



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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MECHANICAL

Valid To: August 31, 2025

Certificate Number: 4286.03

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests:

Measurements: Work Environment

<u>Test</u>	<u>In-house Method</u>	<u>Reference Method</u>
Noise, Sound, Pressure Level	PEE.EL.01	ISO 1996, PARTs 1 and 2
Temperatures for Thermal Stress, Thermometry	PEE.EL.09	UNE – EN ISO 7243
Thermal Comfort	PEE.EL.015	UNE – EN ISO 7730; UNE – EN ISO 7726
Luminosity	PEE.EL.010	NOM – 025; STPS – 2008
Breathable Dust, Gravimetry	PEE.EL.016	NIOSH 0600
Total particles, Gravimetry	PEE.EL.017	NIOSH 0500
Noise, Noise Dosimetry, Sound Pressure Level	PEE.EL.05	ISO 9612
Noise Pressure Level Emitted by Stationary Road Vehicles	PEE.EL.06	ISO 5130:2019

Measurements: Hand-arm

<u>Test</u>	<u>In-house Method</u>	<u>Reference Method</u>
Vibration	PEE.EL.08	UNE – EN ISO 5349-1; UNE – EN ISO 5349-2

Measurements: Whole Body

<u>Test</u>	<u>In-house Method</u>	<u>Reference Method</u>
Vibration in the Whole Body	PEE.EL.011	UNE – ISO 2631-1

Measurements: Buildings

<u>Test</u>	<u>In-house Method</u>	<u>Reference Method</u>
Vibration	PEE.EL.014	UNE – ISO 2631-1; UNE – ISO 2631-2

Measurements in the Field: Flow Cabinets, Extraction Cabins, Laminar Flow Modules, and Sterile Rooms

<u>Test</u>	<u>In-house Method</u>	<u>Reference Method</u>
Filter Integrity ¹	PEV.EL.02	ISO 14644-3, Item B.7
Concentration and Particle Size ¹	PEV.EL.02	ISO 14644-1, Item A4, Annex B and C
Air Flow Laminarity Size ¹	PEV.EL.02	ISO 14644-3, Item B.2, NSF/ANSI 49-2020
Display of Air Flow Standard Direction ¹	PEV.EL.02	ISO 14644-3, Item B.3
Lighting Intensity	PEV.EL.02	ISO 14644, NSF/ANSI 49-2018
Sound Level	PEV.EL.02	ISO 14644, NSF/ANSI 49-2018

Measurements in the Field: Sterile Rooms and Premises with Controlled Environments

<u>Test</u>	<u>In-house Method</u>	<u>Reference Method</u>
Air Flow Rate, Supply and Extraction ¹	PEV.EL.02	ISO 14644-3, Item B.2
Differential Pressure ¹	PEV.EL.02	ISO 14644-3, Item B.1
Thermal Profile ¹	PEV.EL.02	ISO 14644-3, Item B.5 and B.6

Measurements in the Field: Stability Rooms, Warehouses, Cold Rooms, Trucks

<u>Test</u>	<u>In-house Method</u>	<u>Reference Method</u>
Thermal Profile ¹	PEV.EL.04	USP 43 NF 38 Volume 1, Good Storage and Transportation Practices. Supplement 8 Temperature mapping of storage areas Technical supplement to WHO Technical Report Series, No. 961, 2011 Annex 9 Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products.

Measurements in the Field: Empty and Full Chambers

<u>Test(s)</u>	<u>In-house Method</u>	<u>Reference Method</u>
Characterization of Autoclaves, Comparison of Temperatures - Stability Test and Temperature Uniformity ¹	PEV.EL.01	USP 43 NF 38 volume 1 Sterilization and Guarantee of Sterility of Pharmacopical Articles

ELECTRICAL

Measurements in the Field: AC Power Lines

<u>Test(s)</u>	<u>In-house Method</u>	<u>Reference Method</u>
Measurement of Power Frequency Electric and Magnetic Fields from AC Power Lines	PEE.EL.053	IEEE Std 644-2019: IEEE Standard Procedure for Measurement of Power Frequency Electric and Magnetic Fields from AC Power Lines

¹This laboratory performs field testing activities for these test methods.



Accredited Laboratory

A2LA has accredited

ELICROM CÍA. LTDA.

Guayaquil, ECUADOR

for technical competence in the field of

Mechanical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. 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).



Presented this 10th day of October 2023.

A blue ink signature of Mr. Trace McInturff, written over a horizontal line.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 4286.02
Valid to August 31, 2025

For the tests to which this accreditation applies, please refer to the laboratory's Mechanical Scope of Accreditation.