



BIOPHARMACEUTICALS

A Pharmaceutical Development Company.

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

Rely on Irvine's experience, state-of-the-art equipment and expanding capabilities to meet all your biopharmaceutical testing needs.

We work collaboratively to develop and validate complex release assays for products from early clinical phases through commercialization.

Comprehensive Biopharmaceutical Support

- Western, northern, and southern blot
- Residual host cell protein and residual chemical analyses
- Amino acid analysis (AAA USP <1052>)
- Gel electrophoresis: PAGE and agarose
- Capillary electrophoresis: GCE, CZE, cIEF
- Glycan analysis
- Isoelectric focusing (IEF)
- Peptide mapping (USP <1055>)
- Chromatographic techniques (RP, SEC, IEX, and HIC)
- Protein content assay
- Residual and total DNA/RNA
- HPLC (RP, SEC, IC, mixed mode)
- ELISA
- Surfactant analysis
- Sugar analysis
- Anion and cation analysis

Full range testing of small and large biomolecules

- ✓ *Nucleic acids and oligonucleotides*
- ✓ *Peptides*
- ✓ *Natural and recombinant proteins*
- ✓ *Monoclonal and polyclonal antibodies*
- ✓ *Carbohydrates*

Reliable Product Characterization

- Identity: AAA and peptide mapping • Protein content
- Sequence: peptide mapping • Immunoassays
- Genetic stability: peptide mapping • Purity/potency
- Glycosylation: HPIC, CE, LC-QTOF
- Activity: protein/enzyme assays
- Impurity analysis: SDS-PAGE, HPLC, ELISA
- Total protein assay (USP <1057>)
- Disulfide bonds: Thannhauser method
- Determination of extinction coefficients
- Common impurities and contaminants

State-of-the-Art Instrumentation

- HPLC: Waters, Agilent, Dionex
- Ion Chromatograph
- Electrophoresis modules
- Capillary electrophoresis: Beckman Proteomelab™ PA 8000
- ELISA: BioTek
- ELISA: molecular devices
- Ultra-centrifuge: Beckman
- UV transilluminator: BIO-RAD
- Gel DOC (UV/Vis)
- Post column derivatization: Pickering



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Why team with Irvine's Biopharmaceutical Development Department?

From proof of concept to commercialization, depend on the scientific strength of Irvine. We offer reliable expertise, quality systems, state-of-the-art instrumentation, and thorough experience working with a range of biomolecules. What's more, we maintain focus on the leading edge of science, service and seamless collaboration.

Irvine provides a range of services such the development of dosage forms and analytical services for large molecules. Our responsiveness and streamlined project management can help leverage your supply chain capabilities and improve project efficiencies that can reduce time to market.

At Irvine our mission is to provide our clients with outsourcing solutions that make their drug development priorities possible.

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 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

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

Structural Chemistry

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

Aseptic Fill-and-Finish via Affiliate, Avrio Biopharma

- Process Validation
- Lyophilization
- Scale-up Studies

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