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Stability of freeze-dried biological formulations

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Lyophilization or freeze drying is a process widely used in the preparation of biopharmaceuticals and biologicals because it allows greater storage stability for otherwise labile biomolecules, provides a convenient storage and shippage format and following reconstitution rapidly delivers the product in its original formulation, ready for use. Biopharmaceuticals are the fastest growing subsector in pharmaceuticals, and currently generates $120 billion in sales annually; half of new therapeutic proteins will need to be freeze-dried for release, but formulation for freeze-drying is still inefficient and empirical, with only a 60% success rate. Improved analytical methods for characterizing protein stability in freeze-dried glasses, and better theory for understanding degradation routes are sorely needed. There is a complex and poorly understood web of interactions between a given protein, the formulation, and the lyophilization cycle used. This presentation mainly describes the following aspects: 1) Protein aggregation: Does it take place in the amorphous solid or upon reconstitution? 2) Rationale choice of excipients; 3) Rank-order stability prediction based on traditional and emerging methods and 4) Residual water content and stability.

Biography

Singireddy Anandam has completed his PhD from Annamali University and worked as a Senior Research Fellow. He is the Principal of Malla Reddy College of Pharmacy, one of the top ranked institutions in this region. He has published more than 20 papers in reputed journals and has been serving as an Editorial Board Member of repute.

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