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Theoretical study of inhomogeneous lyophilization using CFD

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Lyophilization is an important unit operation for the manufacture of aseptic parenteral drugs. Lyophilization refers to a drying operation performed by sublimation, which is the transition from frozen to gaseous state. The process consists of three stages: the freezing step, sublimation of the formed ice (primary drying) and desorption of the residual water (secondary drying). A known but still poorly understood problem in freeze drying is the different drying rate at different locations of the freeze dryer. In the past, few explanations of this phenomenon were presented such as effect of the edge vial which is caused by an additional heat transfer mechanism presented at the border of the shelf, local variability of the shelf temperature and pressure profile caused by the design of the device, cake structure modification during the freezing step. The aim of this work is to combine experimental measurements with theoretical process analysis, to understand and quantify the effect of vial packing density on drying. Theoretical analysis of the problem was done by the CFD simulation of the primary drying in 7 vials. Primary drying was simulated in the ANSYS FLUENT software, where sublimation of the ice was modelled by the modified species transport module. Influence of the inlet velocity of the cooling medium on the sublimation rate was also investigated. Results of the simulations corresponds with the trends observed in the experiments. Increased packing density results in lower sublimation rate in the vials and increased inlet velocity positively influence the sublimation rate. Current objective is to present complex porous cake model with an addition of another compound to the freeze-dried solution.

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