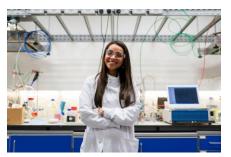


# **ANALYTICAL SERVICES**

### TO SUPPORT PHARMACEUTICAL DEVELOPMENT

As one of the major independent drug development companies in the country, Olon USA 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 USA 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



- Storage Stability
  - ICH
  - Photostability
  - Stability-Indicating
- Quality Control
  - Release Testing
  - o API
  - Drug Product
  - Preclinical to Commercial
- Method Transfers



- Characterization
  - Structure/Purity
  - Reference Standards
  - Impurity Identification
- Preformulation
  - Salt & Co-crystal screening
  - Polymorph screening
  - Hydrates/Solubility
- Chromatography
  - Analytical to prep scale









## CORE CHEMISTRY SERVICES

Analytical Chemistry
Process Chemistry
API Manufacturing

## **RELATED SERVICES**

- Analytical Method Development & Validation
- Kilo Labs
- In-Process Support
- Pilot Plant





## **ANALYTICAL SERVICES**

## TO SUPPORT PHARMACEUTICAL DEVELOPMENT



#### OLON RICERCA'S STATE-OF-THE-ART ANALYTICAL FACILITY INCLUDES:

#### DIVERSIFIED CHROMATOGRAPHY SYSTEMS

<u>UPLC/HPLC</u> systems equipped with diode array, UV/Vis, refractive index, evaporative light scattering and charged aerosol detectors.

<u>HPLC-MS/MS</u> systems equipped with binary gradients, diode array, autosamplers, external quaternary pumps, and on-line degasser systems.

<u>UPLC-QTOF</u> exact mass system equipped with binary gradients, diode array, autosampler, binary pumps, and online degasser systems.

Ion chromatography with conductivity detection.

<u>GC systems</u> equipped with headspace systems and flame ionization, nitrogen-phosphorus, and flame photometric detectors.

<u>GC-MS</u> system equipped with single quadrupole mass selective detector.

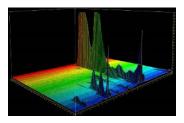
<u>Semi-preparative and preparative HPLCs</u> equipped with UV/vis detectors and fraction collectors.

#### COMPREHENSIVE IN ORGANIC CAPABILITIES

ICP-AES and ICP-MS systems to quantitate trace metals, catalysts, and inorganic salt forms.

Sample preparation by open vessel and closed vessel microwave digestion.

#### X-Ray Powder Diffraction





### MANY COMPLEMENTARY TECHNIQUES

Nuclear Magnetic Resonance (FT-NMR)
Infrared Spectroscopy (FT-IR) Spectroscopy
Raman Microscopy/Spectroscopy
Fluorescence Spectroscopy
UV-Vis Spectroscopy
Differential Scanning Calorimetry (DSC)
Thermal Gravimetric Analysis (TGA)
Dynamic Vapor Sorption (DVS) Analysis
KF Moisture, Automated titrators
Particle Sizing, laser-light scattering
Dissolution
Polarimetry

Optical Microscopy (Polarized)
Hot stage microscopy
Viscosity, osmometry, refractive index

Olon USA is a US-based CDMO 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 USA's business philosophy and is second only to its commitment to safety and regulatory compliance.