# ICH Guidelines for Stability and Photostability Studies

The International Council for Harmonisation (ICH) defines globally accepted guidelines to ensure the safety, efficacy, and quality of pharmaceutical products throughout their shelf life. For stability and photostability studies, these guidelines specify controlled environmental conditions—covering temperature, humidity, and light exposure—that simulate real-world storage and transport scenarios across different climatic zones.

Nihaar Equipment's Stability and Photostability Chambers are engineered to meet and exceed these stringent requirements, enabling precise testing as per ICH Q1A (R2) for stability and ICH Q1B for photostability. With uniform conditions, accurate controls, and comprehensive data logging, our chambers provide reliable, regulatory-compliant results for markets worldwide.

## ICH Q1 (RA) for stability testing of new drug substances and products

| Study Type | Conditions | Study Period (min.) | Application |
|---|---|---|---|
| Long-Term | 25°C ± 2°C / 60% RH ± 5% RH<br>30°C ± 2°C / 65% RH ± 5% RH<br>30°C ± 2°C / 75% RH ± 5% RH | 12 months | General Conditions |
| Accelerated | 40°C ± 2°C / 75% RH ± 5% RH | 06 months | |
| Long-Term | 25°C ± 2°C / 40% RH ± 5% RH<br>30°C ± 2°C / 35% RH ± 5% RH | 12 months | Drug products packed in semi-permeable containers |
| Intermediate | 30°C ± 2°C / 65% RH ± 5% RH | 06 months | |
| Accelerated | 40°C ± 2°C / 25% RH ± 5% RH | 06 months | |
| Long-Term | 5°C ± 3°C | 12 months | Drug products for storage in refrigerator |
| Accelerated | 25°C ± 2°C / 60% RH ± 5% RH | 06 months | |
| Long-Term | -20°C ± 5°C | 12 months | Drug products for storage in freezer |

## ICH Q1B for photostability testing of new drug substances and products

| Study Type | Conditions | Application |
|---|---|---|
| Photostability | Exposure to light intensity of 1.2 million Lux Hours & UV light intensity of 200 Watt | ICH Q1B |