



## Technical Capabilities

At Blue Stream Laboratories, we provide a series of testing programs designed to support the development of both complex biopharmaceutical and small molecule drug products. Our systems are designed to function as an extension of your laboratory, offering our insight and skills to make your job easier and more productive, enhancing your program's success. We believe in providing solutions to your product development needs through program-based initiatives.

### PEPTIDE MAPPING (LC-MS & LC-MS/MS)

- *de novo* Amino Acid Sequencing and Sequence Verification
- Glycosylation Site Mapping
- Disulfide Bridge Mapping
- Post Translational Modification (PTM) Mapping: sulfation, phosphorylation, etc
- Degradation / Stability analysis including oxidation and deamidation
- Glycan Structural Characterization
- Chromatographic "Fingerprint Analysis"
- Stability / Impurity Characterization

### GLYCOSYLATION / GLYCAN CHARACTERIZATION

- Oligosaccharide Profile LC-MS
- Monosaccharide Analysis HPLC
- Quantitative Sialic Acid Determination
- Glycan Structural characterization / confirmation LC-MS/MS
- Glycan Occupancy Determination

### ELECTROPHORESIS LABORATORY

- Capillary Electrophoresis w/ LIF, UV/VIS
- SDS-PAGE - Reducing / Non-Reducing
- Isoelectric Focusing (IEF)
- IPG Strips (immobilized pH gradient)
- Densitometry
- Off Gel Fractionation
- Immuno / Western Blotting

### AGGREGATION AND OLIGOMERIZATION ANALYSIS

- Disulfide Bridge Mapping (LC-MS/MS)
- Analytical Ultracentrifugation (AUC)
- Circular Dichroism (CD)
- Differential Scanning Calorimetry (DSC)
- Size Exclusion Chromatography (SEC)
- Protein Aggregation via Coulter Principle (Multisizer)

### ACTIVITY / POTENCY ASSAYS

- ELISA
- Time Resolved Fluorescence
- Fluorescence Polarization
- Delphia Assay
- Colorimetric / Spectrophotometric
- Surface Plasmon Resonance – Biacore

discovery



## CHROMATOGRAPHIC SERVICES

- Peptide Mapping
- N & O-Linked Oligosaccharide Profiles
- Sialic Acid Quantification
- Monosaccharide Profile Analysis
- SEC - Size / Aggregation Analysis
- Purity, Identity, Quantitation methods
- Stability-Indicating Method Development
- Residuals / Degradation Analysis
- Separation Technologies: RPC, SEC, HIC, IEX, SAX, SCX, NP, WCX
- Detectors: UV, VIS, DAD, ELSD, PAD

## cGMP STABILITY PROGRAM MANAGEMENT

- ICH compliant : Q1A (R2)
- Temperature and humidity-controlled chambers
- -80°C, -20°C, 2-8°C, 25°C, 37°C, 40°C
- QA-audited process
- Alarmed Continuous Monitoring
- Trending of Results
- Method Development and Validation Support
- OOS Investigations

## N-TERMINAL SEQUENCING

- Automated Edman degradation
- De-Blocking of N-Terminus available
- Truncation / Multiple N-Terminus
- Sample Prep for Multiple-Subunit Sequencing

## AMINO ACID ANALYSIS (AAA)

- Extinction Coefficient Determination
- Vaccine Quantification
- Mole Percent Amino Acid Analysis
- Timed Hydrolysis Studies
- Gamma Carboxyglutamic Acid (GLA)
- Tryptophan – Determinations Available

## SPECTROSCOPY

- UV/VIS
- Time-Resolved Fluorescence
- Fluorescence Polarization
- Diode Array



## UPGRADED CAPILLARY ELECTROPHORESIS SERVICES

- Beckman ProteomeLab PA 800 System
- Multiple Detectors for various applications including Laser Induced Fluorescence (LIF)
- Method Development and Qualification services for product-specific cGMP program support
- Multiple platforms for R&D and product development support
- Oligosaccharide Analysis via CE coming soon!

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