Investigating the uniformity of an active coating process in the industrial scale using DEM simulations

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Abstract

Tablet coating in a pan coater is a widely used unit operation in the pharmaceutical industry. It is used to add additional layers onto a tablet. Active coating is one application of the coating process. Here the amount of applied material on the tablets is outermost importance. An active pharmaceutical ingredient is coated on the tablet and the inter tablet coating variation (CoV) has to be very small for an uniform process outcome and to meet the regulatory rules. For this a deep understanding of the process is needed. Experiments are mostly done in the laboratory, due to costs and numerical simulations also concentrated on the laboratory scale because of the programs and computers used limited the size of the simulation. [1], [2]

In this work the application of an active coating was investigated: Gastrointestinal therapeutic systems (GITS, Bayer Pharma AG, Germany) were coated with an aqueous suspension. An industrial size coater (BFC 400, L.B. Bohle, Germany) was used.A Design of Experiments was used with the rotation velocity and drum load given by Bayer. The geometry of the coating apparatus was provided by the manufacturer. The material properties came from measurements[3]. The simulations were done using an in house developed DEM code called "eXtended Particle System" (XPS).[4]

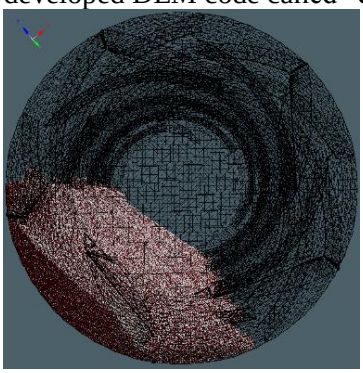

Figure 1: Snapshot of the filled coating drum during the simulation process

The goal was to capture the coating process in the simulation as good as possible and predict the best possible process parameters settings. The CoV (better uniformity) and process time dependence on the spray rate/ rotations rate or the fill level is analyzed. Also the influence of the number of nozzles on the CoV is investigated in the simulations, something which is hard to archive in real experiments in this scale. In general fundamental insights into the coating process were gathered.

References

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