



The American Association for Laboratory Accreditation

World Class Accreditation

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 19th day of April 2011.





Peter Meyer

President & CEO
For the Accreditation Council
Certificate Number 2784.01
Valid to January 31, 2013

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



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

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

BIOLOGICAL

Valid to: January 31, 2013

Certificate Number: 2784.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory 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 British Pharmacopoeia, Appendix XVI European Pharmacopoeia, Section 2.6.1 Japanese Pharmacopoeia, Chapter 54 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>
Validation of Sterilization of Health Care Products – Radiation	ANSI/AAMI/ISO 11137 AAMI TIR 33
Validation of the Sterilization/Reprocessing of Reusable Medical Devices ¹	AAMI TIR 12 ISO 17665
Validation of Cleaning Efficacy of Reusable Medical Devices ¹	AAMI TIR 30
Qualitative Assessment of Antimicrobial Activity of Textile Material, Carpets, Polymeric Materials and Plastics ¹	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 ¹	AATCC Test Methods 100, 174 Part II, ASTM Test Methods E2180, E2149, E2471 JIS Z 2801

Peter Abney
Page 1 of 2

Test Title

Test Method(s)

Antimicrobial Effectiveness¹

USP<51>

Bacterial Endotoxin Testing and Validation

USP<85>, USP<161>
ANSI/AAMI/ISO ST 72
U.S. Dept. of Health and Human Services, FDA

Biological Indicators – Total Viable Spore Count¹

USP<55>

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, Ribosomal DNA Analysis, DNA Sequencing, Microscopic Fungal Analysis

Manual of Clinical Microbiology, Patrick R. Murray, et al., 8th Ed.

Bac-T-Alert System for Automated Sterility Testing

Operation Instructions for the Automated Bac-T-Alert System

Evaluation of Environmental Monitoring Samples

USP <1116>

Microbial Limits¹

USP<61>, Current Edition
USP<62> (Harmonized)

¹These tests are performed at 1279 Kennestone Circle, Marietta, GA 30066



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A2LA has accredited

WUXI APPTec, INC.

Marietta, GA

for technical competence in the field of

Chemical Testing

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Presented this 19th day of April 2011.





Peter R. Meyer

President & CEO
For the Accreditation Council
Certificate Number 2784.02
Valid to January 31, 2013

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



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

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

CHEMICAL

Valid to: January 31, 2013

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:

Test Title

Test Method(s)

Ethylene Oxide Residuals by GC (FID) (Ethylene Oxide, Ethylene Chlorohydrin, Ethylene Glycol by Water or Headspace Extraction)	ISO 10993-7
Heavy Metals	USP<213>
Physicochemical Test Panel, Plastics Nonvolatile Residue Residue on Ignition Heavy Metals Buffering Capacity	USP<661>
Total Organic Carbon	USP<643>
Conductivity	USP<645>
Residue Moisture	USP<921>
Protein Assay by Sigma Test Kit	ASTM D5712
Atomic Absorption Calcium, Lead, Silver, Copper, Magnesium, Rubidium, Cobalt, Sodium, Potassium, Nickel, Iron, Zinc	Client Specified
Spectrophotometric Identification Tests by FTIR	USP<197> ASTM E1252

¹ All tests performed at 1279 Kennestone Circle, Marietta, GA 30066

Peter Meyer
Page 1 of 1