



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

VERSION DATE: June 1, 2008

*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
Antimicrobial Assays		
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
110770	ASTM G22	ASTM G22
110775	ASTM E2180	ASTM E2180
110780	Dynamic Contact	ASTM E2149
110790	Kirby-Bauer Susceptibility	Manual of Clinical Microbiology
190660	USP Antimicrobial Effectiveness - single organism	USP <51>
190665	USP Antimicrobial Effectiveness - 5 organisms	USP <51>
190661	USP Neutralization Validation	USP <1227>
Bacterial Endotoxin (BET / LAL) Testing		
130300	Gel Clot LAL Dilution Assay	USP <85>
131100	Gel Clot LAL Limit Test - Finished Product Testing	USP <85>
130400	Gel Clot LAL Liquid Test	USP <85>
130200	Gel Clot LAL Test Validation	1987 FDA LAL Testing Guideline & AAMI ST 72
130501	Kinetic Chromogenic LAL Limit Test - Finished Product Testing	USP <85>
130601	Kinetic Chromogenic LAL Test Validation	1987 FDA LAL Testing Guideline & AAMI ST 72
130701	Kinetic Chromogenic LAL - Liquid Test	USP <85>
130800	Kinetic Test Kinetic Turbidimetric Limit Test – Finished Product Testing	USP <85>
130801	Kinetic Turbidimetric Liquid Test	USP <85>
130802	Kinetic Turbidimetric Test Validation	1987 FDA LAL Testing Guideline & AAMI ST 72
Bacteriostasis / Fungistasis Testing		
190111	Bacteriostasis/Fungistasis – per organism	USP <71> and ISO 11737-2
190106	Bacteriostasis/Fungistasis - SCDM / One Media / 3 organisms	USP <71> and ISO 11737-2
190105	Bacteriostasis/Fungistasis - USP / Two Media / 6 organisms	USP <71>
Bioburden Testing		
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

MICROBIOLOGY TESTING

Test Code	Test Name	Method Reference
Biological Indicator Testing		
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 Bls)	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
Environmental Testing		
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
170300	Water System Microbial Counts – 100 mL	Standard Methods for Water – Membrane Filtration Method
107501	Water System Microbial Counts & Coliform Count	Standard Methods for Water – Membrane Filtration Method
Inoculated Product Sterility Testing		
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	AAMI TIR 12 or Specified AAMI/ISO Standard
Liquid Sterility Tests		
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
Microbial Identification		
190401	Bacterial / Microbial Identification	Manufacturer's instructions
190640	Colony Morphology (per plate)	Bailey & Scott's Diagnostic Microbiology
190650	Fungal Identification	"Medically Important Fungi – A Guide to Identification and Atlas of Clinical Fungi" or subcontracted to approved vendor
190601	Gram Stain & Cell Morphology	Manual of Clinical Microbiology
190630	Gram Stain & Colony Morphology	Manual of Clinical Microbiology and Bailey & Scott's Diagnostic Microbiology
190410	Growth Promotion per Organism	USP <71>

MICROBIOLOGY TESTING CONTINUED NEXT PAGE

MICROBIOLOGY TESTING

Test Code	Test Name	Method Reference
Microbial Limit Testing		
161300	Microbial Limit Test USP - Confirmatory	USP <61>
161200	Microbial Limit Test USP - Preparatory	USP <61>
161201	Microbial Limit Test USP - Screening	USP <61>
Product Sterility Tests		
400605	AAMI/ISO Method 2, Incremental Dose, Extra Small, 20 Samples	ISO 11737
400610	AAMI/ISO Method 2, Incremental Dose, Small, 20 Samples	ISO 11737
400615	AAMI/ISO Method 2, Incremental Dose, Medium, 20 Samples	ISO 11737
400620	AAMI/ISO Method 2, Incremental Dose, Large, 20 Samples	ISO 11737
400625	AAMI/ISO Method 2, Incremental Dose, Extra-Large, 20 Samples	ISO 11737
400631	Dose Calculation, AAMI/ISO Single Batch Method	ISO 11137
400632	Dose Calculation, VDmax Method	ISO 11137
400630	Dose Calculation, AAMI/ISO Method 1	ISO 11137
400635	Dose Calculation, AAMI/ISO Method 2	ISO 11137
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
1103000	Product Test of Sterility – Verification / Dose Audit – Small [100 or 200 mL of media]	ISO 11737-2
1104000	Product Test of Sterility – Verification / Dose Audit – Medium [300 or 400 mL of media]	ISO 11737-2
1105000	Product Test of Sterility – Verification / Dose Audit – Large [500 or 600 mL of media]	ISO 11737-2
1106000	Product Test of Sterility – Verification / Dose Audit – Extra Large [800 or 1000 mL of media]	ISO 11737-2
1106020	Product Test of Sterility – Verification / Dose Audit – Jumbo [1200 or 1500 mL of media]	ISO 11737-2
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>

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>
300129	Oxidizable Substances	USP 24
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 24
20661	Residual Moisture	USP <921>
400340	Residue on Ignition	USP <281>

CHEMISTRY

Test Code	Test Name	Method Reference
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

All biologics testing is performed per USP and/or 21 CFR 610.12 or as the method references listed for non-biologics samples (USP, FDA, etc.).

PACKAGE TESTING

Test Code	Test Name	Method Reference
38041	Package Validation	ISO 11607
Accelerated Aging / Shelf Life / Expiration Dating Studies		
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	
Microbial Barrier Testing		
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
Package Integrity and Strength Testing		
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 D-1140
38040	Creep Strength	ASTM D-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 (Seal) Adhesion Strength	ASTM D-3330
38030	Seal Tensile Strength	ASTM F-88
Transportation / Distribution Simulation Testing		
30660	Environmental Conditioning	MIL STD 810E
38052	Distribution Simulation Shipper Test	ASTM D-4169, DC13 AL1
30659	ISTA Environmental Conditioning	ISTA Project 2A
38057	Shipper Simulation Test	ISTA Project 1A
38053	Thermal Shock Testing	MIL STD 202F Method 107G
30779	Drop Testing	ASTM D-5276
38063	Compression Testing	ASTM 642

WuXi AppTec is a global leader in providing fully integrated discovery, testing, and manufacturing services for the pharmaceutical, biologics and medical device industries. 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 the medical device/medical products industry, WuXi AppTec's ISO-certified, FDA-registered laboratories provide comprehensive biosafety 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. 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