

Lot Release and Raw Materials Testing



WuXi AppTec is a global leader in providing 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 and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

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Whether the product is medical device, biologic, cell therapy, tissue or combination, GMP requirements dictate that certain testing be conducted to confirm safety and consistency in the incoming raw materials and outgoing product. WuXi AppTec's expertise, years of experience, and uniquely broad menu of services provides manufacturers with a "single-source solution" to support their GMP quality assurance programs.

ASSAYS

WuXi AppTec offers a comprehensive menu of services, with the expertise to advise clients on testing options as well as to develop customized tests that meet special needs.

The following list demonstrates the broad range of assays available for lot release, raw materials testing, vendor qualification and/or process change validation. Some of these tests would be applicable only for certain product types.

TESTING PROGRAMS

Lot Release Testing

WuXi AppTec understands the critical need for timely lot release testing. For biologics, WuXi AppTec supports bulk harvest, bulk drug substance, and drug product testing. For medical devices, WuXi AppTec performs testing needed for final product lot release.

Raw Materials Testing

Periodic testing of incoming raw materials verifies their consistency and safety.

Vendor Qualification

Testing of vendor-supplied product helps ensure that materials are of consistent composition and quality.

Process Change Validation

Changes in the manufacturing process are validated to prove equivalency or comparable efficacy.

Additional services, including customized assays and testing for controlled environments, are available.

- Bacteriostasis/Fungistasis (Sterility Validation)
- Sterility
- Endotoxin Validation (I&E)
- Endotoxin / LAL / BET
- Rabbit Pyrogen
- Cytotoxicity
- Microbial IDs
- Microbial Limit
- Bioburden Recovery Validation
- Bioburden
- Virology
- Molecular Biology
- Mycoplasma
- Hemocompatibility
- Chemical / Physical and FTIR
- Residuals (EO, DNA, water)
- Product-Specific Analytical Assays
- Cell-Based Potency Assays
- Sterilization Cycle Studies and Validations
- Radiation Dose Studies and Audit Programs
- Osteoinductivity (in vitro and in vivo)

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

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

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www.wuxiapptec.com