



Biopharmaceutical Services

Biospectroscopy | Biochromatography | Mass Spectrometry

Method Development & Validation

- Purity, Concentration, Identity, Impurities, Characterization
- Cleaning Validation Analysis (Specific & Non-specific Analysis)
- Residual Impurities Testing
- Extractables & Leachables

Characterization

- Post-Translational Modifications
- Peptide Mapping
- Amino Acid Analysis
- Charge Isoforms
- N- and O-Glycan Profiling
- Molecular Weight Determinations (Exact Mass)
- Aggregates
- Particulates
- Secondary Structure

Lot Release Testing

- Purity/Impurities
- Product Characterization
- Activity
- Identity
- Contaminants

Bioassay | Biosafety | Cell Banking

Molecular & Cell Biology

- Development, Transfer, Optimization and Validation of Cell-Based Potency Assays
- Development, Transfer, Optimization and Validation of ELISA-Based Assays
- qPCR Assays for Residual DNA, Viruses
- USP Cytotoxicity Testing
- Bioprocess Residual Analysis (DNA, HCP, Protein A)
- Rapid Mycoplasma

Cell Banking Services

- Preparation of Master & Working Mammalian and Insect Cell Banks
- Preparation of Production & Non-Production Banks

Residual Impurity Testing

- Antibiotics
- Surfactants, Antifoams
- Residual Solvents
- Extractables & Leachables
- Metals/Ions
- Process-Enhancing Agents

Stability

- Stability Testing
- Stability Storage
- Method Validation
- Protocol Development

Raw Materials

- Complete Compendial Analysis (USP, Ph.Eur, JP, BP, ACS, FCC)
- Pharmaceutical Water Testing (USP, Ph.Eur, BP, JP)
- Elemental Analysis (AA, GFAA, ICP/MS, ICP) Container/Closure Testing (USP, Ph.Eur)
- Amino Acid Analysis

Consulting Services

- Protocol Development and Writing for Method Validation, Method Transfer & Stability Protocol
- Regulatory Consulting

Microbiology

- Sterile Products
- Non-Sterile Products
- Facility Validation Support
- Organism Identification
- Sterility Testing
- Mycoplasma Testing
- Endotoxin Testing

Viral Safety

- Adventitious Virus Assays
- Retrovirus Assays
- Bovine & Porcine Viral Screens
- Infectivity Assays
- Full Master, Working & End-of-Production Cell Bank Characterization

Viral Clearance

- Dedicated Clearance Suites
- Validated Virus Stocks
- AKTA Chromatography Systems
- Validated Virus Titer Methods

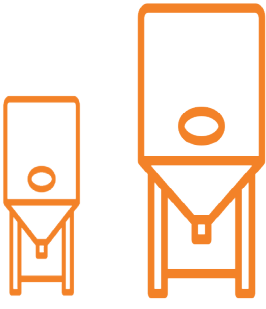
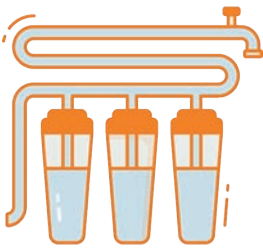

Facility Validation Support

- Cleaning Validations (viral, mycoplasma, microbial organisms)
- Disinfectant Efficacy Studies (viral, mycoplasma, microbial organisms)

Comprehensive Testing Services

- Raw Materials/Excipients, Culture Media, Cell Banks, Bioprocess Intermediates, Drug Substances, Drug Products, Packaging

Biopharmaceutical Manufacturing Process

	<i>Upstream (expansion & harvest)</i>		<i>Downstream (purification)</i>	
Biopharmaceutical Manufacturing Process	Cells	 80ltr tank 12,000ltr tank	 Purification	 Final Product
	Raw materials	Cells	Process Intermediates	Fill & Finish
	Media	Media	Purified Bulk	Formulated Bulk
Materials Tested	Buffer	Virus		Final Product
	Reagents	Unpurified Bulk		
Testing Capabilities	Cell bank Preparation & Testing (MCB & WCB) Cell Line Characterization Culture Media Testing Raw Materials Testing Environmental Monitoring Unpurified Bulk Lot Release Testing End of Production Cell Testing		Bioprocess Residuals Viral Clearance Extractables & Leachables Facility/Process Validation Environmental Monitoring	
			Clinical/Marketed QC Release & Stability Characterization Testing for Final Packaging Environmental Monitoring	

Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing
 Cell Banking Services • Virology Services • Facility & Process Validation
 Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology
 Stability Testing & Storage • Primary & Secondary Package Testing

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**BioPharma
Product Testing**