



STRUCTURAL CHEMISTRY

A Pharmaceutical Development Company.

Analytical Chemistry • Analytical Development • Biopharma • Drug Delivery • Fill Finish • Formulation • Microbiology • Stability

Irvine's leading Structural Chemistry team provides in-depth scientific expertise and acute problem solving skills to provide support of the identification, characterization and development of specific and highly-sensitive methodologies.

From small organic compounds and minerals to macromolecules, 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/MS: Quadrupole, triple quadrupole and quadrupole-time-of-flight of mass spectrometers with APCI & ESI
- LC/MS
- GC/MS:with EI and CI ionization
- GC (multiple detectors)
- HPLC (multiple detectors)
- ICP-MS • ICP-OES
- Flame AA • GFAA
- Ion Chromatograph
- Elemental Analyzer
- FTIR • ATR
- DSC • TGA
- 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
- Structural characterization of protein variants and isoforms

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.



www.irvinepharma.com

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, Irvine's Structural Chemists are unsurpassed.

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

Irvine's specialized comprehensive package of services include:

Analytical Chemistry

- Testing According to USP/NF, EP, BP, JP, ACS, AOAC, and 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

Drug Delivery Technologies

- Inhalation/Nasal Product Testing According to USP <601>
- Transdermal Product Testing
- Device Evaluation

Preformulation/Formulation Development

- Formulation Characterization
- Container/Closure Compatibility Studies

Microbiological Testing

- Quality Control Testing
- Research and Development Testing

Stability Storage and Testing

- Standard and Custom Storage Conditions in Accordance with ICH Guidelines

Aseptic Fill-and-Finish via Affiliate, Avrio Biopharma

- Process Validation
- Lyophilization
- Scale-up Studies



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