



DRUG DELIVERY TECHNOLOGIES

A Pharmaceutical Development Company.

Analytical Chemistry • Analytical Development • Biopharma • Fill Finish • Formulation • Microbiology • Stability • Structural Chemistry

With in-depth experience and a commitment to innovative technologies utilizing advanced instrumentation, Irvine delivers leading-edge delivery device product development.

We specialize in pharmaceutical testing, device evaluation, and chemical and physical characterization.

Range of Transdermal Testing Capabilities

- Assay • Chromatographic purity
- Drug release profile (dissolution)
- Residual Solvents • Stability Studies

Inhalation/Nasal Comprehensive Testing Studies

- Drug product characterization
- Release and stability studies
- Method development, optimization and validation
- Formulation evaluation studies
- Extractables/leachables studies
- Aerodynamic particle size distribution by impaction
- Droplet size determination • Deliverable-dose uniformity
- Pressure testing • Retention of prime • Valve delivery
- Shot weight • Leak rate • Device counters
- Spray pattern • Emitted/delivered dose
- Cyr test (storage orientation) • Drug content assay
- Primary particle size determination • Bulk density
- Water content • Microscopic evaluation
- Spacer evaluations
- Particulate matters (HIAC)

Thorough CMC drug delivery technologies testing
Transdermal

- ✓ Adhesive Systems
- ✓ Reservoir Systems
- ✓ Matrix and Layered Systems
- ✓ Iontophoretic Systems

Nasal/Inhalation

- ✓ Suspension and Aqueous Solutions
- ✓ Pressurized Metered Dose Inhalers (pMDI)
- ✓ Dry Powder Inhalers (DPI)
- ✓ Nebulizers

Transdermal State-of-the-Art Instrumentation

- HPLC: Waters, Agilent, Dionex (UV-VIS, conductivity, fluorescence, PDA, RI, ELSD, CAD) • HIAC
- High resolution chromatography
- Dissolution (apparatus VI) • LC/MS: MSD with APCI & ESI
- LC/MS/MS: Sciex 3000 and 4000 with ESI and APCI
- GC/MS: Agilent MSD with EI and CI ionization source ionization source • IC (detectors: conductivity and ECD)
- GC: direct injection and head space capability (detectors: FID, TCD, ECD and NPD)
- Chromeleon software chromatographic data processor

Inhalation/Nasal Advanced Instrumentation

- Malvern Spraytec™ • Copley Andersen Cascade Impactors™ (28, 60 LPM) • MSP Next Generation Impactor (NGI)™
- Multi-stage liquid impinger • Digital flow meters
- Dose uniformity sampling apparatus (MDI/DPI)
- Copley Scientific model TPK critical flow controller
- InnovaSystem Mighty-Runt Actuator Station
- Copley Scientific Inhaler Testing Data Analysis Software (CITDAS) • Harvard large animal ventilator



Why team with Irvine's Drug Delivery Technologies' Department?

Irvine is known as a dependable resource throughout the pharmaceutical and medical device industry for its experience in transdermal and inhalation/nasal product development support, including formulation as well as device evaluation.

We combine our core competencies in drug delivery technologies' development with an ongoing commitment to state-of-the-art instrumentation and technology. Additionally, we provide an innovative approach to cross-functional scientific management, high quality systems and above-and-beyond project management. This culmination makes Irvine the source to trust for the exceptional quality and reporting distinction your inhalation projects demand.

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

Biopharmaceuticals

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

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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