

“Novel Dry Powder Application of Anti-Tack Agent Utilizing a Wurster Pro™ Spray Gun System”

From Increased Spray Rates to Scale Up Studies

The Background...

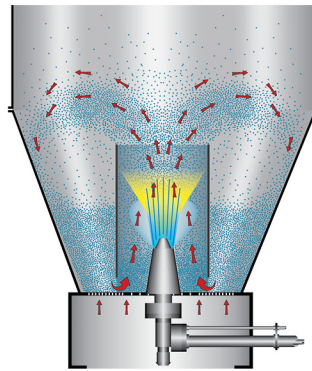
Wurster coating of multi-particulates with polymer suspensions and solutions is widespread in the pharmaceutical industry. Several formulations for polymer coatings of aqueous dispersions and organic solvent based polymers require glidants such as talc to be suspended into the solutions to cut down on tackiness.

The Challenge...

The need to dilute the solution can increase the application time needed for proper drug release or enteric protection. When adding glidant to the solution, it can create sedimentation and plugging in the solution lines or spray guns during the process, causing equipment issues along with increased processing times and inefficient coating. A series of case studies focuses on whether a Wurster Pro™ system, which allows dry powder to be injected separately into the spray zone could be utilized to efficiently coat multi-particulate cores in an existing Wurster system utilizing an enteric polymer and dry powder layering technology.

The Solution...

FREUND’s patented Wurster Pro™ spray gun utilizes the same gun body as the original Wurster processor. The main difference between the Wurster and Wurster Pro™ is with a outer sleeve that is placed around the Wurster Gun. FREUND calls this sleeve the Wurster Accelerator. The accelerator creates an air curtain that diverts product away from the spray nozzle tip, optimizing product movement through the spray zone and reduces processing times. With the Wurster Pro™, the Wurster Accelerator is modified with slightly larger holes. It still creates the air curtain, which allows for greatly increased spray rates. However, it also allows for the application of a powder to be introduced into the processing area concurrently with the coating solution. This allows for the glidant to be applied as an isolated excipient instead of being included in the solution formulation. This has been shown to save processing time and solution preparation time.



The Conclusion...

We have determine using the Wurster Pro™ system proved to be an effective method to apply anti-tack agent as a dry powder for aqueous and solvent based polymer solutions that require anti-tack agents. The polymer application rate can be increased at least 10%.

The efficiency of polymer application is better than conventional application methods in the scale-up batches tested.



Wurster Pro Gun

Additional Highlights

- ✓ Lubricants and Glidants Function Better Dry vs Wet
- ✓ Eliminate Suspensions in Solutions
- ✓ Increases Spray Rate
- ✓ Can Reduce Total Amount of Lubricant/Glidant Needed
- ✓ Removes Sedimentation/ Clogging in Lines & Spray Gun
- ✓ Agglomeration Rates: <2% on all Trials

Who We Are...

For 60 years, FREUND has been a world-class custom granulation and coating equipment solution provider prepared to satisfy your requirements on a global scale.

We offer Fluid Beds, Roll Compaction, High Shear Granulators, Tablet Coaters, Spray Dryers and Powder Handling.

Our Mission:
Creating Essential Technologies For a Brighter Tomorrow



Case Study 1: Wurster vs Wurster Pro™ Spray Rates

The purpose of this study was to determine how much faster the solution could be sprayed using the Wurster Pro™ system compared to a standard Wurster set up. The process parameters and trial data is shown below. You can see the process time on the Wurster Pro™ system is **26 minutes faster!** Dissolution testing was conducted by stirring the coated sugar spheres in water and measuring the moisture in 3 mL samples over time to determine the sugar concentration in the water. Since the dissolution profiles are very similar, this proved that the release rates from the coatings for each process were the same.



