

Service Programs

At Blue Stream Laboratories, we provide a series of comprehensive testing programs designed to support the development of both biopharmaceutical and small molecule drug products. Our systems are designed so that we may function as an extension of your laboratory, offering our insight and skills to make your job easier and more productive, thereby enhancing your program's success.

We believe in providing solutions to your product development needs through program-based initiatives. While a single assay or methodology may, at times, be the right answer, more commonly the best solution is constructed through a more comprehensive approach.

PROTEIN/PEPTIDE CHARACTERIZATION

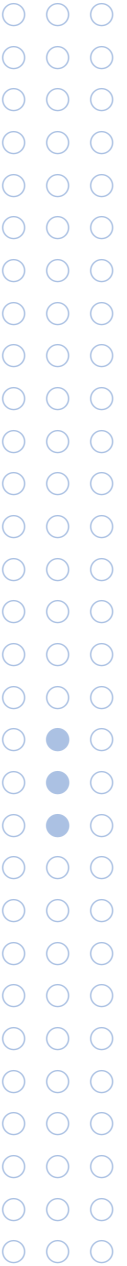
We have the necessary technologies, instrumentation, and expertise to fully support the characterization of protein and peptide products. Technological platforms for product characterization include the following:

- Mass Spectrometry for protein/peptide primary structure analysis/confirmation
 - Full or Partial Sequence Support
 - Glycosylation Profiling and Mapping
 - Disulfide Bridging Determination and Mapping
- Mass Spectrometry for analysis of protein Post Translational Modification including glycosylation, sulfation, phosphorylation
- Various modes of spectrometry for protein secondary structure analysis
- Automated Edman degradation for N-terminal sequence analysis
- HPLC/MS in combination with enzymatic digestion and fluorescence detection for oligosaccharide profiling and quantitation of sialylation
 - Oligosaccharide Analysis
 - Monosaccharide Analysis
 - Sialic Acid Determination
 - Glycan Structural characterization/confirmation
- Peptide Mapping
 - Lot comparison “Fingerprint Analysis”
 - Complete fragment sequence support
- SDS-PAGE, IEF and 2-D gel electrophoresis coupled with Densitometry
- Immunoblotting
- Amino acid analysis and determination of extinction coefficient
- SEC-HPLC for aggregation and oligomerization analysis
- RP-HPLC for purity and impurity analysis
- Immunoassays for protein/peptide quantification and residual contaminant analysis
- *In-vitro* biological assay for potency determination

PROCESS EQUIVALENCY

We provide in-depth support when conducting process equivalency studies. These capabilities are comprised of the following:

- Peptide mapping by HPLC with in-line mass spectrometry for primary structure and side chain modification comparison
- UV-Vis, fluorescence, and FTIR spectroscopies for comparison of secondary structural features
- Chromatography and immuno techniques for analysis of purity and impurities
- Size exclusion chromatography for comparison of oligomeric structures and levels of aggregation
- Carbohydrate Profile Comparison with or without MS confirmation
 - Oligosaccharide Analysis
 - Monosaccharide Analysis
 - Sialic Acid Determination
- *In-vitro* biological and immunological assays for potency evaluation
- IEF Gel Electrophoresis coupled with Densitometry



STABILITY

Blue Stream provides ICH compliant stability services. The available storage chambers accommodate a number of storage conditions and product packaging formats. We can design or assist in the design, set-up, and management of stability programs, and prepare study protocols based on industry standards or specific client needs.

The execution of stability programs at Blue Stream is based on systematic and thorough record keeping, protocol-directed handling of materials, storage and then disposition. Besides performing the required testing at the appropriate time points, we can conduct trend and statistical analysis of the data, as appropriate, in order to assist the client in establishing product expiry/shelf-life. At the end of each study, Blue Stream will issue a QA Audited Stability Program Final Report.

LIPOSOMAL PRODUCT SUPPORT SERVICES

Blue Stream has extensive capabilities to support characterization, release testing and stability assessment of liposomal-based products.

- Liposome analysis for identity, purity and quantitation of the lipid components
- Analysis for identity, purity and quantitation of the liposomal active pharmaceutical ingredient(s)
- Liposome size distribution analysis
- Liposomal encapsulation efficiency

FORMULATION DEVELOPMENT AND SUPPORT

Our technical expertise allows us to offer formulation development and formulation improvement services. We utilize a combination of high through-put screening approaches, along with spectroscopic analyses and phase diagrams to screen for excipients and conditions such as pH, ionic strength, temperature, etc., and, thus, identify optimal formulations that can lead to improved storage temperatures and longer product shelf-life.

SMALL MOLECULE CHARACTERIZATION AND LOT-RELEASE TESTING

- Analysis for identity, purity and quantitation of the active pharmaceutical ingredient(s) via HPLC
- Identity testing via FTIR-IR and MS
- Residuals determination
- Stability Program Management

RAW MATERIALS AND PROCESS/ MANUFACTURING SUPPORT

- Raw Material Identity and Purity Determination via HPLC, Mass Spectrometry, or FTIR
- Impurity/Residuals Determination via HPLC or GC
- Cleaning Validation Support Programs

QUALITY ASSURANCE AND REGULATORY COMPLIANCE

Essential to the provision of compliant services is a comprehensive understanding of the evolving regulatory environment and in-house systems that assure compliance with governing regulatory rules and regulations. We understand the agencies' requirements, and our systems are designed to provide a testing environment that will satisfy our clients' phase-specific quality compliance demands.

Our commitment to compliance is as integral to our success, and that of our clients, as our commitment to innovative science.

INTERNAL QUALIFICATION/ CALIBRATION PROGRAM

We've established robust programs to ensure proper and consistent instrument and equipment functionality and performance. HPLCs, spectrometers, plate readers, storage units and other equipment are qualified prior to their introduction into laboratory operations. In addition to the initial qualification, Blue Stream Laboratories conducts annual performance verification and periodic calibration, which can range from daily to quarterly calibration depending on the instrument/equipment.

BLUE STREAM LABORATORIES
10N ROESSLER ROAD
WOBURN, MA 01801

T: 781.932.8400
F: 781.932.8600
www.bluestreamlabs.com