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Spray Dry Granulation in Fluid Bed Technology and Scale Up

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PURPOSE

- Conventionally, the processes of spray drying and granulation are done using different equipment.
- Spray drying is a process used by many different industries to develop a powder that is oftentimes poorly flowing. Spray drying is also a continuous process that will develop powder quickly that frequently requires further processing by granulation due to the poor flowability and small particle size of the powders that are generated.
- Granulation can be done using multiple methods such as, high shear mixing, fluid bed granulation, or roll compaction. Wet granulations are typically done in batch processes which can cause bottlenecks in the manufacturing process if spray drying throughputs exceed the batch capabilities of the wet granulation lines, or in cases where granulation capabilities aren't present, lead to reduced product performance.
- It is possible to eliminate the need for two machines by combining spray drying and granulation into one singular process. It can also be used to control the final particle size of the material to ensure the desired final product specifications are met. The main purpose of this study was to demonstrate the use of fluid bed technology as a single piece of equipment that is capable of spray drying and granulating in a single process.

METHOD(S)

- Spray Dry Granulation was conducted using the FC-LAB 3 FLO-COATER® (FREUND Inc.) with a 12-liter container and a spray gun spraying down from a port near the top of the expansion chamber. It was also conducted using the FC-60M FLO-COATER® (FREUND Inc.) with a 220-liter container and a spray gun spraying up from the lowest top spray port.
- An aqueous solution consisting of 25% maltodextrin (Grain Processing Corporation, M100) was sprayed in both systems.
- There was no dry powder present inside the machine at the start of the process as solution was sprayed dried and granulated during the process. The process was considered complete once the material grew to the desired particle size.
- Samples were withdrawn from a sample port throughout the process and LOD (Loss-On-Drying) measurements were determined using the Mark-3 moisture analyzer (Sartorius) as well as particle size distribution measurements using the QICPIC Particle Size Analyzer (Sympatec GmbH).

RESULT(S)

Figure 1 shows the particle size data recorded through samples taken during the process in the FC-60M FLO-COATER®. The first sample taken is spray dried material at a d50 of 24.13 µm. As shown in figure 1, the particle size data shows growth from spray dried material to granulated material throughout the process. The span on the material gradually became narrower until the process was complete. The final particle size reached for trial 1 is 246.10 µm.

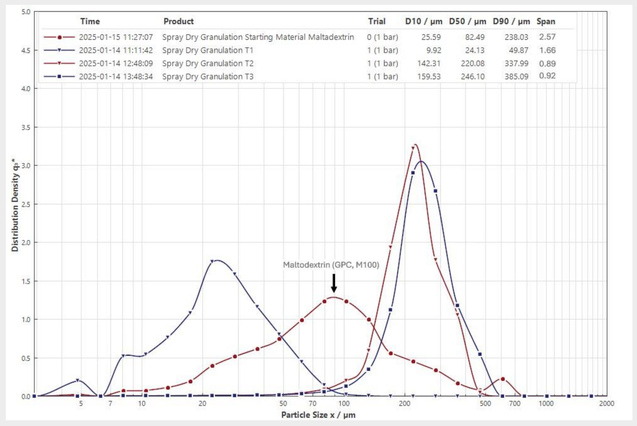

Figure 1: *Particle size data recorded by QICPIC Particle Size Analyzer during trial 1 of the spray dry granulation process on the FC-60M.*

Figure 2 shows particle size results for samples taken through the process on the FC-LAB 3 FLO-COATER®. The same trend can be observed as the particle grows from sprayed dried material to granulated material. The final particle size for trial 4 is 158.72 µm.

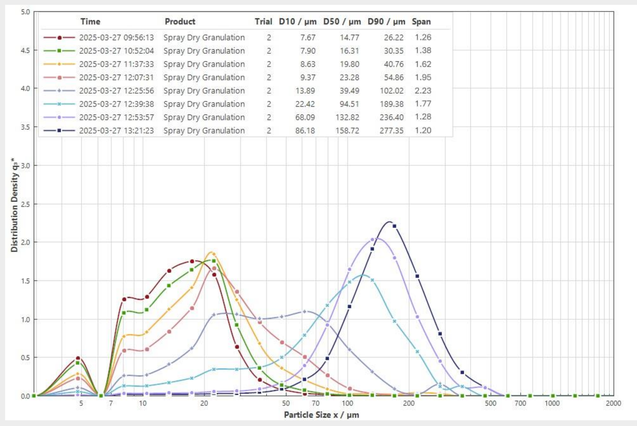

Figure 2: *Particle size data recorded by QICPIC Particle Size Analyzer during trial 4 of the spray dry granulation process on the FC-LAB 3.*

The FC-60M FLO-COATER® controlled the final particle size by changing spray rates and airflow. Trial 2 and 3 on the FC-60M FLO-COATER® varied spray rate and airflow inside of the machine. The results for trial 2 with a higher airflow and spray rate resulted in a larger granule with a final particle size of 281.37 µm. The same spray rate in trial 3 was ran with a lower airflow and resulted in a smaller granule of 251.31 µm. The same trend was observed in the FC-LAB 3 FLO-COATER®. Trial 2 had a lower airflow and spray rate which resulted in a smaller granule. The process was replicated on each machine with slight parameter changes to show repeatability of the process as shown in the table below.

Trial	Machine	Airflow (CFM)		Spray Rate (g/min)		Atomization Pressure (psi)		Bulk Density (g/cc)	Tap Density (g/cc)	d10 (µm)	d50 (µm)	d90 (µm)	Yield
-	-	Start	Final	Start	Final	Start	Final	-	-	Final	Final	Final	-
1	FC-60M	1100	950	180	570	50	65	0.54	0.67	159.53	246.10	385.09	81%
2	FC-60M	950	1200	250	600	50	50	0.56	0.61	184.28	281.37	395.34	88%
3	FC-60M	700	700	250	600	50	50	0.55	0.62	161.03	251.32	385.33	88%
4	FC LAB-3	30	45	12	30	50	17	0.38	0.49	86.18	158.72	277.35	71%
5	FC LAB-3	30	42	11	27	45	17	0.3	0.38	65.54	117.44	194.51	85%

CONCLUSION(S)

- Spray dry granulation successfully demonstrated the use of a fluid bed as a single piece of equipment capable of spray drying and granulating the same material in a single process.
- It can be concluded from this investigation that spray dry granulation can serve as a versatile process with flexibility to control the final particle size.

FC-LAB 3 FLO-COATER®

FREUND