

Designed Experiment Helps Solve Tablet Sticking Problem

Schiff Nutrition International, Salt Lake City, Utah, develops, manufactures, markets, distributes and sells vitamins, nutritional supplements and sports nutrition products. The company recently embarked upon an engineering project to solve an intermittent problem -- a multimineral tablet sticking inside the dies of a high-speed rotary tablet press. They also hoped to improve the tablet's hardness in order to better withstand packaging and shipping.

The production staff varied press parameters without success. They then developed a statistically-designed experiment. It was a mixture design that allowed specific constraints on each of the constituents. The experimental results indicated that the standard formulation provided close to optimal properties for the multimineral tablet. "It was clear that the formulation itself was not causing the problem," said Jarom Webster, Research and Development Scientist for Schiff Nutrition. "So we searched for other factors that could be playing a role and discovered that when we moved the operation from a single-sided to a double-sided press the problem went away."

Product background

Joe Weider founded the sports nutrition industry in 1940. Schiff Nutrition began as the nutritional products division of Weider Health and Fitness (formerly called Weider Nutrition). Schiff's core brands include Schiff®, Tiger's Milk®, and Fi-Bar. The company manufactures these products in a highly controlled, state-of-the-art manufacturing facility constructed in 1997 at its Salt Lake City headquarters. Schiff follows a standardized set of Good Manufacturing Practices (GMPs) for nutritional supplements developed by the National Nutritional Foods Association (NNFA), the largest dietary supplement trade association in the United States.

Schiff's multimineral tablet is made using the following process. First a mixture of various powders is weighed and blended and discharged into bulk sacks. Next, these sacks are moved to another processing area where the blended material is loaded into hoppers that feed the tablet presses.

Factors and responses

The primary active ingredients of the tablet are magnesium and chelated zinc. It requires three different binders that make up approximately half of its composition – to be precise: 49.3 percent by weight. Additional ingredients include a lubricant, a glidant and a disintegrant. The four components experimented on by Webster were:

- A. Binder 1 (from 0 to 49.3 weight % of total tablet weight)
- B. Binder 2 (0 to 49.3%)
- C. Binder 3 (0 to 49.3%)

The responses for the experiment included the tablet hardness at three different levels of compression in the tablet press as measured on a Dr. Schleuniger 6D hardness tester. Webster also evaluated the time required for the tablets to disintegrate in a 37 °C water

bath. He also tested punch tightness, which measures the force exerted by the lower punch to eject the tablet from the die. This is important because under certain circumstances powder can stick to the die wall and potentially jam up the press.

Here is the complete list of responses:

- 1) Tablet hardness at 15 KiloNewtons (KN) compression force, measured in kilopons
- 2) Hardness at 30 KN
- 3) Hardness at 45 KN
- 4) Disintegration time at 45 KN
- 5) Punch tightness (Newtons)
- 6) Tablet weight relative standard deviation (RSD) (%)

Experimental design

After identifying the factors and responses, Webster used Design-Expert[®] software from Stat-Ease, Inc. (Minneapolis, Minnesota) to design the experiment.

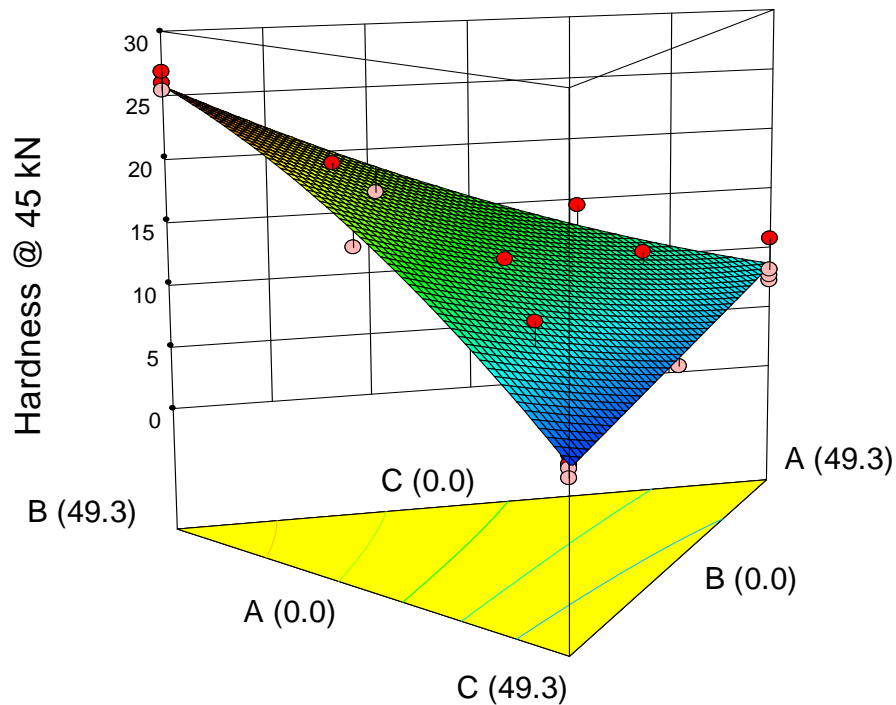


Figure 1: Response surface for critical hardness response

It provided specialized tools to keep the three ingredients within their specified total. The program laid out 20 formulations, including a number of replicates for estimating experimental error. The test matrix evaluated all of the factors simultaneously and probed higher order and multiple component interaction effects.

“A key factor in the success of DOE at Schiff has been the outstanding technical support provided by Stat-Ease,” Webster concluded. “They have responded quickly and with a high level of expertise whenever I have run into a problem. For example, in another DOE study, before I embarked on 35 runs I emailed my design to Stat-Ease’s staff of statistical consultants and asked for a review. They got back to me within 24 hours with confidence-building feedback.”

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