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Designing Spray Dried Particles with a Pressure Nozzle at Small Scale

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PURPOSE

The purpose of this study is to determine the critical process parameters that impact the spray dried particle's characteristics by generating powders using a pressure nozzle in a small-scale spray dryer. The focus will be on formulations related to amorphous solid dispersions (ASDs). Operating at small scale during the process development phase is very important for many ASD formulations as the APIs are often very expensive.

METHODS

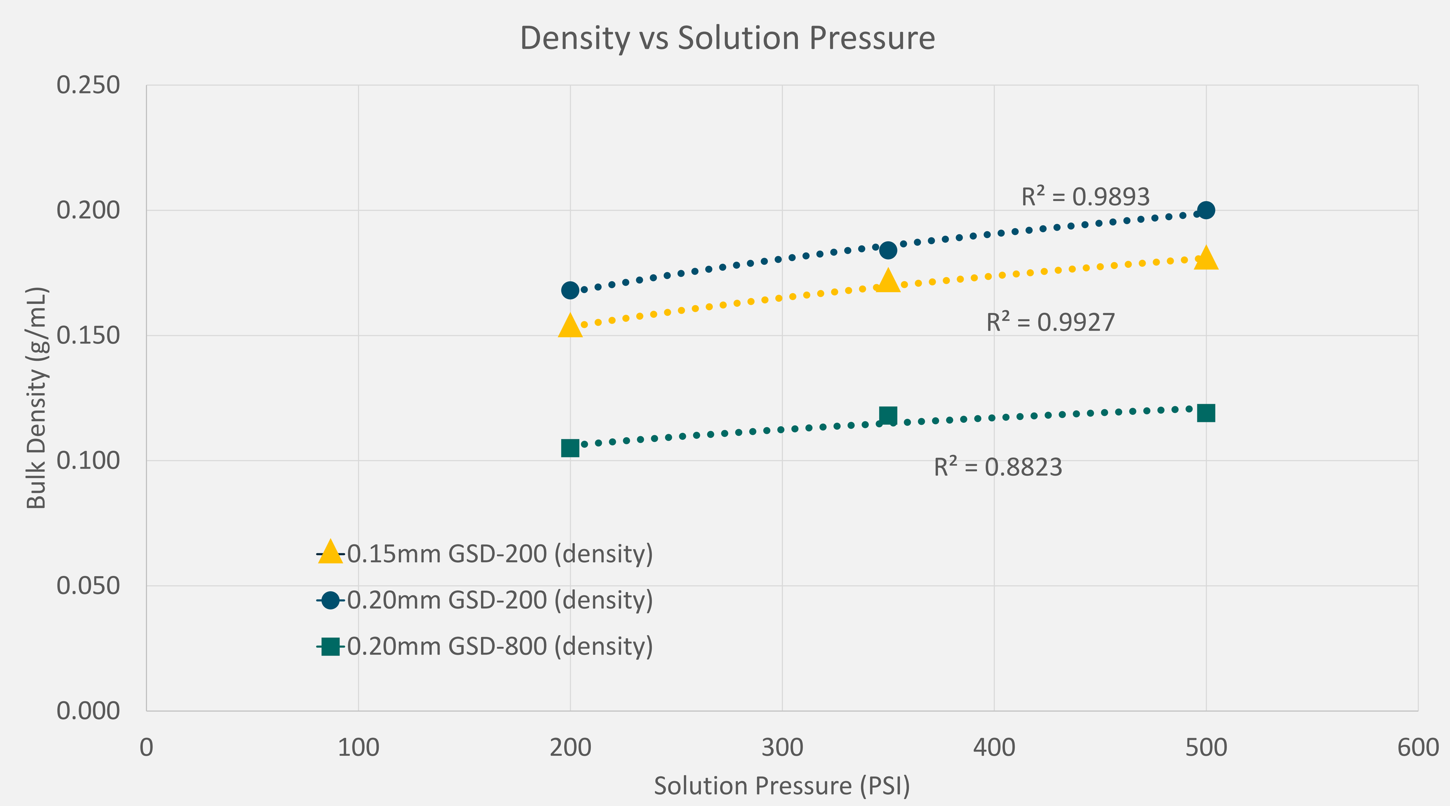
The formulation chosen for the spray drying trials was 10% HPMC-AS in acetone. HPMC-AS is a polymer that is compatible with multiple bio-unavailable APIs. Spray drying trials were conducted on a small spray dryer, the GSD-200, using two different nozzle sizes, 0.15mm and 0.20mm. The collected powder was analyzed to evaluate residual solvent, bulk density, and particle size distribution (PSD). For all trials, the system was operated in closed loop with a nitrogen gas purge and solvent recovery. The drying gas flow rate was set to 17 CFM and the inlet gas temperature was set to 90-100 °C. A high-pressure positive displacement pump was used to deliver the solution. The pump was operated at a range of speeds to deliver the solution at pressures ranging from 200 PSI to 500 PSI. After the GSD-200 trials were completed, the process was repeated on a pilot scale machine, the GSD-800, using the same 0.20mm nozzle and high-pressure pump. The drying gas flow rate was set to 80 CFM and the inlet temperature was set to 90 °C. The resulting powder collected was analyzed to evaluate residual solvent, bulk density, and PSD. The data was then plotted to determine trends that are useful in designing a spray drying process.

