



ANALYTICAL DEVELOPMENT

A Pharmaceutical Development Company.

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

Look to the expertise of Irvine's analytical development team for cutting-edge capabilities, acute problem solving and seamless project management.

We deliver prompt development and validation results including comprehensive preformulation and formulation.

Extensive Analytical Method Development and Validation Services

- Assay and related substances
- Chromatographic purity
- Stability indicating assays
- Forced degradation studies
- Dissolution
- Gap analysis and remedial validation
- Residual solvents
- Extractables/leachables
- Chiral drugs
- Cleaning procedures
- Characterization of reference standard and drug substances
- Process validation support
- Method transfer/training
- Formulation development and product deformulation support
- Comparative studies
- Reference standard qualification
- Counterfeit product evaluation
- Vendor qualification

Capable support of multiple dosage forms

- ✓ *Injectables (lyo and non-lyo)*
- ✓ *Inhalation/Nasal*
- ✓ *Solids, semi-solids, liquids*
- ✓ *Transdermal*

State-of-the-Art Instrumentation

- HPLC: Waters, Agilent, Dionex (UV-VIS, conductivity, fluorescence, PDA, RI, ELSD, CAD)
- High resolution chromatography
- GC/MS: Agilent MSD with EI and CI ionization source
- GC: direct injection and head space capability:
Detectors: FID, TCD, ECD and NPD
- LC/MS: MSD with APCI & ESI
- IC (detectors: conductivity and ECD)
- DSC and TGA
- Dissolution (apparatuses I, II, VI)
- LC/MS/MS: Quadrupole, triple quadrupole and time-of-flight of mass spectrometers with APCI and ESI
- HIAC
- Chromeleon software chromatographic data processor



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Why team with Irvine's Analytical Development Department?

Irvine's Analytical Development group has experience in support of various dosage forms within the generic and branded pharmaceutical industries. The team's diverse background has enabled Irvine to develop an in-depth understanding of all facets of the drug development process. In addition, Irvine offers extensive experience in Gap Analysis and Remedial Validation of existing methodologies to comply with current CDER/ICH guidelines for validation.

As development partners, we design detailed protocols for Method Development, Validation, and Technology Transfer as per the product's phase in the drug development process.

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

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

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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