DIRECT COMPARISON OF WET-GRANULATION PROCESSES IN A HIGH-SHEAR GRANULATOR AND AN INNOVATIVE ROTOR PROCESSOR

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PURPOSE

To compare wet-granulation processes in a high-shear granulator and an innovative rotor processor.

METHODS

An immediate release (IR) formulation (shown in Table 1) was used in this study. One set of processes was conducted using a 25-liter high-shear granulator (Vector GMX-25). Comparison processes were performed in a 17.5-liter rotor processor (Vector Granurex GX-40). The load of dry blend was adjusted for each type of equipment to achieve appropriate product movement. The amount of water added was varied to observe the effect on particle size. Process parameters are listed in Table 2. High-shear granulation (HS) particles were dried via fluid-bed whereas the rotor-granulated (RG) particles were dried in the rotor processor. After drying, the particles were sieved to determine arithmetic mean diameter (D_{50}).

Table 1 – Immediate Release Formulation

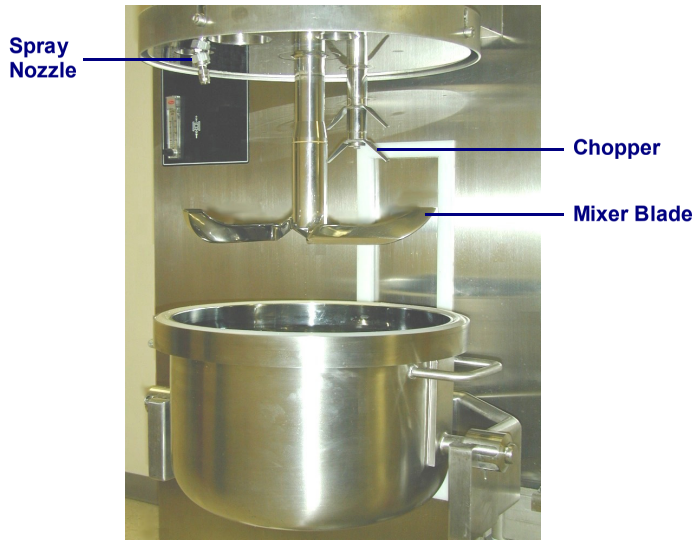
Dry Ingredients	HS Granulations	RG Granulations
Starch 1500	15%	15%
MCC, 50M	30%	30%
Lactose	55%	55%
Batch Volume (L)	12.0	7.8
Batch Weight (Kg)	6.1	4.0
Bulk Density (g/cc)	0.512	0.512

Table 2 – Processing Parameters

Process Parameters	HS Granulations	RG Granulations
Pre-Mix Time	3 minutes	3 minutes
Water Added (Kg)	1.6 / 1.8 / 2.0 / 2.2	1.6 / 1.8 / 2.0
Water Infusion Rate	266 g/min	75 g/min, 10 min 100 g/min, balance
Mixer Blade / Rotor Speed (Water Infusion)	5.4 mps	6.3 mps, 10 min 7.3 mps, balance
Wet Mass Time (WMT)	3 minutes	—
Mixer Blade Speed (WMT)	8.5 mps	—
Air Temperature (Drying)	70°C	70°C
Product Temperature (Drying)	50-55°C	50-55°C
Rotor Speed (Drying)	—	5.2 mps