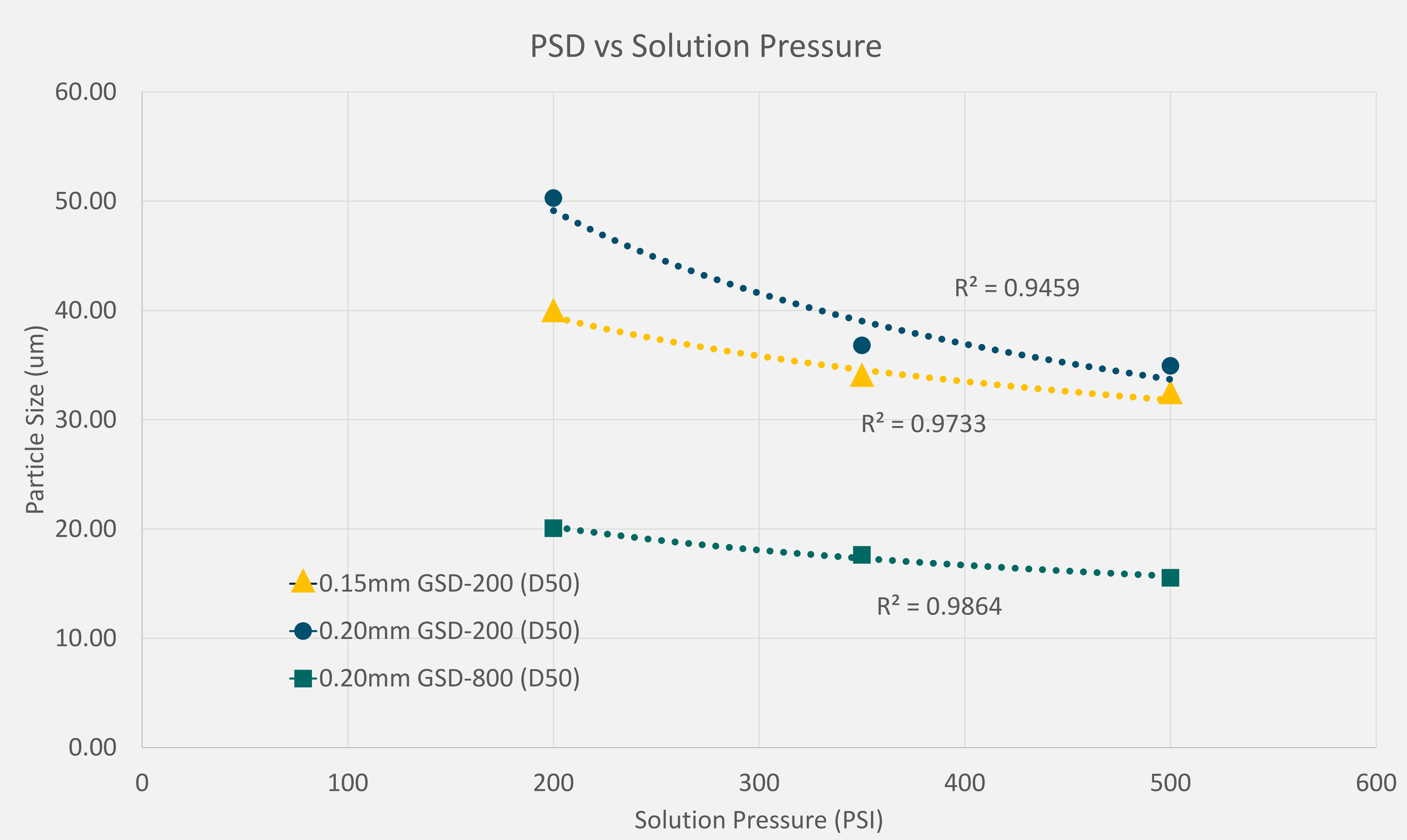
GENESIS™ GSD-800 Spray Dryer

GENESIS™ GSD-200 Spray Dryer with Extension Insert

RESULTS

For all trials, in the small-scale spray dryer and the pilot spray dryer, there were two very distinct trends. First, in the range of 200 PSI to 500 PSI of solution pressure, as the pressure was increased, the particle size decreased. The other trend was in bulk density. As solution pressure increased, the bulk density increased. For all trials, the residual solvent was in the range of 3% to 6%. The figures below show the average particle size and bulk density trends.





RESULTS

Another trend when only looking at the GSD-200 trials is the particle size increases as nozzle size increases. This is intuitive. However, the particle size decreases using the same nozzle going from the GSD-200 to the GSD-800. The trial data table below explains this. The outlet/product temperatures for the GSD-800 trials were higher, making it a drier process, leading to the smaller particle sizes.

Equipment	Nozzle Size (mm)	Inlet Gas Temp (°C)	Outlet Gas Temp (°C)	Solution Pressure (PSI)	Drying Gas Flow (CFM)
GSD-200	0.15	90-100	40-50	200	17
GSD-200	0.15	90-100	40-50	350	17
GSD-200	0.15	90-100	40-50	500	17
GSD-200	0.20	90-100	40-50	200	17
GSD-200	0.20	90-100	40-50	350	17
GSD-200	0.20	90-100	40-50	500	17
GSD-800	0.20	90	60-70	200	85
GSD-800	0.20	90	60-70	350	85
GSD-800	0.20	90	60-70	500	85

CONCLUSION

With the proper equipment and set-up, particles can be generated at a small scale using a pressure nozzle for the purpose of designing a production process without having to use large quantities of material. Each data point only required less than 1kg of solution (100g of polymer). Although the particle characteristics using the same pressure nozzle in each system did not exactly match, the trends were the same, so the design process is scalable.