



## SCOPE OF SERVICES

Pace Analytical Life Sciences (PLS) offers a wide range of cGMP-compliant, ISO/IEC 17025 accredited testing services.

### Analytical Chemistry

- Method Development and Validation
- API and Finished Products
  - Release Testing
  - Stability Storage and Testing
- Compendial Testing
  - USP/NF, EP, BP and JP
- Assay and Impurity
- Dissolution
- Organic Volatile Impurities USP <467>
- Residual Solvents
- Particle Size Determination
- Extractables and Leachables
- Physico-Chemical:
  - Elastomeric Closures USP <381>
  - Plastics Aqueous and
  - Non-Aqueous USP <661>
- Oxygen and Moisture Permeation

### Physical Testing

- Oxygen and Moisture Permeability
- Static Decay
- Tensile and Elongation
- Peel Testing
- Container/Closure Testing
  - Seal Strength
- Adhesion Testing, Pressure Sensitive
- Adhesive
  - Instron
  - Imass Peel Test
- Hand Rollers
- Roll Down Machines
- Temperature/Humidity Controlled Areas

### Instrumentation / Techniques

- HPLC:
  - UV/VIS, RI, PDA and Fluorescence
- Gas Chromatography:
  - FID, TCD and ECD
  - Headspace GC
- Mass Spectrophotometry
  - GC/MS
  - LC/MS
  - LC/MS/MS
- Dissolution USP <711>
- ICP and AA
- Ion Chromatography
- Karl Fischer:
  - Direct and Residual
  - Coulometric
- FTIR
- UV/VIS Spectrophotometry
- Total Organic Carbon (TOC) <643>
- MOCON
- Cascade Impactors USP <601>

### Stability Services (ICH)

- Storage and analysis
 

25°C/60%RH	30°C/65%RH
30°C/70%RH	40°C/75%RH
- Custom Conditions available, including Cycling Studies

### Additional Consulting Services

- Protocol Development
  - Validation Protocols
  - Stability Protocols
- Method Transfer Protocols

### Microbiology Services

- Facility Support
- USP Water Testing
- Environmental Monitoring USP <1116>
- Product Release Testing

### Sterile Products

- Bacterial Endotoxins USP <85>
- Sterility Testing USP <71>
- Ethylene Oxide Residual and Analysis
- Particulate Analysis USP <788>
- Biological Indicators

### Non-Sterile Products

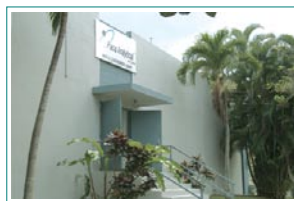
- Microbial Limits USP <61>
- Antimicrobial Effectiveness Testing USP <51>
- Bioburden Testing
  - USP, EP, JP, AOAC and BP
- Method Development / Validation USP <1227>

### Organism Identification

- Rapid Microbial Identification and Characterization Dupont RiboPrinter<sup>®</sup>
- BIOLOG System
- Aerobic Bacteria
- Yeasts and Molds



PLS operates a 40,000 square foot state-of-the-art facility located in the Minneapolis/St. Paul area. We are FDA registered, DEA registered, cGMP compliant and ISO/IES 17025 accredited.



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