



**MAJOR EQUIPMENT:**

- GC-FID (Agilent 5890 and 6890) with Headspace/Liquid Injection Capabilities
- GC-MS
- HPLC (UV, Diode, CAD, RI)
- LC-MS
- GC-MS
- FT-IR
- NMR (2 x 300 MHz)
- UV/Vis
- ICP-OES
- KF (volumetric and coulometric)
- Melting Point
- TGA/DSC

The facility houses a state-of-the-art analytical laboratory and controlled environmental chambers to support ICH stability studies. Cambridge Major provides analytical support for in-process controls, quality control release testing, reference standard qualification, and method development/validation in compliance with FDA cGMP requirements and ICH guidelines.

CML performs most compendial testing according to USP/NF, EP, BP, JP, and ACS monographs. This can be for raw materials, intermediates, or API release testing.

Our method development and validation services includes:

- Stability Indicating Methods
- Organic Volatiles Impurities
- Cleaning Validation/Verification method (specific and non-specific)
- In-Process Controls
- Forced Degradation and Impurity Identification

CML also offers comprehensive stability storage & testing by ICH guidelines. This includes ambient, intermediate, and accelerated conditions.

