SAN GERMAN, PR FACILITIES & EQUIPMENT LIST



FACILITY INFORMATION

Pace® Life Sciences operates a network of eight [8] locations to provide contract product development and laboratory testing services to the pharmaceutical, biopharmaceutical / biologics, and medical device industries. Our customers range from new and innovative start-up companies through to the veteran industry leaders. Our contract product development services help bring new therapies to market and our contract laboratory services to ensure the purity, potency, safety, efficacy, and shelf life of marketed products.

Pace® Life Sciences in San German, Puerto Rico, has been providing chemistry and microbiology testing services to industry for more than 30 years. Steady growth of our business has contributed to recent expansion of this facility to increase our capacity and offer new capabilities.

Key attributes of this facility include:

- Microbiology Suite Remodel (Phase II)
- · FDA registered
- DEA registered for the handling of controlled substances, schedules II V
- 3,000 ft² business office in Guaynabo
- Sample courier services

The laboratory has robust risk-management strategies to ensure continuous reliable operations:

- Diesel-powered electrical generators supply backup power to all key building equipment, such as computer network systems, stability storage chambers and microbiology incubators.
- The computer network systems and certain laboratory areas utilize Uninterruptible Power Systems (UPS) to cover the momentary gaps in supply, ease the transition and ensure clean power to critical systems.
- A continuous monitoring system (CMS) captures data (e.g., temperature and/or humidity) every few minutes in designated ambient laboratory areas, stability storage chambers and microbiology incubator systems to ensure that environmental control systems are operating properly.

Our labs are cGMP-compliant, FDA registered, and DEA registered.

LABORATORY INSTRUMENTS

CHROMATOGRAPHY	MANUFACTURER/MODEL
Gas Chromatograph (FID, TCD, FID/TCD) (10)	Agilent 6890
HPLC (UV/VIS, PDA, RI) (14)	Waters Alliance 2695, Agilent 1200, Agilent 1260
Gas Chromatograph (TCD)	Agilent 6850
Headspace Samplers (4)	Agilent G1888, Tekmar HT3

ELEMENTAL METALS EQUIPMENT	MANUFACTURER/MODEL
Atomic Absorption Spectrophotometer	Perkin Elmer PinAAcle 900t
Spectrophotometer Cold Vapor	Perkin Elmer FIMS 400
Technique (Mercury Analysis)	

STABILITY STORAGE	MANUFACTURER/MODEL
Stability Storage Chambers (6)	Bahnson
Stability Storage Chambers (6)	Bannson

DISSOLUTION/ELUTION EQUIPMENT	MANUFACTURER/MODEL
Apparatus I & II (4)	Distek, VanKel
Apparatus III (2)	Agilent

SPECTROSCOPY	MANUFACTURER/MODEL
InfraRed (FTIR/ATR) (2)	Perkin Elmer Spectrum 100
Spectrophotometer UV/VIS	Evolution 220
Colorimeter (2)	HACH DR-850
Flame Photometer	Cole Palmer

FACILITY MONITORING	MANUFACTURER/MODEL
Surface Air Samplers (SAS) (7)	PBI 180, PBI 360
RCS High Flow Microbial Monitor	Biotest 940215
Particle Counter, Laser Type (7)	APC Plu, Climet Cl-450t
Hydrocarbon Analyzers (3)	USI's 6200P
Oxygen, CO2, CO Portable Meter	RKI Instruments Eagle
Hygrometers	V WR Scientific
Dew Point Meter/Moisture Analyzers [3]	General Electric MMY-245
Chronometers/Timers (32)	Fisher, Control Co., Radio Shack
Data loggers (61)	Sensitech TT-4, Logtag
Flow Meters, General Use (14)	Cole Parmer, VWR, Dwyer
Flow Meters, Digital (3)	Agilent, Shimadzu
Pressure Gauges (9)	ColeParmer, Noshok, WICA, Dwyer
Velometer	Alnor RY05
Thermocouple Validator	Kaye 2010

MICROBIOLOGY TESTING	MANUFACTURER/MODEL
Microbial Identification	Bruker Maldi Biotyper Charles River Axcess™ System
Bacterial Endotoxin Kinetic/ Turbidimetric System (2)	Bio-Tek
Vitek Densi-Chek Plus	BioMerieux
Incubators (15)	Fisher Scientific, Precision, VWR, Thermo Electron, LabLine, Lunaire
Autoclave (3)	Consolidated Corp. SSR3APB, AMSCO Eagle 3000, Steris SV-120
Microscope (2)	Fisher, Nikon
Stereoscope	Nova
Laminar Flow Hoods (8)	Baker, Nuaire
Colony Counter (2)	Darfield Quebec 3327
Biological Safety Cabinet (5)	Esco, Baker, Nuaire, Biogard

Our labs are cGMP-compliant, FDA registered, and DEA registered

LABORATORY EQUIPMENT	MANUFACTURER/MODEL
Titrators (3)	Mettler Toledo DL55, DL38, T50, V30
Titrators, Coulometric	Mettler C30X
Total Organic Carbon Analyzer (2)	GE Sievers M9
Polarimeter	Rudolph Autopol IV
Polarimeter Quart Calibration Cell (2)	Rudolph
Osmometer	Wescor Co.
Viscometers, Cannon Fenske (4)	Ace Glass, Cannon
Viscometers, Rotational (2)	Brookfield LVDV-II+P & RVDV-II+P
Viscometers, Ubbelohde (7)	Cannon
Viscometer, Zahn	BYK Gardner
Fluorometer	Turner Instr. 450/94000-01
Melting Point Apparatus, 0 to 400 °C	Electrothermal 9100
Refractometer, Digital	Rudolph J257
Particle Size, Rotap Sieve Shaker	WS Tyler RX29
Particle Size, Vibrational Shaker	Retsch AS 200
Particle Size, Air Jet (2)	Hosokawa
Conductivity Meters (3)	Oakton 510, Mettler Toledo pH
Meters (2)	Mettler Toledo
Turbidimeters (2)	HF Scientific, Thermo
Scientific Muffle Furnace (2)	Thermoline
Balances, Top Loading (4)	Denver, Mettler
Balances, Analytical (6)	Mettler
Centrifuge (3)	Thermo Electron, Eppendorf
Density Tester, Scott Volumeter	Mettler
Tapped Density	Pharmatron
Texture Analyzer	Brookfield CT3 1000
Nitrogen Analyzer	Büchi K-355
Weight Per Gallon Cup (2)	BYK Gardner
Liquid Particle Counter (2)	Beckman
pH Meter (2)	Mettler Toledo
Washer	Steris
Purified Water System	Millipore
Balance, Toploading (2)	Mettler Toledo
Balance, Analytical	Mettler Toledo
Refridgerators (8)	Fogel, Thermo, VWR

