Dry Powder Application of Acetaminophen to Multi-Particulates Utilizing a Modified Wurster Spray Gun System

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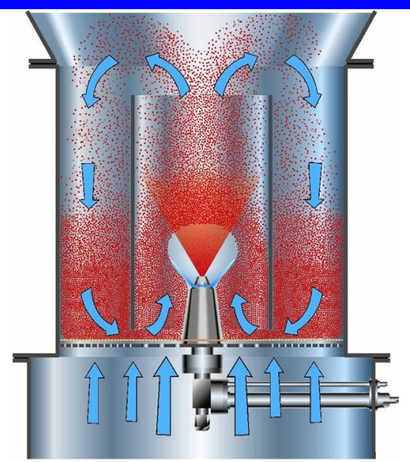
INTRODUCTION

Bottom Spray Wurster technology is commonly used in the pharmaceutical industry as a method for applying active and functional coatings to various multi-particulate substrates. For medium to high drug load applications this technology often becomes complicated when processes require large volumes of dilute solutions or poorly soluble API's require organic solvents. Large suspension volumes force long duration spray times, can be subject to sedimentation with solution line and spray gun problems leading to agglomeration of substrate particles. Dry powder layering utilizing GXR conical rotor technology has recently offered a viable, fast, efficient alternative for creating high payload coatings onto multi-particulates, but the technology is not yet widely available in the marketplace on the commercial scale. This study focuses on whether a modified Wurster gun could be utilized to efficiently coat multi-particulate pellets in an existing Wurster system utilizing dry powder layering technology.

METHODS

25 kg of 18/20 mesh Suglets (Colorcon) were loaded into a Freund-Vector VFC-60 fluid bed equipped with an 18" straight sided Wurster insert. 5 kg of micronized acetaminophen (APAP) (Mallinckrodt) was put into a KTron KT-20 loss-in-weight powder feeder and was applied through a modified Accelerator air ~~sleeve~~ on the spray gun. Simultaneously, a 10% solution of PVP K-30 (BASF) was sprayed through the same spray gun to bind the APAP powder to the Suglets. Batches were repeated to confirm results.

EQUIPMENT



Freund-Vector VFC-60 with 18" Wurster

RESULTS

RESULTS

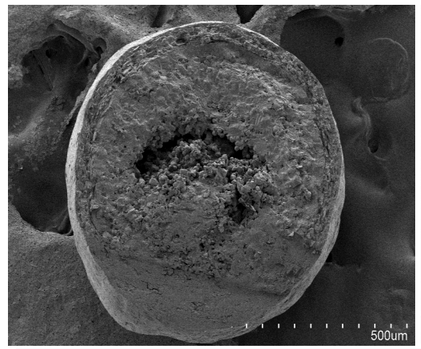
APAP powder was applied at 100 g/min through the modified accelerator air ~~sleeve~~ while the PVP binder was applied at 150 g/min. A 20% weight gain of APAP was applied in a total process time of 50 minutes, with no agglomeration. The process was also efficient, with a 96.57% total process yield. Results were compared directly to a standard wurster coating process utilizing a 10% concentrated solution of APAP applied to the same batch size.

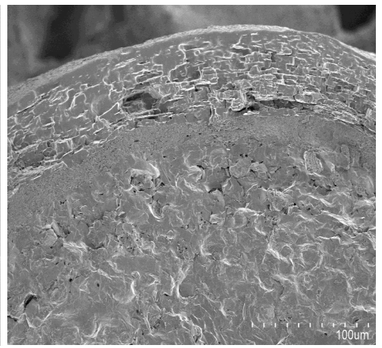
Process Results

Process	Process Time	Agglomeration %	Final Particle Size (D50)	Batch Size (kg)	Yield (%)	API addition rate (g/min)
Standard Wurster Spray Coating	110 mins	0.5	1026 microns	30	98.1	50 g/min
Wurster with Dry Powder Addition	50 mins	0.7	1030 microns	30	96.57	100 g/min

Modified Wurster Accelerator ~~Sleeve~~ with talc being delivered from the 45° air holes. Mounted on a standard Fruend-Vector Wurster spray gun.

In-Process picture showing 18" wurster being fed with talc by a K-Tron powder feeder.





SEM images show the coating layer on the surface of the sugar sphere

CONCLUSIONS

The processing results showed that the APAP powder was successfully applied to the Suglets utilizing dry powder layering technology in a Wurster system. The ability to apply powder at a 100% solids level leads to a reduction in process time versus standard solution based coating in a Wurster.

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