



BIOLOGICS TESTING SOLUTIONS

Protein Chemistry and Analytical Services

Analytical Services

- Mass spectrometry
- Biophysical characterization
- Glycosylation/Glycan characterization
- Chromatography & electrophoretic methods
- N-terminal sequencing and amino acid analysis
- ELISA and immunoassay development
- Potency assays

To help clients generate the data needed to gain the level of product characterization required for regulatory submission, Charles River offers protein analysis as part of an integrated package of expert analytical services. We have extensive experience in developing and establishing protein characterization methods, including product-specific *in vitro* potency assays. These characterization services are also a part of our stability and product release support services, where we offer key identity, purity and potency assays.

Analytical Experience

Our skilled analytical chemistry staff has worked with a broad spectrum of molecules including small molecules, peptides, lipids, proteins, glycoproteins and protein conjugates. We offer services ranging from method development and validation to process/cleaning validation and sample analysis as well as drug substance, finished product and impurity analysis. In addition, we perform International Conference on Harmonisation (ICH) and custom stability testing for drug substances and finished products for both clinical supplies and marketed products.

Advanced Analytical Techniques

According to current regulatory guidelines, extensive analysis of a molecule is necessary to establish a well-characterized biologic or to demonstrate comparability between a biosimilar and the reference product. Due to these regulatory requirements, protein characterization and analytical testing play a critical role in the process development and manufacturing of biopharmaceuticals. As biopharmaceuticals are often complex molecules, regulatory authorities recommend a number of orthogonal analytical procedures. However, no one battery of tests fits all proteins, and the selection of specific assays for analyzing a particular protein will depend on the nature of the protein in question. Testing of the drug substance is complemented by quantification of excipients and physicochemical testing appropriate to the drug product presentation.

EVERY STEP OF THE WAY

Analytical Capabilities

The breadth of Charles River's analytical capabilities allows us to tailor a characterization plan to suit the needs of each of our client's products. The methods below, combined with our extensive portfolio of assays for biologics development, provide a complete approach that allows clients to partner with Charles River throughout the entire development process.

Available Methods			
Mass Spectrometry	Biophysical Characterization	Chromatography/ Electrophoresis/Sequencing	Other Techniques
Peptide mapping	Dynamic light scattering	RP-HPLC, IEC, HIC	Spectrophotometric assays
Intact molecular weight determination	Differential scanning calorimetry	Capillary zone electrophoresis	Visible/Subvisible particulates
Post translational modification analysis	Analytical ultracentrifugation	IEF and cIEF	Water determination
Disulfide bridge mapping	Circular dichroism	SDS-PAGE and CE-SDS	Osmolality
Amino acid sequencing	SPR via Biacore	Western blot	Optical rotation
N- & O-linked oligosaccharide profiling	Intrinsic tryptophan fluorescence	Residuals and impurities analysis	Head space analysis
Glycosylation site mapping	Extrinsic fluorescence	Degradant analysis	Total protein
		Sialic acid quantification	Free thiols
		Monosaccharide profile analysis	Protein sequencing