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Lyo Calculator – the Calculator of Primary Freeze-Drying

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ABSTRACT

Freeze-drying (lyophilization) is an important process of a pharmaceutical solution state transformation for storage. Due to complexities of the process and costs related to experiments, numerical simulations of freeze-drying become more useful and cost-efficient for research and development of the process and the hardware. Many numerical models have been created to model separate steps of the drying process. However, these models are not available for any user. This work presents an open-source model of primary drying in a vial. Pseudo steady-state heat and mass transfer model was used to compute vapor pressure, drying time, product temperature, and percent of fluid dried as functions of time. To verify the numerical model, results were compared to experimental data of a mannitol (5%) solution and a numerical model created by M.J. Pikal. Results show accuracy within 20% at low chamber pressures and shelf temperatures. Simulations and analysis showed that the tool can be successfully used as a basic approximation of drying results for a single vial and constant chamber pressure and shelf temperature.

KEYWORDS

Freeze-drying, lyophilization, CFD, heat and mass transfer