



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

WUXI APTEC, INC.¹
 1265 Kennestone Circle
 Marietta, GA 30066
 Ginger Lane Phone: 888-847-6633

BIOLOGICAL

Valid To: January 31, 2019

Certificate Number: 2784.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory at the location listed above as well as the one satellite laboratory location listed below to perform the following microbiological and biological tests for biopharmaceutical/biotechnology, medical device/medical product, and textile industries:

<u>Test Title</u>	<u>Test Method(s)</u>
Sterility Testing – Validation of Sterility Tests Direct Immersion, Membrane Filtration Fluid Path, In Situ	USP<71>; 21 CFR Part 610.12; British Pharmacopoeia (BP), Appendix XVI; European Pharmacopoeia (EP), Section 2.6.1; Japanese Pharmacopoeia (JP), 4.05; ANSI/AAMI/ISO 11737-2
Estimation of the Population of Microorganism on Product – Microbial Enumeration and Recovery	ANSI/AAMI/ISO 11737-1; USP<61> and <62> (Harmonized); USP<61> (Non-Harmonized); USP<1227>; EP 2.6.12 and 2.6.13; JP 4.05
Validation of Sterilization of Health Care Products – Radiation	ANSI/AAMI/ISO 11137; AAMI TIR 33
Bacterial Endotoxin Testing and Validation	USP<85>, USP<161>; ANSI/AAMI/ISO ST 72
Microbial Analysis of Water	USP<1231>; “Standard Methods for the Examination of Water and Wastewater”, American Public Health Association, Current Edition
Organism Identification – Gram Stain, Biochemical Profile, DNA Sequencing, Microscopic Fungal Analysis	Manual of Clinical Microbiology, Patrick R. Murray, et al., 8 th Ed.
Evaluation of Environmental Monitoring Samples	USP <1116>

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¹ This accreditation covers testing performed at the main laboratory listed above, and the following satellite laboratory listed below:

WUXI APPTEC, INC.
1279 Kennestone Circle
Marietta, GA 30066

<u>Test Title</u>	<u>Test Method(s)</u>
Validation of the Sterilization/Reprocessing of Reusable Medical Devices	AAMI TIR 12; ISO 17665
Validation of Cleaning Efficacy of Reusable Medical Devices	AAMI TIR 30
Qualitative Assessment of Antimicrobial Activity of Textile Material, Carpets, Polymeric Materials and Plastics	AATCC Test Methods 147, 30 Part III; 174 Part 1, 174 Part III; ASTM Test Methods G21
Quantitative Assessment of Antimicrobial Activity of Textile Material, Carpets, Polymeric Materials and Plastics	AATCC Test Methods 100, 174 Part II; ASTM Test Methods E2180, E2149, E2471; JIS Z 2801; ISO 22196
Antimicrobial Effectiveness	USP<51>
Biological Indicators – Total Viable Spore Count	USP<55>
Microbiological Examination of Non-Sterile Products	USP<61>; USP<62> (Harmonized)



Accredited Laboratory

A2LA has accredited

WUXI APPTec, INC.

Marietta, GA

for technical competence in the field of

Biological Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *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 8 January 2009).



Presented this 25th day of January 2017.

A handwritten signature in black ink, written over a horizontal line.

President and CEO
For the Accreditation Council
Certificate Number 2784.01
Valid to January 31, 2019

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



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WUXI APPTEC, INC.
1279 Kennestone Circle
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CHEMICAL

Valid To: January 31, 2019

Certificate Number: 2784.02

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following chemical tests for biopharmaceutical/biotechnology and medical device/medical product industries:

<u>Test Title</u>	<u>Test Method(s)</u>
Ethylene Oxide Residuals by GC (FID) (Ethylene Oxide, Ethylene Chlorohydrin, Ethylene Glycol by Water or Headspace Extraction)	ISO 10993-7
Heavy Metals	USP<231>
Physicochemical Test Panel, Plastics (USP 38) Nonvolatile Residue Residue on Ignition Heavy Metals Buffering Capacity	USP<661>
Physicochemical Test Panel, Plastics Absorbance Acidity or Alkalinity Total Organic Carbon Terephthaloyl Moieties and Ethylene Glycol (<i>USP <661.2> only</i>)	USP <661.1>; USP <661.2>
Total Organic Carbon	USP<643>
Conductivity	USP<645>
Residual Moisture	USP<921>
Protein Assay by Modified Lowry	ASTM D5712
Atomic Absorption Calcium, Lead, Silver, Copper, Magnesium, Rubidium, Cobalt, Sodium, Potassium, Nickel, Iron, Zinc	USP (element-specific monograph) EPA (element-specific section)

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Accredited Laboratory

A2LA has accredited

WUXI APPTec, INC.

Marietta, GA

for technical competence in the field of

Chemical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *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 8 January 2009).



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President and CEO
For the Accreditation Council
Certificate Number 2784.02
Valid to January 31, 2019

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