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An Introduction to the Stochastic Nature of Nucleation in Freeze-Drying

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The stochastic nature of nucleation is often considered a limitation in the freeze-drying process, as it introduces variability that can affect both product quality and process efficiency. Since nucleation occurs at different temperatures and times, it influences the size of ice crystals, which in turn affects the sublimation rate and the porous structure of the final product. Non-uniform nucleation can prolong drying time, increase energy costs, and impair product rehydration. Additionally, products with varying structures may exhibit different physicochemical properties, which is particularly critical in the pharmaceutical and food industries. Various methods have been developed to mitigate this issue; however, the underlying mechanisms of nucleation stochasticity remain poorly understood. This study aims to introduce the problem of stochasticity and identify the key factors contributing to heterogeneity. The tested factors include sample volume, solution composition, and vial positioning. All of these factors were found to influence nucleation stochasticity.