A COMPARISON OF A NOVEL ROTOR PROCESSOR WITH A WURSTER PROCESSOR, SHOWING THE EFFICIENCY, UNIFORMITY AND TOTAL PROCESS TIME TO APPLY A SUSTAINED RELEASE POLYMER TO ACETAMINOPHEN BEADS

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PURPOSE

To compare two methods for applying a sustained release polymer to acetaminophen beads and identify processing time, efficiency, solvent usage and dissolution results.

METHODS

20-25 mesh sugar/starch beads containing 60 mg/g acetaminophen were coated with Ethocel Premium 10 FP (Dow Chemical), a sustained release polymer, using two distinct methods. The active beads were coated to a target polymer content of 30% w/w.

In one case, dry ethylcellulose polymer was layered onto the active loaded beads using a K-Tron T20 powder feeder and a Granurex GX-40 rotor processor (Vector Corporation). Triethyl citrate (TEC) emulsified in water with Tween 80 was used to adhere the polymer powder to the active beads.

In the Wurster trials, the polymer was dissolved in acetone, plasticized with TEC and applied as a 10% solution in a VFC-LAB 3 Wurster processor (Vector Corporation) on to the beads.

FORMULATION AND PROCESS CONDITIONS

Formulation	Wurster Process	Rotor Process
Acetaminophen Beads (g)	3000	3000
Polymer Type	Ethocel Premium 10 FP	Ethocel Premium 10 FP
Weight (g)	1285	1285
Acetone (g)	**11,565**	**0**
Triethyl Citrate (g)	257	351
Tween 80 (g)	0	2

Process	Wurster Process	Rotor Process
Final Batch Size (g)	4542	4638
Product Temperature (°C)	38	18
Air Volume (CFM)	72	10
Polymer Addition Rate (g/min)	3.5	8
Solution Amount (g)	**13,107**	**1,560**
Total Process Time (min)	**297**	**160**

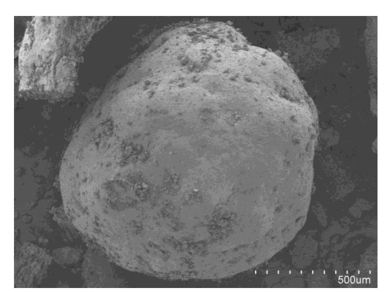
EQUIPMENT

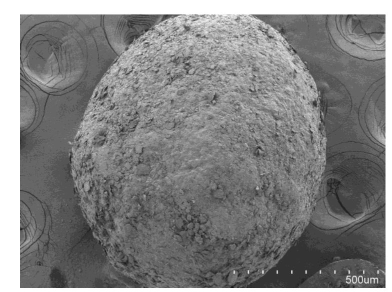
VFC-LAB 3 Wurster Processor

GX-40 Granurex Rotor Processor

FINAL PRODUCT CHARACTERISTICS

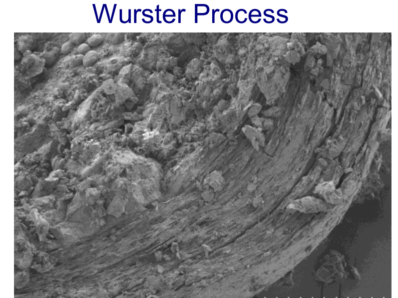
	Wurster Process	Rotor Process
Mean Particle Size, X_{50} (μ)	858.4	862.2
Agglomeration (%)	10	0
Density (g/cc)	0.671	0.652
Sphericity	92	92
Coating Percentage (%)	30.0	30.0
Active Loading (mg/g)	59	61
Yield (%)	93.2	96.1

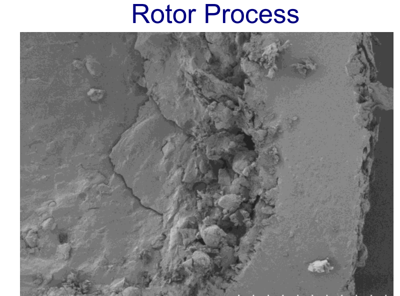




Wurster Process

Rotor Process



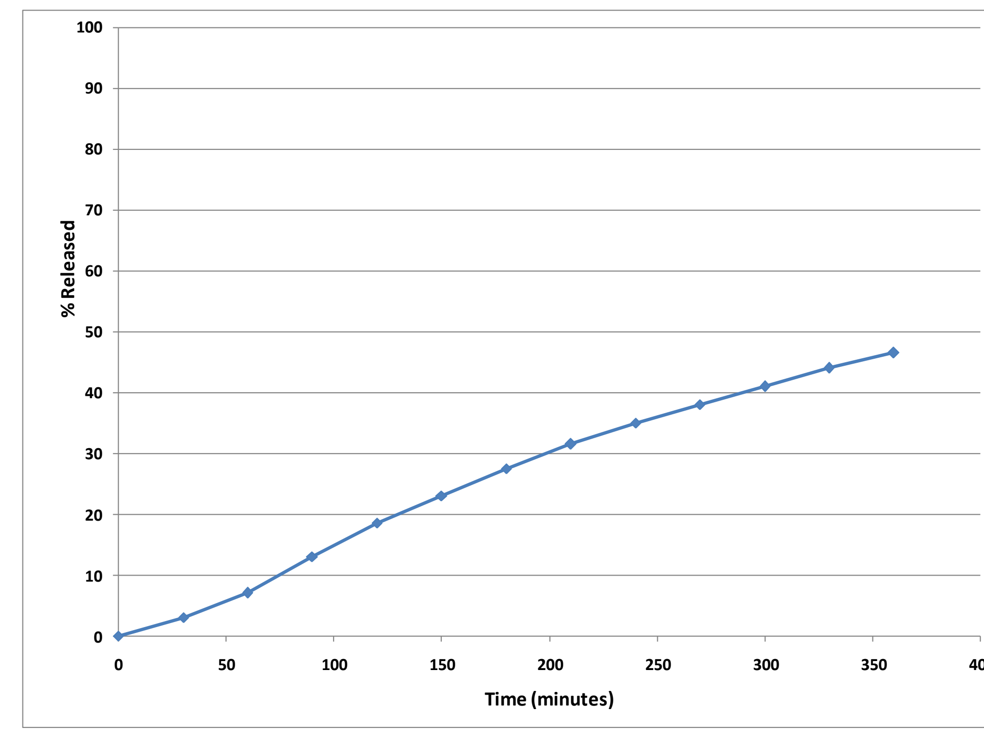


RESULTS

Both trials produced finished beads that were uniform and smooth in appearance. In the rotor process the addition of the plasticizer throughout the powder layering process aided in formation of a uniform film on each bead. In the Wurster process the polymer was plasticized in solution. By eliminating the need to dissolve the polymers and spray them onto the beads, significant time savings was achieved in the rotor process.

Dissolution testing showed that the release of the active was delayed as expected.

DISSOLUTION PROFILE—DRY POLYMER LAYER PROCESS



CONCLUSIONS

Considerable time savings over a Wurster process can be realized by applying ethylcellulose polymers by powder layering on a rotor processor. Additional time and material savings are achieved by eliminating the polymer solvent preparation step.