

Analytical Services

WuXi AppTec provides a comprehensive range of analytical testing services to ensure product quality and consistency during all stages of pharmaceutical and biopharmaceutical development. For biotechnology-derived products as well as synthetic peptides and oligonucleotides, WuXi AppTec's testing services provide the analysis required to ensure product quality and consistency during Pre-IND; Phases I, II, and III clinical trials; and post-BLA/NDA stages of pharmaceutical development.

ANALYTICAL METHODS AVAILABLE:

• HPLC (SEC, RP and IEX) • SDS PAGE • Western Blotting • Flow Cytometry • Cell-Based Potency Assays • ELISA/Immunoassays • PCR and qPCR • FTIR • Karl Fischer Moisture Determination • Capillary Gel Electrophoresis (CGE) • IEF • UV Spectrophotometry • Osmolality • Amino Acid Analysis • Particulates

AVAILABLE SERVICES INCLUDE:

Lot Release (Bulk Drug Substance & Final Drug Product)

WuXi AppTec can develop or perform technology transfer from the Sponsor for the various analytical methods required for the following lot release program criteria:

- Purity
- Consistency
- Identity

Lot release assays can be verified, qualified or validated at WuXi AppTec and can be run under GMP or GLP conditions.

Detection and Estimation of Process-Related Impurities

Includes:

- Host Cell Protein and DNA (e.g., human, hamster, murine, e. coli, simian and canine)
- Protein A
- Antibiotics
- Insulin / Growth Factors

Reference Standard Characterization

A battery of regulatory-compliant tests needed to characterize primary and secondary reference standards are available, including methods for molecular weight and extinction coefficient determinations.

Product Stability

WuXi AppTec can perform the technical transfer, development and validation of stability-indicating assays including forced degradation studies on bulk drug substance (BDS) and final drug product (DP). WuXi AppTec maintains several ICH validated chambers at a variety of temperature and humidity settings.

Rees system data is collected and maintained at WuXi AppTec and all equipment is supplemented with both emergency electrical power and secondary data recording devices. Mapping of the chambers is performed every three years and calibration performed every year. Chambers are physically inspected once a day for temperature and humidity verification. Stability programs are conducted under GLP guidelines. Individual assays can be run under either GMP or GLP conditions.

Safety Tests

The necessary safety tests that are part of any lot release or stability program are also available from WuXi AppTec. Safety test methods include sterility, bioburden, endotoxin (LAL), as well as mycoplasma and virus detection assays. WuXi AppTec also maintains a state-of-the-art molecular biology laboratory for the detection of viruses, mycoplasma, host cell DNA, gene/construct copy number and genetic stability studies.

Bioanalysis of Preclinical / Clinical Samples

WuXi AppTec can perform high-throughput analysis for monoclonal antibodies, therapeutic proteins, gene therapy agents, transgene products, and immune response to the drug product in plasma samples from preclinical toxicokinetic studies or human clinical trials.

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

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