

Combination Product Testing



HOW TO

Stay on the right regulatory paths to get from concept to commercialization



The Leader in Combination Product Services



Combination Product Testing Considerations



WuXi AppTec is the global leader in Combination Product Services (CPS) – unmatched in its ability to offer clients an alignment of expertise and long history of testing and manufacturing services for medical devices, tissue products, biologics and pharmaceuticals.

As convergence of these products accelerates, WuXi AppTec is uniquely positioned, with specialized programs and years of experience, to provide the services – and guidance – manufacturers require.

COMBINATION PRODUCTS			
	PHARMACEUTICALS	DEVICES	BIOLOGICS & TISSUE
	REGULATORY PATHS		
	<i>Including: IDE • NDA • IND • 510K • PMA • BLA • CE Mark</i>		
Product Characterization / Chemistry	Analytical	Extractable / Leachable	Bioanalytical
Efficacy / Performance	Clinical & Non Clinical - <i>In vitro</i> - <i>In vivo</i>	Clinical & Non Clinical - <i>In vitro</i> - <i>In vivo</i>	Clinical & Non Clinical - <i>In vitro</i> - <i>In vivo</i>
Safety	Toxicology	Biocompatibility	Biosafety
Microbial Contamination	Microbial limits/enumeration Microbial IDs Endotoxin	Bioburden Microbial IDs Endotoxin	Microbial enumeration/bioburden Microbial IDs Endotoxin Mycoplasma Bacterial clearance/inactivation
Sterility	USP sterility Sterile fill process validation	Sterilization process validation Product/BI sterility	Aseptic processing validation 21 CFR 610.12 sterility
Viral Contamination	<i>Not Applicable</i>	<i>Not Applicable</i>	Virus screening Viral clearance/inactivation
Package Characterization / Validation	Packaging material selection, microbial barrier, interaction	Packaging material selection, microbial barrier, interaction	Packaging material selection, microbial barrier, interaction
Package Integrity	Package integrity validation – shelf life / expiration / closure integrity / simulated distribution	Package integrity validation – accelerated aging / simulated distribution / seal integrity	Package integrity validation – shelf life / expiration / closure integrity / simulated distribution
Stability	Molecular stability	Aging / Expiration	Shelf life Forced degradation
Clinical	Scope / Design Study Management		
Compliance	Gap Analysis Risk Assessment Regulatory Submission		

NOTE: This chart is not an all-encompassing list of testing options and is not designed to serve as the outline for a specific testing program.

For more information on our services for combination products, please contact a WuXi AppTec Account Manager at + 1 (651) 675-2000 / (888) 794-0077 or info@wuxiapptec.com.
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