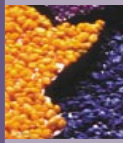


Flow of Solids

Bulk Solids: Science / Engineering / Design



The Newsletter for Jenike & Johanson, Inc.
Spring 1999
Vol. XIX



The Inside View

First, I would like to thank those readers who responded to our last issue with comments and suggestions. We appreciate any suggestions that will make this newsletter more useful to our readers.

In this issue, you'll read about a segregation problem in a pharmaceutical application. This information is relevant to most of our readers, not only those in the pharmaceutical industry, because segregation is a problem common to all industries handling powders and other bulk solids.

John W. Carson
John W. Carson, Ph.D.,
President Jenike & Johanson, Inc.

Case in Point: Improving product quality by reducing segregation in a pharmaceutical application

The Problem

Particle segregation (separation) is a concern in most industries. However, it probably receives the greatest attention in the pharmaceutical industry, where only very slight variations in the concentration of active drug are permitted. Drugs that are produced in solid dosage form (i.e., tablets and capsules), contain many ingredients. If the active ingredient (possibly a very low percentage of the entire blend) is not uniformly distributed, the finished product will not fall within content uniformity specifications and the entire batch may be rejected. Rejected batches are unacceptable from both quality and financial standpoints.

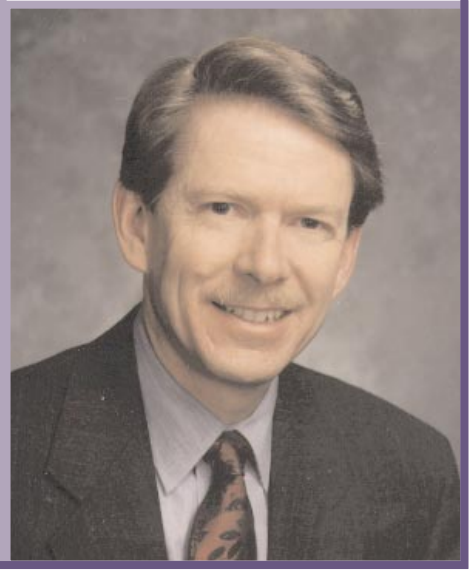
A leading pharmaceutical firm was in the process of validating a new tablet product. The process begins with several ingredients being added to a tumble blender. The blended material is discharged into two portable containers, which in turn are relocated above a tableting press. Initial tests during scale-up showed high active ingredient percentages in the tablets produced from the material which discharged last from each container.



The company contacted Jenike & Johanson to assist in determining the cause of the problem and to recommend a solution. The first step in solving any problem is to gather all of the available information. Jim Prescott, a senior project engineer at Jenike & Johanson, went on-site to observe the process and equipment first-hand, and to discuss the situation with key individuals. Typical areas of concern with such a process include the tumble blender (which may not be creating a homogeneous blend), the portable containers (which may be promoting segregation due to a funnel flow discharge pattern), the transfer chute from the portable container (which may be a non-symmetrical Y-branch feeding two inlets to the press), and the press feed hopper below the chute (which also could provide a funnel flow discharge pattern).

Prior to the site visit, Mr. Prescott recommended that flow properties tests be conducted on four variations of the formulation to determine their handling characteristics. These tests, which included cohesive strength, wall friction, compressibility, permeability, and segregation potential, were conducted at Jenike & Johanson's Westford, Massachusetts facility.

continued on page 2



Case in Point: Improving product quality by reducing **segregation** in a pharmaceutical application



During the site visit, Mr. Prescott found that the material discharged significantly faster from the center of the portable containers. This was supported by flow properties tests, which indicated that the existing surface of the containers was too frictional to provide mass flow. As is typical of a funnel flow discharge pattern, the material discharging at the end of the run was initially along the hopper walls.

The flow pattern in the containers would be less of a concern if the material remained uniformly blended. However, during the filling of the container, segregation occurred which resulted in fine particles accumulating near the perimeter of the container. This was due to both fluidization and dusting segregation mechanisms. During free-fall into a container, particles tend to separate from each other, with fine particles forming dust clouds. When the falling stream impacts the pile, it can become aerated, and generate more dust. In this case, the airborne dust was carried by the airstream, causing it to settle along the walls. Aerated material, at the point of impact of the falling stream, drove fines to the surface of the pile, from where they slid down the pile towards the walls of the container. The combination of a side-to-side segregation pattern, during filling of the containers, with a funnel flow discharge pattern was causing the recorded trend of high assays at the end of each run.

the blender to the portable container, using a retractable let-down tube. Such dust control equipment is used on large scale operations, such as ship loading, but no such equipment has been available for the pharmaceutical industry. Without an off-the-shelf piece of equipment available, Jenike & Johanson engineers further developed the concept, then designed and built the new PharmaSok™ filling system. [See article on page 3 for a more complete description.]

