

ADVANCED ANALYTICS TO ENABLE DEVELOPMENT OF BIOLOGIC-BIOLOGIC COMBINATION THERAPY

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Biologic combination therapy is emerging and fast growing in biopharmaceutical industry. Co-formulation of two or more biologics can provide benefits such as reduction in medication errors and convenience to patients. It does increase complexity to characterization and control strategy development due to similar physiochemical properties and/or vastly different ratio between individual components. Here we present a case study of co-formulated monoclonal antibodies at a fixed ratio, where one of the components is predominant. Characterization and monitor of product variants in the minor component in the mixture are very challenging for conventional methods. A new QC friendly mass spectrometry based analytics has been successfully developed and utilized to quantitatively measure specific CQA of the minor component in the co-formulated biological combination mixtures. Presentation includes systematic characterization, CQA identification and risk assessment in analytical development. Challenges encountered during development of new analytics will also be discussed.