



BIOLOGICS SERVICES

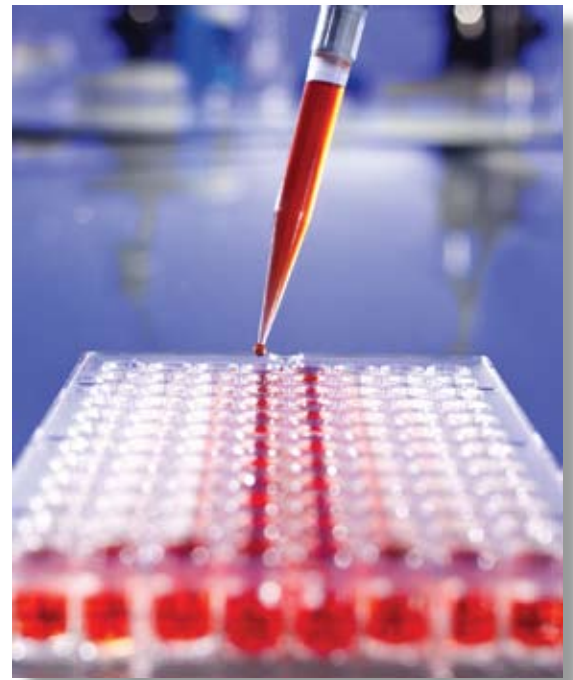
Product Characterization

**Extensive methodologies for accurately characterizing
your product and performing comparability assessments**

*ILLUSTRATION:
Model of protein structure*

 **药明康德**
WuXi AppTec

Product Characterization Services for Biologics



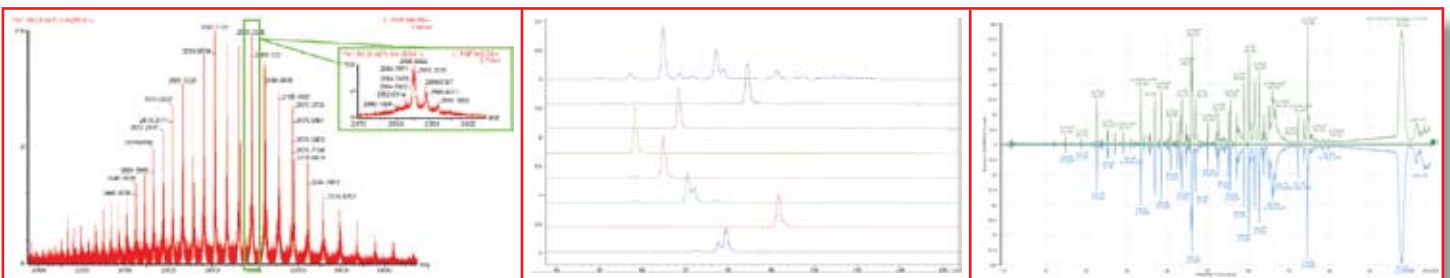
WuXi AppTec provides a comprehensive range of analytical testing services to characterize complex biological vaccines and therapies. Many of these assays can then be further developed and validated to measure product quality and consistency in lot release and stability testing programs.

Our testing services provide the high-quality analysis required throughout discovery, development, clinical trials, and commercialization. Assays can be transferred, developed, verified, qualified or validated at WuXi AppTec and can be run under R&D, GLP or GMP conditions. For custom assays, technology transfer protocols have been developed to efficiently move assays from your labs to WuXi AppTec.



Characterization expertise for a wide variety of therapeutics:

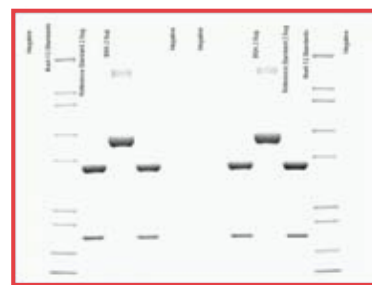
- Recombinant Proteins
- Monoclonal Antibodies
- Protein Subunit Vaccines
- Peptides
- Oligonucleotides/RNAi/Antisense Products
- Plasmid Gene Therapy or Naked DNA Vaccines
- Viral Vaccines and Gene Therapy
- Cell Therapy or Whole Cell Vaccines



Reference Standard Characterization

A battery of regulatory-compliant tests needed to characterize your product or reference standard are available, including methods for determination of molecular weight, peptide mapping, glycan composition and extinction coefficient determinations. Available methods include (but not limited to):

