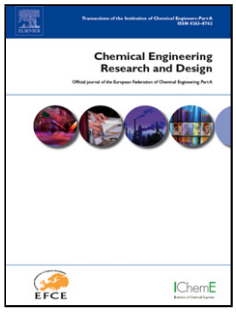

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Prediction of product morphology of lyophilized drugs in the case of Vacuum Induced Surface freezing.

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Abstract

In pharmaceutical industry, freeze-drying is often used to produce protein therapeutics that are stable during shipping and long-term storage. The design of adequate freezing process is a crucial aspect to be considered as influences the final morphology and, hence, physico-chemical properties of the lyophilized product. In this study, a mechanistic model is developed for better understanding the relationship between morphology of lyophilized samples and freezing conditions. More specifically, we focus on Vacuum Induced Surface Freezing that is a recent, promising technology that allows a precise control of temperature of nucleation. Model simulations were validated by comparison with the lyophilized product morphology as observed by Scanning Electron Microscopy. The model was found to give accurate results for

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