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Lyophilized Protein Powders: A Review of Analytical Tools for Root Cause Analysis of Lot-to-lot Variability

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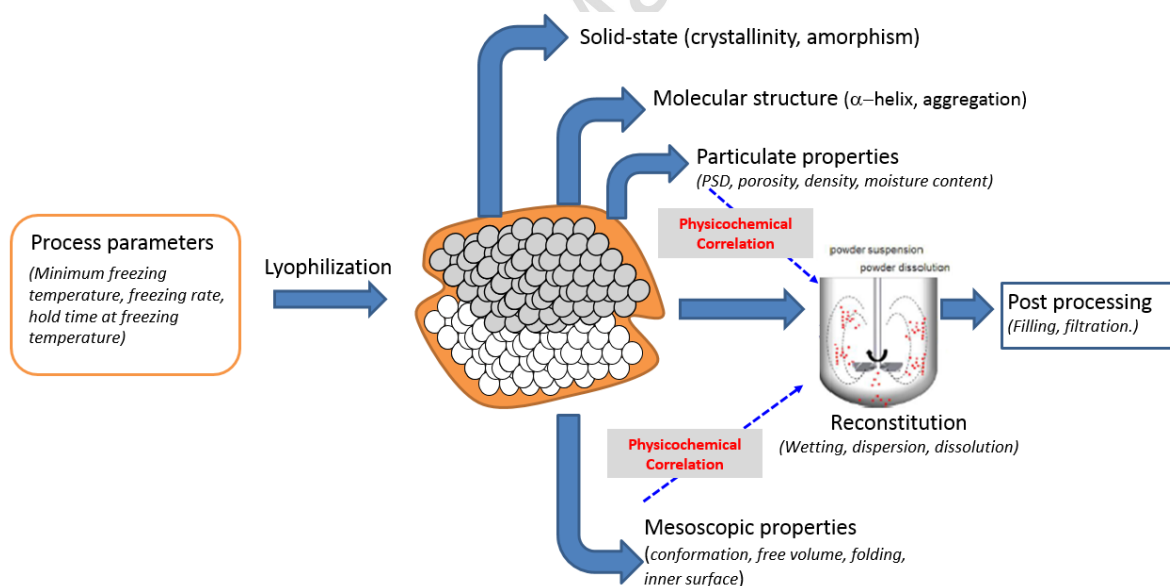
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Highlights:

- Solid-state protein investigations
- Determination of lot-to-lot variabilities in lyophilized protein powders
- Molecular, particulate and bulk properties of protein powders
- 10 • Structural properties and chemical stability of protein pharmaceuticals
- Analytical methods for batch-to-batch variability in lyophilized materials

Graphical Abstract



15 Abstract

Lyophilization of proteins can introduce lot-to-lot variabilities in different product properties that are crucial in terms of product performance and stability. As these variations can raise several issues related to the product quality, the characterization of the physical and chemical properties of protein lots is required, to identify critical deviations between the lots

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