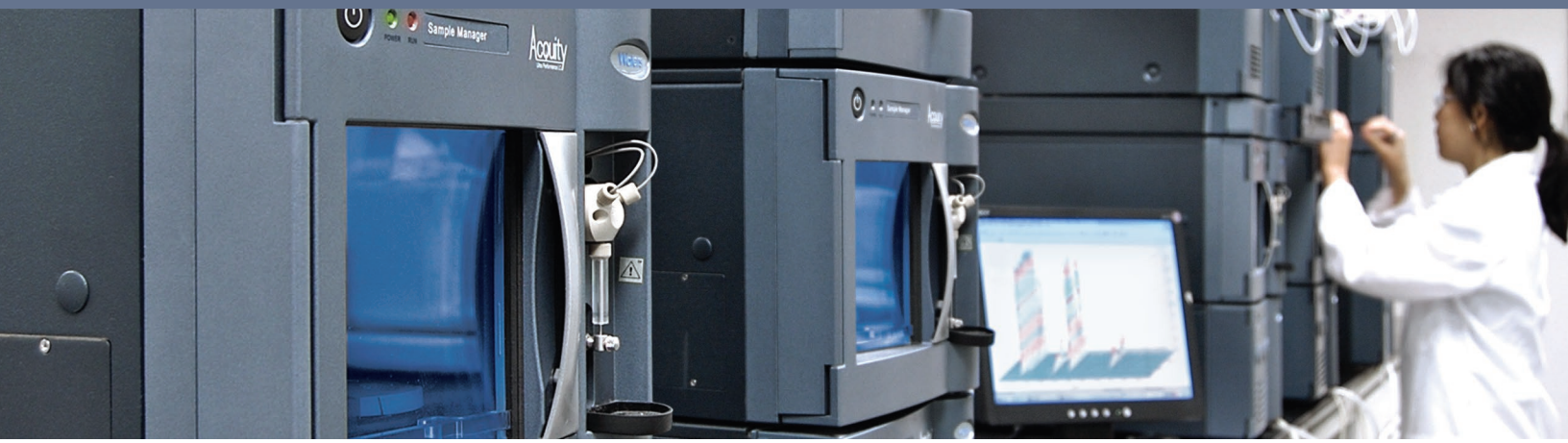
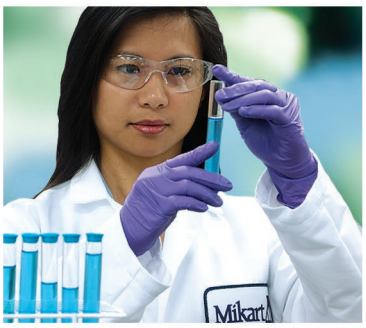
Analytical Services



Pre-formulation Research & Testing
Method Development & Validation
Stability Testing
Documentation for Regulatory Submissions



With more than 35 years of drug development expertise, Mikart has the depth and experience you need to support your analytical chemistry requirements for solid and liquid oral dosage products. We offer a wide range of analytical and validation services including:

- Pre-formulation Research & Testing (Drug Substance Characteristics, Impurity Analysis, and Degradation Pathways)
- API Characterization
- API and Finished Product Methods Development & Validation
- Stability-indicating UPLC and HPLC Assays & Impurity Methods
- Cleaning Validation Methods
- Method Transfer
- Specification Development
- Statistical Analysis
- Comprehensive Reports for the Quality Overall Summary (QOS) and CMC Sections for New Drug Application (NDA) Submissions

Our methods are developed and validated to cGMP standards and are fully compliant with all CFR and ICH guidelines. API and finished product test methods are developed utilizing the following instrumentation: UPLC, HPLC, GC, (UV, PDA, CAD detection), IR, AA and wet chemistry.

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