Numerical and Experimental Validation of a Pilot Scale Wurster Coater Application

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ABSTRACT

Wurster coaters are widely used devices in the pharmaceutical, chemical and food industry for coating purposes. It is essentially a batch process where the beads are fluidized by the fluidization air distributed by a perforated plate. The highest velocities in the coater are reached in the Wurster tube, where particles are sprayed and accelerated upwards. The spray either contains the active pharmaceutical ingredient (API) or modifies the drug release profile. After leaving the tube, particles fall down in the down-bed region, staying there until being drawn back into the tube again. During this path the liquid coating film is evaporating from the bead surface and the solid coating film is being formed.

There are a couple of important phenomena occurring simultaneously in the Wurster coating process that have an effect on the structure of the film formed on the bead: gas- particle momentum and heat transfer, liquid film evaporation rate from the particle surface and evaporative cooling, humidity rise in the coater, heat loss to the environment. Therefore, the quality of the coating, and consequently the drug performance is influenced by the chosen coater operating parameters.

Since using purely empirical methods is often time consuming, several simulation approaches have been used to optimize the coating process. Simulation tools give insights into the coating process which cannot be acquired by experiments that rely on the information from the device sensors. Simulations are usually used to get information about the exact particle positions and trajectories, residence and cycle times (RT and CT), but they rarely account for the thermodynamic and mass balance of the process.

In this work we validate a coupled CFD-DEM model with the experiments run on a pilot scale Glatt GPCG 1.1 Wurster coater. Four specially designed experiments were done in order to validate the CFD-DEM modeling approach. The information about the temperature and humidity distribution in the device was collected with several sensors during experimental runs. The temperature and humidity data at different locations in the device were compared with the simulation results, and a good agreement of data validated our coupled CFD- DEM model. The simulation included the real batch size with the unscaled particle size distribution.

Using this model we predict the particle velocities in the system, particle temperature, liquid film coverage of the bead surface, and evaporation rate. We identify the hot and cold zones in the coater and the high humidity region where most of the spray evaporation takes place. The RT of the particles in those zones plays an important role for the coating film formation. The model will be further used for other Wurster coater scales and for the development of the process scale- up strategy.