

## Drug Product (DP) and Isolation, Identification & Characterization (IIC)

Ricerca's Analytical Chemistry group has more than 25 years of experience in analytical laboratory services, with over 17 years in the pharmaceutical industry. This experience includes synthesis, raw material and intermediate testing, API and drug product testing, as well as analysis of radiolabeled compounds and controlled substances. 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 Harmonisation (ICH). 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 most drug product testing
- Dissolution testing

### Impurity isolation, identification and characterization

- Isolation, identification and characterization of impurities and degradants from drug substances, drug products and industrial 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

- GLP characterization of isolated impurities for use as reference materials
- Multiple identification tools on site: LC-MS/MS, NMR, FTIR, LC-DAD, etc.
- Synthesis of authentic materials from reference standards & isolated impurities available on site

### Major equipment

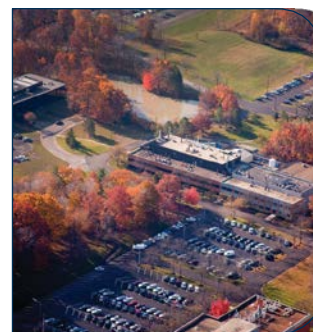
- LC systems with fraction collection on analytical-, semiprep- and preparative-scale chromatography
- HPLC systems equipped with photodiode array, EV/Vis, refractive index, electrochemical, evaporative light scattering and fluorescence detectors
- Experience with technical transfers with international and domestic pharmaceutical companies
- GC-MS and LC-MS systems
- GC systems equipped with flame ionization, electron capture, nitrogen phosphorus and flame photometric detectors
- Bruker Avance™ III 400 MHz NMR. Access to higher field NMRs at the University of Akron and Case Western Reserve University (>750 MHz)
- FTIR
- Dissolution baths

### Core chemistry services

- Analytical chemistry
- Process chemistry
- Engineering & API manufacturing
- Radiochemistry

### Related services

- Analytical method development and validation
- Kilo labs
- In-process support
- Pilot plant
- Dissolution testing
- Microbiology
- DMPK
- Degradant/impurity identification
- Toxicology/pharmacology
- Regulatory support



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