Weight variation in filled two-piece capsules is a common occurrence. This article tells you why the weight of your filled capsules can vary and how to fix the problem.

During a webinar about capsule filling last year, I asked attendees to choose the most prevalent problem they faced operating their capsule filling process. As Figure 1 shows, the audience—comprising people working in 20 different countries—made it clear that weight variation dominated. Not only was weight variation of filled capsules the primary cause of difficulty, it received more votes than the next two leading categories combined.
The problem of weight variation in filled two-piece capsules is like a sleeping giant. It’s often tip-toed around for fear of upsetting it, and weight variation doesn’t jump out at you like dented ends or split capsules do. As the need for content uniformity increases and regulations become more strict, manufacturers must ensure weights are within a limited range from capsule to capsule throughout production.

This article describes how to use “5M and 1P” root-cause analysis to identify the most common sources of weight variation and how to prevent them when filling capsules using a tamping-style automatic filler. The 5M and 1P method goes by different names, but the principles are the same. The five M’s stand for machine, material, method, measurement, and Mother Nature. The P stands for people. The root cause of most quality problems can be assigned to one of these six areas. Identifying and addressing them is a sure-fire way to improve your operation.

The process as designed

In tamping-style capsule fillers, the objective is to create uniform powder slugs in a five-step process that uses a dosing bowl, product bed, tamping pins, and a dosing disc (Figure 2).

Slug formation begins at tamping station one, where penetration of the pins into the dosing disc is the deepest of the five stations. Thereafter the penetration becomes shallower, in stair-step fashion, typically in increments of 2 to 3 millimeters. In this manner material is added and the slug of compressed particles grows. At the end of the tamping process, these cohesive and uniform slugs are transferred cleanly into the open body of the capsules.

The photos above show slugs that were exposed by pushing the capsule body up from the bottom of a segment. Note that the upper portion of the slug—which extends beyond the capsule body—maintains its form in the top photo. This is the desired result, a slug that allows the machine to close the capsule without disturbing the powder, thereby locking all the material into the finished capsule. The loose slugs shown below it will lead to weight variation and other problems.
To achieve consistent weights, you should run powders that are formulated to cohere into slugs. You must also set the tamping stations correctly. Here’s a good starting point, which can be fine-tuned as needed for your powder: Set the last—station five—so the pins are level with the top of the dosing disc. Then set each preceding station 2 to 3 millimeters deeper. See Table 1.

This setup is effective for most product types, but not when the powder doesn’t compress into a slug. In those cases, try using a thicker dosing disc and applying less compressive force, which may reduce weight variation caused by “splash-out,” where powder squeezes out of the bore past the pin during compression. The changes, however, won’t produce a clean-cut slug, so weight variation is still likely at the transfer station and during capsule closing.

### Material

The formulation of the fill material is always important, and although preparing a formulation to fill capsules is much simpler than preparing one to make tablets, many people still over-formulate for capsules. The most common mistake is adding too much flow agent, such as silicon dioxide. A small amount is effective when it’s used sparingly to distribute powder within the bowl, but adding more than necessary creates a problem that’s difficult to reverse. Operators often complain that the powder begins flowing like water inside the bowl, at which point it will no longer compress. Instead, it moves past the periphery of the tamping pin during penetration instead of remaining in the bore (splash-out).

A better option to over-lubricating is retrofitting the bowl with one or more attachments—whisks, diverters, or a cone—to force the powder into the area it belongs. The attachments allow you to overcome powder flow issues and avoid the risk of creating a product that won’t compress, which leads to weight variation.

Another way to fight weight variation on a tamping-style machine involves the wiper block at the powder transfer station. The wiper block’s function is to clean the disc before the slugs are transferred into the capsule bodies. Directly after the wiper block is station one, where slug compression begins. That arrangement can lead to an uneven product bed on the trailing side of the station. You can resolve the problem by bypassing the first station.

### Machine

Machine readiness is the variable you control the most. Make sure the capsule filler is in prime condition to run capsules. Pay special attention to three major components: the tamping pins, tamping springs, and dosing disc.

