

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

PARTICLE TESTING AUTHORITY

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MECHANICAL

Valid To: December 31, 2022 Certificate Number: 3636.01

In recognition of the successful completion of the A2LA evaluation process, including an assessment of the laboratory's conformance with the U.S. FDA Good Manufacturing Practice Standard (GMP) per 21 CFR 210 and 211, accreditation is granted to this laboratory to perform the following tests <u>for physical characterization of solid and powder materials:</u>

<u>Test</u>	Test Method
Particle Size Analysis – Laser Diffraction Methods	ISO 13320
Light Diffraction Measurement of Particle Size	USP <429>
Standard Test Method for Particle Size Distribution of Catalytic Materials by Laser Light Scattering	ASTM D4464
Determination of Particle Size Distribution by Gravitational Liquid Sedimentation Methods – Part 3: X-ray Gravitational Technique	ISO 13317-3
Determination of Particle Size Distributions – Electrical Sensing Zone Method	ISO 13319
Particle Size Analysis – Image Analysis Methods – Part 2: Dynamic Image Analysis Methods	ISO 13322-2
Particle Size Analysis – Dynamic Light Scattering (DLS)	ISO 22412
Determination of the Specific Surface Area of Solids by Gas Adsorption (BET Method)	ISO 9277
Standard Test Method for Carbon Black – Total and External Surface Area by Nitrogen Adsorption	ASTM D6556
Specific Surface Area	USP <846>

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<u>Test</u>	Test Method
Specific Surface Area of Alumina or Quartz by Nitrogen Adsorption	ASTM C1069
Pore Size Distribution and Porosity of Solid Materials by Mercury Porosimetry and Gas Adsorption – Part 1: Mercury Porosimetry	ISO 15901-1
Porosimetry by Mercury Intrusion	USP <267>
Pore Size Distribution and Porosity of Solid Materials by Mercury Porosimetry and Gas Adsorption – Part 2: Analysis of Mesopores and Macropores by Gas Adsorption	ISO 15901-2
Pore Size Distribution and Porosity of Solid Materials by Mercury Porosimetry and Gas Adsorption – Part 3: Analysis of Micropores by Gas Adsorption	ISO 15901-3
Standard Test Methods for Estimating Average Particle Size of Metal Powders and Related Compounds Using Air Permeability	ASTM B330
Standard Test Methods for Estimating Average Particle Size of Alumina and Silica Powders by Air Permeability	ASTM C721
Particulate Matter in Injections	USP < 788 > Method 1
Bulk Density and Tapped Density of Powders	USP <616>
Density of Solids – Gas Pycnometry for the Measurement of Density	USP <699>
Colloidal Systems – Methods for Zeta-potential Determination – Part 2: Optical Methods	ISO 13099-2
Standard Test Method for Carbon Black – Void Volume at Mean Pressure	ASTM D7854
Thermal Analysis (Limited to DSC and TGA)	USP <891>
Water-Solid Interactions in Pharmaceutical Systems	USP <1241>
Standard Test Method for Hydrogen Chemisorption on Supported Platinum Catalysts by Volumetric Vacuum Method	ASTM D3908

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Accredited Laboratory

A2LA has accredited

PARTICLE TESTING AUTHORITY

Norcross, GA

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 9th day of February 2021.

Vice President, Accreditation Services For the Accreditation Council

Certificate Number 3636.01

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