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The organizing committee has tried to correct any obvious flaws they found in the submitted abstracts and to supplement missing information to the best of its knowledge. However, the committee cannot be held responsible for any remaining flaws. We hope you thoroughly enjoy the conference and look forward to engaging in fruitful and respectful discussions.

IMPACT OF THERMAL INTERACTIONS ON VIAL-TO-VIAL UNIFORMITY AND QUALITY OF FREEZE-DRIED PHARMACEUTICALS

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Abstract

Freeze-drying is a crucial technology for pharmaceutical manufacturing, where product stability and homogeneity are paramount. Due to the stochasticity of ice nucleation and thermal coupling among vials, each vial experiences a unique thermal history, increasing batch heterogeneity. The freezing conditions of pharmaceuticals in vials strongly influence the morphology of the dried product and its drying time.

Specifically, this study investigates the role of thermal interactions during freezing. The experimental campaign involved the evaluation of the effect of various vial formats, loading conditions, and cooling rates on the morphology of the dried product. The experimental results were complemented by a 1D mathematical model that predicts thermal history, product morphology, and drying time of an entire batch of vials.

The study revealed that thermal interactions among adjacent vials significantly influence nucleation temperature distributions and freezing rates. When thermal interactions are not negligible, the nucleation time distributions were broad and shifted towards longer nucleation times compared to non-interacting vials. This result was attributed to the additional heat received from adjacent nucleating vials. The dried product showed smaller and more heterogeneous pore size distributions. Conversely, non-interacting vials displayed consistent nucleation times, larger pore size and narrower distributions. These differences directly impacted drying times: interacting configurations exhibited prolonged and heterogeneous drying, whereas non-interacting configurations achieved shorter and more uniform drying.

The model predictions closely matched experimental results, validating its use in capturing the complex dynamics of thermal coupling. These findings underline the importance of considering thermal interactions when designing freeze-drying processes to minimise batch heterogeneity and enhance the quality of the final product.

Keywords: *freeze-drying, thermal interactions, product morphology, product heterogeneity, drying performances, mathematical modelling*