**Tamping pins.** When new, the pins should have a mirror finish and their working end, the tip, should be squared off 90 degrees to vertical. The mirror finish prevents product from adhering, and the precisely machined tip prevents product from escaping from the disc bore during compression. When the pins become worn and/or damaged, replace them.

**Tamping springs.** The springs are located above the tamping pins to provide both support and relief to the pins during compaction. If you’re over-compressing, the springs may break, which will lead to poor compaction and the weight of the powder slugs will vary.

**Dosing disc.** The bores of the dosing disc often get damaged by tamping pins that are misaligned at setup or by a worn guide ring that allows the pins to move laterally (side-to-side).

If weight variation stems from a damaged or worn dosing disc, there’s an easy way to pinpoint the problem during a production run. As shown in Figure 3, most tamping-style machines have 12 lower segments mounted to the index table and six stations on the dosing disc. Because there are twice as many segment stations, each location on the dosing disc corresponds to two segments 180 degrees apart. As shown in the diagram, location F on the dosing disc transfers product into segments four and 10, while location E transfers into stations three and nine, and so on.

If the dosing disc has a damaged bore at location B, it will affect both segment six and segment 12. To identify

<table>
<thead>
<tr>
<th>Station</th>
<th>Penetration</th>
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<tr>
<td>5</td>
<td>Level with disc</td>
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<tr>
<td>4</td>
<td>3 mm</td>
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<tr>
<td>3</td>
<td>6 mm</td>
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<tr>
<td>2</td>
<td>9 mm</td>
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<td>1</td>
<td>12 mm</td>
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the problem, disconnect the capsule polisher and catch capsules directly at the ejection chute and weigh them while tracking which capsules came from which segment. This is easy to do because the location of the disc at the transfer station will always correspond to the segment at the ejection station. Note: If the problem is a damaged spring or tamping pin, there could be weight variation at every segment.

**Method, measurement, and people**

There are multiple combinations of settings that will produce capsules of the same average weight. But more important than the average weight is the relative standard deviation (weight variation). To prevent wide variation, choose an appropriate dosing disc for each of your products. Next, make sure the operators are trained to identify the appropriate powder level in the bowl and how to set it. The same goes for pin penetration.

Here’s an example to illustrate my point about average weights versus weight variation. Imagine the target is a gross fill weight of 648 milligrams in a size 0 capsule, and four different operators are seeking to meet it. To do so, each operator uses different settings, and they all obtain the target average weight. Good, right? Not so fast. Look at the differences in standard deviation in Table 2. Only Operator 3 succeeded in running the filling process correctly.

**Observations:**
- Operator 1 relied on the volume that a very thick disc provides and got some very high and low individual weights. That happened because the machine couldn’t form a clean, transferrable slug.
- Operator 2 ran the process with too little product in the bowl, so coverage over the dosing disc was uneven.
- Operator 3 achieved a very low relative standard deviation by using the proper disc, bowl level, and pin settings for this formulation. These are the best results.
- Operator 4 used an undersized disc and compensated for it by overworking the tamping pins and springs, which could damage those parts and others.

**Mother Nature**

Humidity, because it contributes to making powders sticky, is a common cause of weight variation on tamping-style fillers. Just as flour sticks to a mixing bowl when a little water is added, powders exposed to overly humid conditions can adhere to the tamping pins (photo).

That may sound extreme, but I recall running a product trial where the relative humidity in the filling room exceeded 60 percent, and weight variation was a big problem. After we brought in some dehumidifiers, the RH dropped to 40 percent and the powder was much easier to fill.

**Conclusion**

A variety of conditions can lead to weight variation, but you can identify them and fix them. Instead of leaving it to chance, address the areas outlined in this article with your operators, formulators, and maintenance technicians; that’s the first step to improving your process. For more training, contact your capsule supplier’s technical service department.

**Acknowledgment**

Brian Dexheimer and Robert Jennings provided photos for this article.

![Excessive humidity can cause powders to adhere to the tamping pins.](image)
Reference


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Further reading

For more information about running your capsule filling process, see Stephen Lee’s earlier T&C articles:

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