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In Silico Study of the Effect of Including Lactose Fines in Modeling Dry Powder Inhaler Performance

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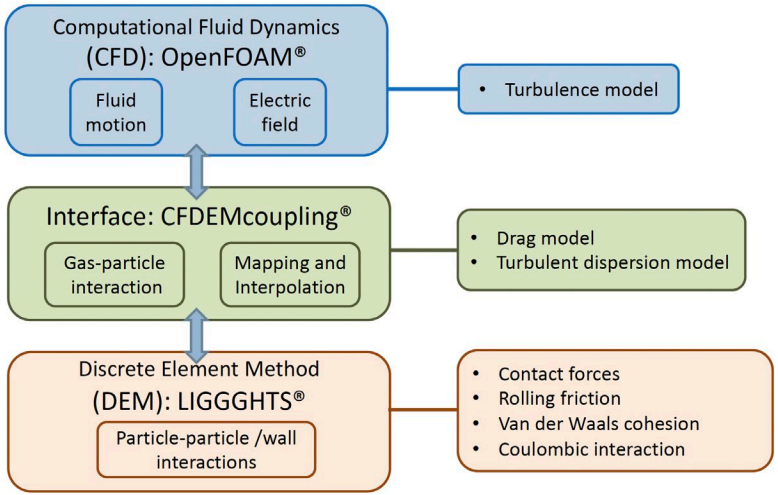
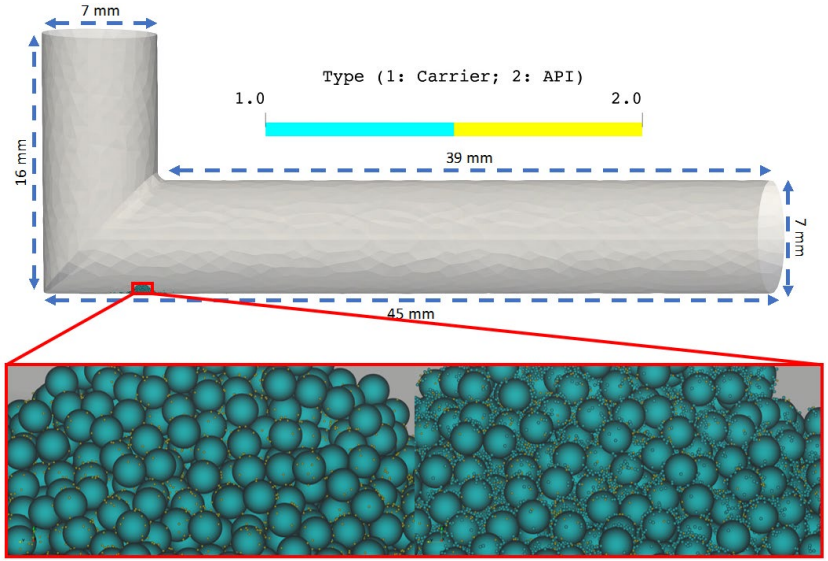
Introduction

- Currently available dry powder inhaler (DPI) models use one representative size for both active pharmaceutical ingredient (API) and carrier particles (e.g., lactose monohydrate) and do not reflect the particle size distribution (PSD) data that are reported in new drug applications (NDAs), especially lactose fines.
- A coupled computational fluid dynamics and discrete element method (CFD-DEM) model was used to simulate performance of a DPI that capture the particle-particle interactions and fluid transport in a realistic geometry.
- **Goal:** provide an in silico platform to gain insight on whether the effect of lactose fines needs to be considered in making modeling decisions.





Findings/Results

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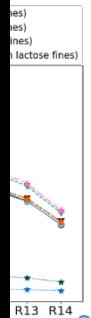

Conclusion

- A CFD-DEM model was developed to study the effect of lactose fines in a simulation of DPI performance.

- Simulation results showed that lactose fines appear to help prevent formation of larger API agglomerates, but they also may increase the chance of API particles binding to the carrier particles.

- Although this difference may not be large in this study with this simple L-shaped device, it may have significant implications further downstream in the upper airway or in more complex DPI device geometries, such as those on the U.S. market that use a blister cap, capsule, or reservoir-based system.

Thank you!


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