The Result

Tests with the PharmaSok at our facility in San Luis Obispo, California showed a dramatic reduction in the observed dust, normally generated during container filling. The first unit was shipped at the end of January, and trials are currently being conducted under actual process conditions.



According to the manager of formulation development, "It is common, across the pharmaceutical industry, to address problems of this nature during scale-up of a new product, especially a direct blend. Validation requirements are stringent, and rightfully so; however, this makes it a very time consuming and costly process. The improvement anticipated in this case is significant in terms of saving both time and expense - for our company as well

as the consumer. We fully anticipate that the solution provided by Jenike & Johanson will help us control this process, and we hope to try it with some of our other products."

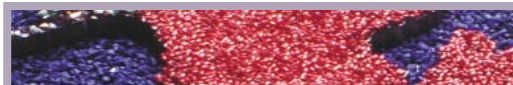
Behind the Scenes: Meet Tom Troxel

Name: Tom Troxel
Title: Vice President
Joined J&J: 1982
Job Description: In addition to heading up J&J's California facility, Tom provides experienced consulting for bulk solids handling applications, ranging from large scale mining operations to pharmaceutical tableting applications.



Of note: Tom also oversees the design, construction, and supply of specialized equipment that is supplied through our California office. This commonly includes items such as mass flow screw feeders, elongated slide gates for use with screw and belt feeders, tumble blenders, and solids pumps. More unique items with which Tom has been involved include a custom 200 cu. ft. tumble blender for a highly segregating mix, and an air-assisted discharger that increased the discharge rate while maintaining a high density with kaolin clay.

"What keeps me interested at J&J is the wide range of projects in which we get involved. We solve bulk solids handling problems with materials ranging from cake mix to copper ore. We also educate clients to help themselves; we advise clients on solving specific problems; and we design and supply custom equipment when off-the-shelf items won't work. Every day offers something new and challenging."



1999 AIChE Course Dates

For over 20 years, experienced engineers from Jenike & Johanson have presented one of AIChE's most successful courses, Flow of Solids in Bins, Hoppers, Chutes, and Feeders. Remaining dates and locations for 1999 are as follows: May 18-19 in Philadelphia, July 29-30 in New York, Sep. 20-21 in Chicago, and Nov. 4-5 in Dallas.

This course is offered through AIChE's continuing education program. To register, call AIChE at (800) 242-4363. The fee is \$895 for members and \$995 for non-members.



PharmaSok™ Filling System Eliminates Dusting

In the production of drugs in solid dosage form (*i.e.*, tablets, capsules), dusting and the resulting segregation can cause unacceptably high variations in the concentration of active ingredient (which is usually only a small percentage of a blend). This poor content uniformity creates product losses and safety hazards which can cost pharmaceutical manufacturers millions of dollars annually.

Transferring mixed powders from a blender to a bin creates a dust cloud, which settles on top of the pile and also concentrates along the bin walls. This finer material, commonly the active ingredient, often discharges at the end of a batch run, producing tablets that are not within specifications. Entire batches are failed as a result.

The PharmaSok filling system (patent pending) is a new method of preventing these problematic dust clouds from forming. It



includes a rolling stand, FDA compliant tubing (the "sock"), and a PLC-operated retraction unit. The system is rolled in place beneath the blender, to which it is sealed. An empty portable container is then positioned below the system. The operator discharges the powder mixture from the blender through the PharmaSok, into the container. Because the powder is completely contained, there is no free-fall, and therefore, no dust cloud. The PharmaSok automatically retracts the tubing at a pre-set speed, filling the container gradually without dust or segregation. The used tubing is automatically rolled up for easy disposal as it retracts.

The PharmaSok filling system is supplied through ProModus, a division of Jenike & Johanson. For more information, call (978) 392-1863, or visit the ProModus booth (#2084) at the Interphex show in New York, April 20-22.

Did you know?

Many companies have found it economical to use outside expertise to solve problems, rather than develop these capabilities in-house. However, this outsourcing makes it more difficult to control the spread of proprietary information. When selecting consultants, it is important to assess their commitment to maintaining confidential information. Unlike some academic and other publicly-funded institutions, Jenike & Johanson, Inc. is not obligated to publicize who we are working for, the subject matter of the work, or the results. In fact, we have a strict policy against disclosure of proprietary information, and all of our employees sign an agreement to this effect. Whether or not we have a formal agreement with a client, we treat all client information the same - namely, no disclosure unless you authorize it.

