Optimization of an Existing Wurster Process to Create Enteric Coated Omeprazole Pellets on a Conical Rotor Granulator

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PURPOSE

The purpose of this study was to take an existing Wurster process that created enteric coated omeprazole beads on a Wurster and transfer it to a conical rotor to reduce the processing time and pieces of equipment required to complete the process.

METHODS

The existing process consisted of multiple steps. First, a sugar/starch NP was loaded into a Wurster coater and a suspension of omeprazole was sprayed with an HPMC binder to create an omeprazole loaded bead. Those beads were then coated with a barrier and enteric coating. Following the polymer coating, the beads were placed into a top spray granulator and co-granulated with a cushioning agent to allow for tabletting. In the rotor process, micronized omeprazole powder was placed into a Vector GXR-35 rotor and directly spheronized into small beads in the size range of 200-400 microns. Those beads were then immediately coated with the seal and enteric coating in the GXR-35. Following the enteric coating the cushioning agent was added via dry powder layering in the GXR-35 utilizing a KTron KT-20 powder feeder. Tablets were pressed using a Vector Colton 2216 press and dissolution testing was completed.

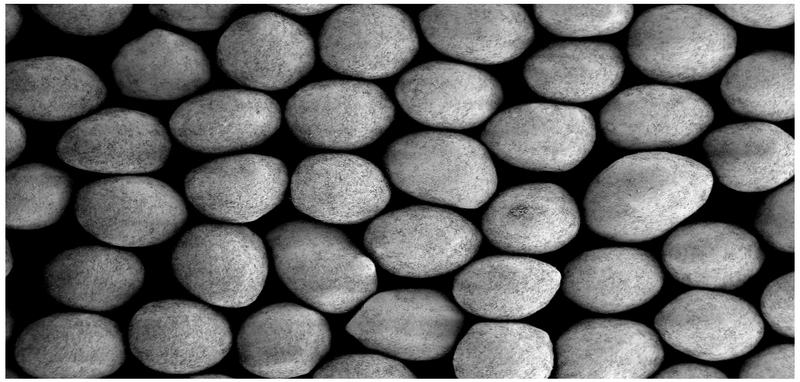
EQUIPMENT

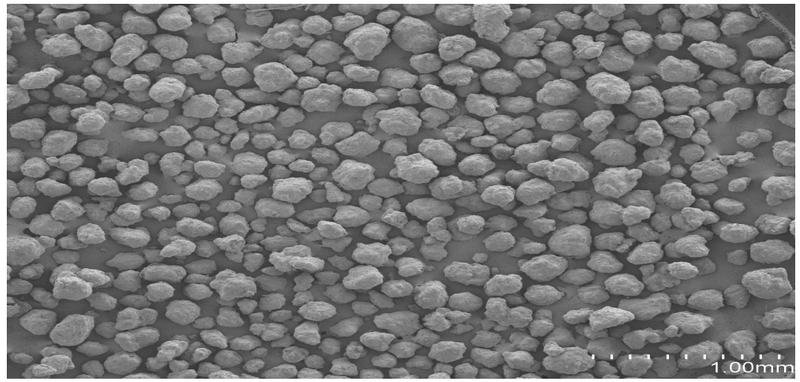
Vector Corporation Granurex
GXR-35

RESULTS

PROCESS DATA

Wurster Process		Granurex Process	
Pieces of Process Equipment Used	2	Pieces of Equipment Used	1
Total Process Time	12 hours	Total Processing Time	6 hours
Omeprazole Loading/Bead	30%	Omeprazole Loading/Bead	49%
Tablet Acid Resistance (30% bead/tablet)	77-88%	Tablet Acid Resistance (30% bead/tablet)	81-90%
Tablet Acid Resistance (50% bead/tablet)	54-62%	Tablet Acid Resistance (50% bead/tablet)	51-56%
Method for Applying Cushioning Agent	Co-granulation	Method for Applying Cushioning Agent	Powder Layering





The entire Wurster process took approximately 12 hours to complete and resulted in a large dosage form due to the use of a sugar starch core. The finished tablets had an average acid resistance of 77-88% of label claim. The process done in the GXR-35 rotor was completed in 6 hours and resulted in a smaller dosage form due to the absence of a core in the omeprazole beads. The finished tablets had an average acid resistance of 81-90% of label claim.

CONCLUSIONS

Transferring the process from the Wurster coater and top spray fluid bed to the GXR rotor resulted in a more efficient, faster process that was completed in one machine without the need to transfer the product. The processing time was cut in half with fewer product handling steps and fewer pieces of equipment used. The tablets produced from the rotor made beads showed slightly better acid resistance and were also smaller than the tablets produced from the Wurster-made beads.