



ANALYTICAL SERVICES

CML strives to promote the concept of "right the first time - every time." Quality control testing is of critical importance, due to the nature of our products. High level methods development and testing at all stages of the process (raw materials, intermediates, and API) is critical, and is the cornerstone of our culture of prevention rather than detection.

Analytical Services

- Method Development
- Method Validation
- Forced Degradation
- Impurity Identification
- Stability Studies
- Low Level Impurities
- Genotoxic Methods
- Reference / Impurity Standard Qualification

CML provides a wide variety of analytical support services for development and manufacturing, consistent with the appropriate phase of drug development. Our method development philosophy is "fit for purpose," meaning we will provide the appropriate level of development/validation to support your API based on where your compound is in the development cycle.

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