Equipment Set-Up:

- ✓ FC-LAB 3 FLO-COATER® with 8" Wurster Insert
- ✓ Wurster Pro™ Spray Gun
- ✓ 3.5 mm Air Cap
- ✓ 1.2 mm Nozzle
- ✓ Screen Filters
- ✓ 1" Partition Height
- ✓ PG2 Wurster Plate
- ✓ #16 Silicon Tubing
- ✓ Dry Powder Feeder

Process Parameters:

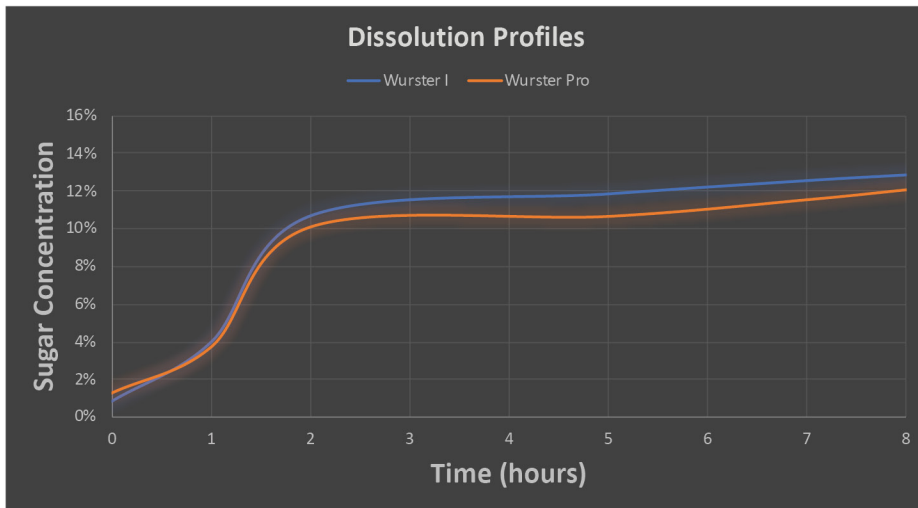
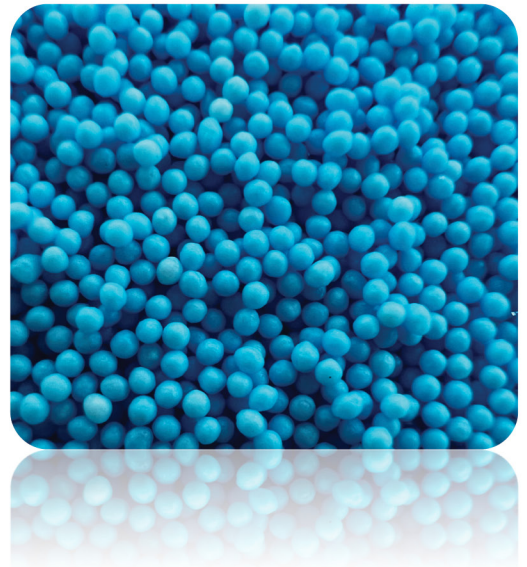
- ✓ Airflow: 100 CFM
- ✓ Inlet Temp: 43-46° C
- ✓ Product Temp: 32-34° C
- ✓ Atomization Air Pressure: 30 PSI
- ✓ Eductor/Accelerator Air Pressure: 60 PSI

Formulation/Cores:

- ✓ Ethocel 10 dissolved in an Ethanol/water solution at 7.5% solids
- ✓ **3kg** batch of 18/20 mesh sugar spheres

Set-Up	Weight Gain (%)	Solution Rate (g/m)	Talc Rate (g/m)	Process Time (min)	Agglomeration Rate (%)
Wurster	5.5	19.4	0.48	108	1.86
Wurster Pro™	5.6	25.5	0.67	82	1.85

Wurster Pro™ was sprayed at the fastest possible rate to stay under 2% agglomeration



Case Study 2: Scalability - FC-LAB 3 to FC-15M

The purpose of this study was to determine how scaling up can increase productivity of coated multi-particulates with equal or better results to conventional coating methods. With the process parameters and trial data shown below, you can see the Wurster Pro™ trial was much faster, with a 25 minute reduction in spray time!

Dissolution profiles of the FC-LAB 3 trials to the FC-15M trials were conducted and verified that the process could be scaled by maintaining a constant product temperature.



