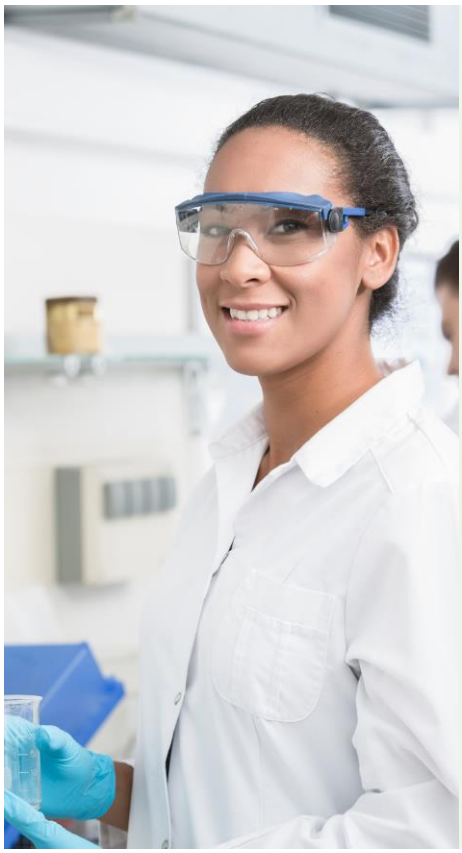
IMPURITY ISOLATION, IDENTIFICATION & CHARACTERIZATION

Olon USA's Analytical Chemistry team has decades of experience in laboratory services and has serviced the pharmaceutical industry for more than 30 years. This experience includes isolating and identifying new impurities in raw materials, intermediates, APIs, and drug products. The structural elucidation of new impurities can be followed by a full characterization to permit new reference materials to be qualified.

KEY SERVICES

- Isolation, identification and characterization of impurities and degradants from drug substances and drug products
- Isolation of unknowns from mg to multi-gram level
- Preparative-scale chromatography
- Identification work submitted to FDA with full approval
- Synthesis and characterization of authentic materials as reference standards
- Analytical methods developed and validated for quantitation of newly identified compounds



MAJOR EQUIPMENT

- UPLC/HPLC systems equipped with PDA, UV/Vis, ELSD, RI, and CAD detectors
- Liquid Chromatography coupled to Mass Spectrometry featuring Triple-Quad and Q-TOF technologies
- GC-MS and Headspace-GC
- GC systems with FID
- FT-NMR (2D and quantitative)
- FTIR and Raman
- UV-vis
- Microscopy
- Dissolution
- Particle Size by Light Scattering
- Ion chromatography
- Dynamic vapor sorption
- KF and titration systems
- ICP-AES, ICP-MS
- Thermal Analysis
- X-ray powder diffraction

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 United States Drug Enforcement Administration (DEA) licensed facility.

CORE CHEMISTRY SERVICES

Analytical Chemistry

Synthetic Chemistry

API Manufacturing

RELATED SERVICES

Method Development and Validation
ICH Stability Studies
Release Testing
Regulatory Support
Salt, Co-crystal and Polymorph Selection
Reference Standard Preparation
Characterization
Synthetic chemistry services