

A Complete Guide for

STICKY FORMULATIONS





636-926-8900 natoli.com



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Introduction

This guide provides a best-practices approach to troubleshooting capsule-filling problems when handling a sticky product formulation.

A sticky formulation is one of the most common causes of issues during capsule filling. A capsule filler requires tight tolerances between the machine's tooling components, including the dosing disks, tamping pins, and sealing plate, as well as between the capsules and the segments' bores, which hold the capsules during filling. Friction between the formulation and these tooling components during high-speed operation can cause a sticky formulation to cake and glaze onto the tooling surfaces, restricting the components' movement and leading to inconsistent capsule weights, capsule splits, non-separation, and even machine crashes.

Manufacturers often hope for a silver-bullet approach—one single solution that will fix every sticky formulation issue—but the solution is rarely that simple. Several factors often combine to cause a material to stick, and the problem is best solved using a systematic approach.

Solutions to Try First

The following items are a good place to begin troubleshooting when facing a sticky formulation for a capsule product. These are common contributors to sticking and can be fixed with minimal disruption to operations.

Control the Humidity

Many formulations have hygroscopic properties, meaning they will absorb moisture from their immediate environment. As the moisture level in a formulation increases, it becomes stickier. Operating in a lower humidity environment will reduce moisture in the formulation and the likelihood of material buildup on the tooling. A good range for many products is between 35 and 45 percent relative humidity. Also, keeping holding containers closed as much as possible will minimize the formulation's exposure to humidity in the environment.

Control the Temperature

You may be able to minimize stickiness by controlling the temperature in all production and storage areas. One manufacturer even found success by positioning a cold-air duct directly at the capsule filler's dosing station. The optimal temperature to minimize stickiness for most formulations is between 60° and 75°F, although some formulations may have especially low melting points and require a cooler temperature.

Dry the Compressed Air

Even if the compressed air supply has a dryer positioned after the compressor, the air can pick up condensation traveling to the capsule filler from its source. This condensation can then find its way into segment bores at the machine's cleaning station and cause the formulation to stick. Installing an air dryer/water separator on the incoming pressurized air supply directly at the capsule filler can eliminate this problem.

Slow the Machine

Decreasing the capsule filler's operating speed can sometimes reduce the negative effects of a sticky formulation, as the machine will often do a better job of containing the powder in the appropriate areas.



Solutions to Try First (cont.)

Verify Slug Formation & Transfer

Proper slug formation is a key attribute of good capsule filling because it promotes weight control, reduces waste, and keeps the formulation within the correct areas of the tooling. If the machine doesn't form a proper slug, loose powder can migrate into undesired areas of the machine and coat the parts. A quality slug should hold its cylindrical form during transfer from the dosing disk into the capsule body, and once again maintain its form as the machine pushes the capsule body into the cap.

Ensure Proper Transfer Station Alignment

During dosing, the transfer station is where the formulation moves from the bowl into the lower segment. The lower segment bores should align perfectly with the dosing disk bores before the slug is transferred. If they are misaligned, material can shave off the side of the slug during transfer, and the loose powder will find its way into the segment bores. You can prevent this by using transfer alignment pins to qualify proper alignment.

Establish the Proper Gap at Dosing

The optimal gap between the bottom of the dosing disk and the top of the tamping ring can be dependent on the formulation. For non-sticky formulations, a gap at or near .005 inch will prevent excessive powder from escaping and building up on machine components. However, with some formulations, that same gap can cause the dosing bowl to seize because of sticking. In such cases, increasing the gap significantly—as large as .015 inch—may help. If a larger gap is necessary to successfully run the formulation, be sure excess powder is removed via the machine's tamping ring support base vacuum ports. If the machine isn't equipped with this feature, be sure to periodically clean out excess powder.



Solutions to Try Next

If sticking is still an issue after troubleshooting the first-tier solutions, try the following. These solutions require a larger investment in operations but may help solve a persistent sticking issue.

Add a Cleaning Station

You can minimize buildup of a sticky formulation by upgrading your capsule filler with a cleaning station. The cleaning station will be located directly after the machine's ejection station and uses pressurized air to intermittently blow residual powder from the segment bores into a vacuum hood located above the segments.

Upgrade the Cleaning Station

If your filling machine already has a cleaning station but you are still experiencing powder buildup, you may need to upgrade the cleaning station to include brushes on the cleaning pins. The brushes will help scrub material out of the segment bores in conjunction with the blasts of compressed air, resulting in a more thorough cleaning.

Reduce the Tamping Pin Diameter

Friction from the tamping pins entering and exiting the dosing disk can generate heat and cause sticking problems. To reduce the friction generated, you can try reducing the tamping pin diameter by one size. For example, if you are running size 00 tooling, try using size 0 tampers at the five tamping stations and the transfer station.

Use Plastic Parts

Parts made of a lubricious, food-grade plastic, such as polyethylene terephthalate polyester (PET-TX) can also reduce friction and minimize sticking problems. This plastic is internally lubricated with Teflon and is FDA approved. Many manufacturers have used dosing disks, transfer pins, tamping rings, and even bushed guide rings made of this plastic to successfully encapsulate the stickiest formulations.



If All Else Fails

If sticking problems persist after you've tried all the previous solutions, you may need to consider the following options.

Coat Problematic Parts

Using coated parts has proven effective in many cases, but it is relatively expensive and doesn't always resolve sticking issues. Typical parts that require coating include tamping pins, dosing disks, and segments. Common coatings include chromium nitride (CrN), zirconium nitride (ZrN), boron, and diamond-like carbon (DLC).

Polish Problematic Parts

Another option to alleviate sticking is to polish problematic parts using micro/chemical polishing. This method uses a polish consisting of a fine, abrasive chemical to remove small peaks on critical surfaces, making the surface finish much smoother. It's recommended to have a professional complete this task or to receive proper training beforehand. While this polishing method has proven effective, it can be expensive.

Test New Coatings & Processes

Testing unproven methods can also be expensive, but manufacturers facing a dire-enough sticking problem may be willing to try anything. Technology is advancing quickly, and coating and material options will surely be available in the not-too-distant future that may prove effective.

Change the Formulation

Adding a lubricant or a flow aid to the formulation may also help reduce sticking. However, developing a drug product formulation is costly and time consuming, so even small changes can seem daunting. As a result, manufacturers are typically reluctant to consider changing their formulation to reduce sticking until they've exhausted all other solutions.







Conclusion

Sticking problems are common in encapsulation processes, and there is no one-size-fits-all solution. Often a combination of solutions is required. Following the suggestions discussed in this article will help to eliminate many of the common root causes of sticking and increase your odds of successfully encapsulating sticky formulations.

Jon Carlisle is the founder of Carlisle Precision Encapsulation Parts, a subsidiary of Natoli Engineering. The company is a leading manufacturer of aftermarket change part

kits and spare replacement parts for encapsulation machines.