

## Model-based optimization of the primary drying step during freeze-drying - DTU Orbit (08/11/2017)

### Model-based optimization of the primary drying step during freeze-drying

Since large molecules are considered the key driver for growth of the pharmaceutical industry, the focus of the pharmaceutical industry is shifting from small molecules to biopharmaceuticals: around 50% of the approved biopharmaceuticals are freeze-dried products. Therefore, freeze-drying is an important technology to stabilise biopharmaceutical drug products which are unstable in an aqueous solution. However, the freeze-drying process is an energy and time-consuming process. The use of mechanistic modelling to gather process knowledge can assist in optimisation of the process parameters during the operation of the freeze-drying process. By applying a dynamic shelf temperature and chamber pressure, which are the only controllable process variables, the processing time can be decreased by a factor 2 to 3.

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