



The Leader in Combination Product Services



# Method References for WuXi AppTec's Microbiology, Chemistry and Package Testing

**VERSION DATE: May 2010**

*NOTE: Methods listed in this document are current as of the above date.  
Subsequent or more recent methodologies may be utilized as appropriate.*

# MICROBIOLOGY TESTING

Test Code	Test Name	Method Reference
<b>Antimicrobial Assays</b>		
110710	AATCC Method 100	AATCC Method 100
110720	AATCC Method 147	AATCC Method 147
110730	AATCC Method 174, Part 1	AATCC Method 174, Part 1
110740	AATCC Method 174, Part 2	AATCC Method 174, Part 2
110750	AATCC Method 174, Part 3	AATCC Method 174, Part 3
110700	AATCC Method 30, Part III	AATCC Method 30, Part III
110760	ASTM G21	ASTM G21
110775	ASTM E2180	ASTM E2180
110780	Dynamic Contact	ASTM E2149
110790	Kirby-Bauer Susceptibility	Manual of Clinical Microbiology
190655	JIS Z 2801	JIS Z 2801 and ISO 22196
190660	USP Antimicrobial Effectiveness - single organism	USP <51>
190665	USP Antimicrobial Effectiveness - 5 organisms	USP <51>
190661	USP Neutralization Validation	USP <1227>
<b>Bacterial Endotoxin (BET / LAL) Testing</b>		
130300	Gel Clot LAL Dilution Assay	USP <85>, 1987 FDA LAL Testing Guideline & AAMI ST 72
131100	Gel Clot LAL Limit Test - Finished Product Testing	USP <85>, 1987 FDA LAL Testing Guideline & AAMI ST 72
130400	Gel Clot LAL Liquid Test	USP <85>, 1987 FDA LAL Testing Guideline & AAMI ST 72
130200	Gel Clot LAL Test Validation	USP <85>, 1987 FDA LAL Testing Guideline & AAMI ST 72
130501	Kinetic Chromogenic LAL Limit Test - Finished Product Testing	USP <85>, 1987 FDA LAL Testing Guideline & AAMI ST 72
130601	Kinetic Chromogenic LAL Test Validation	USP <85>, 1987 FDA LAL Testing Guideline & AAMI ST 72
130701	Kinetic Chromogenic LAL - Liquid Test	USP <85>, 1987 FDA LAL Testing Guideline & AAMI ST 72
130800	Kinetic Test Kinetic Turbidimetric Limit Test – Finished Product Testing	USP <85>, 1987 FDA LAL Testing Guideline & AAMI ST 72
130801	Kinetic Turbidimetric Liquid Test	USP <85>, 1987 FDA LAL Testing Guideline & AAMI ST 72
130802	Kinetic Turbidimetric Test Validation	USP <85>, 1987 FDA LAL Testing Guideline & AAMI ST 72
<b>Bioburden Testing</b>		
1606000	Aerobic Bioburden	ISO 11737-1
1604000	Fungal Bioburden	ISO 11737-1
1605500	Spore Bioburden	ISO 11737-1
1605600	Anaerobic Bioburden	ISO 11737-1
1607000	Aerobic and Fungal Bioburden	ISO 11737-1
1608000	Aerobic and Spore Bioburden	ISO 11737-1
1603010	Aerobic Bioburden Panel - Aerobic / Fungi / Spore Count	ISO 11737-1
1607500	Aerobic / Fungi / Anaerobic Bioburden	ISO 11737-1
1604500	Aerobic / Spore / Anaerobic Bioburden	ISO 11737-1
1605000	Total Bioburden Panel - Aerobe / Fungi / Spore / Anaerobe Count	ISO 11737-1
1602000	Bioburden Recovery Validation - Inoculation Method	ISO 11737-1
1601000	Bioburden Method Validation - Repetitive Recovery - (5 total extractions)	ISO 11737-1
<b>Biological Indicator Testing</b>		
1201000	Biological Indicator Direct Transfer – Sterility Test	ANSI/AAMI/ISO 14161 and 11138 or Manufacturer's Instructions
120080	Biological Indicator – self contained	ANSI/AAMI/ISO 14161 and 11138 or Manufacturer's Instructions
190300	Biological Indicator – USP: Total Viable Spore Count (Composite of 3 BIs)	USP <55> and USP Official Monograph for Biological Indicators
120200	Biological Indicator - USP: Total Viable Spore Count (Single BI)	USP <55> and USP Official Monograph for Biological Indicators
1203000	Inoculated Biological Indicator (within product)	ANSI/AAMI/ISO 14161 and 11138 or Manufacturer's Instructions

