



Micro Testing Equipment List

Category	Equipment / Technique	Types, Makes, Models	Comments (e.g. Applications)
Absence of Specified Organisms	USP\EP <61><62>Microbial Limits	Current USP	Can validate other methods as well
Antimicrobial Effectiveness / Preservative Efficacy	USP <51> and additional organisms	Current USP	
Bioassay	USP <81> Antibiotic potency assay	Protocol SR Plate Reader	Experience with Anitbiotic Dissolution Potency
Cleaning and Disinfectant studies	Surface Sample or Use Dilution		
Bioburden	USP <61> or specified method		
Endotoxins	Gel Clot		
Endotoxins	Kinetic Chromogenic	Charles River Endoscan	
Endotoxins	Kinetic Turbidimetric	Charles River Endoscan	
Sterility	Half Suit Isolator	Walker Barrier Systems	Complete Qualified under cGMP
Sterility	Steritest	Millipore	
Sterility	Membrane Filtration		
TAMC - Membrane Filtration	USP <61> or specified method	Pall Microfunnel system	
TAMC - Plate Count	USP <61> or specified method		
TYMC - Membrane Filtration	USP <61> or specified method	Pall Microfunnel system	
TYMC - Plate Count	USP <61> or specified method		
Container Closure Integrity	Dye Ingress Method	Pressure/Vacuum Vessel	
Media Growth Promotion	Per USP	All Organisms	
On-Site Environmental Monitoring	Cleanrooms and aseptic areas	MAS 100 air sampler	
On-Site Environmental Monitoring	Cleanrooms and aseptic areas	Particle counter	
Biological Indicator Testing	All indicators any type		
Environmental Monitoring Samples	Incubate and read plates		
Media Fill Support	Incubate and read vials		
Rapid Methods Development Support		Various	Assist in selection and development