Protein and Peptide Characterization
in Biopharmaceuticals

Molecular Weight Analysis (MALDI–TOF, LC–MS)
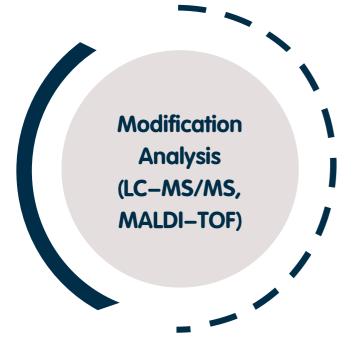
Molecular mass determination achieves precise molecular weights for protein/peptide drugs. Common protein drugs include antibodies (intact, deglycosylated, or reduced MW can be measured), growth factors, etc.; Common peptide drugs include insulin, cabergoline, terlipressin, etc.
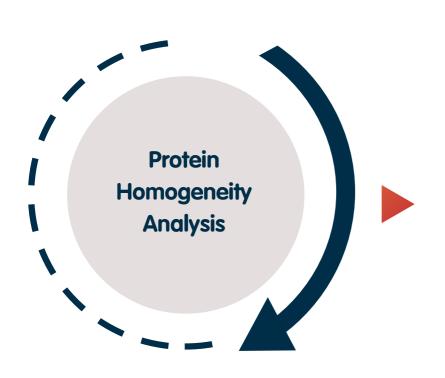
Peptide Mapping Analysis (LC–MS/MS)

Peptide profiling of protein/peptide drug molecules is a key element of drug quality control, which is important for theo–retical sequence confirmation, advanced structural analysis, and biological function study.

Peptide profiling can confirm the theoretical sequence and modification of protein/peptide.

1) Protein sequence confirmation: visualize theoretical se–quences matching with different abundance, peptide cov–erage of conventional protein samples can reach up to 100%

2) Peptide mapping analysis: provides all information on amino acid sequences.

3) N/C–terminal amino acid sequence: provides N/C termi–nal amino acid sequence information

Modification Analysis (LC–MS/MS, MALDI–TOF)

1) Glycopeptidomics analysis

2) N– or O–glycan profiling

3) Sialic acid analysis

4) Difulfide bond localization

5) Other PTMs: methylation, acetylation, phosphorylation, oxidation, etc.

Protein Homogeneity Analysis

1) Protein aggregation analysis (SEC–HPLC): protein drugs aggregate to form polymers easily. The formation of polymers may reduce the overall drug activity and en–hances side effects; thus , controlling polymer content in the final product is significant.

2) Charge state analysis (isoelectric focusing, WCX–HPLC): the occurrence of post–translational modi–fications may lead to changes in charged states and isoelectric points with protein drugs.

In line with the ICH Q6B Guidance, Creative Proteomics offers protein analysis and charac–terization services, including structure analysis, physicochemical properties, biological activi–ty, immunochemical properties, as well as purity and impurity determination to ensure the quality and consistency of your products.

Contact Us

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