Equipment Set-Up:

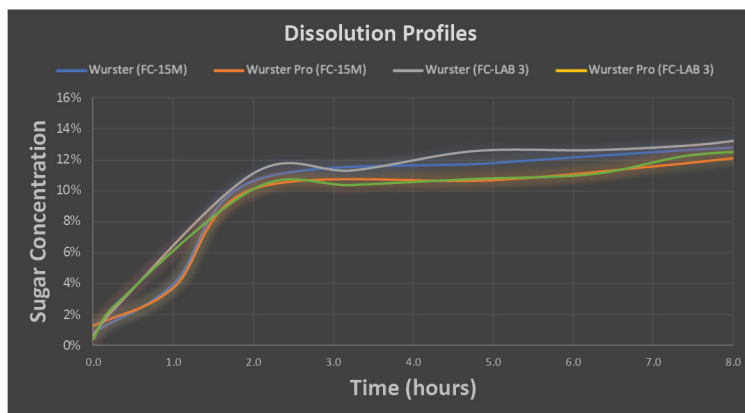
- ✓ FC-15M FLO-COATER® with 9" Wurster Insert
- ✓ Wurster Pro™ Spray Gun
- ✓ 3.5 mm Air Cap
- ✓ 1.2 mm Nozzle
- ✓ Screen Filters
- ✓ 1.5" Partition Height
- ✓ PG2 Wurster Plate
- ✓ #16 Silicon Tubing
- ✓ Dry Powder Feeder

Process Parameters:

- ✓ Airflow: 150 CFM
- ✓ Inlet Temp: 45-47° C
- ✓ Product Temp: 31-33° C
- ✓ Atomization Air Pressure: 35 PSI
- ✓ Educator/Accelerator Air Pressure: 70 PSI

Formulation/Cores:

- ✓ Ethocel 10 dissolved in an Ethanol/water solution at 7.5% solids
- ✓ **5kg** batch of 18/20 mesh sugar spheres



Set-Up	Weight Gain (%)	Solution Rate (g/m)	Talc Rate (g/m)	Process Time (min)	Agglomeration Rate (%)
Wurster	5.0	25.5	0.64	137.6	0.39
Wurster Pro™	4.9	30.5	0.82	112.3	0.77

Wurster Pro™ was sprayed at the fastest possible rate to stay under 2% agglomeration



Case Study 3: Scalability - FC-LAB 3 to FC-60M

This study was to determine that it's possible to scale from a FC-LAB 3 to a FC-60M FLO-COATER®, processing both standard Wurster and Wurster Pro™. Both processing achieved a 5% weight gain but the Wurster Pro™ reduced processing times by **40 minutes**.

Dissolution profiles of the FC-LAB 3 trials to the FC-60M trials were conducted once again and verified that maintaining a constant product temperature that the process could be scaled.



Equipment Set-Up:

- ✓ FC-60M FLO-COATER® with 18" Wurster Insert
- ✓ Wurster Pro™ Spray Gun
- ✓ 9 mm Air Cap
- ✓ 2.2 mm Nozzle
- ✓ Screen Filters
- ✓ 1.25" Partition Height
- ✓ PG2 Wurster Plate
- ✓ 6.4mm Silicon Tubing
- ✓ Dry Powder Feeder

Process Parameters:

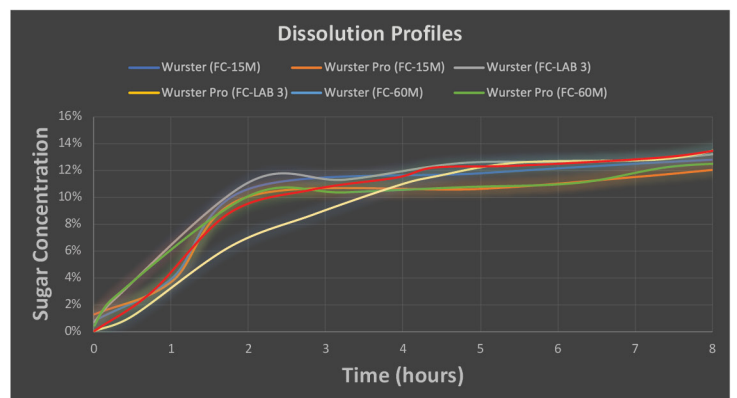
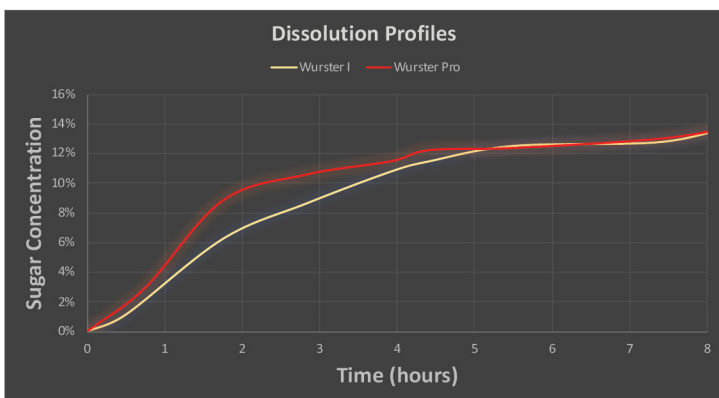
- ✓ Airflow: 520 CFM
- ✓ Inlet Temp: 45-46° C
- ✓ Product Temp: 32-34° C
- ✓ Atomization Air Pressure: 60 PSI
- ✓ Eductor/Accelerator Air Pressure: 60 PSI

