

## Case Study: Commercial Scale-Up of Small molecules using Fluid bed microencapsulation

### Executive Summary

Renejix performed a technology transfer from small scale to the desired 10x commercial scale for a small pharmaceutical company. Within 1 month, the process technology development experts at Renejix created feasibility trails for the drug layers and modified released coating processes. The process engineers and manufacturing scientists optimized procedures to enable commercial production of the drug.

### The Challenges

Small Molecule Properties	The small molecule had specific characteristics that required controlled and precise coating techniques. The molecule was a controlled drug substance.
Coating Requirements	The coating process involved the use of organic solvents and heated atomized air to achieve optimal coating uniformity and adherence.
TARGET PRODUCT PROFILE	The objective was to achieve a uniform and controlled coating on the small molecule particles to enhance its stability and controlled release properties.

### The Renejix Solution

Renejix employed a systematic approach to scale up the fluid bed Wurster coating process for the small molecule, addressing the challenges and ensuring successful commercial production.



DEVELOPMENT



DELIVERY



SUPPLY

## Evaluation

The process parameters used in the small-scale manufacturing facility were thoroughly evaluated to understand their impact on the coating quality and efficiency. The data from the small-scale batches provided a baseline for process optimization and scale-up.

## Feasibility and Optimization:

Renjix conducted feasibility and engineering trials on the coating process at the desired commercial scale using larger fluid bed Wurster coating equipment. By considering factors such as spray rate, air volume, and material properties, the process was optimized to achieve optimal fluidization and prevent issues like particle agglomeration.

## Process Validation and Quality Control:

Renjix performed comprehensive process validation studies to ensure the commercial scale process consistently met the desired product specifications. Robust quality control measures were implemented throughout the scale-up process to monitor and verify critical quality attributes of the coated small molecule particles.

Table 2 summarizes the scale-up of the Wurster process from the commercial to small scale Wurster coating machines. In the small-scale, the spray rate and inlet air volume were set to 350 g/min and 400cfm, respectively. While the theoretical scaled-up spray rate is calculated as 875 g/min, when the air volume is increased to 1600 cfm. However, the actual spray rate was only increased to 1050g/min (a factor of 3.47 to prevent over-wetting and pellet agglomeration near the spray nozzle. This optimized spray rate ensured that the desired critical quality attributes were achieved (See Figure 1 below).

**TABLE 2: EQUIPMENT & PROCESS PARAMETERS FOR SCALE-UP FROM SMALL-SCALE TO COMMERCIAL SCALE**

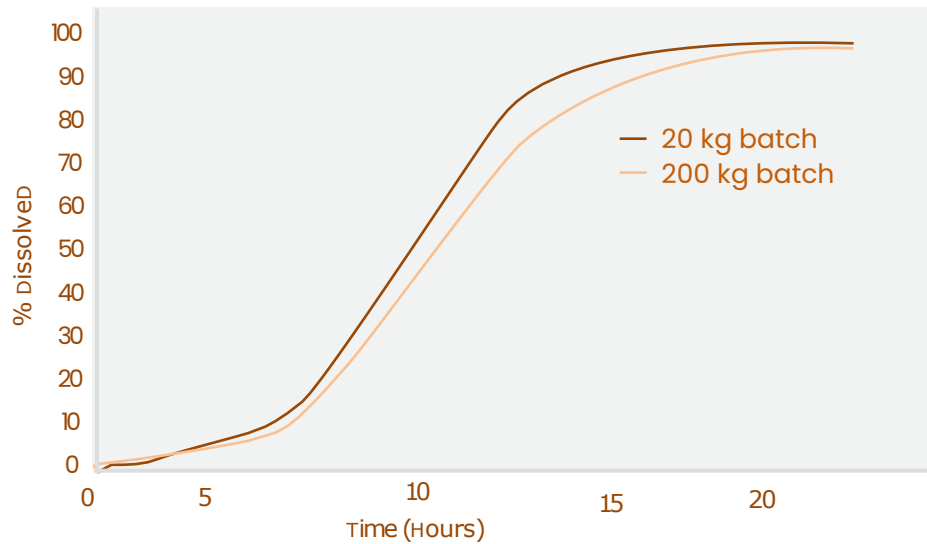
Parameters	Small-Scale	Commercial Scale	Actual Scale-Up Factor
Batch size (kg)	20	200	10
Initial charge	14.2	142	10
Inlet air volume (cfm)	400	1600	4
Spray rate (g/min)	350	800	3.2
Product temp (C)	44	44	
% Yield	96.3	96.4	

## Results and Benefits:

The commercial scale-up of the fluid bed Wurster coating process for the small molecule yielded several positive outcomes:

- **Consistent Product Quality:**  
The optimized process parameters and rigorous quality control measures ensured consistent coating quality across different batch sizes and production runs.
- **Enhanced Yield and Stability:**  
The scale-up process resulted in improved product yield while maintaining the stability and integrity of the small molecule.
- **Controlled Release Properties:**  
The coating process successfully achieved the desired controlled release properties of the small molecule, enhancing its therapeutic efficacy and patient compliance.

Figure 1 Dissolution profile for the small-scale (20 kg) and scaled-up (200 kg) batches.



## Conclusion

Renelix successfully commercialized the small molecule manufacturing method by utilizing expertise in fluid bed Wurster coating and using a systematic scale-up approach. The refined process parameters, extensive quality control methods, and focus on material qualities allowed for the development of a high-quality product with controlled release properties. Scale-up formulas can provide a good basis on which to set initial parameters. Fine tuning of the parameters is necessary to achieve the target product profile. Renelix's staff and scientists that have close to 3 decades of Wurster coating experience have delivered efficient scale up processes time and time again to provide superior products.



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