# MICROBIOLOGY TESTING

Test Code	Test Name	Method Reference
<b>Environmental Testing</b>		
1701000	Environmental Air Sample Count	USP <1116> and ISO 14698-1
1702000	Environmental Surface Sample Count	USP <1116> and ISO 14698-1
107500	Water System – Coliform Count	Standard Methods for Water – Membrane Filtration Method
170506	Water System – Total Coliform & Pseudomonas Counts	Standard Methods for Water – Membrane Filtration Method
170507	Water System – Total Microbial, Coliform & Pseudomonas Counts	Standard Methods for Water – Membrane Filtration Method
170400	Water System Microbial Counts – 1 mL	Standard Methods for Water – Membrane Filtration Method and USP <1231>
170300	Water System Microbial Counts – 100 mL	Standard Methods for Water – Membrane Filtration Method and USP <1231>
107501	Water System Microbial Counts & Coliform Count	Standard Methods for Water – Membrane Filtration Method
<b>Inoculated Product Sterility Testing</b>		
1221010	Inoculated Product Sterility – Extra Small [<100 mL of media]	ISO 11737-2
1221000	Inoculated Product Sterility – Small [100 or 200 mL of media]	ISO 11737-2
1221210	Inoculated Product Sterility – Medium [300 or 400 mL of media]	ISO 11737-2
1221410	Inoculated Product Sterility – Large [500 or 600 mL of media]	ISO 11737-2
1221610	Inoculated Product Sterility – Extra Large [800 or 1000 mL of media]	ISO 11737-2
1221620	Inoculated Product Sterility – Jumbo [1200 or 1500 mL of media]	ISO 11737-2
1902000	Product Inoculation	Specified AAMI/ISO Standard
<b>Liquid Sterility Tests</b>		
190501	Liquid Sample Population Confirmation	USP <55> and USP Official Monograph for Biological Indicators
1222000	Liquid Sterility Tests - Direct Transfer	USP <71> and ISO 11737-2
1223000	Liquid Sterility Tests - Membrane Filtration – < 200 mL	USP <71> and ISO 11737-2
1225000	Liquid Sterility Tests - Membrane Filtration – 200 ml to 1000 mL	USP <71> and ISO 11737-2
1229100	Product Sterility, Membrane Filtration, Fluid Path – >100 mL	USP <71> and ISO 11737-2
1229500	Product Sterility, Fluid Path Fill – ≤ 200 mL	USP <71> and ISO 11737-2
1229600	Product Sterility, Fluid Path Fill – 300 to 700 mL	USP <71> and ISO 11737-2
1229650	Product Sterility, Fluid Path Fill – > 800 mL	USP <71> and ISO 11737-2
<b>Microbial Identification</b>		
190401	Bacterial / Microbial Identification	ABI 3130 Genetic Analyzer, RiboPrinter <sup>®</sup> , Vitek <sup>®</sup> 2 Compact System
190640	Colony Morphology (per plate)	General Diagnostic Microbiology References
190650	Fungal Identification	ABI 3130 Genetic Analyzer
190601	Gram Stain & Cell Morphology	General Diagnostic Microbiology References
190630	Gram Stain & Colony Morphology	General Diagnostic Microbiology References
<b>Microbial Examination Testing</b>		
161400	Microbial Enumeration Test (USP/EP)	USP <61> and EP 2.06.12
161401	Test for Specified Microorganisms (USP/EP)	USP <62> and EP 2.06.13
161402	Suitability of Counting Method for Microbial Enumeration (USP/EP)	USP <61> and EP 2.06.12
161403	Suitability of Test Method for Specified Microorganisms (USP/EP)	USP <62> and EP 2.06.13

