



CUSTOM POWDER SYSTEMS®

THE CONTAINMENT COMPANY

Dramatic yield increase through use of anti-segregation technologies.

A unique solution improves yields from less than 75% to more than 98%.

The Problem

The Director of a major generic pharmaceutical company discusses problems with manufacturing one of its key products:

"Our material handling process was very inefficient and we were lucky to yield 50% in-spec product, and the handling labor was extensive. I can't even begin to tell you how frustrating it was. Saying this formulation was a challenge is an understatement. The majority of the ingredients are fines blended with large spherical granules. Any movement or disturbance causes the spheres to float to the top of the batch. We knew the main cause of the low yields was due to ingredient segregation occurring between the V-blender and the Tablet Press, but we were at a loss to find a feasible cure to the segregation issue."

The yield issues came to the attention of Custom Powder Systems (CPS) during an on-site visit for another on-going project. As the team walked through the process they discovered the product was loaded into drums from the V-blender. The drums were then moved across the facility into the compression room and hand scooped from drums into the Tablet Press feed inlets.

Analysis

The data gathered on-site was analyzed and three major areas where segregation was occurring were identified:

1. **The transfer from the V-blender to drums.** The distance the product was freefalling into the drum caused the batch ingredients to separate—fines to the bottom and spheres to the top.

2. **Transport of drums.** The manual handling process of loading full drums onto pallets, moving the pallets across the plant and elevating to the Tablet Press inlet further agitated and segregated the product.

3. **Scoop Feeding.** The process of scooping product out of drums into the tablet press produced a second instance of product free-fall induced segregation.

Initial Recommendations

The recommendation was to replace the V-blender and drum transfer with an IBC (Bin) Blender and IBCs. This type of system would eliminate the first two points of the existing process that induced segregation. Using CPS's patented EZ-Down system to transfer the product from the IBC to the Tablet Press would eliminate the third segregation point.

"Their first recommendation to change to a Bin Blending system was excellent but we were reluctant to consider anything that may require modification to the ANDA we filed for this drug. We challenged them to come up with an alternate solution that didn't involve changing the blender."

The Challenge

CPS returned with a two-part solution. First was to provide a custom designed container, later named the "Transfer Hopper" (TH) and a mobile lift to raise it. The TH is elevated so the bottom of the hopper is positioned within inches of the bottom of the V-Blender outlet valve. This assures the product has almost no free fall into the TH when the Blender is emptied. Once the blender valve is opened, the hopper is slowly lowered by the lift providing a controlled, segregation-free discharge from the blender.

The second part of the solution was CPS's patented EZ-Down System that prevents product segregation by eliminating product free-fall. This device has a bladder that inflates to pinch off a flexible downspout running between the IBC outlet and the Tablet Press inlet. Once the IBC valve is opened the bladder is deflated at a controlled rate allowing the weight of the product to push downward through the flexible downspout in a uniform "slug".

Results

"This system exceeded our greatest expectations. Our yields jumped from less than 75% to over 98%, plus we dramatically reduced the labor needed to perform the process. Our return on investment was almost immediate. We are now updating our other lines with this system."

For more information, contact our process and containment experts at:

Custom Powder Systems

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