



## STABILITY TESTING

*A Pharmaceutical Development Company.*

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

Trust Irvine for a wide range of stability services with assured quality, dependability and timeliness.

*Irvine provides full stability testing and support services for all types of drug products, ranging from API, small molecules to biopharmaceutical drug products and drug-coated medical devices.*

### Expansive Services

- Stability protocol generation
- Stability testing
- Stability storage
- Stability summary report generation
- Stability time points and conditions specific report generation

### Comprehensive Stability Studies

- Preclinical stability
- Clinical stability
- Stability indicating method development and validation
- Release testing
- Method transfer and analyses qualification
- Assay, impurities, dissolution, water content, etc. of various formulations

*We support your projects*

- ✓ Clinical trials
- ✓ BLAs
- ✓ IND
- ✓ NDA
- ✓ ANDA

### State-of-the-Art Storage Systems

*Including all ICH Conditions*

- 25°C/60% RH
- 30°C/65% RH
- 40°C/75% RH
- 25°C/40% RH
- 40°C/25% RH
- 25°C
- 60°C
- Refrigerator, 5°C
- Freezer, -20°C
- Ultimate freezer, -70°C
- Photostability chambers – supports ICH photostability options I & II

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

## Why team with Irvine's Stability Testing Department?

We have expanded our state-of-the-art cGMP stability storage facilities to include even more walk-in and reach-in validated environmental chambers set to various temperatures and humidity conditions. The ongoing expansion, along with our renowned commitment to outstanding project management, further enhances Irvine's position as an industry leader in stability programs.

For the quality control and security your projects demand, all cGMP validated environmental chambers and our photostability chambers are monitored 24 hours a day by a computer-based Environmental Monitoring System. Our walk-in, reach-in, UV/visible and fluorescent photostability chambers are supported by back-up chambers, a reserve generator and an electronic notification system.

We have the latest Stability Laboratory Information Management System (LIMS) to ensure the highest ICH compliance. The system accommodates sophisticated sample management, as well as allows the Stability Department to generate cumulative reports.

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

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

### Microbiological Testing

- Quality Control Testing
- Research and Development Testing

### 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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