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Increased Spray Rates for Particulate Coating Using Wurster Pro Technology

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PURPOSE

Bottom spray Wurster coating is a widely used process for applying API or functional coating for sustained and extended release or just barrier coating on to multi-particulates. In many cases, the process can be very long because high spray rates are not able to be achieved without agglomerating the particulates. This is especially true when using coating systems that are tacky. For such systems, talc or other glidants are typically added to the coating solution which helps to reduce the tendency of agglomeration. This allows for slightly faster spray rates. One of the draw backs of such systems is that there are solids suspended in the solution which can cause sedimentation and plugging of spray nozzles. Such suspensions also need to be stirred continuously to avoid any such issues during processing. Wurster Pro was developed as a novel method to remove talc or other anti-tacking agents from coating solutions and supplied in a powder form without sacrificing its advantages to attain high spray rates. The primary goal of this work was to evaluate if Wurster Pro can provide comparable coating efficiency at relatively higher spray rates than the standard Wurster process.

METHOD(S)

The coating trials were initially conducted using a VFC-LAB 3 FLO-COATER® (Freund-Vector Corporation) with an 8” Wurster insert in a standard set-up with a 12L product container. For Wurster Pro set-up, a precision powder feeder (Coperion, K-Tron), was used to deliver anti-tacking agent, talc, during the process. For both the processes, 3 kg sugar spheres (Suglets® 18/20) were used as a core material. The coating formulation for the standard Wurster process contained 7.5% w/w ethyl cellulose, 0.75% w/w dibutyl sebacate (DBS), 2.5% w/w micronized talc in ethanol:water mixture (9:1 w/w). This formulation served as a discriminating coating system to compare the standard Wurster and Wurster Pro processes due to its significantly tacky nature. The Wurster Pro formulation was the same as the standard process except that the talc was applied in a dispersed powder form. The process was considered complete when theoretical weight gain of 5% w/w was achieved. The talc powder used for Wurster Pro was dispersed into a fine mist by supplying compressed air (accelerator air) to further improve coating efficiency and reduce agglomeration. The coated pellets were dispersed in DI water and aliquots were subjected to loss-on-drying for evaluation of percent solids released over a period of time to evaluate comparative coating efficiency between the two processes. The dissolution profiles are shown in Graph 1. This process was repeated using an VFC-15M FLO-COATER® (Freund-Vector Corporation) with a 9” Wurster insert to test scalability. Finally, the process was repeated on a production scale using an VFC-60M FLO-COATER® (Freund-Vector Corporation) with an 18” Wurster insert. Dissolution was only completed for the 8” and 9” processes.

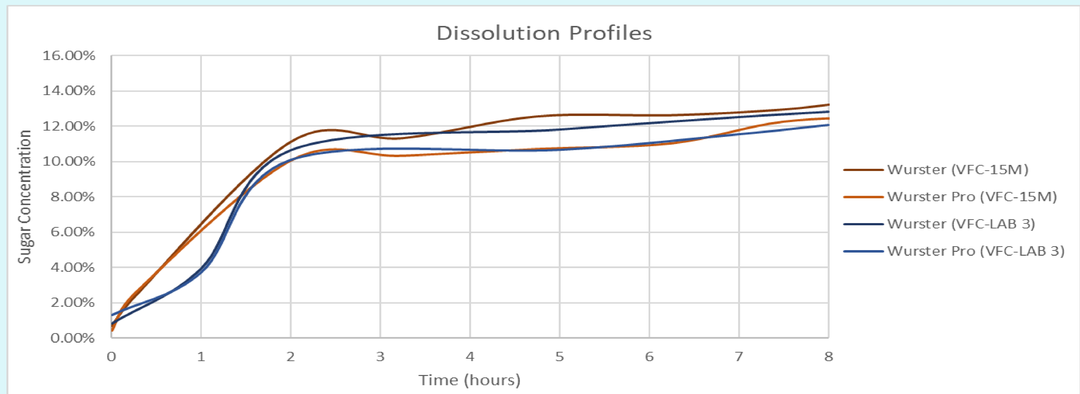
RESULT(S)

All processes were optimized to achieve the highest possible spray rate without agglomerating more than 2% of the product when the full coating amount was applied. The coating was considered complete when 5% weight gain was achieved. Using the 8” Wurster on the VFC-LAB 3, the spray rate was increased from 19 g/m to 25 g/m. This resulted in a 25% reduction in total spray time. Using the 9” Wurster on the VFC-15M, the spray rate was increased from 25 g/m to 32 g/m. This resulted in an 18% reduction in total spray time. Lastly, using the 18” Wurster in the VFC-60M, the spray rate was increased from 110 g/m to 135 g/m. This resulted in a 13% reduction in total spray time, which is 40 minutes for the production scale system per batch. All of the data for the trials is shown in Table 1. Not only did Wurster Pro reduce processing time, but it also prevented any nozzle plugging issues that can occur when solid particles are suspended in the coating solution. In all trials, the total amount of talc applied to the process, dry or in solution, was held constant. The amount of talc necessary in powder form could potentially be reduced by using powder feed screws with less open volume. This would allow for better powder dispersion.

8" Wurster (VFC-LAB 3)						
		Solution Spray Rate		Talc Spray Rate		
Set-Up	Weight Gain (%)	Target (g/m)	Actual (g/m)	Target (g/m)	Actual (g/m)	Agglomeration (%)
Wurster	5.4%	19	19.5	0.50	0.49	0.98%
W-Pro	5.5%	25	25.3	0.70	0.68	1.79%
9" Wurster (VFC-15M)						
		Solution Spray Rate		Talc Spray Rate		
Set-Up	Weight Gain (%)	Target (g/m)	Actual (g/m)	Target (g/m)	Actual (g/m)	Agglomeration (%)
Wurster	5.0%	25	25.5	0.63	0.64	0.39%
W-Pro	4.9%	32	30.5	0.80	0.82	0.77%
18" Wurster (VFC-60M)						
		Solution Spray Rate		Talc Spray Rate		
Set-Up	Weight Gain (%)	Target (g/m)	Actual (g/m)	Target (g/m)	Actual (g/m)	Agglomeration (%)
Wurster	5.1%	110	120.3	2.75	3.01	0.73%
W-Pro	5.1%	135	134.9	3.35	3.35	1.11%

Table 1: Wurster Pro Scaling Data

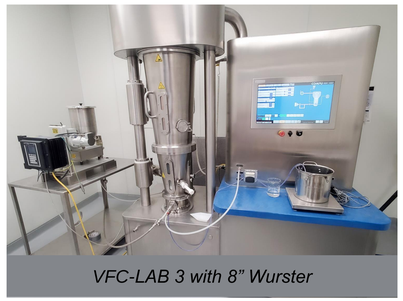
After the trials using the 8” Wurster and 9” Wurster were complete, dissolution testing was conducted to verify that the coating applied by a Wurster Pro process functioned similarly to the standard Wurster process. The profiles shown in Graph 1 indicate that the coating functionality is equivalent for standard Wurster and Wurster Pro, and that the process is scalable.



Graph 1: Wurster Pro Dissolution Profiles for 8” and 9” Trials

CONCLUSION(S)

The Wurster Pro provided two major advantages over the standard Wurster process. It allowed the anti-tacking agent, talc, to be removed from the coating solution and added in a powder form. It also permitted processing at an increased spray rate and thus, reduced the overall processing time. The Wurster Pro process was scalable and highly reproducible.



VFC-LAB 3 with 8” Wurster

VFC-60M with 18” Wurster

Wurster Pro Gun

Coated Sugar Spheres