

Novel Enteric Coating of Multi-Particulates with Dry Powder Application of Glidant Utilizing a Modified Wurster Spray Gun System

Brian Jensen, Larry Maher, Shawn Engels, Prachi Shah
Freund-Vector Corporation, Marion, Iowa USA

PURPOSE

Bottom Spray Wurster technology is commonly used in the pharmaceutical industry as a method for applying active and functional coatings, including enteric coatings, to multi-particulate substrates. Typically dilute solutions or suspensions of polymer mixed with appropriate glidant to reduce blocking during the drying of the polymer coat is applied via air atomizing spray guns. Having to dilute the solution can increase the application time needed for enteric protection. Having to add glidant to the solution can create sedimentation and plugging in the solution lines. This study focuses on whether a modified Wurster gun could be utilized to efficiently coat multi-particulate cores in an existing Wurster system utilizing an enteric polymer and dry powder layering technology.

METHOD

18/20 mesh cores containing 10% Acetaminophen were loaded in to a Freund-Vector VFC-3 fluid bed equipped with an 8" tapered Wurster insert and in to Freund-Vector VFC-60 fluid bed equipped with an 18" straight sided Wurster insert. An enteric polymer, Eudragit L 30 D (Evonik) was applied as a 30% w/w suspension via the spray system. Micronized talc (Spectrum) was put into a KTron KT-20 loss-in-weight powder feeder, and was simultaneously applied through a modified Accelerator air sleeve on the spray gun. As a control, Eudragit L 30 D was also applied per the manufacturers recommendation in a conventional manner with the glidant added to the suspension. Batches were repeated to confirm results.

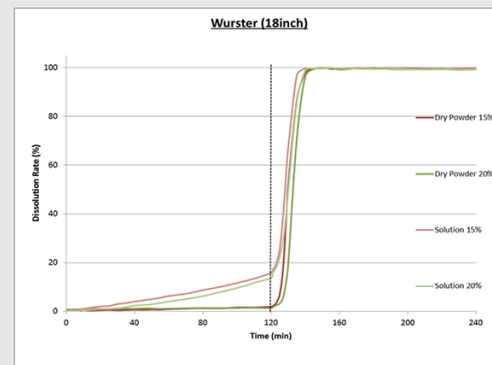
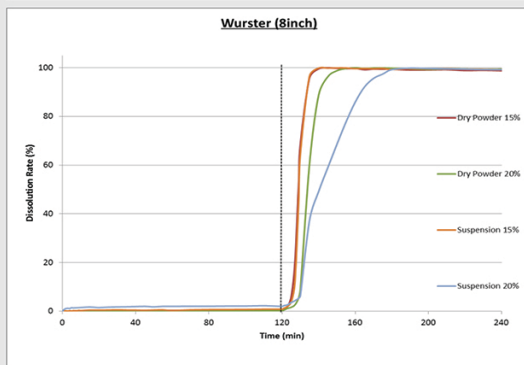
EQUIPMENT



Spray Gun with Diverter Sleeve

RESULTS

In the 8" Wurster using the powder application, the coating was applied in 43 minutes at an 86% efficiency, while the suspension application was applied in 119 minutes at an 84% efficiency. In the 18" Wurster using the powder application, the coating was applied in 42 minutes at a 96% efficiency while the suspension was applied in 117 minutes at an 83% efficiency.



PROCESS VIDEO



CONCLUSION

Using the Wurster Accelerator to apply the glidant as a dry powder, the 20% polymer application was accomplished almost three times faster than conventional methods. The efficiency of polymer application was as good or better than conventional application. Leakage in acidic medium was less than conventional application. Agglomeration was acceptable at far less than 1% for all application methods.

Using the Wurster Accelerator Dry Powder Application System will increase productivity and produce coated multiparticulates that are equal or superior to conventional coating methods.

