Thesis Chemistry Inc.
Bringing Molecules to Life

DiTEBA
RESEARCH LABORATORIES INC.

Thesis Chemistry and Diteba Research Laboratories Announce Integrated CMC Services For Active Ingredients

Thesis Chemistry and Diteba Research Laboratories have brought together their proven technical and regulatory expertise in process chemistry, cGMP fine chemical production and analytical testing to serve the pharmaceutical industry with timely Chemistry, Manufacturing and Control (CMC) services for rapidly advancing a small-molecule drug from concept to commercialization.

We understand the ever-growing complexity of our customer's needs, and we are committed to delivering personalized services with effective scientific results. The molecular structures of drug molecules are becoming increasingly diverse as scientists improve upon potency, selectivity and safety. Many new drug candidates possess multifaceted heterocyclic rings and are being developed as single stereoisomers. These demanding molecular structures require experience in a broad range of chemical processing and analytical technologies from a CMC partner. Today's CMC partner must also be firmly grounded in the latest global compliance requirements. Furthermore, outsourcing is simplified when a drug innovator can rely upon the CMC partner to support their material supply requirements from pre-clinical to launch. Thesis Chemistry and Diteba Research Laboratories can satisfy your outsourcing needs in precisely these ways.

Our CMC services firstly come into play when a drug candidate enters late-stage discovery or pre-clinical development. We excel in:

- Chemical route design and selection
- First-time, scale-up preparation of the active ingredient
- Isolation and characterization of the pure chiral isomers or diastereomers
- Analytical method development
- Bioanalytical testing of *in vitro* and *in vivo* ADME and toxicology samples
- Isolation, characterization and preparation of drug metabolites

As a drug candidate moves towards an IND filing and first-in-man trials, we deliver expertise in:

- Process development
- cGMP kilo-lab production
- Raw material sourcing
- Analytical method development
- Stability testing
- Preparation of CMC documentation
- Bioanalytical testing of clinical samples

Partnership through Expertise, Innovation & Compliance

Thesis Chemistry Inc.
1200 Franklin Blvd., Cambridge, ON N1R 6T5
Ph: (510) 620-1289 Fax: (519) 620-2964
www.thesischemistry.com

Diteba Research Laboratories Inc.
1620 Tech Avenue, Unit #3, Mississauga, ON L4W 5P4
Ph: (905) 625-7995 Fax: (905) 625-3767
www.diteba.com

We continue to support our customer's Phase II clinical to launch needs with a seamless supply of the active ingredient or an advanced intermediate from the kilo-lab into the pilot plant and thence into the commercial plant. As material quantities increase, manufacturing economics become of critical importance. Our services include:

- New process development through our proven experience with chemical, enzymatic and separation technologies
- Process optimization and validation
- Raw material sourcing
- cGMP manufacture of active ingredient or process intermediates
- Isolation and identification of process impurities and degradation products
- Preparation and characterization of reference materials
- Forced degradation studies
- Development and validation of stability-indicating analytical methods
- Release testing of raw materials, intermediates, active ingredient and drug product
- ICH stability testing on drug substance and product
- Dissolution testing
- *In vitro* release rate testing for topical semi-solid formulations
- Physical/chemical testing
- Bioanalysis of clinical samples

From start to finish, your project will be continuously directed by a senior manager who has extensive experience in CMC development. Our business philosophy is to be a partner and to support our customer's outsourcing needs to the fullest extent desired. *We understand our success ultimately lies in your success.* All of our services are available à la carte or through an integrated CMC package tailored to meet your specific project requirements.

With modern facilities centrally located near Toronto, Thesis Chemistry and Diteba Research Laboratories are always close by and easy to reach.

Please contact us to find out how we can assist you with your CMC drug development needs.

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