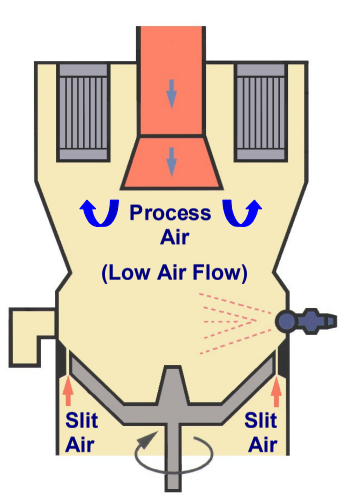
EQUIPMENT

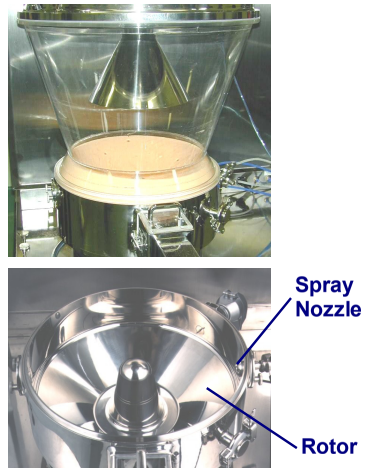
High Shear (HS) Granulator



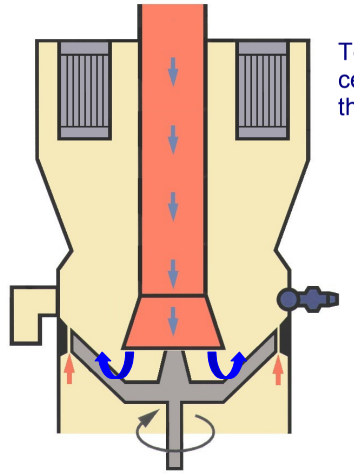
Rotor Granulator (RG) Processor

Granulation Mode -

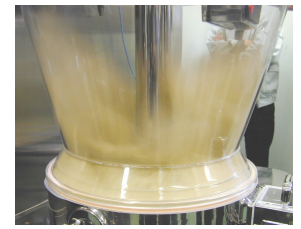




Drying Mode -

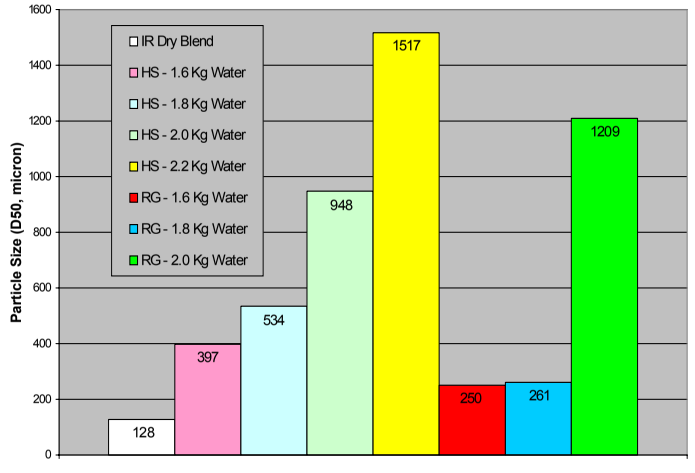


To facilitate drying, the movable center column is lowered and the process air flow is increased.

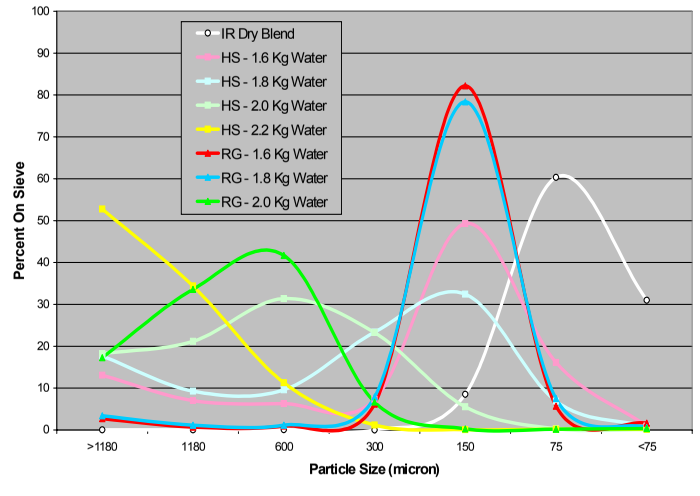


RESULTS

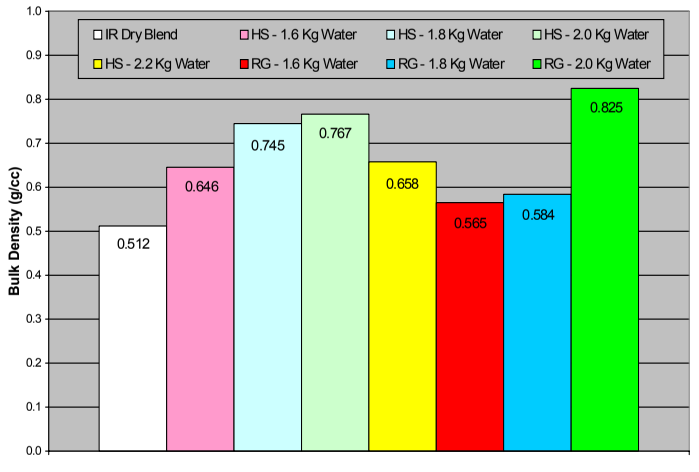
Particle Size (D50) Comparison



Particle Size Distribution



Bulk Density Comparison



CONCLUSIONS

Increasing water addition appears to increase particle size for both high-shear and rotor processing. High-shear processing requires a lower percentage of water addition to produce granules of a larger particle size. This is probably due to the larger shear forces generated in the high-shear granulator than in the rotor processor. However, the rotor processor produced more spherical granules with very uniform particle size distribution for lower amounts of water addition. The increased uniformity is probably due to finer atomization, lower spray rate, and improved distribution of the granulation agent as well as more uniform product movement through the spray zone. As water addition increased in the rotor, the product movement deteriorated and resulted in particle size distribution resembling the high-shear granulator.

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