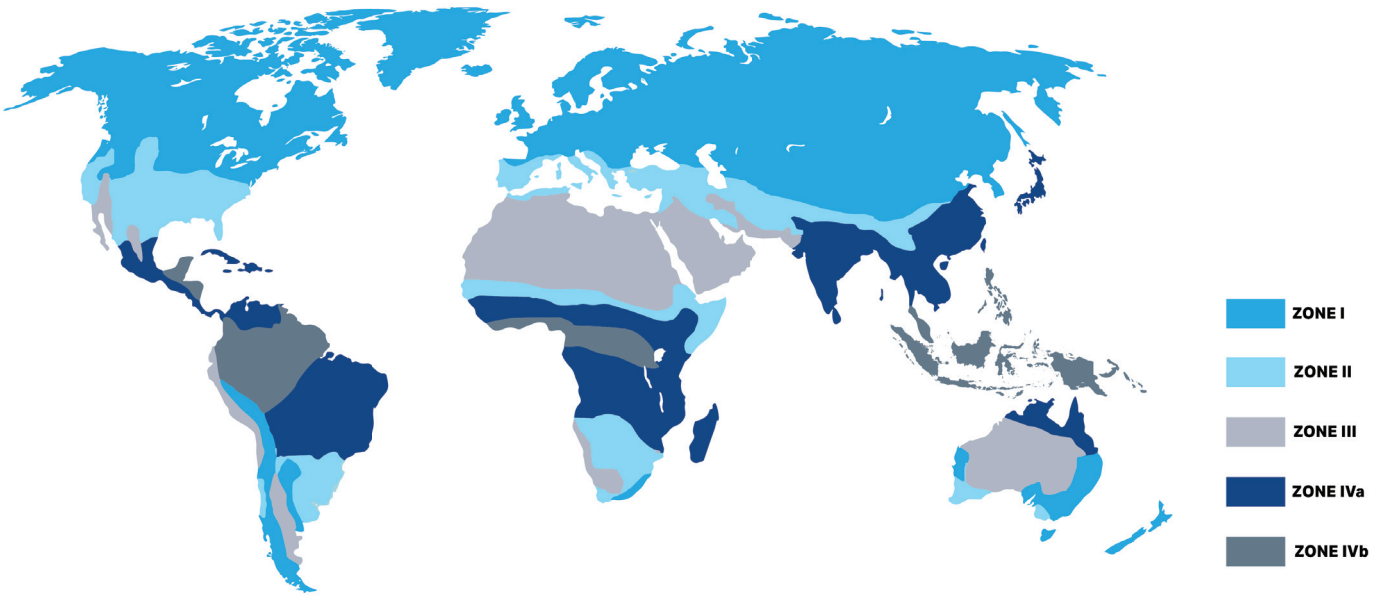
The lab must know where your product will be sold to design a stability protocol with the correct parameters, such as temperature and humidity. Choose from the following countries/regions:

☐ United States ☐ Europe ☐ China ☐ Canada ☐ Japan ☐ Middle East

The following Zones represent different climate conditions to ensure products remain stable and effective in the regions where they're sold.

Zone	Description	Temperature	Relative Humidity	Geographical Areas
I	Temperate zone	21°c	45% RH	Southern Canada, Europe, Parts of Russia
II	Mediterranean/Subtropical Zone	25°c	60% RH	Mediterranean region, parts of Australia, Southern USA
III	Hot/Dry Zone	30°c	35% RH	North Africa, Middle East, Desert areas in the USA
IVa	Hot Humid/Tropical Zone	30°c	65% RH	Southeast Asia, Central Asia, Africa, Parts of South America
IVb	Hot/Higher Humidity Zone	30°c	75% RH	Regions near the equator, dense rainforest areas

ICH CLIMATE ZONES VISUALIZED



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Choose the Appropriate Time Points

A time point is a scheduled stage in a stability study when a sample is pulled and tested to assess changes in quality, potency, or appearance over time. The following time points are customary for a stability study:

- **Accelerated:** 0, 1, 2, 3, 6 months
- **Long-Term:** 0, 1, 2, 3, 6, 9, 12, 18, 24, or 36 months

Test the Correct Number of Batches

It's important to test samples from the correct number of batches to produce quality data for your study. Whether you have existing data about the batch also must be considered. Follow the guidelines below:

- **Long-Term: Minimum 3 batches**
  (if it's a new batch and there is no existing data available)
- **Accelerated: 1 batch**
  (existing data is available)

Test Parameters Available

At each pull point, clients may select:

- ☐ **Active ingredient potency** *(assay)*
- ☐ **Degradation products / impurities**
- ☐ **Physical attributes** *(color, specific gravity, appearance, pH, odor and viscosity)*
- ☐ **Microbiological quality** *(USP <61>, <62>, <51> PET)*
- ☐ **Packaging compatibility** *(Exterior assessment ex. pump functionality, label integrity, simulated use test)*

Uncertain How to Proceed? Seek Recommendations

Designing a stability study requires knowledge of current regulations, industry guidelines, and scientific best practices. This can be daunting, which is why Certified Laboratories' Stability Team provides consulting and recommendations based on our extensive knowledge of ICH, FDA, and other important guidelines and regulations. This helps you rest assured that you will receive the data you need to make the best decisions.

Questions?

→ **Contact our Stability Team**

Ready to begin testing?

→ **Tell us about your stability testing needs here.**

Find More Answers in Our Resource Library

CERTIFIED-LABORATORIES.COM/RESOURCE-LIBRARY/