



PHARMACEUTICALS, MEDICAL DEVICES AND DRUG-DEVICE COMBINATION PRODUCTS

Pace Analytical Life Sciences is a full-service contract analytical testing laboratory providing chemistry and microbiology testing services to the pharmaceutical and medical device industries. We have expertise in testing many dosage forms, including: transdermal delivery systems, aerosols, creams/ointments, oral tablets and capsules, medical devices and device/drug combination products.

ANALYTICAL CHEMISTRY SERVICES

- Method Development and Validation
- Raw Material / Compendia Testing (USP, EP, JP, BP, FCC, ACS)
- Finished-Product Release Testing
- HPLC and GC Assays
- Dissolution / Elution/Drug Release Profiles
- Extractable / Leachable Testing
- Elemental Impurities (ICP-OES, ICP-MS, AA, GFAA, CVAA)
- Mass Spectroscopy (LC-MS, LC-MS/MS, GC-MS, ICP/MS)
- Cleaning Verification / Validation
- Residual Solvents analysis
- Aerosol Testing Services (ACI/NGI)

STABILITY STORAGE

- ICH Storage Conditions ~ 8,000 cu. ft. Storage
- -80°C, Reach-In
- -20°C, Reach-In
- 5°C, Walk-In
- 25°C/60% RH, Walk-In
- 30°C/65% RH, Walk-In
- 40°C/75% RH, Walk-In
- 37°C, 45°C, and 50°C Accelerated Aging
- Custom Conditions and Reach-In Chambers
- Photo-Stability, ICH Q1b (Option 2)
- Continuous Monitoring and Emergency Power Systems

MICROBIOLOGY SERVICES

- Method Development and Validation
- Raw Material/Compendia Testing (USP, EP, JP, BP, FCC, ACS)
- Finished-Product Release Testing
- Bioburden
- Sterility testing
- Bacterial Endotoxins
- Particulate Matter USP <788>
- Biological Indicators
- Microbial Limits Testing
- Antimicrobial Effectiveness Testing
- Environmental Monitoring Services
- Microbial Identification

PHYSICAL TESTING

- Temperature and Humidity Controlled Lab
- Instron Testing (2-, 20-, 100-, and 200-lb load cells)
 - Tensile and elongation
 - Peel force, peel to steel
 - Release Liner Adhesion
- Probe-Tack / Loop-Tack Testing
- Shear Testing
- Penetrometer Testing (gels)
- Container Closure Integrity / Ingress Testing
- Burst / Creep Package Integrity
- Hardness Testing

COMPLETE LABORATORY PROGRAMS

- On-site / Off-site Dedicated Staff
- Laboratory Capital Equipment
- Calibration / Qualification / Maintenance Program



Pace Analytical Life Sciences operates two state-of-the-art laboratories totaling over 60,000 square feet of laboratory space: one in Oakdale, MN, and the other in San German, Puerto Rico. Our labs are cGMP-compliant, FDA established, DEA registered, and ISO/IEC 17025:2005 accredited.

