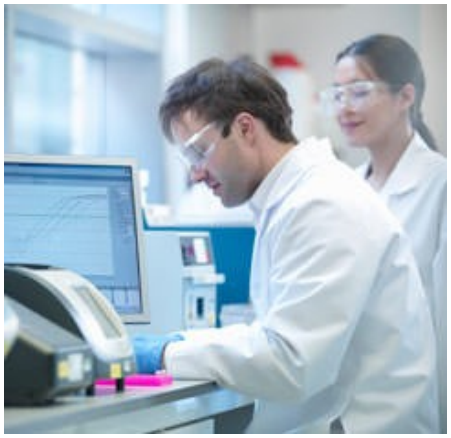
Reference Standard Testing and Distribution

Olon Ricerca's reference standards characterization, storage and distribution program entails periodic scheduled certification of your standards and markers, and includes the issue of certificates of analysis. Materials are stored in a secure facility in a LIMS-based controlled access, chain-of-custody, inventory system and are retested and distributed per your request.

OVERVIEW

- Secure and controlled access
- LIMS-based inventory system
- Initial purity assignment and structural elucidation
- Periodic scheduled recertification of standards
- Managed distribution
- Chain-of-custody documentation
- GLP, GMP, and QA reviewed certificates of analysis
- ICH stability and photostability
- Isolation, purification and synthesis of standards
- DEA registered and licensed



Olon Ricerca is an FDA registered cGMP/GLP compliant contract manufacturing facility which is DEA licensed and a member of SOCMA (the society of chemical manufacturers and affiliates). Olon Ricerca's analytical chemistry department provides analyses to support R&D, clinical, and commercial activities. Complete method development and validation is available to support regulatory requirements.

Core chemistry services

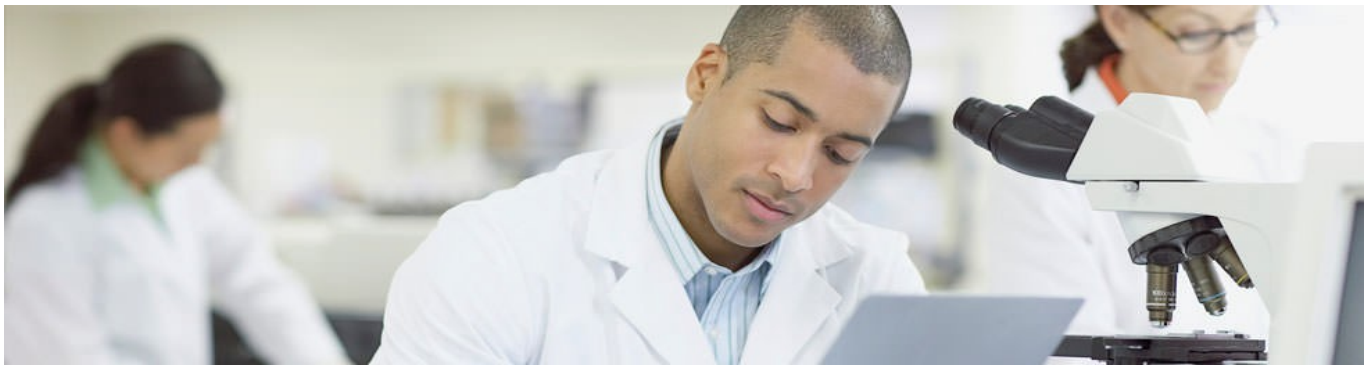
- Analytical chemistry
- Process chemistry
- API manufacturing

Related Services

- Method development and validation
- Stability Testing
- Synthesis
  - Standards
  - Markers
  - Stable label
- Standards purification
- Degradant/impurity identification
- Regulatory Support

Stability Testing

As a major independent drug development company, the scientists at Olon Ricerca Bioscience are experts in performing stability investigations that comply with the GLP/cGMP regulatory requirements of the Food and Drug Administration (FDA) and the International Conference on Harmonisation (ICH) guidelines.



Olon Ricerca is an FDA registered, DEA licensed cGMP/GLP compliant contract manufacturing facility offering drug substance and drug product stability studies to support R&D, clinical, and commercial activities

Facilities

- Secure, gated facility
- Walk-in and reach-in stability chambers
- Qualified and mapped equipment
- Continuous alarm monitoring
- Emergency back-up power
- Redundant back-up chambers
- LIMS based stability module

Storage Conditions

- -80 °C
- -20 °C
- 5 °C
- 25 °C/60% RH
- 30 °C/65% RH
- 40 °C/75% RH
- ICH photostability
- Custom conditions

Stability Services

- Study and protocol design
- Long-term stability testing
- Accelerated stability testing
- Drug substance and Drug Product
- Photostability testing
- Commercial stability testing
- Customized interim and final reports
- Storage & Distribution

Related Services

- Forced Degradation studies
- Method development & validation
- Dissolution testing
- Quality control
- Microbiology testing
- Degradant & impurity identification
- Preformulation
- Quality assurance/regulatory affairs

Core Chemistry services

- Analytical chemistry
- Process chemistry
- API manufacturing

Related Chemistry Services

- Storage & Distribution
- Solid Form Screening
- Reference Standard testing
- API and Impurity Synthesis
- GMP kilo labs
- In-process support
- Pilot plant
- Regulatory support