ADDENDUM

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THE EFFECT OF CONSECUTIVE BATCH PROCESSING ON PARTICLE SIZE AND THERMAL BEHAVIOR IN A HIGH-SHEAR GRANULATOR

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PURPOSE

To incorporate wet-mass, or high shear, mixer blade power consumption information.

METHODS

In addition to the methods reported in the original poster, the mixer blade power was also monitored. Power trends were overlaid on the "Thermal Trends" graphs previously reported. Revised graphs are shown in the Results section.

Note: Formulations and process parameters are reprinted for reference in Tables 1 and 2.

Table 1 – Formulations

Dry Ingredients	Controlled Release A	Controlled Release B	Immediate Release C
HPMC, K 100 M	30%	--	--
HPMC, K 4 M	--	30%	--
Starch 1500	--	--	15%
MCC, 50M	--	--	30%
Lactose	70%	70%	55%
Total Weight (Kg)	15.70	16.59	18.34
Bulk Density (g/cc)	0.423	0.447	0.489

Table 2 – Processing Parameters

Process Parameters	Controlled Release A	Controlled Release B	Immediate Release C
Pre-Mix Time	3 minutes	3 minutes	3 minutes
Water Infusion Time	10 minutes	8 minutes	8 minutes
Water Added (%, Kg)	35.7% , 8.7 Kg	28.1% , 6.5 Kg	24.7% , 6.0 Kg
Wet Mass Time	5 minutes	7 minutes	7 minutes
Time Between Consecutive Batches	6 to 9 minutes	8 to 9 minutes	6 to 8 minutes

RESULTS

REVISED **CR Formulation A Summary**

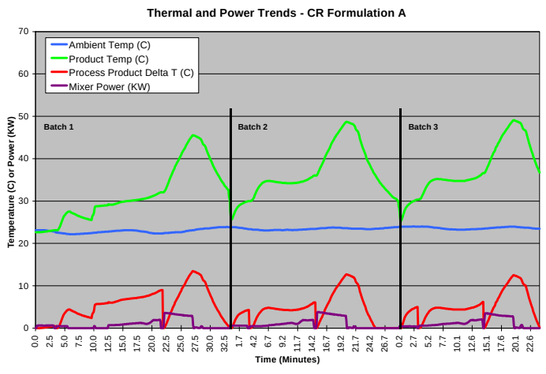
Parameter	1st Batch	2nd Batch	3rd Batch
D50 (Oven), µm	1182	1056	1054
D50 (FB), µm	1148	1040	1064
ΔT, °C	13.3	12.3	12.3
Peak Power, KW	3.6	3.8	3.5
Time to Reach Peak Power, Min	0.3	0.3	0.3

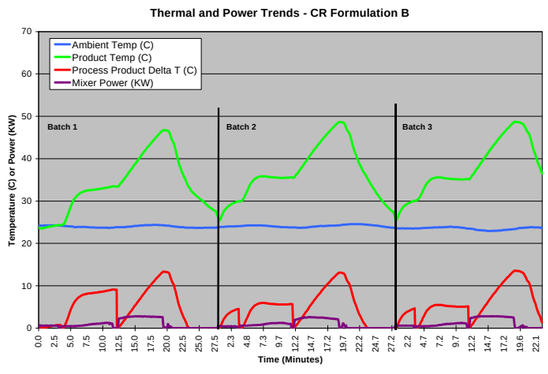
REVISED **CR Formulation B Summary**

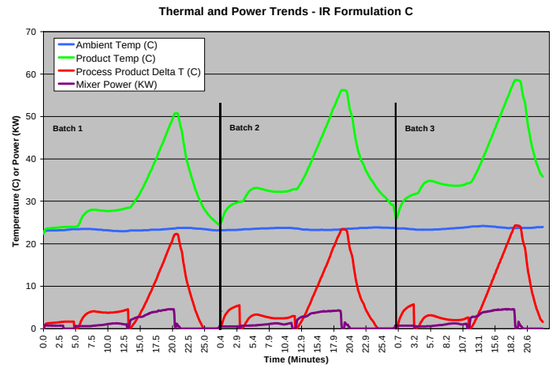
Parameter	1st Batch	2nd Batch	3rd Batch
D50 (Oven), µm	761	794	721
D50 (FB), µm	826	790	767
ΔT, °C	13.3	13.0	13.4
Peak Power, KW	2.8	2.6	2.8
Time to Reach Peak Power, Min	2.7	2.3	1.6

REVISED **IR Formulation C Summary**

Parameter	1st Batch	2nd Batch	3rd Batch
D50 (Oven), µm	1147	1377	1545
D50 (FB), µm	1157	1444	1525
ΔT, °C	21.8	22.9	24.0
Peak Power, KW	4.6	4.3	4.6
Time to Reach Peak Power, Min	6.2	6.5	6.0







CONCLUSIONS (REGARDING MIXER POWER)

Mixer power trends were slightly different for each of the formulations. Mixer power for CR Formulation A rose almost immediately to peak power during the wet-mass stage and then gradually reduced in magnitude, whereas CR Formulation B rose rapidly, leveled off, and did not reach peak power until 23 - 39% of the wet-mass time was completed. IR Formulation C did not reach peak power until almost the end of the wet-mass time. The small rise and fall of the mixer power at the end of each granulation occurred during the discharge of the product. For the formulations used in this study, temperature rise during wet mass (ΔT) appeared to provide a better endpoint correlation to particle size than peak mixer power.

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