

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, more commonly known as ICH, issues guidelines recommended for adoption to the regulatory bodies of the European Union, Japan and the USA. Of interest to us are the environmental guidelines for storage and stability testing. The complete document, Q1A(R2): Stability Testing of New Drug Substances and Products (Second Revision), is available at <http://www.ich.org/cache/compo/276-254-1.html>.

Summarized below are the recommended environmental conditions. An increasing number of pharmaceutical companies are requesting the calibration of data loggers to cover these requirements.

General Case;

Study	Storage condition	Minimum time period
Long Term	25°C ± 2°C / 60% RH ± 5% RH, or 30°C ± 2°C / 65% RH ± 5% RH	12 months
Intermediate	30°C ± 2°C / 65% RH ± 5% RH	6 months
Accelerated	40°C ± 2°C / 75% RH ± 5% RH	6 months

Refrigerator storage;

Study	Storage condition	Minimum time period
Long Term	5°C ± 3°C	12 months
Accelerated	25°C ± 2°C / 60% RH ± 5% RH	6 months

Freezer storage;

Study	Storage condition	Minimum time period
Long Term	-20°C ± 5°C	12 months

Semi-permeable containers;

Study	Storage condition	Minimum time period
Long Term	25°C ± 2°C / 40% RH ± 5% RH, or 30°C ± 2°C / 35% RH ± 5% RH	12 months
Intermediate	30°C ± 2°C / 65% RH ± 5% RH	6 months
Accelerated	40°C ± 2°C / ≤ 25% RH	6 months