



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Pace Analytical Life Sciences, LLC
291 US Hwy 22
Lebanon, NJ 08833

Fulfills the requirements of

ISO/IEC 17025:2017

In the field of

TESTING

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

A handwritten signature in black ink, appearing to be 'Jason Stine', is positioned above a horizontal line.

Jason Stine, Vice President

Expiry Date: 13 May 2028

Certificate Number: L2388



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017.
This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory
quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Pace Analytical Sciences, LLC

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TESTING

ISO/IEC 17025 Accreditation Granted: **28 April 2026**

Certificate Number: **L2388** Certificate Expiry Date: **13 May 2028**

Mechanical Testing

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Distribution Simulation (0.5 - 150) lbs	ASTM D4169, D7386 ISTA 1, 2, 3 Series Tests	Packages, Drums, Tubes, Mailers	Lansmont Vibration Table Lansmont Compression Table Lansmont Drop Tester Pack-Vac Altitude Chamber Chambers for pre- conditioning PVC Pipe and 4lb weight
Compression Resistance (0.5 – 5 000) lbs	ASTM D642	Packages, Drums, Tubes, Mailers	Lansmont Compression Table
Vibration (1 – 300) Hz	ASTM D999, D4728, ISO 11608-1	Packages, Drums, Tubes, Mailers, Syringes	Lansmont Vibration Table
Drop (Shock) (0.5 – 150) lbs	ASTM D5276 ISO 11608-1	Packages, Drums, Tubes, Mailers, Syringes	Lansmont Drop Tester
Concentrated Impact 4 ft-lbf	ASTM D6344	Packages, Drums, Tubes, Mailers	PVC Pipe and 4lb weight
Low Pressure (High altitude) Sea Level – 16 000 feet	ASTM D6653	Packages, Drums, Tubes, Mailers	Haug-Pack Altitude Chamber

Mechanical Testing

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Environmental Conditioning (-40 – 70)°C (10 – 93%) RH	ASTM D4332, ISO 11608-1	Packages, Drums, Tubes, Mailers, Trays, Pouches, Envelopes, Syringes	Any chamber based on client request.
Peel Strength (0.5 – 10) lbs	ASTM F88	Trays, Pouches, Envelopes	Instron
Visual Inspection	ASTM F1886	Trays, Pouches	Human
Dye Penetration	ASTM F1929	Trays, Pouches	Human / Vacuum Chamber
Dye Penetration	ASTM F3039	Trays, Pouches	Human / Vacuum Chamber
Burst Strength (0.5 – 100) psi	ASTM F1140	Trays, Pouches, Bottles, Tubes	BT-1000-V5 Package Tester
Bubble leakage	ASTM F2096, D3078	Trays, Pouches, Bottles, Tubes	Haug Pack-Vac Altitude Chamber
Torque (0.5 – 50) in-lbs	ASTM 2063	Bottles	Tornado Torque Tester
Tensile strength and Elongation (0.5 – 500) lbs 10-1 000%	ASTM D882	Plastics, films	Instron
Tensile / Compressive Testing	ISO 11608-3, ISO 7864, ISO 11040-4, ISO 11040-8	Syringes, Needles, Finished Containers for NIS	ISO 11608-3: Leakage, Plunger force ISO 7864: Bond between hub and needle tube ISO 11040-4: Flange break resistance, Luer cone break resistance, Glide force, Needle penetration, Needle pull-out force, Closure system liquid leakage, LLA collar pull-off force, Cap pull-off force ISO 11040-8: Breakloose and extrusion force
Leakage by Pressure Decay 300 – 330 kPa	ISO 80369-7, ISO 80369-20	Small bore connectors, Syringes	Enersol Automated Leakage by Pressure Decay Tester & Enersol Connector Assembly Device

Mechanical Testing

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Positive Pressure Liquid Leakage 200 – 330 kPa Up to – 3 N Axial Force	ISO 80369-7, ISO 80369-20, ISO 7886-1, ISO 8537	Small bore connectors, Syringes	Enersol Falling Drop Positive-Pressure Liquid Leakage Tester & Enersol Connector Assembly Device
Subatmospheric Pressure Air Leakage -80 to -88 kPa	ISO 80369-7, ISO 80369-20	Small bore connectors, Syringes	Enersol Automated Subatmospheric Pressure Air Leakage Tester & Enersol Connector Assembly Device
Reference Connector Assembly / StressCracking 27.5N Axial 0.8 – 0.17 N·m Torque	ISO 80369-7, ISO 80369-20	Small bore connectors, Syringes	Enersol Connector Assembly Device, Automated Leakage by Pressure Decay Tester, & Enersol Falling Drop Positive-Pressure Liquid Leakage Tester
Resistance to Separation From Axial Load 23 – 35 N	ISO 80369-7, ISO 80369-20	Small bore connectors, Syringes	Enersol Separation Force Device & Enersol Connector Assembly Device
Resistance to Separation From Unscrewing 0.0198 – 0.200 N·m	ISO 80369-7, ISO 80369-20	Small bore connectors, Syringes	Enersol Unscrewing Torque Device & Enersol Connector Assembly Device
Resistance to Overriding 0.15 – 0.17 N·m	ISO 80369-7, ISO 80369-20	Small bore connectors, Syringes	Enersol Connector Assembly Device
Dead Space / Dosing	ISO 7886-1, ISO 11608-1	Syringes	Balance
Penetrability	USP <381>	Elastomeric	Autoclave, Penetrometer
Fragmentation / Coring	USP <381>, ISO 11608-3	Elastomeric, Finished Containers for NIS	Autoclave,
Self-Sealing / Resealability	USP <381>, ISO 11608-3	Elastomeric, Finished Containers for NIS	Autoclave, vacuum oven