MICROBIOLOGY TESTING CONTINUED NEXT PAGE

# MICROBIOLOGY TESTING

Test Code	Test Name	Method Reference
<b>Product Sterility Tests</b>		
400605	AAMI/ISO Method 2, Incremental Dose, Extra Small, 20 Samples	ISO 11737-2 and ISO 11137-2
400610	AAMI/ISO Method 2, Incremental Dose, Small, 20 Samples	ISO 11737-2 and ISO 11137-2
400615	AAMI/ISO Method 2, Incremental Dose, Medium, 20 Samples	ISO 11737-2 and ISO 11137-2
400620	AAMI/ISO Method 2, Incremental Dose, Large, 20 Samples	ISO 11737-2 and ISO 11137-2
400625	AAMI/ISO Method 2, Incremental Dose, Extra-Large, 20 Samples	ISO 11737-2 and ISO 11137-2
400631	Dose Calculation, AAMI/ISO Single Batch Method	ISO 11137-2
400632	Dose Calculation, VDmax Method	ISO 11137-2 and TIR 33
400630	Dose Calculation, AAMI/ISO Method 1	ISO 11137-2
400635	Dose Calculation, AAMI/ISO Method 2	ISO 11137-2
1228800	HIMA Pyronema Study (< 200mL of media) Sterility	HIMA "Screening Procedure for Pyronema," 1994
1228700	HIMA Pyronema Study (> 200mL of media) Sterility	HIMA "Screening Procedure for Pyronema," 1994
1220010	Product Sterility, USP – Extra Small [< 100 mL of media]	USP <71>
1220000	Product Sterility, USP – Small [100 or 200 mL of media]	USP <71>
1226000	Product Sterility, USP – Medium [300 or 400 mL of media]	USP <71>
1227000	Product Sterility, USP – Large [500 or 600 mL of media]	USP <71>
1228000	Product Sterility, USP – Extra Large [800 or 1000 mL of media]	USP <71>
1228010	Product Sterility, USP – Jumbo [1200 or 1500 mL of media]	USP <71>
1128010	Product Sterility, USP – Jumbo (2000 mL of media)	USP <71>
1103010	Product Test of Sterility – Verification / Dose Audit – Extra Small [< 100 mL of media]	ISO 11737-2, ISO 11137-2, and TIR33
1103000	Product Test of Sterility – Verification / Dose Audit – Small [100 or 200 mL of media]	ISO 11737-2, ISO 11137-2, and TIR33
1104000	Product Test of Sterility – Verification / Dose Audit – Medium [300 or 400 mL of media]	ISO 11737-2, ISO 11137-2, and TIR33
1105000	Product Test of Sterility – Verification / Dose Audit – Large [500 or 600 mL of media]	ISO 11737-2, ISO 11137-2, and TIR33
1106000	Product Test of Sterility – Verification / Dose Audit – Extra Large [800 or 1000 mL of media]	ISO 11737-2, ISO 11137-2, and TIR33
1106020	Product Test of Sterility – Verification / Dose Audit – Jumbo [1200 or 1500 mL of media]	ISO 11737-2, ISO 11137-2, and TIR33
1103020	Test of Sterility – Extra Small [< 100 mL of media]	ISO 11737-2
1103030	Test of Sterility – Small [100 or 200 mL of media]	ISO 11737-2
1104010	Test of Sterility – Medium [300 or 400 mL of media]	ISO 11737-2
1105010	Test of Sterility – Large [500 or 600 mL of media]	ISO 11737-2
1106010	Test of Sterility – Extra Large [800 or 1000 mL of media]	ISO 11737-2
1106030	Test of Sterility – Jumbo [1200 to 1500 mL of media]	ISO 11737-2
400645	USP Product Test, Fluid Path Fill	USP <71>
<b>Sterility Method Suitability Testing (B/F)</b>		
190410	Growth Promotion per Organism	USP <71>
190106	Sterility Method Suitability Test (B/F) – One Medium – Immersion	USP <71> and ISO 11737-2
190107	Sterility Method Suitability Test (B/F) – One Medium – Membrane Filtration	USP <71> and ISO 11737-2
190111	Sterility Method Suitability Test (B/F) – Per Organism, Per Medium – Immersion	USP <71> and ISO 11737-2
190112	Sterility Method Suitability Test (B/F) – Per Organism, Per Medium – Membrane Filtration	USP <71> and ISO 11737-2
190105	Sterility Method Suitability Test (B/F) – USP / Two Media – Immersion	USP <71>
190104	Sterility Method Suitability Test (B/F) – USP / Two Media – Membrane Filtration	USP <71>