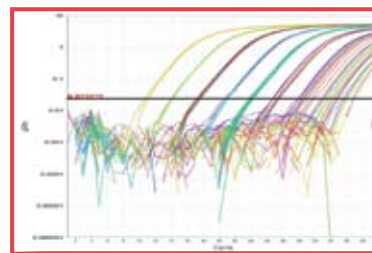
- SDS PAGE & IEF Gels
- Western Blotting
- Flow Cytometry / FACS
- ELISA / Immunoassays
- HPLC (SEC, RP, IEX)
 - Sialic Acid Content
 - Monosaccharide Composition
 - Amino Acid Analysis (AAA)
 - Extinction Coefficient Determination
 - Vitamin & Amino Acids Analysis in Spent Media
 - Antibiotics
 - Adenovirus Particle Number
- Mass Spectrometry (MS, MS/MS or LC/MS/MS)
 - Mw Determination
(includes assays for MAb intact, heavy & light chains)
 - Peptide Mapping and Sequencing
 - Di-Sulfide Bond Mapping
 - Methionine Oxidation Analysis
- HPAEC-PAD for N- & O-glycan Population Analysis
- Capillary Isoelectric Focusing (cIEF)
 - Protein Glycan Isoform Pattern
 - pI Determination
- Capillary Gel Electrophoresis (CE, CGE)
- DNA Sequencing
- PCR, qPCR and TD-PCR
- Total Protein by BCA, Coomassie, UV/VIS
- Biacore
- UV Spectrophotometry
- Circular Dichroism (CD)
- Surface Plasmon Resonance for Binding Affinity
- Micro-Flow Imaging (MFI) for Subvisible Particle Analysis
- Dynamic Light Scattering (DLS)
- FTIR
- Karl Fischer Moisture Determination
- Osmolality
- Particulates
- ICP and ICP MS
- GC and GC MS
- CDC and ADCC Potency Assays
- Custom cell-based potency assays utilizing *in-vitro* and *in-vivo* methodologies



PRODUCT COMPARABILITY

Whether evaluating production lots to a reference standard or performing comparability studies of biosimilars or biobetters, WuXi AppTec has the full-range of product characterization assays available to provide the detailed analysis required to pass scientific and world-wide regulatory standards.

DETECTION & ESTIMATION OF PROCESS-RELATED IMPURITIES



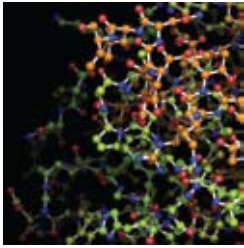
It may be necessary to fully characterize process-related contaminants or impurities in the bulk substance or final product. In addition to analytical characterization assays listed previously, available process residual analysis also includes:

- Protein A
- Detergents
- Antibiotics
- Growth Factors
- Insulin
- Host Cell Protein
- Media Components
- Host Cell DNA / DNA Sizing

SAFETY TESTS

The safety tests that are part of any product characterization program are also available from WuXi AppTec. Test methods include bioburden/microbial enumeration, sterility and endotoxin (LAL), as well as mycoplasma and virus detection assays. In addition, our state-of-the-art molecular biology laboratory offers virus and mycoplasma detection assays, gene/construct copy number, and genetic stability studies using PCR and DNA sequencing methodologies.





Product Characterization Services for Biologics

*WuXi AppTec provides services of exceptional quality,
utilizing more than 20 years' experience in the
analysis and testing of complex biological products.*

PROGRAM FEATURES & BENEFITS

- ▶ Industry-leading technical personnel experienced in a wide variety of analytical methodologies to ensure high-quality performance.
- ▶ Analytical laboratories established in multiple locations worldwide to serve your global product development needs.
- ▶ Extensive array of state-of-the-art equipment/instrumentation and a battery of developed and validated methods to provide a single-source for analytical characterization services.
- ▶ Comprehensive and regulatory-compliant quality systems for performing analysis GLP or GMP, assuring that WuXi AppTec meets worldwide regulatory scrutiny.
- ▶ Custom assay program with pre-established technology transfer protocols to speed your timelines to final result.
- ▶ Project management to oversee every step of your project – from initiation to final report delivery.

**Contact WuXi AppTec for product characterization services:
(1) 651-675-2000 / 888-794-0077 • info@wuxiapptec.com • www.wuxiapptec.com**