Customised GMP Stability Storage & QC Testing

Mylnefield Lipid Analysis provide a full complement state of the art cGMP stability storage and analytical testing resource along with the expertise to support commercial stability studies, release testing and quality control analysis for active pharmaceutical ingredients and drug products in virtually all dosage forms and delivery systems.

GMP stability storage solutions include:

- Stability storage at typical ICH conditions for API and finished product
- Customised stability storage
- Accelerated stress studies at high temperature and humidity
- 24 hour continuous monitoring and recording of conditions
- Back – up power to stability chambers and monitoring system
- Controlled access facility
- Sample management during study
- Dispatch to testing sites for subcontracted analytical testing

Mylnefield Lipid Analysis can follow the customers own protocol or can write the stability storage protocol for approval by the customer before commencing the study.

Our standard storage conditions meet ICH guidelines Q1A and Q1B. Each cGMP stability chamber has been fully mapped and both our stability chambers and the computer systems used to control and monitor stability studies, are fully validated in compliance with EU and US cGMP regulations and are 21 CFR Part 11 compliant.

To complement stability storage, our scientists have years of experience performing analytical testing on a wide range of lipid based drug substances and drug products to GMP requirements in MHRA and FDA approved laboratories. Extreme attention to detail and the highest levels of quality assure our clients that their stability program *will* be successfully implemented.

Analytical services supporting stability programmes include:

- Long term stability testing
- Accelerated stability testing
- Comparative stability testing
- Forced degradation studies
- Stability testing of active Pharmaceutical Ingredients (API) and Clinical Trial Material (CTM) - these services support clinical trials, IND, NDA and aNDA applications.

Our stability programmes offer an ongoing commitment to careful, client focused communication, accurately managed pull schedules and continual review of regulatory requirements.

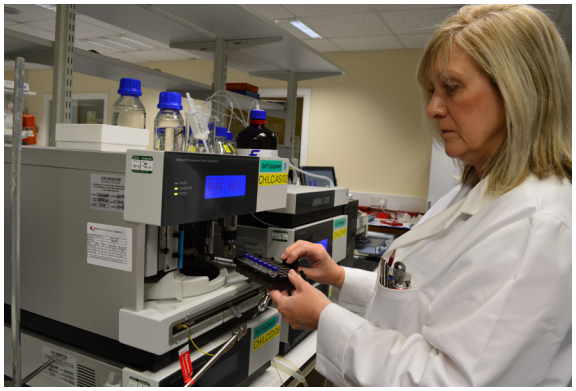
Conditions Available

25°C/60% RH (+2°C/=5% RH)
Real time storage

40°C/75% RH (=2°C/+5% RH)
Accelerated storage

All stability storage systems are fully validated in compliance with EU and US cGMP regulations and are 21 CFR Part 11 compliant.

mylnefield
lipid analysis



Please contact us in confidence to discuss any aspect of your stability requirements.

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