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Significance of stability and temperature excursion studies for biosimilars

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To ensure product safety and efficacy, protein therapeutics must meet defined quality characteristics after manufacture as well at the end of their designated shelf lives. Many physical and chemical factors can affect the quality and stability of biopharmaceutical products, particularly after long-term storage in a container-closure system likely to be subject to variations in temperature, light, and agitation with shipping and handling. Compared with traditional chemical pharmaceuticals, proteins are considerably larger molecular entities with inherent physiochemical complexities.

Proteins are typically sensitive to slight changes in solution chemistry. They remain compositionally and conformationally stable only within a relatively narrow range of pH and osmolarity, and many require additionally supportive formulation components to remain in solution, particularly over time. Even lyophilized protein products experience degradation.

Advances in analytical chemistry have identified many degradation pathways that can occur in recombinant protein therapeutics over time. These pathways generate either chemical or physical instability.

Biography

Rajiv Dua is currently Analytical and Stability coordinator, at Lupin Ltd (Biotech division), India. He is responsible for designing and conducting stability studies involved in multiple projects, coordinating in exploratory and comparative studies. He holds Masters in Biochemistry and B.Sc. (Chemistry major) from University of Pune, India, as well as, holds Post Graduate Diplomas in Operations and Hospital/Healthcare Management. He has over 5 years of experience in biosimilar industry. His professional life started with Intas Biopharmaceuticals R&D unit dealing with analytical method development and stability studies of biotherapeutic proteins. He has co-authored research and review articles related to biosimilars and also hold a formulation patent.

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