

# Drug Product and Isolation, Identification & Characterization

Olon Ricerca's Analytical Chemistry group has more than 25 years of experience in analytical laboratory services, with over 20 years in the pharmaceutical industry. This experience includes synthesis, raw material and intermediate testing, API and drug product testing, as well as analysis of stable-labeled compounds and controlled substances. Olon Ricerca 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 Harmonization (ICH). Olon Ricerca is a United States Drug Enforcement Administration (DEA) licensed facility.

### Drug Product Testing

- Development and validation of analytical methods for drug products on the market as well as validation of methods for NDA submissions and earlier pre-NDA and commercial drug product release testing
- Commercial drug product storage stability studies including a full range of qualified storage stability chambers suitable for pre-IND to commercial studies
- Experience with technical transfers with international and domestic pharmaceutical companies
- Diverse analytical techniques and skills needed to support drug product testing
- Dissolution testing

### Impurity Isolation, Identification and Characterization

- Isolation, identification and characterization of impurities and degradants from drug substances and drug products
- Isolation of impurities from mg to multi-gram level
- Fraction collection via analytical and preparative-scale chromatography
- Impurity isolation and identification work submitted to FDA with full approval

- Characterization of isolated impurities for use as reference standards
- Multiple identification tools on site: LC-MS, LC-MS/MS, NMR, FTIR, Raman, LC-DAD, etc.
- Synthesis of authentic materials as reference standards

### Major Equipment

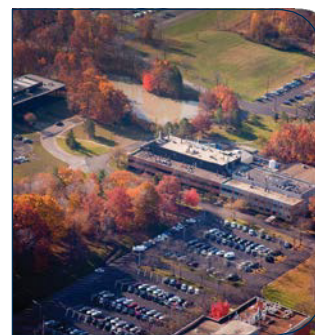
- UPLC/HPLC systems equipped with PDA, UV/Vis, ELSD, and CAD detectors
- LC systems with fraction collection on analytical, semiprep and preparative scale chromatography
- LC-MS and LC-MS/MS systems
- GC-MS and HS-GC
- GC systems FID, ECD, NPD, and flame photometric detectors
- FT-NMR
- FTIR-ATR/Raman
- UV-vis/Microscopy
- Viscosity/Osmometry
- Dissolution baths
- Particle Size by Light Scattering
- Ion chromatography
- Dynamic vapor sorption
- KF and titration systems
- ICP - AES
- Thermal Analysis
- X-ray diffraction

### Core Chemistry Services

- Analytical chemistry
- Process chemistry
- Engineering & API Manufacturing

### Related Services

- Method development
- Method validation
- Release testing
- Stability testing
- Degradant/impurity identification
- Salt/Polymorph Selection
- Reference Standard prep and characterization
- Regulatory support



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