

# Analytical Services To Support Pharmaceutical Development

As one of the major independent drug development companies in the country, Olon Ricerca Bioscience 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). Olon 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 (UL)
  - Antimicrobial effectiveness
  - Antibiotic potency
  - Bioburden
- Extractable and leachables testing
- Chromatography
  - Analytical to preparative scale

### Core Chemistry Services

- Analytical chemistry
- Process chemistry
- Engineering & API manufacturing

### Related Services

- Analytical method development and validation
- Kilo labs
- In-process support
- Pilot plant
- Dissolution testing
- Microbiology



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Olon 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

Olon Ricerca Bioscience is a US-based CRO supporting the development and manufacture of APIs and performance materials in support clinical supply, market development and commercial distribution. Olon Ricerca's extensive process/synthetic chemistry, analytical chemistry and engineering expertise provides a synergy that excels at first-time scale-ups and subsequent development of safe, reliable, robust and cost effective manufacturing processes. Meeting client needs has been the foundation of Olon Ricerca's business philosophy and is second only to its commitment to safety and regulatory compliance.