Optimization of Tablet Coating Processes using Discrete Element Method Simulations.

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Introduction
In the pharmaceutical industry, drum coating is a widely used unit operation to produce film tablets. The applied coating layer(s) fulfill different functions, e.g. taste masking and coloring, API release modification, or application of an additional API. For all these aspects, both inter-tablet uniformity and intra-tablet uniformity are of great importance [1].

In recent years, parallel to an increased effort in experimental work, numerical simulations of particle motion using the Discrete Element Method (DEM) have proven to be an important tool in the detailed investigation of the tablet coating process; indeed, of all particle-based pharmaceutical processes [2,3].

Goals
- Analyze and understand the effects of parameters
  - fill volume
  - pan rotation speed
  - on the process quality, e.g.
    - Mixing efficiency
    - inter- and intra-tablet coating uniformity
- Perform scale-up from lab- to pilot- and finally production scale.

Numerical Methods
- The Discrete Element Method is applied to numerically reproduce the tablet motion inside the coating apparatus. The simulations are done with EDEM (DEM Solutions. Ltd., Edinburgh, UK) in combination with self-written additional modules and post-processing scripts.
- The geometry of the coating apparatus is provided by the manufacturer (L.B. BOHLE Maschinen + Verfahren GmbH, Ennigerloh, Germany)
- Material parameters are taken from measurements (Experiments done at the Heinrich-Heine University)
- Tablets have a bi-convex tablet shape, this is modeled by the "glued spheres" approach.

Results
The blue spheres are spray droplets, with darker shades denoting bigger droplets. The tablets are colored from light red to dark red according to coating mass. Uncoated tablets are light yellow.

Conclusions
- Basic DEM Simulations provide attributes like position, velocity or rotation of the tablet.
- From this, the post-processing algorithms extract information on residence times.
- Additionally, modules were developed to model the spray directly, leading to detailed information on the coating mass distribution.
- In summary, the simulation allows to study the influence on process parameters on the product quality in great detail.

References