

Package + Stability Testing for Combination Products

Package and stability concerns grow complicated when products include varying combinations of components and packaging materials. WuXi AppTec, as the leader in combination product services, not only offers a comprehensive menu of the required assays, but also provides the expertise to counsel clients in the design of their complex testing programs.

For more than a decade, WuXi AppTec has used a multi-disciplined approach to build customized programs that meet the needs of manufacturers, helping to navigate the complex and evolving regulations for combination products. Leveraging our unparalleled experience in device, tissue, biologics and pharmaceuticals, we offer guidance that initiates with your earliest package planning concepts and takes you to and beyond commercialization.



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.

WX
LISTED
NYSE

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 package and stability testing 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:* • Package design for tray configuration
 - Validation of sealer for tray
- B:* • Package design for putty vial
 - Closure integrity for putty vial
 - Forced degradation study for putty

In-Process Phase

- D:* • Package validation on final tray configuration (post sterilization)
 - Accelerated aging package validation on tray configuration
- B:* • Stability (shelf life) study initiated on putty in vial
- F:* • Simulated distribution study on shipper containing final packaged trays

Finished Product Phase

- B:* • Stability (shelf life) study completed on putty in vial
- F:* • Real time aging study on final packaged tray

EXAMPLE 2

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

Development/Screening Phase

- D:* • Package design for implant holder and pouch
 - Validation of pouch sealer
- P:* • Packaging design and characterization
 - Sealer validation

In-Process Phase

- D:* • Package validation on final pouch configuration (post sterilization)
 - Accelerated aging package validation on pouch configuration
 - Pouch packaging validation post distribution simulation
- P:* • Molecular stability study
- F:* • Simulated distribution study on shipper containing pouches

Finished Product Phase

- P:* • Real time stability study on sterilized product
- F:* • Real time aging study on final sterilized product in pouch

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

U.S.
+1 (651) 675 2000 • +1 (888) 794 0077
info@wuxiapptec.com

The Leader in Combination Product Services

www.wuxiapptec.com