

Quantex Laboratories offers a complete range of stability testing services to assist you with your stability testing requirements. These include a stability testing and support services for all types of drug products, ranging from API, small molecules to biopharmaceutical drug products and drug-coated medical devices. We can handle your complete stability study needs - from providing the appropriate storage for your samples, to pulling samples at specified intervals, to testing them according to the specified procedures and time table you require. Or, if you prefer, we can analyze samples that you store and send to us at specified testing intervals. All stability studies are carried out in compliance with FDA and ICH guidelines.

Each of our stability chambers operates independently with its own temperature and humidity controls. Temperature and humidity set-point windows are ± 2 degrees C and $\pm 5\%$ RH, respectively. All storage chambers are continuously monitored by 21 CFR part 11 compliant computerized and hardwired security systems. Chambers are also connected to automatic emergency generator power to ensure the integrity of stored samples. If a chamber should go out of specification, an alarm will notify personnel for immediate attention and corrective action.

Stability Studies capabilities includes:

- Accelerated stability
- Long-term stability
- Shelf Life studies (2 years & 3 years)
- Stability indicating method development
- Assay and impurities of various formulations
- Method transfer and analyst qualification
- Release testing
- Preclinical stability
- Clinical stability

Stability Support services include:

- Stability protocol development & generation
- Sample storage
- Stability data trending analysis
- Stability report generation
- Statistical analysis for shelf life confirmation

Our stability services support your projects for:

- Release testing
- Self life confirmation
- IND
- NDA
- ANDA
- BLA



Storage Conditions Available

We have numerous temperature and humidity conditions available in our qualified stability storage chambers, including all conditions needed to comply with the ICH guidelines.

- 25° C / 60% R.H.(Primary ICH Long Term Condition)
- 40° C / 75% R.H.(Accelerated ICH Condition)
- 30° C / 60% R.H.(Intermediate ICH Condition)
- 30° C / 65% R.H.(Intermediate ICH Condition)
- 25° C Ambient Humidity
- 5° C Refrigerated
- Custom temperature and humidity conditions (available upon request)



www.quantexlabs.com