

Analytical Services To Support Pharmaceutical Development

As one of the major independent drug development companies in the country, Ricerca Biosciences offers a wealth of experience in conducting studies designed to comply with the GLP/cGMP regulatory requirements of the Food and Drug Administration (FDA) and the International Conference on Harmonisation (ICH). Ricerca is a DEA licensed facility.

Key services

- Method development
 - Impurity/assay/potency
 - Chiral methods
 - Stability indicating
 - Residual solvents
 - Cleaning methods
 - Dose formulation analysis
 - Forced degradation
- Method validation
- Method transfers
- Storage stability
 - ICH
 - Photostability
 - Stability indicating
- Release Testing
 - API
 - Drug product
 - Preclinical to commercial
- Characterization
 - Structure/purity
 - Reference standards
 - Impurity identification



- Preformulation
 - Salt screening
 - Polymorph screening
 - Solubility
- Quality Control
- Microbiology
 - Bacterial endotoxin (U/L)
 - Antimicrobial effectiveness
 - Antibiotic potency
 - Bioburden
- Extractable and leachables testing
- Chromatography
 - Analytical to preparative scale

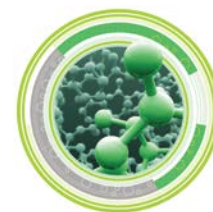
Core chemistry services

- 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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Ricerca's state-of-the-art analytical facility includes:

Diversified chromatographic systems

- HPLC systems equipped with photodiode array, UV/Vis, refractive index, electrochemical, evaporative light scattering and fluorescence detectors
- LC-MS/MS systems equipped with binary gradients, UV systems, autoinjectors, external quaternary pumps, on-line degasser systems and online -RAM radioactive flow detectors
- Ion chromatographs equipped with UV/Vis, pulsed amperometric and conductivity detectors
- GC systems equipped with flame ionization, electron capture, nitrogen-phosphorus and flame photometric detectors
- GC and LC mass spectrometry
- Semi-prep LC
- Pyrolysis GC mass spectrometry

Comprehensive inorganic capabilities

- ICP-AES and AAS/HGA systems to quantitate trace metals and salt forms
- Sample preparation via molten salt fusion and microwave dissolution
- X-ray powder diffraction



Concord, OH, USA

Many complementary techniques

- 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
- Tablet hardness, tablet friability
- Light microscopy
- Hot stage microscopy
- Viscosity, surface tension

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.