



## Pharmaceutical Testing Services

USP/EP/CFR

### ICH Stability Studies

#### Sterility Testing

- Product inoculation
- Membrane filtration
- Steritest™/Sterisolustest™

#### Endotoxin Testing

- Chromogenic
- Turbidimetric
- Inhibition/enhancement

### Antimicrobial Effectiveness Testing

#### Microbial Limits Testing

#### Antimicrobial Testing

#### Minimum Inhibitory Concentration Testing

#### Particulate Testing

#### Product/Package Stability Studies

#### Container Closure Integrity Testing

#### Aseptic Fill Validations Testing

### Biologics Testing

- Mycoplasma screening
- Mycobacterium screening
- Bacteriophage/viral screening
- Protein assays
- Electrophoresis
- SDS/PAGE

### Related Services

- Biocompatibility/toxicology
- Environmental monitoring
- Package stability and validation
- Contract manufacturing
- Water validations
- Virology testing

Microtest's impressive array of services makes it the preferred choice for testing both pharmaceutical-based and biopharmaceutical-based products. The company's expanded capabilities amplify its recognized leadership in testing and contract manufacturing for pharmaceutical and biotechnological clients.

Our pharmaceutical testing applies specialized knowledge to increase your competitive advantage. We provide the expertise to solve your problems, achieving quicker regulatory approval and faster time to revenue. And we offer the flexibility to give you control, with high-quality testing customized to your requirements. You all but eliminate schedule disruption. Costs and risk are reduced. And you guarantee rapid, reliable turnarounds.

### Taking Advantage of a Single Source

With Microtest, your process and product continually meet or exceed your requirements. And our full range of sterility validation and release testing ensures that you consistently deliver a safe and effective product to market.

Our unique single-source advantage as both tester and contract manufacturer lets Microtest support your full product release. As a growing supplier of fill/finish operations, for example, we've got the systems, procedures, and people in place to service your needs — and those of the FDA, EMEA, or any other drug-regulating organization worldwide — from testing through stability through raw material validation and vendor qualification to aseptic filling.



### Investing in People and Technology

We've tripled our professional staff, adding more personnel with advanced credentials, skills, and experience. We've also expanded critical areas such as chromatography, aseptic processing, and process support, while doubling our total pharmaceutical testing laboratory space.

In sum, Microtest has implemented a \$7.5 million investment in new facilities, laboratories, technology, and personnel. It's all part of our ongoing commitment to constant improvement.

## Our Technology

- Gas chromatography
- Gas chromatography/mass spectrography (GC/MS)
- HPLC
- Gel electrophoresis
- UV/VIS
- FTIR
- Karl Fisher
- HIAC –ROYCO particulate tester
- Vial integrity/dye immersion
- pH
- Conductivity
- Osmolality (via Freezing Point Depression)
- USP/EP testing

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## The Knowledge That Solves Your Problems The Flexibility That Gives You Control

Microtest's pharmaceutical testing services are constructed on a foundation of scientific knowledge, process flexibility, assured quality, and recognized customer service. From cell bank characterization to final product release testing, no other laboratory offers our advanced capabilities mix.

### Expertise

Microtest has been a leader in testing services since 1984. Bring us your product development, validation, or manufacturing challenges; our resources and experience will be equal to your test. Make us an integral part of your product development process and supply chain. Our collaborative approach relies on your input and involvement. With a management heritage in U.S. FDA regulation, we deliver quick regulatory approvals without schedule disruptions.

### Flexibility

We develop the procedures your solution requires; tests are performed to your unique specifications. Only Microtest enables custom testing methods for smoother development cycles. As global regulations or client schedules change, we respond with the fastest possible

### Quality

Our passion for quality ensures pharmaceutical-grade quality assurance. Naturally, we comply with FDA, ICH, and EMEA standards, with testing that can be customized to meet your needs — or those of drug regulatory bodies worldwide. Our ISO 9001-certified and FDA-regulated facilities are managed to the strictest guidelines and GLP/GMP standards. We minimize lab excursions, out-of-spec tests, and schedule departures, so you get accurate results, on time and on budget.

### CUSTOMER SERVICE

We provide a transparent, collaborative client relationship. At Microtest, you can interact directly with the analyst conducting your program. This readily available expertise, plus clear, concise documentation, helps guide you through every step of the regulatory process.