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Vacuum Induced Surface Freezing as an effective method for improved inter- and intra-vial product homogeneity

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Abstract

The stochastic nature of nucleation makes it difficult to control batch homogeneity in conventional freezing, and this lack of control is in contrast with the current emphasis on Quality by Design. Among the techniques which have been developed to overcome this problem, Vacuum Induced Surface Freezing is probably the most promising for application in manufacturing, because it does not require additional equipment and can be scaled-up more easily than other proposed approaches. In this work, we summarize the impact of Vacuum Induced Surface Freezing on product morphology, and the efficiency of the subsequent drying steps as well. We will show that this controlled freezing approach is extremely beneficial for both the efficiency of the freeze-drying process, and the quality and homogeneity of the final product. The hope is that this work could contribute to the commercial implementation of controlled nucleation technology, overcoming the final resistance to its widespread use. It is our opinion that this would be a substantial improvement, beneficial for both the pharmaceutical industry and the end users.

Keywords: Freeze drying, Freezing, Controlled nucleation, Pharmaceutical

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