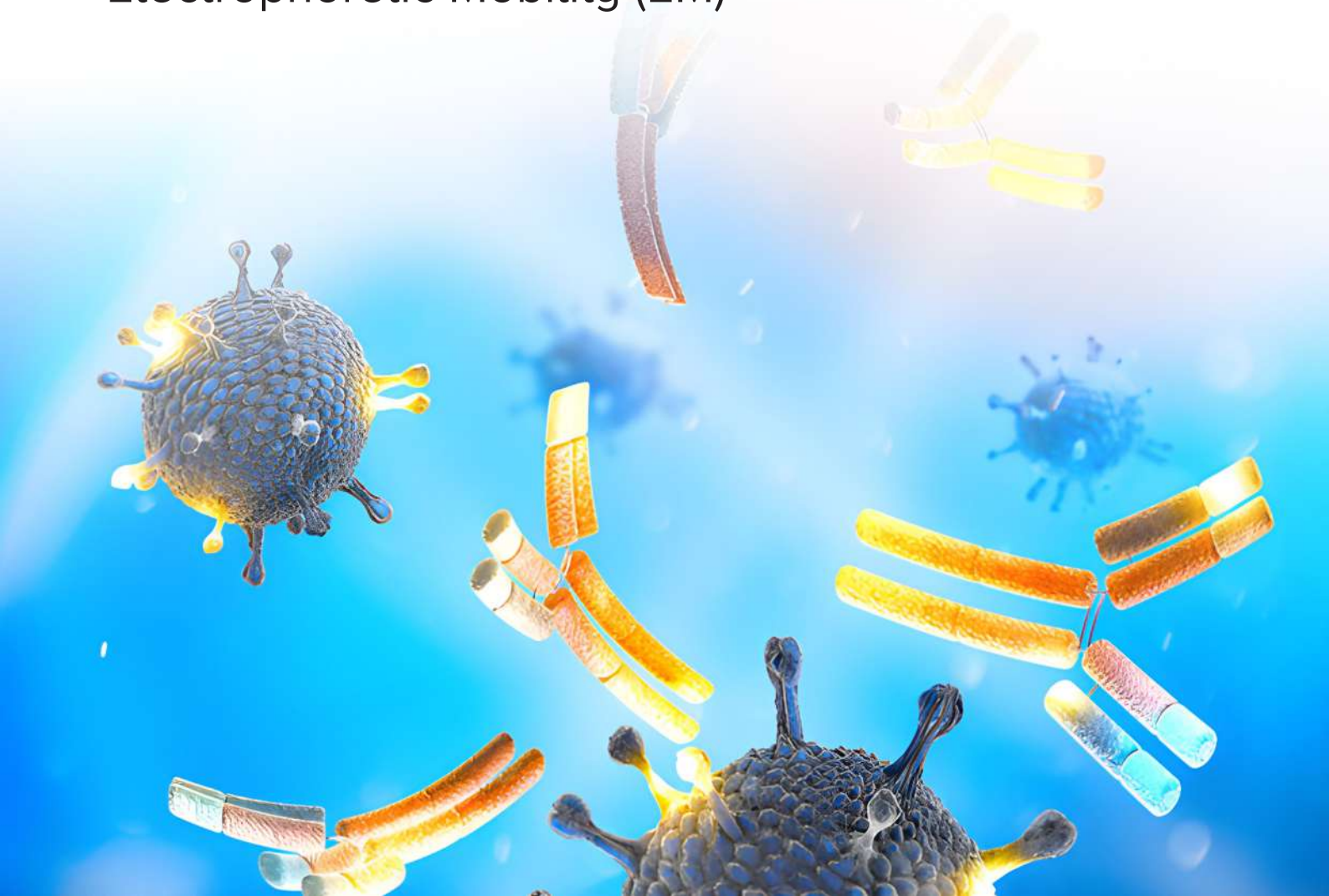
heads

veeda clinical research®

BIONEEDS

Molecular Characterization of Biopharmaceuticals

High Resolution Mass Spectrometry (HRMS), Liquid Chromatography (LC), Electrophoretic Mobility (EM)



Importance of Physico-chemical Characterization

This scientific briefing underscores the importance of Physico-chemical techniques in characterizing biopharmaceuticals for drug development. Biopharmaceuticals, including proteins, antibodies, vaccines, and nucleic acid-based drugs, have transformed disease treatment but require precise analysis due to their complex nature. Physico-chemical characterization involves examining physical and chemical properties to ensure safety, efficacy, and consistency. Understanding their characteristics at various levels, such as primary structure, is essential for quality control and optimization of these therapeutic agents.

Glimpse of Analytical Prowess in Physico-chemical Characterization

High-Resolution Mass Spectrometry (HRMS):

Biotherapeutics Characterization: HRMS is crucial for characterizing proteins, peptides, oligos, biopolymers, conjugated & fusion proteins. It helps in determining the molecular weight, peptide & disulfide mapping, release glycans, post-translational modifications, & overall structural integrity of proteins.

Liquid Chromatography (LC):

Peptide and Protein Separation: LC is extensively used for the separation of peptides and proteins in complex mixtures. Reversed-phase LC is commonly employed in the analysis of biopharmaceuticals.

Drug Formulation Studies: LC is utilized for studying drug formulations and assessing the stability of biopharmaceuticals under various conditions.

Impurity Analysis: LC is employed for detecting and quantifying impurities in biopharmaceuticals, ensuring product quality and safety.

