



FORMULATION

A Pharmaceutical Development Company.

Analytical Chemistry • Analytical Development • Biopharma • Inhalation • Microbiology • Stability Testing • Structural Chemistry

Irvine's Formulation Team consists of highly skilled, experienced scientists with a comprehensive understanding of all facets of the drug development process and a track record of successful formulation development.

Irvine's integrated team approach unites our expert formulation group with scientists from other departments such as, Structural Chemistry, Analytical Development, and Biopharmaceuticals, to provide a comprehensive set of capabilities that will efficiently accelerate the development of your drug candidates, from small molecules to macromolecules.

State-of-the-Art Instrumentation

- VirTis 25L Genesis EL Freeze Dryer with sample thief and Maestro software
- Microfluidics Microfluidizer Model M-110P High Shear Homogenizer
- LYOSTAT2 Freeze drying microscope system
- Malvern Mastersizer 2000 with wet and dry modules
- HPLCs with a diverse range of detectors
- Large number of dissolution apparatus
- DSC/TGA

Expert formulation tailored to your API and investigative needs

- ✓ Multiple dosage forms
- ✓ Container/closure compatibility
- ✓ Fill-finish of drug product
- ✓ CMC section preparation
- ✓ Technology in-process transfer to CMO

In-depth Pre-formulation Services

- Solubility and pH-rate profile
- Log D/Log P
- Excipient compatibility
- Stability evaluation

Comprehensive Formulation Services

- Parenteral dosage forms
- Solid, liquid and lyophilized dosage forms
- Emulsions/suspensions
- Liposome and microsphere encapsulation
- Lyophilization cycle development
- Ad-mixture and container/closure compatibility studies
- Pilot batch production and stability analysis
- Toxicology supply manufacturing/dosing solutions
- Fill-finish of drug product (2009)
- Development report in support of CMC

Dependable Technology Transfer

- Batch record development
- Method transfer, development and validation
- Scale-up studies



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Why team with Irvine's Formulation Development Department?

Irvine's senior Formulations team each has over 20 years of small and large molecule formulation development experience. Their in-depth knowledge covers a diverse range of products, from generics to ophthalmics, as well as a wide variety of dosage forms and routes of delivery.

Irvine's preformulation studies are designed with an anticipated formulation strategy, route of administration, and ultimate formulation configuration in mind. Our formulation experts unite a thorough understanding of your needs along with the data on the physico-chemical properties of the compounds.

In addition to our formulation capabilities, Irvine also conducts the necessary analyses, container/closure compatibility studies and pilot batch studies required to move your product through the regulatory process. We also provide comprehensive CMC support.

Beginning in early 2009, we will also perform clinical trial material manufacturing at Avrio BioPharma, our wholly owned subsidiary.

Our Project Management Team Serves You Better

Our signature service assigns you a single, dependable point of contact who guarantees all of the benefits of valued partnership such as strategic planning meetings, weekly reports, high quality data, and detailed post-project follow-up.

We invite you to visit us, audit our laboratories, discover our insight, and learn more about our passionate commitment to partnering excellence. To learn more, please visit www.irvinepharma.com or call 877-445-6554.



In addition to Formulation Development, Irvine offers extensive testing services in the following areas:

Analytical Chemistry

- Compendial Testing According to USP/NF, EP, BP, or JP Standards
- Testing According to ACS and AOAC Methods
- Testing According to Client-provided Methods

Analytical Development

- Method Development and Validation
- Process Validation Support
- Cleaning Validation and Verification
- Comparator Studies and Reference Standard Qualification

Biopharmaceuticals

- Method Development and Validation
- Product Characterization and Quality Control Testing

Inhalation

- Inhalation/Nasal Product Testing According to USP <601>
- Device Evaluation
- Product Characterization and Quality Control Testing
- Method Development and Validation

Microbiological Testing

- Quality Control Testing
- Research and Development Testing
- Method Development and Validation

Stability Storage and Testing

- Stability Studies
- Standard Storage Conditions in Accordance with ICH Guidelines and Customized Storage Conditions
- Chamber and Sample Management

Structural Chemistry

- Extractable/Leachable Studies
- Reference Standard Characterization
- Structural Elucidation of Unknowns
- Investigational Studies

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