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Strategic considerations for LC-MS analysis of large biological therapeutics

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During recent years, a sudden rise in interest for biosimilar molecules by large pharmaceuticals has been evident due to two major factors i.e., larger application of biosimilars strategy to control escalating health-care cost and impending expiration of patents of popular blockbusters. Analytical strategy adopted for these molecules, widely differs from that of small molecules, due to inherent variations in living systems involved during manufacturing process and large size of biomolecules. Considering these facts, regulators have also emphasized multidimensional (structural, cellular potency and similar clinical efficacy) approach for their market approvals.Analytical strategy adopted for qualification and quantitation of P-38 (Mol. Wt. 44 kDa) and mAb (Mol.Wt. 141 kDa) molecules, demonstrate a systematic approach towards such applications. Qualitative analysis included BioConfirm set-up and acquisition of Q1 spectrum for molecules. Mol. Wt. was confirmed through deconvoluted spectrum approach and had a good agreement with theoretical reference. Phosphogluconoylation (for P-38) and glycans presence (for mAb) were manifested in decisions for quantitation strategy.Selection of multiple qualifier ions (m/z 3156.6988 and 2736.0254) for single quantifier ion (m/z 3087.5633) was adopted for establishing linearity from 15 to 300 nanogram for P-38 (top-down approach). To demonstrate bottom-up approach; mAb was digested with LysC enzyme and extracts were analyzed to establish a linearity for range of 1 to 4000 microgram range using four quantifier ions (m/z 495.7553, 481.7634, 321.5115 and 288.1718). Above strategy provides a clear rational approach for discovery researches to begin and implement analytical instrumentation approach towards large biological therapeutics quantitation.

Biography

Kuldeep Sharma has over 12 years of experience in bioanalytical, regulatory compliance and drug discovery domains with zeal to learn and grow better. His primary responsibility includes management and strategic positioning of bioanalytical and PK group to build a strong & productive team at research area to support drug development research and ensure departmental compliance with GLP and relevant quality standards, preclinical studies (i.e., pharmacokinetics and toxicokinetics studies on animals, *in-vitro* assays, tissue distribution and *in vitro* and *in vivo* metabolic profiling) and clinical studies.

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