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Identification by DSC (Up to 280) °C	USP <661.1>	Plastics	Differential Scanning Calorimeter (DSC)

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Identification by Internal Reflectance (400 – 4 000) cm-1	USP <661.1>	Plastics	Fourier Transform Infrared Spectrophotometer (FTIR)
Physicochemical Tests	USP <661.2>	Plastics	Autoclave, oven, TOC Analyzer, UV/Vis Spectrophotometer
Spectral Transmission (290-450) nm	USP <660>	Glass	UV/Vis Spectrophotometer
Glass Grains / Surface Glass	USP <660>	Glass	Autoclave, Ball Mixer
Physicochemical Tests	USP <661.1>	Plastics	TOC Analyzer, UV/Vis Spectrophotometer
Extractable Metals	USP <661.1>, ISO 7886-1, ISO 8537, ISO 7864	Syringe, Needle	ICP-MS
Plastic Additives	USP <661.1>	Plastics	HPLC
Spectral Transmission (190 – 800) nm	USP <671>	Plastics	UV/Vis Spectrophotometer
Moisture Permeation	USP <671>	Plastics	Chambers
Physicochemical Tests	USP <381>	Elastomeric	Autoclave, UV/Vis Spectrophotometer, Atomic Absorption,
UV Absorbance (220 – 360) nm	USP <381>	Elastomeric	UV/Vis Spectrophotometer
Atomic Absorption	USP <381>	Elastomeric	Atomic Absorption
Chromatography	USP <621>	Pharmaceutical Raw Material; Gases	Gas Chromatograph, High Performance Liquid Chromatograph
Infrared Absorption	USP <197>	Pharmaceutical Raw Material	Fourier Transform Infrared Spectrophotometer (FTIR)
Arsenic	USP <211>	Pharmaceutical Raw Material; Glass	Visual
Loss on Drying	USP <731>	Pharmaceutical Raw Material; Pharmaceutical Coil	Oven
Residue on Ignition	USP <281>	Pharmaceutical Raw Material; Pharmaceutical Coil	Furnace Oven
Visible, Infrared, Atomic Absorption	USP <851> Spectrophotometry and Light-Scattering	Pharmaceutical Raw Material	Atomic Absorption Spectrophotometer/FTIR/UV/Vis Spectrophotometer

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
pH	USP <791> pH, ISO 7886-1, ISO 8537, ISO 7864, ISO 9692	Pharmaceutical Raw Material, Syringe, Needle	pH meter
Water Determination	USP <921> Water Determination	Pharmaceutical Raw Material	Karl Fischer
Refractive Index	USP <831> Refractive Index	Pharmaceutical Raw Material	Refractometer
Specific Gravity	USP <841> Specific Gravity	Pharmaceutical Raw Material	Pycnometer
Total Organic Carbon Analysis (TOC)	USP <643>	Pharmaceutical Raw Material	TOC analyzer
Auxiliary Packaging Components	USP <670>	Packaging Components	Depends on the test. Oven, Chamber
Resistance to corrosion	ISO 9626	Needle	Visual
Elemental Impurities	USP<232>/<233>	Raw Material or API	ICP-MS
Viscosity	USP<911>/<912>	Raw Material or API	Viscometer

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Microbiological Examination of Non-Sterile Products: Enumeration (<1CFU – TNTC per Unit Sample)	USP <61>	Raw materials, in-process, and finished product	Incubator, hood, balance
Microbiological Examination of Non-Sterile Products: Tests for Specified Organisms (Presence/absence per Unit Sample)	USP <62>	Raw materials, in-process, and finished product	Incubator, hood, balance
Antimicrobial Effectiveness Testing (Log Reduction)	USP <51>	In-process and finished product	Incubator, balance
Bacterial Endotoxin Testing (<0.015EU/mL Sample Solution)	USP <85>	Raw materials, in-process, and finished product	Micropipette, dry bath, balance

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Biological Reactivity Testing (Up to – 4 Biological Reactivity Grade)	USP <87>/ ISO 10993	Raw materials, in-process, and finished product	Incubator, hood, balance, caliper
Water Analysis (<1CFU – TNTC per Unit Sample)	USP <1231>	Raw materials, in-process, and finished product	Incubator, hood
Environmental Monitoring (<1CFU – TNTC per Unit Sample)	USP <1116>	Environmental	Air sampler, incubator
Microbiological Examination of Non-Sterile Products Tests for Burkholderia Cepacia Complex	USP<60>	Drug Products and Raw Materials	Incubator, hood, balance
Application of Water Activity Determination to Nonsterile Pharmaceutical Products	USP<1112>	Drug Products	Water Activity Meter
Sterility	USP<71>	Finished Products	Isolator



Jason Stine, Vice President