

Stability Testing to Support Pharmaceutical Development

As one of the major independent drug development companies in the country, Ricerca Biosciences offers a wealth of experience and expertise in supporting stability investigations designed to comply with the GLP/cGMP regulatory requirements of the Food and Drug Administration (FDA) and the International Conference on Harmonisation (ICH) guidelines.

Facilities

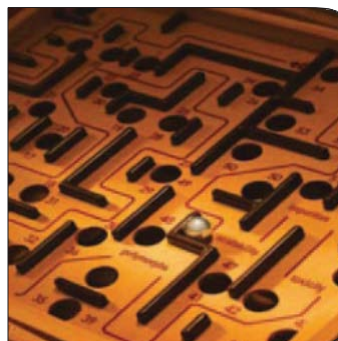
- Walk-in and reach-in stability chambers
- Qualified, calibrated, and validated equipment and stability chambers
- Continuous electronic monitoring
- Full generator back-up
- Back-up chambers

Standard chamber conditions

- -20 °C
- 5 °C
- 25 °C/60% RH
- 30 °C/65% RH
- 40 °C/75% RH
- ICH photostability

Services

- Study and protocol design
- Long-term stability testing
- Accelerated stability testing
- Drug substance stability testing
- Drug product stability testing
- Photostability testing
- Forced degradation studies
- Commercial stability testing
- Customized interim and final reports



Related services

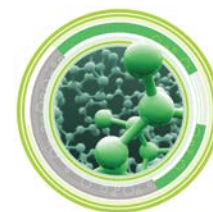
- Analytical method development/ stability indicating
- Analytical method validation
- Dissolution testing
- Quality control
- Microbiology
- Degradant/impurity identification
- Preformulation
- Quality assurance/regulatory affairs

Core chemistry services

- Analytical chemistry
- Process chemistry
- Engineering & API manufacturing
- Radiochemistry

Related services

- Analytical method development and validation
- Kilo labs
- In-process support
- Pilot plant
- Dissolution testing
- Microbiology
- DMPK
- Degradant & impurity identification
- Toxicology & pharmacology
- Regulatory support



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Major equipment

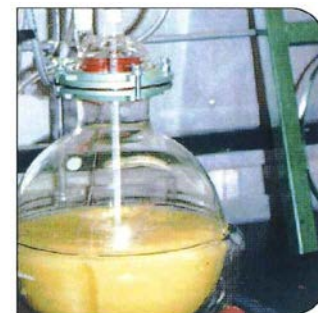
- Environmental chambers
 - Continuously monitored and controlled
 - Emergency power back-up
- PE Sciex API 4000/3000/365 LC-MS/MS systems equipped with Shimadzu binary gradients, UV systems, auto-injectors, external quaternary pumps, online degasser systems, and online 11-RAM radioactive flow detectors
- Liquid Chromatography
 - Perkin Elmer 200 series LCs with binary and quaternary capabilities
 - Detectors include: variable wavelength, diode array, refractive index, evaporative light -scattering, fixed wavelength, and fluorescence
 - Column switching capabilities
 - Column heaters: range 5 to 75 °C
 - Autosampler with Peltier Tray from 4 to 50 °C
- Gas Chromatography
 - Hewlett-Packard 5890/6890 series GCs
 - Hewlett-Packard 7694 Automated Headspace Analyzers
 - Detectors include: FID, ECD, NPD, FPD, (S and P) and MSD

Other services

- cGMP production of pharmaceutical intermediates and preclinical/clinical test materials
- GLP characterization of test and control articles (21 CFR 58.105)
- Standardized microbiological tests
- Acute, subchronic and chronic toxicology studies
- Neurotoxicity and reproductive studies
- Metabolism and pharmacokinetics investigations
- Immunoassays

Many complementary techniques

- Metabolism and pharmacokinetics investigations
- Nuclear Magnetic Resonance (NMR)
- Infrared Spectroscopy (IR)
- Differential Scanning Calorimetry (DSC)
- Thermal Gravimetric Analysis (TGA)
- UV/Vis, automated titrations, KF moisture
- Particle counting
- Particle sizing, laser-light
- Dissolution
- Light microscopy
- Viscosity, surface tension
- X-ray diffraction



Ricerca Biosciences: Your research partner of choice

Ricerca Biosciences, a contract drug development organization, provides science-based services to the pharmaceutical, biotech, and specialty chemical industries for the development and commercialization of new innovative products. Ricerca's 260,000 ft² complex is located on a 43-acre site in Concord, Ohio. The facility is equipped with a full complement of well-maintained instrumentation and processing equipment operated in rigorous regulatory compliance to the highest quality standards.