Formulation/Cores:

- ✓ Ethocel 10 dissolved in an Ethanol/water solution at 7.5% solids
- ✓ **50kg** batch of 18/20 mesh sugar spheres

Set-Up	Weight Gain (%)	Solution Rate (g/m)	Talc Rate (g/m)	Process Time (min)	Agglomeration Rate (%)
Wurster	5.1	120	3	302.5	0.73
Wurster Pro™	5.1	135	3.35	262.3	1.11

Wurster Pro™: Sprayed at the fastest possible rate to stay under 2% agglomeration

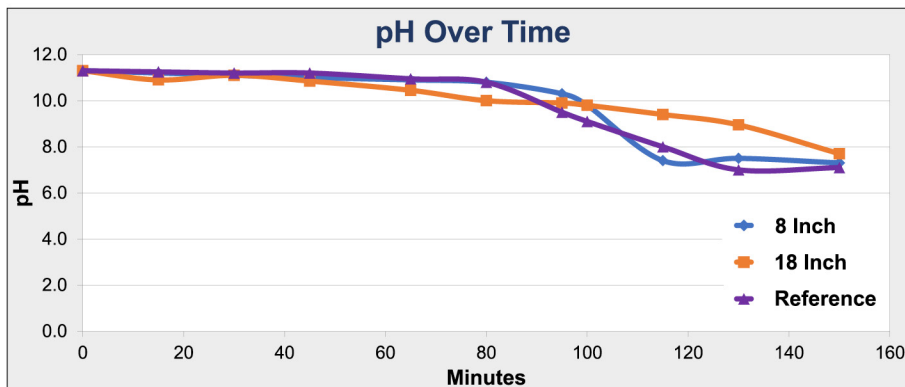


Case Study 4: Scalability - Coating Salt with PVDC

The purpose of this study demonstrates the scalability of the Wurster Pro™ process coating multi-particulate cores of 150-300 micron salts and comparing the results of batch sizes ranging from 4 kg all the way to 250 kg.

An aqueous coating solution formulation of polyvinylidene chloride (PVDC) at 58% dry solids concentration was used. Batch sizes of 4, 40, and 250 kg were processed utilizing various FC FLO-COATER® fluid bed systems with wurster inserts of 8", 18", and 32". PVDC was applied to 20% coating weight levels. Talc (Spectrum) with a nominal size of 10-40 micron was applied at the lowest possible addition rate as the anti-tack agent. Application of the talc was done using a Wurster Pro™ spray gun system along with a powder feeder (K-Tron 20), and air eductor.

Parameters	8 Inch	18 Inch	32 Inch
Batch Size (kg)	4	40	250
Anti-Tack Solids Coating Solids (%)	14	14	14
Product Bed Temp (°C)	34	32	35
Inlet Air Temp (°C)	40	60	50
Inlet Air Flow (M ³ /H)	135	1400	4400
Solution Spray Rate (g/min)	30	420	1100
Powder Rate (g/min)	2.5	35	130
Spray Time (min)	58	43	103



Results:

- ✓ Efficiencies of 98 % were achieved on all three Wurster Pro™ systems.
- ✓ Reduced level of anti-tack agent from 22- 25% of coating solids in solution from previous production processes to 14% when adding anti-tack agent as dry powder.