## CHEMISTRY

Test Code	Test Name	Method Reference
400258	Absorbency Test, USP	USP Monograph
400100	Absorbent Gauze, USP	USP Monograph
400549	Ammonia – Identification/Assay	USP <191>, USP Monograph
400159	Atomic Absorption (AA) Analysis	EPA 7000, USP <851>
300111	Buffering Capacity	USP <661>
400550	Calcium and Nitrate – Identification/Assay	USP <191>
400434	Calcium (Residual)	EPA 7140, EPA 3010
400120	Chloride	Standard Methods 4500
400130	Conductivity	USP <645>
194990	ECH and EG Analysis	ISO 10993-7
195200	ECH Water Extraction	ISO 10993-7
195600	EO (Headspace Extraction) and EC (Water Extraction)	ISO 10993-7
195500	EO and ECH (Water Extraction)	ISO 10993-7
195210	EO Headspace Analysis	ISO 10993-7
194500	EO Residual Panel (Headspace Extraction) - EO, ECH and EG	ISO 10993-7
195000	EO Residual Panel (Water Extraction) - EO, ECH and EG	ISO 10993-7
195100	EO Water Analysis	ISO 10993-7
195250	EO Water Analysis - Exhaustive	ISO 10993-7
400170	Fourier Transform Infrared (FTIR) Scan	ASTM E1252, USP <197>
400150	Gas Chromatography	USP <621>
400160	Glutaraldehyde Residues	VICH GL25
400200	Heavy Metal Analysis - USP Method I	USP <231>
400210	Heavy Metal Analysis - USP Method II	USP <231>
400220	Heavy Metal Analysis - USP Method III	USP <231>
400547	Heavy Metals (Mn, Cu)	ASTM D1278
300140	Hydrogen Peroxide Determination	USP Monograph
400155	Impurities ID & Quantification	USP <191>
400501	Karl Fischer Water Titration	USP <921>
400546	KOH Number	ASTM 1076
400250	Melting Point	USP <741>
400499	Miscellaneous Chemistry	N/A
400315	Nitrates & Heavy Metals	EP Monograph, EP 2.4.8
300112	Nonvolatile Residue-Physicochemical Test	USP <661>
38110	Osmolality	USP <785>
300129	Oxidizable Substances	USP Monograph
400260	pH	USP <791>, ASTM E70
400270	Physicochemical Tests - Elastomeric Closures for Injections	USP <381>
400280	Physicochemical Tests - Plastics	USP <661>
400551	Potassium\KOH - Identification\Assay	USP <191>, USP Monograph
400290	Protein Assay	ASTM D5712
400300	Purified Water, USP (TOC, Conductivity)	USP Monograph
400310	Purified Water, USP (pH-Cond-TOC)	USP Monograph

