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Application of HPLC techniques to biological products

Biological products are gaining importance in recent times. However, the product development process is way too complex compared to small molecules. The key processes involved in biological products, in general, are – manufacturing of active raw materials, purification, formulation, dosage form manufacturing, and analysis. One has to also make sure that the biological activity is retained throughout the life of the biological product. The critical quality attributes for the biological products include physical, chemical, biological and microbiological properties. The key problem is the micro-heterogeneity. HPLC techniques – Size Exclusion Chromatography, Ion Exchange Chromatography and Hydrophobic Interaction Chromatography, were used to analyze an antibody, which provided insight into the molecular weight, charge, purity, activity, and primary/secondary and tertiary structures. The assays were used to determine degradation products under various stability conditions. The presentation would demonstrate the complexity of analyses needed for the biological products.

Biography

Hemant N Joshi completed his PhD in Pharmaceutical Chemistry from the University of Kansas and MBA in International Business from Fairleigh Dickinson University. He worked in several companies as a Formulation Scientist including Glaxo (India) Ltd., Bristol-Myers Squibb, Forest Labs, Barr Labs and Spectrum Pharmaceuticals. He is the Founder of Tara Innovations LLC – a Contract Research Organization involved in product and analytical method development.

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