



## MICROBIOLOGICAL TESTING

*A Pharmaceutical Development Company.*

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

When you need experienced and responsive microbiological support, Irvine stands ready.

*Our comprehensive resources, scientific expertise, strict cGMP compliance and committed project management become a working extension of your laboratory.*

### Raw Material Testing

- Microbial limits testing based on USP, EP, JP
- LAL endotoxin quantification (gel-clot and kinetic chromogenic methods)

### In Process Testing

- Bioburden testing

### Final Product Testing

- Sterility testing
- Antimicrobial effectiveness testing
- Closure integrity testing (microbial ingress and dye immersion)
- 48-hour Mycoplasma detection via MycoAlert®

### Manufacturing Support

- Water quality testing
- Environmental monitoring
- Bacterial identification with OmniLog® system
- 48-hour Mycoplasma detection via MycoAlert®

### Method Development and Validation

- Specialized microbiology testing

*We perform the tests you need at all stages*

- ✓ Raw Material
- ✓ In-Process
- ✓ Final Product

### R&D Microbiology Testing

- Sterility test validation (bacteriostasis/fungistasis)
- LAL validation (inhibition/enhancement)
- Closure integrity testing (microbial ingress and dye immersion)
- Sterilization validations (steam, EO, gamma radiation, chemical)
- Bioburden recovery
- Method development and validation
- Environmental monitoring

### State-of-the-Art Instrumentation

- Millipore Steritest™ system
- LAL kinetic chromogenic microplate reader
- Biolog I.D. system
- M Air T® Millipore air tester
- Class 1000 sterility suite with class 100 LAF hood



[www.irvinepharma.com](http://www.irvinepharma.com)

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## Why team with Irvine's Microbiology Department?

As the demand for precision in microbiological data rises, trust Irvine to deliver. We offer extensive testing services via our highly qualified microbiology team. Our depth of expertise combined with our novel approach to attentive project management and high quality reporting ensure the timeliness your projects demand.

Irvine offers a broad range of compliant, high quality microbiological services. Tests are performed according to official compendial methods such as USP, EP, BP, JP, AAMI, ISO standards and client specific protocols. A validated Class 1000 clean room suite with Class 100 LAF hoods provide the highest quality sterility testing for finished product release.

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](http://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

#### 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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