Capillary Electrophoresis (CE):

Protein Analysis: CE is employed for the separation and analysis of proteins based on their charge and size. It is particularly useful for the analysis of monoclonal antibodies and other protein-based therapeutics.

Impurity Detection: CE is sensitive to impurities and can be used for impurity detection in biopharmaceuticals.

Isomer Separation: CE can be used for separating protein isoforms and analyzing their individual properties.

Gel Electrophoresis:

Protein Size and Purity: Gel electrophoresis, including sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE) and agarose gel electrophoresis, is commonly used to determine the size and purity of proteins.

Western Blotting: Gel electrophoresis is an integral part of Western blotting, a technique used to detect specific proteins in a sample.

Nucleic Acid Analysis: Gel electrophoresis is also used for the separation and analysis of nucleic acids, such as DNA and RNA.

Role of High Resolution Mass Spectrometry in Biopharma:

High-resolution mass spectrometry (HRMS) is a powerful analytical technique widely employed in the characterization of biopharmaceuticals. It enables precise measurement of the mass-to-charge ratio (m/z) of ions with high accuracy and resolution. HRMS is particularly valuable in the analysis of large and complex biopharmaceutical molecules, such as proteins, peptides, and monoclonal antibodies. Here are some key applications and advantages of using high-resolution mass spectrometry for biopharmaceutical analysis:

- Amino Acid Sequence Confirmation
- Post-Translational Modification (PTM) Identification
- Intact Protein Mass Measurement
- Subunit Analysis
- Disulfide Bond Analysis
- Charge Variant Analysis
- Intact Mass Mapping for Monoclonal Antibodies
- Quantitative Analysis
- De Novo Sequencing
- Detection of Low Abundance Species

Liquid Chromatography for Process and Product Variants:

Liquid chromatography (LC) is a versatile analytical technique widely used in the biopharmaceutical industry for the analysis of process and product variants. It offers high-resolution separation of complex mixtures, making it instrumental in characterizing the various components of biopharmaceuticals. Here's an overview of how liquid chromatography is employed for the assessment of process and product variants in the biopharmaceutical context:

- Ion-Exchange Chromatography (IEX)
- Size-Exclusion Chromatography (SEC)
- Hydrophobic Interaction Chromatography (HIC)
- Hydrophilic Interaction Chromatography (HILIC)
- Multi-Dimensional Chromatography
- High-Performance Liquid Chromatography (HPLC) and Ultra-High-Performance Liquid Chromatography (UHPLC)
- Two-Dimensional Liquid Chromatography (2D-LC)
- Liquid Chromatography-Mass Spectrometry (LC-MS)
- Method Development and Validation

Electrophoretic Mobility: Capillary Electrophoresis for Molecular Heterogeneity:

Capillary electrophoresis (CE) is a powerful analytical technique used in biochemistry, molecular biology, and chemistry for separating and analyzing different molecules based on their electrophoretic mobility in a capillary filled with an electrolyte solution. When it comes to studying molecular heterogeneity, capillary electrophoresis offers several advantages:

- High Resolution
- Sensitivity
- Speed
- Automation and Miniaturization
- Applicability to Various Analytes
- Quantitative Analysis
- Derivatization Techniques

Researchers often use capillary electrophoresis in combination with various detection methods, such as fluorescence, absorbance, or mass spectrometry, to gain insights into the molecular heterogeneity of samples. Overall, capillary electrophoresis is a versatile and powerful technique that contributes significantly to the understanding of molecular diversity in biological and chemical systems.

The PA 800 Plus system is a robust analytical, kit-based platform that can help you with:

Monoclonal antibody and next-generation protein applications:

- Purity/Heterogeneity with gold standard CE-SDS in minutes
- Glycan analysis with award-winning Fast Glycan technology
- Charge heterogeneity with fast and simple CZE or with hi-res cIEF

Gene therapy and nucleic acid applications

- mRNA purity and integrity analysis
- Capsid protein purity
- AAV Empty vs. Full
- Plasmid and linear double-stranded DNA (dsDNA) analysis
- Small RNA or DNA analysis
- Cell therapy

ZipChip for High Throughput Analyses of Charge Variant, Intact and Native Mass of Antibody, Peptides, Metabolites and Oligonucleotides:

ZipChip is a microfluidic separation platform developed by 908 Devices for high-throughput analyses, including charge variant analysis, intact mass analysis of antibodies, peptide analysis, metabolite analysis, and oligonucleotide analysis. Here are some key aspects of its applications :

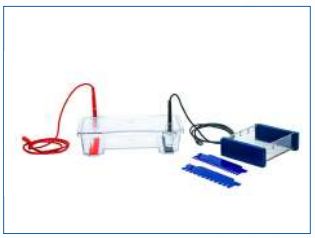
- Charge Variants
- Peptides
- Metabolites
- Native Antibody
- Intact Antibodies
- Oligonucleotides

State-of-the-art Infrastructure for Molecular Characterization Solutions

Technology

Xevo G3 QTof
Mass Spectrometer

QExactive
Mass Spectrometer



Gel Electrophoresis
System (1D and 2D)

Prominence i-Series
Liquid Chromatography

PA800 Plus
Capillary Electrophoresis

ZipChip
Micro CE-MS

Informatics Platforms

Waters_connect

Biopharma finder

32karat

Veeda Clinical Research Limited
(Biopharma Division)

No. P3-A, 1st Main Road, Peenya Industrial Area,
1st Stage Bengaluru 560058, India
info@veedacr.com | www.veedacr.com | +91 7967773000

• Partners in creating a healthier tomorrow •