

PARTNERSHIP

It's what turns services into solutions.



CMC (CHEMISTRY, MANUFACTURING, AND CONTROL)

GMP ANALYTICAL TESTING FOR NEW CHEMICAL ENTITIES AND COMMERCIAL PRODUCT SUPPORT

QUALITY. *It's how you get from formulation to the pharmacy.*

Ensure comprehensive product analysis with Frontage's team of experienced analytical scientists.

WE HAVE AN
UNPARALLELED
COMPLIANCE AND
QUALITY TRACK
RECORD

We specialize in analytical method development, validation and transfer for product development and clinical trial materials (CTM) manufacturing

support, as well as commercial product release and stability testing. Our services are designed to help sponsors throughout the drug development process in their effort to fully characterize drug substances, developmental formulations and commercial drug products.

Our facilities house a wide range of the latest analytical instrumentation for a comprehensive array of methods. And, we continually keep pace with technology to ensure compliance with evolving regulatory and market requirements.

ANALYTICAL SERVICES

- Analytical method development, validation and transfer
- Stability testing and storage (all ICH conditions)
- In-vitro bioequivalence and dissolution / diffusion IVRT and IVPT evaluations
- API and finished product testing
- Unknown impurity identification
- Comparator product analysis / reverse engineering
- Extractable and leachable studies
- Small molecule and biologics testing

EXPERIENCE

Frontage brings experience in analyzing a variety of dosage forms including oral solid, liquid, lyophilized, topical, liposomes / emulsions / suspensions and other products.

Our chemists' expertise includes chromatography, dissolution/diffusion testing, UPLC, HPLC/MS, UPLC/MS, GC/MS, IC, ICP/MS, Xevo G2-XS QTof HRMS, CESI 8000, Maurice, among others.

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STABILITY MANAGEMENT SERVICES

Frontage offers a variety of storage conditions for test samples to meet the demands of drug development requirements in different markets throughout the world. We have the scale of equipment to handle large studies and specialized studies alike.

- Ten walk-in stability chamber rooms for standard storage conditions (5°C, 25°C/60%RH, 30°C/65%RH, 40°C/75%RH) - approximately
- 10,000 total cubic feet of capacity. Reach-in chambers (-70°C, -20°C, 25°C/40%RH, 40°C/NMT 25%RH, 30°C/75%RH) for special container requirements and complex products
- Photo-stability chamber meeting ICH accelerated light exposure study requirements

QUALITY ASSURED

With an excellent compliance history, Frontage operates under strict adherence to ICH and US FDA GMP guidelines. Our facilities and processes undergo routine audits and inspections from sponsors and regulatory authorities. Our SOPs, while robust, have the flexibility to accommodate a variety of protocols, templates and reporting formats according to client requirements and preferences.

FRONTAGE'S COMMITMENT

For many sponsors who rely on service partners to help develop and commercialize their products, good science is not enough. For more than 18 years, Frontage has earned a reputation for collaboration, responsiveness and the ability to customize service and deliverables that are aligned with the needs of our clients.

Frontage Laboratories, Inc. is a CRO providing integrated, scientifically-driven research, analytical and development services throughout the drug discovery and development process to enable biopharmaceutical companies to achieve their drug development goals. We offer our clients comprehensive services in analytical testing and formulation development, drug metabolism and pharmacokinetics (DMPK), bioanalysis, preclinical safety and toxicology and early phase clinical studies. We have enabled many innovator, generic and consumer health companies of all sizes to file IND, NDA, ANDA, BLA and 505(b)(2) submissions in global markets allowing for successful development of important therapies and products for patients. We have successfully assisted clients to advance hundreds of molecules through development to commercial launch in global markets. We are committed to providing rigorous scientific expertise to ensure the highest quality and compliance.

FOR MORE INFORMATION, CONTACT US AT: sales@frontagelab.com **OR VISIT US AT:** frontagelab.com

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