

Microbiology Services for Combination Products

Comprehensive Testing Programs Compliant With International Standards



At WuXi AppTec, we know the challenges you face in complying with the wide range of evolving microbial testing standards related to your combination product.

Well developed test plans and coordinated implementation are essential for addressing these regulatory challenges. With our unparalleled experience with combination products, WuXi AppTec can guide you in the development of your critical testing programs and provide you with a comprehensive menu of testing services to assure your combination product meets the requirements of all the industries it encompasses:

- medical device regulations
- biologics regulations
- pharmaceutical regulations

WuXi AppTec

Bio / Pharma Combo Products Medical Devices

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biotechnology and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

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Representative Case Studies: Combination Product Testing

While each combination product offers its own unique set of challenges, following are representative “case studies” that demonstrate how WuXi AppTec has developed and performed successful microbiology programs in support of regulatory submissions.

D = Device Component(s) B = Biologic Component(s) P = Pharmaceutical Component(s) F = Final Product

EXAMPLE 1

Aseptically packaged kit with device and biologic components (orthobio putty kit)

Development/Screening Phase

- D:
- Bioburden on spatula, mixing container and syringe (includes Microbial IDs)
 - Sterility screening of purchased saline solution
- B:
- USP Microbial Enumeration (Microbial Limits) of putty raw material
 - USP Test for Specified Microorganisms (Microbial Limits) of putty raw material
 - Bacterial Endotoxin screening for putty raw material

In-Process Phase

- D:
- Radiation sterilization validation of spatula, mixing container, syringe
 - Validation of aseptic fill of saline in syringe
- B:
- Validation of disinfection step for putty processing (bacterial/viral clearance)
- F:
- Validation of aseptic assembly of all components into kit

Finished Product Phase

- D:
- Quarterly radiation sterilization dose audits of device components
- F:
- 21 CFR 610.12 / USP Sterility test for batch release of kit
 - Bacterial Endotoxins test for batch release of kit

EXAMPLE 2

Terminally sterilized drug-coated device (antimicrobial-coated bone anchor)

Development/Screening Phase

- D:
- Bioburden of implant (includes Microbial IDs)
- P:
- Antimicrobial activity screening of antimicrobial raw material
 - Bacterial Endotoxins screening of antimicrobial raw material
 - *In vitro* biofilm assessment of simulated coated implant material

In-Process Phase

- D:
- Ethylene oxide sterilization validation of coated implant
 - Bioburden on coated implant
- P:
- Antimicrobial activity test for coated implant
 - *In vitro* biofilm test for coated implant

Finished Product Phase

- F:
- Bioindicator sterility test for release of each lot
 - Bacterial Endotoxins test for release of each lot

For more information on WuXi AppTec's services please contact:

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The Leader in Combination Product Services

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