



## STRUCTURAL CHEMISTRY

*A Pharmaceutical Development Company.*

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

Irvine's industry-leading Structural Chemistry team provides in-depth knowledge and years of expertise to provide support of the identification, characterization and development of specific and highly-sensitive methodologies.

*From small organic compounds and minerals to macromolecules, such as peptides, oligonucleotides, and proteins, our team of experienced structural chemists devote their expertise and work side-by-side with our clients to generate an optimal development and manufacturing strategy.*

### State-of-the-Art Instrumentation

- LC/MS and MS/MS • LC/MS • GC/MS
- HPLC w/multiple detectors • GC w/multiple detectors
- Ion Chromatography • Elemental Analyzer • FTIR • DSC
- TGA • ICP • AA • TOC

### Industry-leading Structural Chemistry Services

- Extractables/Leachables studies
- Reference standard characterization
- Structural elucidation of target/lead compounds
- Structural elucidation of unknowns
- Impurity and degradation, identification and characterization
- Synthesis and purification of impurities and degradation products
- Elemental analysis
- Amino acid analysis
- Peptide mapping
- Glycan analysis
- Enantiomeric studies
- Full NMR data interpretation
- Residual analysis in support of biotechnology-derived products
- Residual Solvent Screening by GC/MS

### 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.



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## Why team with Irvine's Structural Chemistry Department?

With a multidisciplinary team including biochemists, synthetic organic chemists, and analytical chemists, Irvine offers an array of approaches and techniques to characterize drug structures and analyze their purity at every step of the development process. In addition, Irvine's integrated team approach unites our structural chemists with scientists from other departments to provide a comprehensive set of capabilities that will efficiently accelerate and strengthen the process of characterizing and identifying complex chemical and protein compounds.

Irvine's Structural Chemistry team has expertise that goes beyond chemical characterizations to include a deep understanding of all facets of drug development that can impact the successful development and launch of a product. This includes experience analyzing different routes of administration, meeting regulatory requirements, solving packaging issues, and identifying potential problems in manufacturing. With in-depth academic history, diverse industry experience and influential industry involvement via posters and presentations, Irvine's Structural Chemists are unsurpassed.

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](http://www.irvinepharma.com) or call 877-445-6554.



In addition to Structural Chemistry, 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

### Formulation Development

- Preformulation Studies
- Formulation Characterization
- Container/Closure Compatibility Studies
- Technology in-process transfer to CMO

### 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

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