Cambrex

Overview
Analytical services

Analytical services capabilities and expertise

Cambrex is a leading global contract development and manufacturing organization (CDMO) that provides drug substance, drug product, and analytical services across the entire drug lifecycle.

With over 40 years of experience and a growing team of over 2,200 experts servicing global clients from North America and Europe, Cambrex is a trusted partner in branded and generic markets for API and finished dosage form development and manufacturing.

Analytical solutions Quality asured

Trust our analytical development and testing experts to rapidly advance your molecule for the greatest chance of success.

Method development & validation
Material characterization
Compendial & release testing
Stability storage & testing
Biopharmaceutical testing
Microbiology & cleanroom services
Impurity isolation, identification & characterization
Reference standard qualification

Robert A. Matthiesen
Manufacturing
Chemist II

Method development & validation

The analytical testing methods used to monitor potency and purity for raw materials, drug substances and drug products are your primary view into the quality of your materials. Cambrex focuses on efficiently developing robust and high quality analytical methods that deliver reliable results. We have a vast range of capabilities in instrumentation and detectors including high-throughput column screening. We employ a phase appropriate validation strategy to support programs from early clinical to commercial. Our team of experts has a proven reputation for taking on tough challenges and delivering a quality method.

Material characterization

Our highly skilled scientists can evaluate materials to determine suitable polymorphic forms and provide critical quality attributes such as thermal analysis and particle size. We also have an established strategy for elemental impurities, proven to exceed regulatory expectation with unparalleled turnaround time:

- **Thermal analysis (TGA/DSC)**
- **X-ray powder diffraction**
- **Laser particle size determination (wet or dry dispersion) with particle imaging**
- **Elemental impurities (ICP/MS) including risk assessments**

Compendial & release testing

Cambrex has a broad range of testing capabilities to support compendial testing (USP, Ph.Eur. JP, JPE, ACS) of excipients, drug substances, and drug product. We understand that quick turnaround times and robust, quality data are vital to your success. Our experienced team can support wet chemistry testing, spectrophotometric analysis, chromatographic assays (HPLC, UPLC, TLC, and GC), CCIT, and particulate matter testing (HIAC and microscopic).

Stability storage & testing

Stability storage and testing is a critical component in drug development. Cambrex offers a variety of storage conditions with our walk-in and reach-in chambers that meet the ICH Q1A requirements. Our chambers are mapped, fully qualified and are equipped with continuous monitoring with an added security of reserve power.

In addition to traditional shelf-life stability studies, Cambrex routinely performs specialized studies such as freeze/thaw, compatibility, and photostability studies. Our analytical experts can support your stability testing at all phases of development and we offer a seamless experience from sample receipt to the issuance of the report.

Biopharmaceutical testing

Cambrex has extensive experience in drug metabolism and pharmacokinetic (DMPK), bioanalytical, and biopharmaceutical analyses. Our biopharmaceutical analyses support GMP and non-GMP method development, validation, and routine analysis for drug substance, drug product, and intermediates.

- **Release and stability testing and storage**
- **Material characterization**
- **Structural chemistry**
- **Impurity isolation and characterization**
- **Method development, optimization, verification, validation, and transfers**

Microbiology & cleanroom services

Cambrex microbiology testing services are fully compliant with all GMP and GLP testing standards. We offer a wide range of testing to support your regulatory requirements and are driven by the importance of high quality, process efficiency and reliable turnaround time.

- **Sterility***
- **Endotoxin***
- **Microbial limits**
- **Microbial identification**
- **Bioburden***

*ISO 17025 accreditation.

Cambrex has extensive cleanroom services to support ongoing and routine environmental monitoring at your facility including: plate analysis, personnel monitoring, compressed air/gas testing, water system monitoring, temperature and humidity monitoring, differential pressure monitoring, incubation and enumeration, phenotypic and genotypic identification, and cleanroom certification.

Impurity isolation, identification & characterization

Cambrex has extensive experience to support impurity isolation and characterization. Our capabilities include mass directed isolation/purification of low-level impurities, structural elucidation, NMR analysis, impurity synthesis, followed by response factor determination to correctly assess levels of impurities within your drug substance or drug product. We recognize that these projects can be a critical path to support your regulatory submission and we have a seamless approach to deliver quality results quickly.

Reference standard qualification

Cambrex has a distinct niche for qualifying and managing reference standards over the life of your molecule. Reference standards are thoroughly characterized to ensure identity, strength, quality, purity, and potency. Partnered with our process chemists, we have the capability to synthesize additional reference materials and markers and qualify them for GMP use.

How can Cambrex help you advance? **www.cambrex.com**