

Analytical Services

It is of vital importance to develop and utilize analytical methods that are both accurate and expedient, as they perform a critical and decisive role at all stages of product development. The data generated is required not only by research and development scientists, but also by process chemists, process engineers and quality control chemists to keep products moving along the pipeline.



Synomics Pharma Services develops and employs analytical methodology that not only helps monitor and measure parameters that are critical to the quality of the product or the active ingredient(s), but also to

generate information regarding production processes for both active and finished products. Synomics Pharma Services is dedicated to delivering high quality through design excellence, communication and efficiency.

CONTRACT ANALYTICAL SERVICES

Synomics Pharma Services routinely provides contract analytical services to meet the requirements of GMP or GLP guidelines, or both. Services include:

- Method development
- Method validation
- Method verification/transfer
- Sample analysis
- Bioanalysis
- Lot and batch release testing
- Identification of degradants and metabolites
- Structure elucidation
- Detection and identification of impurities
- Residual solvent analysis
- Extractables and leachables
- Dissolution testing
- Product composition
- Content – uniformity/impurities
- Customized analytical testing

INSTRUMENTATION AND TECHNOLOGY

Synomics Pharma Services is committed to investing in state-of-the-art instrumentation and qualified scientists who will work closely with clients to develop methods that will deliver efficient and quality data. Instrumentation includes:

- PE Sciex API-3000 LC/MS/MS
- Waters Quattro Micro LC/MS/MS
- PE Sciex API-100 LC/MS
- Waters 2695 HPLC Systems (PDA)
- Agilent 6890 and 5890 GC Systems (FID, FPD, μ ECD, NPD, TCD, Tekmar Headspace)
- Agilent 5973 GC/MS Systems
- Hewlett-Packard 8453 UV-Vis Spectrophotometer
- Scanalytics AMBIS 4000 TLC Plate Scanner
- Bio-Rad Immunoassay Analyzer

REGULATORY COMPLIANCE

Synomics Pharma Services maintains the highest standards of regulatory compliance in facilities, validated instrumentation and quality systems to meet both GLP and GMP requirements for FDA, EPA and ICH. Our facility maintains active licenses for DEA Schedule II and IV controlled substances and for radioactive materials use.

CONTACT INFORMATION

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