Q&A with

Q I was told that a 70° conical hopper will reliably discharge any bulk solid. Is this angle steep enough to ensure mass flow?

A No, not for many applications. Mass flow occurs when the friction between the bulk solid and wall surface is low enough to allow the material to slide along the hopper walls. This friction can vary greatly with the surface finish and the material of construction of the walls. Surprisingly, a smoother surface is not always better. Some fine powders tend to adhere to a smooth surface, similar to a suction cup on smooth glass. Variations in the moisture content and temperature of the bulk solid can also affect friction properties.

If you have any bulk solids handling questions, or if you have suggestions for future articles, please contact:

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Flow-of-Solids Industry Calendar

"You get the benefit of years of experience."
"Instructors were very knowledgeable, well prepared, and professional"
- From course attendee evaluations of recent Jenike & Johanson presentations



**April 20-22, 1999,
New York, NY**



INTERPHEX

Interphex, the International Pharmaceutical Exposition & Conference. Jim Prescott, senior project engineer at Jenike & Johanson, will present courses titled "Pharmaceutical Powder Handling Part I: Providing Consistent, Reliable Flow," and "Part II: Maintaining Solid Dosage Form Quality." To register, contact Reed Exposition Companies, (203) 840-5848. Stop by and see us at booth 874.



- Blending and Segregation and Their Effects on Product Quality
 - Flow Aids: Common Types and Their Proper Uses
 - Retrofit Troublesome Solids Handling Equipment to Improve Flow and Product Quality
 - Design of Transfer Chutes to Minimize Buildup, Abrasive Wear, and Dust Generation
- To register, contact Reed Exposition Companies, (203) 840-5848. Come see us at Booth 1826.

May 24-28, 1999, Pittsburgh, PA

Duquesne University, Graduate School of Pharmaceutical Sciences, presents a seminar on Pharmaceutical Unit Processes and Solid Dosage Form Development. Jim Prescott, senior project engineer at Jenike & Johanson, will present a session on "Solids Blending, Segregation, and Sampling."

April 26-28, 1999, Princeton, NJ

The Institute for International Research presents a conference on Pharmaceutical Solid Dosage Forms. Jim Prescott, senior project engineer at Jenike & Johanson, will present a workshop on "Utilizing Solids Handling Technology to Maintain Content Uniformity."

April 28-30, 1999, Santiago, Chile

Two in-house courses presented at Jenike & Johanson Chile Ltda.

- Bin and Feeder Design
- An Introduction to Pneumatic Conveying

**May 10-13, 1999,
Chicago, IL**

**Powder &
Bulk Solids**
CONFERENCE/EXHIBITION

24th annual Powder and Bulk Solids Conference/Exhibition.

Jenike & Johanson personnel plan to present the following:

- Solve Solids Flow Problems in Bins and Hoppers
- How to Select or Troubleshoot Volumetric and Gravimetric Feeders to Ensure Reliable Flow
- Fine Powders: Reliably Handling Bulk Solids That Can Behave Like Fluids

June 20-24, 1999, Vancouver, BC, Canada

1999 International Conference on Powder Metallurgy & Particulate Materials. Brian Pittenger, senior project engineer at Jenike & Johanson, will be giving a presentation titled, "Powder Uniformity Considerations in Feed, Storage, and Processing."

August 11-13, 1999, Porsgrunn, Norway

Reliable Flow of Particulate Solids III. An international symposium bringing together the leading experts in characterizing and handling particulate solids. John Carson, Ph.D., president of Jenike & Johanson will be presenting two papers.

September 14-16, 1999, Toronto, Canada

Two in-house courses presented at Jenike & Johanson Ltd.

- Bin and Feeder Design
- An Introduction to Pneumatic Conveying

Hot Off the Press

Blending Case Studies of Highly Segregating Bulk Solids

by David Craig, Ph.D., John Carson, Ph.D., and T. Anthony Royal (ICBMH '98, 6th International Conference on Bulk Materials Storage Handling and Transportation)

Bulk Properties of Powders

by John Carson Ph.D. and Brian Pittenger (ASM Handbook - Powder Metal Technologies and Applications)

Controlling Segregation when Feeding to Agglomerators

by Brian Pittenger and John Carson, Ph.D. (The Institute for Briquetting and Agglomeration, Proceedings, Vol. 25, Oct. 1997, pp. 25-36.)

Developing a Better Understanding of Wall Friction

by James Prescott, Donald Ploof, and John Carson, Ph.D. (Powder Handling and Processing, 1999)

To order any of these free papers, or for a full list of papers, write on your company letterhead to:
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