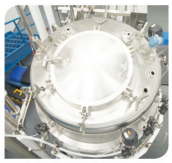
eurofins | Alphora


# Clinical development and cGMP manufacturing services

**Eurofins Alphora is an FDA-Approved CDMO focused on API and Drug Product development and manufacturing services. Our talented team of scientists specialize in complex small molecules and formulation strategies for poorly soluble compounds. IND enabling development and clinical manufacturing strategies are a focus for Alphora. Our Drug Product team works closely with clients to match project objectives with the science to deliver the right formulation on time.**

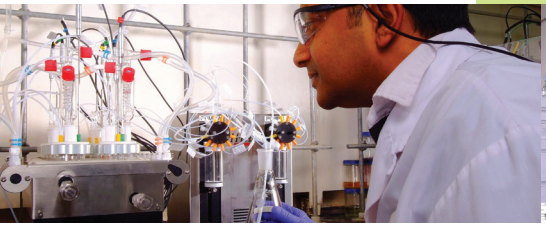

## Pre-Formulation

Alphora offers a wide range of IND enabling drug product services. Our Ph.D. scientists have extensive experience in material characterization, analytical chemistry and strategies for developing poorly soluble compounds. Our Pre-Formulation laboratory is fitted with a suite of Pion Inc. equipment focused on solubility, absorption and In-Vitro/In-Vivo correlation studies. Capabilities include:

- Solubility & Absorption Studies—Pion Inc. Suite of Equipment (µDISS, µFLUX, Macro DISS)
- Salt and Polymorph Screening; Excipient selection and screening
- Prototype Stability—ICH Stability (Temperature, Humidity and Photo)
- GLP Formulation Support—Formulation Preparation and Analysis
- Stability Indicating and Cleaning Method Development
- Physical Characterization

## Formulation Development

Alphora's formulation scientists and Process Engineers are experts in poorly soluble compounds and high containment operations. Our formulation development lab and pilot plant suites are specifically designed for high containment and outfitted with cGMP matching technologies. Alphora's Scientists follow a data driven approach to clinical formulation development of Parenteral and Oral dosage forms.

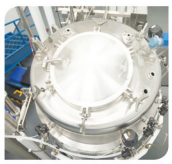



Eurofins Alphora

Alphora Research Inc.
2395 Speakman Drive, Suite 2001
Mississauga, Ontario L5K 1B3
Canada

T | 905 403 0477
F | 905 403 8744
alphoraresearch.com

eurofins | Alphora


# Clinical development and cGMP manufacturing services

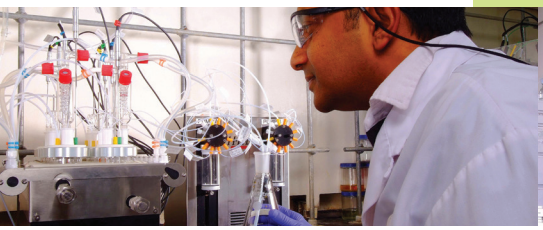
## Formulation services capabilities include:

- High Containment Development Suites (2019)
- Particle Size Reduction—Jet Milling
- Method Development & Validation
- GLP Formulation Support
- Excipient Compatibility
- Poorly Soluble Compounds
- Amorphous Dispersions, Liquid, and Semi-Solids
- Prototype Stability

## cGMP Manufacturing Services

Our Operations team has extensive experience in cGMP clinical drug product manufacturing. Our state-of-the-art facilities and cGMP compliant systems are specifically designed for quick to clinic operations. Alphora's team of tenured Engineers and Project Managers specialize in process transfer and scale-up strategies, providing a seamless transition of programs from development through cGMP manufacturing. Capabilities include:

- High Containment Operations (2019)
- cGMP Clinical Manufacturing (Oral Dosage Forms)
- Micronization—Jet Milling
- Drug-in-Bottle and Drug-in-Capsule
- Formulated Powder-in-Capsule
- Liquid and Semi-Solid in Capsule
- cGMP Stability
- Drug Product Release
- Packaging and Labeling
- cGMP Storage and Distribution



Eurofins Alphora

Alphora Research Inc.
2395 Speakman Drive, Suite 2001
Mississauga, Ontario L5K 1B3
Canada

T | 905 403 0477
F | 905 403 8744
alphoraresearch.com