CHEMISTRY TESTING CONTINUED NEXT PAGE

## CHEMISTRY

Test Code	Test Name	Method Reference
20661	Residual Moisture	USP <921>
400340	Residue on Ignition	USP <281>
400360	Total Organic Carbon (TOC)	USP <643>
400500	Total Solids	Standard Methods 2540
varies	Trace Metals	Standard Methods 3111, USP <851>
400490	Trace Metals - ICP Scan	EPA 200.7
400255	Turbidity	Standard Methods 2130
400510	UV/VIS Spectrophotometry	USP <851>
400540	Water For Injection, USP	USP Monograph
400548	Zinc Oxide – Identification/Assay	USP Monograph

## BIOLOGICS TESTING

Biologics testing is performed per USP and/or 21 CFR 610.12 or – as appropriate/applicable – per the same method references listed above for non-biologics samples.

## PACKAGE TESTING

Test Code	Test Name	Method Reference
38041	Package Validation	ISO 11607
<b>Accelerated Aging / Shelf Life / Expiration Dating Studies</b>		
38058	Accelerated Aging @ 37°C/year	ASTM F-1980
38035	Accelerated Aging @ 40°C/year	
38034	Accelerated Aging @ 55°C/year	
38036	Accelerated Aging @ 60°C/year	
38037	Accelerated Aging - Custom	
<b>Microbial Barrier Testing</b>		
38060	Microbial Ingress / Immersion Challenge	ASTM F-1608
38051	Whole Package Microbial Aerosol Challenge with Sterility Test	PDA Technical Report No. 27
38059	Whole Package Microbial Talc Challenge with Sterility Test	PDA Technical Information Bulletin No. 4
<b>Package Integrity and Strength Testing</b>		
30787	Visual Inspection	ASTM F-1886
30788	Preconditioning Cycle Prior to Aging	Custom
30807	Pressure Strength Test	Custom
38033	Bubble Emission Test	FPA / SPMC 005-98
38152	Bubble Emission – ASTM	ASTM F-2096
38039	Burst Strength	ASTM F-1140
38040	Creep Strength	ASTM F-1140
38038	Dye Penetration	ASTM F-1929
30714	Gurley Gas Permeation Test	ISO 5636/5
38062	Leak Test by Vacuum	ASTM D-4991, ASTM D-3078
38061	Peel Adhesion Strength (Tape)	ASTM D-3330
38030	Seal Adhesion Strength	ASTM F-88
38091	Liquid Dye Immersion	PDA Technical Report No. 27, ASTM E-165
<b>Transportation / Distribution Simulation Testing</b>		
30660	Environmental Conditioning	MIL STD 810E, ASTM D-4332
38052	Distribution Simulation Shipper Test	ASTM D-4169
30659	ISTA Environmental Conditioning	ISTA Test Series
38057	ISTA Transportation Simulation Test	ISTA Test Series
38053	Thermal Shock Testing	MIL STD 202F Method 107G
30779	Drop Testing	ASTM D-5276
38063	Compression Testing	ASTM D-642

WuXi AppTec is a global leader in providing fully integrated, discovery, development, testing, and manufacturing services for pharmaceuticals, biopharmaceuticals and devices/combination products. Research-driven and customer focused, with operations in China and the U.S., WuXi AppTec offers a broad portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

For devices/combination products, WuXi AppTec's ISO-certified, FDA-registered laboratories provide comprehensive testing and contract services. Testing programs are designed to ensure the success of regulatory submission and the continued quality/consistency required for commercialization. In addition to services that assure manufacturing, packaging, and sterilization is in accordance with GMP guidelines, we offer the entire range of relevant test modalities that study biological safety and biocompatibility, as well as combination product-specific testing, such as antimicrobial efficacy studies (both *in vitro* and *in vivo*). Contract services include cGMP processing/manufacturing for device, combination and tissue products.

**For more information on WuXi AppTec's services,  
please contact an Account Manager at  
(+1) 651-675-2000 • 888-794-0077  
or email  
info@wuxiapptec.com**



**www.wuxiapptec.com  
www.comboproducts.com**