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Chromatography		
Data Acquisition System	12	Waters Empower II
GCs: including FID, ECD and TCD	3	Agilent 6890
GC/MS	2	Agilent 5890/5973
		Agilent 6890/5973
Headspace Analyzers	1	Gerstel MPS 2 Twister
	1	Perkin Elmer HS 40XL
	1	Agilent 7964
Automated Thermo Desorbition (ATD) for GC/MS	2	Perkin Elmer ATD 400
Turbo Matrix for GC/MS	1	Perkin Elmer TurboMatrix ATD
Oven Manifolds	4	Custom built from Varian 3600 GCs
HPLCs: including UV/VIS, RI, PDA and ECD	17	Agilent 1100
	4	Waters Alliance
	4	Waters Component
	1	Waters Module 1
	1	Waters Acuity
	2	Agilent 1100MSD/Agilent 1100
	2	Waters Acuity
	4	Dionex DX-500 System
Spectroscopy		
UV/VIS Spectrophotometer	1	Beckman Coulter DU-800
FTIR Spectrometer-solid phase	2	Nicolet Magna IR 560
FTIR Spectrometer-gas phase	2	MIDAC Corp. (Custom)
Elemental Metals Equipment		
Atomic Absorption - Flame and Graphite Furnace	1	Perkin Elmer AAnalyst 800
Inductively Coupled Plasma (ICP) Spectrometer	1	Perkin Elmer Optiva 3300DV
	1	Thermo iCAP Duo 6500
Inductively Coupled Plasma (ICP-MS)	1	Thermo X-series II
Mercury Analyzer	1	Perkin Elmer FIMS 1000
Dissolution / Elution Equipment		
Dissolution baths Apparatus I, II and V	2	Hansen Research SR6, 2 Hansen Research SR8
Dedicated Dissolution Testing Lab Space	4	Distek 2100B, 2 Distek Bathless systems
	4	VanKel
Physical Testing Equipment		
Controlled Temperature / Humidity Lab Space		
Andersen Cascade Impactors	13	Andersen Instruments Inc. Model 10-709
Instron	2	Instron 4201, Instron 5565
I-Mass	1	Instrumentors, Inc. SP-2000
Probe-Tack Adhesive Tester	1	Testing Machines Incorporated
Static Decay Meter	1	ETS (Electro-Tech Systems, Inc) 406D
Durometer	1	Shore Type D
Tablet Hardness Tester	1	Dr Schleuniger Pharmatron 8M
Heat Sealer	1	Sencorp 12AS/2
Burst / Creep Package Integrity Tester	1	Carleton Technologies
Precision Micrometer	1	TMI (Testing Machines, Inc) 49-60
Microbiology Testing Equipment		
Sterility Suite	1	(ISO Class 7 / Fed Std 209E Class 10,000)
Stereoscope	1	Nikon SMZ-2T, Model H-III (camera)
Light Microscope with Florescent source	1	Olympus BX50F4
Riboprinter	2	Dupont Qualiconn Riboprinter
Liquid Particle Counting System	1	HIAC Model 9703
Millipore SteriTest-Closed Sterility Test System	1	Catalog # TQNXLFF01, Serial Number 383
Kinetic Bacterial Endotoxin Testing System	1	Charles River Endosaf EndoScan V
		software package
Autoclave	1	Steris SV-120
	1	Consolidated
Laminar Flow Hoods	3	Baker EG6320 (2)
Image Analyzer/Microscope	1	Fryer Image Analyzer / Nikon Eclipse E400
	1	Nikon Eclipse E600
	8	Biotest 940310
Active Air Sampler for Viable Microbial Particles		
Laser Particle Counter, Active Air Sampler for Total Airborne Particulate	4	Met One 237B
Biological Safety Cabinets	5	Baker SG600 (4), Baker B40-112 (1), Labconco 36205-00
		VWR 1927 (1), Fisher 146E (1), VWR
Microbial Incubators	14	
Laboratory Equipment		
UV Developer Box and UV Viewing System	1	Hitachi HV C20/Chromato-vue C71/Camag Repostar 3
Soxtherm Automated Extraction Apparatus	4	O I Analytical Soxtherm
RotoVap/Waterbath	1	Buchi (R114)(B480)
Total Organic Carbon Analyzer	1	Tekmar-Dohrmann Phoenix 8000
Karl Fischer Titrator	2	Accumet Model 100
	1	EM Science Aquastar C3000
Auto Titrator-Karl Fischer/Potentiometric	1	Brinkmann / Metrohm (751 GPD Titrino)
Auto Titrator-Potentiometric	1	Mettler Toledo DL70ES
Rotational Viscometer	1	Brookfield LVDV II+
Inherent Viscosity Meter	1	Rheotek RPV-1
Moisture Balance	1	Arizona Instruments
Freezer Mill	1	Spex 6850
pH/Conductivity Meters	2	Accumet AR50
	1	Mettler Toledo InLab 740
Accelerated Solvent Extractor	1	Dionex ASE 200
Muffle Furnace	2	Thermolyne 48000
Vacuum Oven	1	Yamato ADP 21
Microwave	1	Anton Parr Multiwave 3000
Polarimeter	1	Rudolf Research Model Autopol IV
Osmometer	1	Wescor Vapro 5520
Turbidimeter	1	HF Scientific MICRO 1000IR