COMPARISON OF WET-GRANULATION PROCESSES USING TOP-DRIVE AND BOTTOM-DRIVE HIGH-SHEAR GRANULATORS

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PURPOSE

To compare wet-granulations produced using top-drive (TD) and bottom-drive (BD) high-shear granulators.

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 top-drive high-shear granulator (Vector GMX-25). Comparison processes were performed in a same sized bottom-drive high-shear granulator (Powrex FM-VG-25). Process parameters are listed in Table 2. The following parameters were kept constant: load, dry blend time, water infusion spray rate, and wet-mass time. Mixer blade speeds were standard manufacturer settings. A series of trials using increasing amounts of water were conducted with each granulator to observe the effect on particle size. Resulting granulations were divided and dried via fluid-bed and in an oven. Bulk density and arithmetic mean particle size (D_{50}) were determined for each granulation.

Table 1 – Immediate Release Formulation

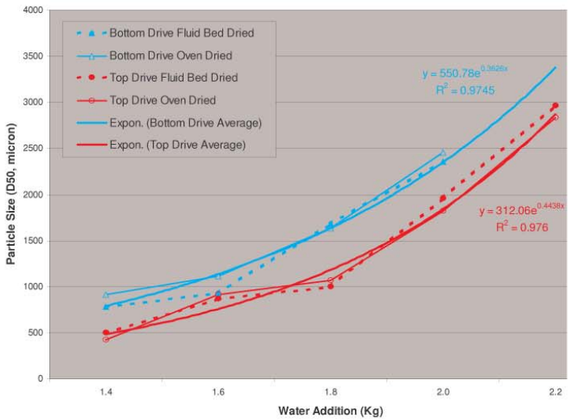
Dry Ingredients	TD Granulations	BD Granulations
Starch 1500	15%	15%
MCC, Avicel PH-101	30%	30%
Lactose	55%	55%
Batch Volume (L)	12.0	12.0
Batch Weight (Kg)	6.1	6.1
Bulk Density (g/cc)	0.510	0.510

Table 2 – Processing Parameters

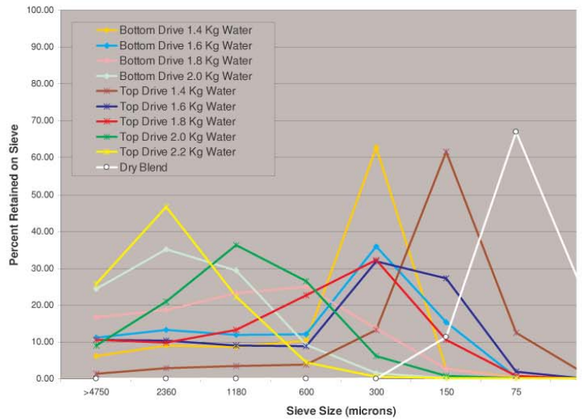
Process Parameters	TD Granulations	BD Granulations
Pre-Mix Time	3 minutes	3 minutes
Water Added (Kg)	1.4 / 1.6 / 1.8 / 2.0 / 2.2	1.4 / 1.6 / 1.8 / 2.0
Water Infusion Rate	266 g/min	266 g/min
Mixer Blade Speed (Water Infusion)	274 rpm 5.4 mps	205 rpm 4.2 mps
Wet Mass Time (WMT)	3 minutes	3 minutes
Mixer Blade Speed (WMT)	430 rpm 8.4 mps	400 rpm 8.1 mps
Air Temperature (Drying)	65-70°C	65-70°C

RESULTS

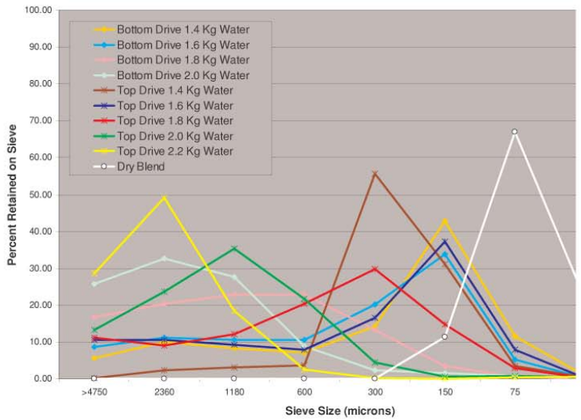
Particle Size (D_{50}) Comparison



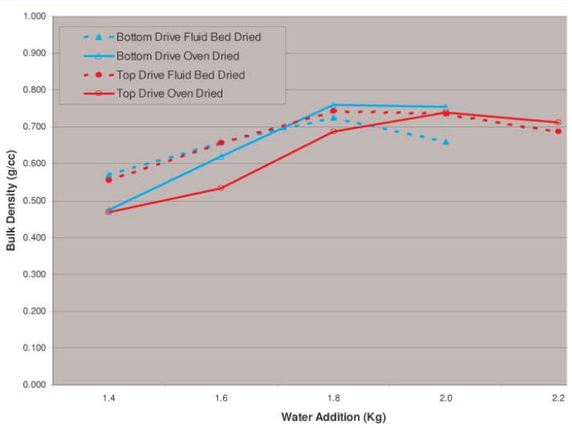
Oven Dried Particle Size Distribution



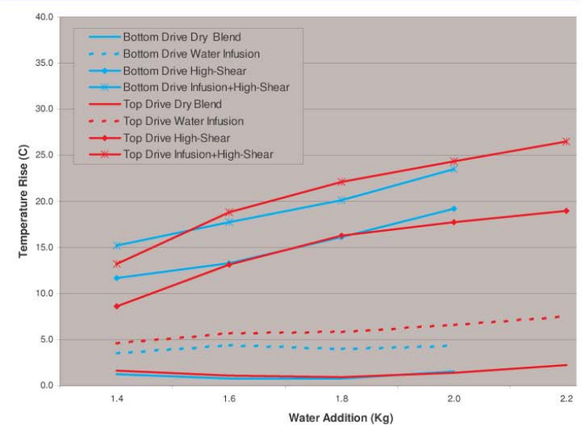
Fluid Bed Dried Particle Size Distribution



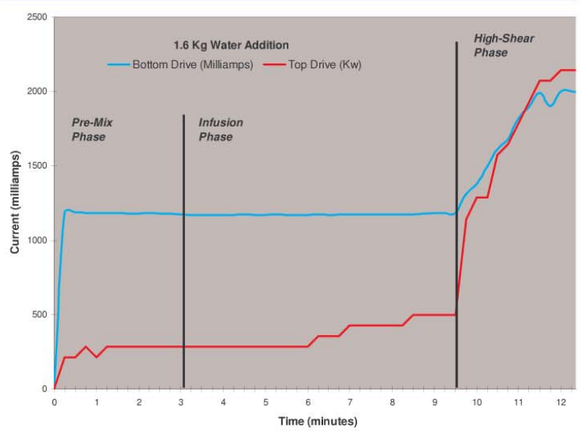
Bulk Density Comparison



Temperature Rise Comparison



Power / Current Comparison



CONCLUSIONS

For the same amount of water added, the mean diameter and the percentage of coarse granules generated by the bottom-drive granulator was slightly higher than obtained with the top-drive granulator. In both granulators, the relationship between the D_{50} and the amount of water can be described by an exponential equation with similar exponential power factors: 0.36 for the bottom-drive unit and 0.44 for the top-drive unit. The slight difference in particle size is probably due to the shape of the product chamber and location of the chopper. However, there is no significant difference in bulk density or the rise in temperature during high-shear. For those granulations where the particle size distributions are similar, the shape of the power/current curves are similar.

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