tablet press operation

Sticking and picking: Some causes and remedies

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Sticking occurs when granules attach themselves to the faces of tablet press punches. Picking is a more specific term that describes product sticking only within the letters, logos, or designs on the punch faces. This article explains the causes of sticking and picking and describes the steps you can take to resolve both problems.

When a product begins sticking to the punch face, the blame game starts. Unchecked, the finger-pointing can zoom around to encompass every person with a hand in the tablet-making process. No one wants to bear the responsibility for the problem.

From your colleagues in R&D you hear, "It didn't stick to the punches in our single-station lab press. Check with the tablet press operators. They're not running the tablet press correctly." When you check with the tablet press operators, they say it's a granulation problem. "If the product had been granulated correctly we wouldn't have sticking problems." The people in quality assurance point out that the product is sticking to the tooling. They suggest that you look for worn tooling or tooling that needs to be polished. Or maybe the tools weren't made correctly to start with. "Call the tooling vendor," they say.

And so it goes.

Is the problem coming from the tablet press or the product formula? Is it the tooling or is it the granulating and drying process? Is it the operators? No one knows for sure.

Sticking and picking

Sticking is one of the most common problems of tablet making. It occurs when granules attach and stick to the faces of the punches instead of locking together to create a uniform tablet. The photos above show examples of tablets rejected because of sticking. Figure 1 shows the face of an upper punch with sticking product. Picking is a specific type of sticking in which particles stick within the letters and logos that are embossed or debossed on the faces of the compression tooling. See Figure 2.

Regardless whether it's sticking or picking, the result is a defective tablet. To salvage the batch, you may have to visually inspect the tablets. This certainly will slow production and decrease yields, but there is no alternative. The formulation is completed; you can't send it back down the hallway for reprocessing.

Sticking can happen at any time throughout a batch. It occurs most often at the initial setup of the tablet press, but it might just as easily appear randomly in a production run. It might also appear at regular, predictable times.

With some products, sticking is so predictable that operators consider it a success when they can run for 2 hours without any sticking.

FIGURE 1

Product sticking to the face of an upper punch

Knowing the moisture content, particle size distribution, and other product properties will help you predict whether a product will compress without sticking. However, even products that meet your specifications may stick and pick. The fact is, you may not know how well a product will compress until it is on the tablet press.

This article will offer some strategies to identify the causes of and solutions to sticking and picking. The source of the problem may relate to the product, the tooling, the upstream processes, or the operation of the tablet press. It might also be a combination of these factors.

Sticky granules make good tablets...right?

When a tablet press is set up for the first production run, the operator will first adjust the weight cams to get the correct tablet weights. (Actually, you adjust the position of the lower punch in the die. In doing so, you control the volume of the die cavity. At a given bulk density, the die volume will correspond directly to tablet weight.)

Once you have the weights right, you adjust to attain the proper tablet thickness. Tablet hardness is determined by a combination of variables, including tablet weight, tablet thickness, press speed, and the dwell time of the upper punch in the die at full compression force.

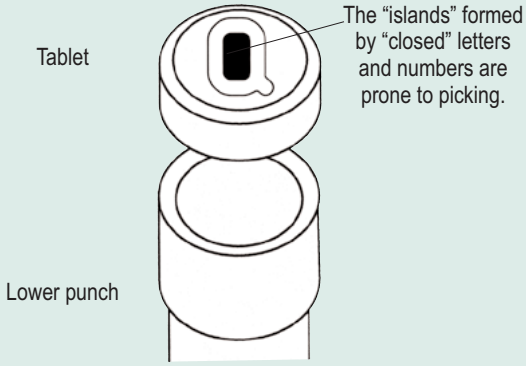
Products with granules that are super-sensitive to compression—call them sticky granules—can form excellent tablets. But they are also prone to sticking to the punch faces. If this is the problem on your press, you are likely to see the problem worsen over the course of the production run. That's because granules super-sensitive to compression will readily compact as they flow through the hopper and into the feed frame.

If a powder compacts before it reaches the die cavity, the bulk density of the formulation increases, impeding your ability to control the tablet weights. As the weight of the tablets fluctuates, so does the compressive force. This variation in force, in turn, can exacerbate the product's tendency to stick. That starts a downward trend, and that's why the sticking gets worse and worse.

Experienced tablet press operators know a trick about compression: If sticking is a problem, they quickly overcompress the product and make very hard tablets for a few press revolutions. This quick action, known as "shocking the press" can work very well. Why? The answer is fairly simple: The stronger compaction forces cause the granules to bind with the tablet and pull the stuck granules away from the punch face. But be careful when using this method to shock the press. If you overload the punches, you will damage them or even break them.

FIGURE 2

An example of picking



Experienced operators can also "save" a sticking batch when inexperienced operators don't know where to start. Experienced operators, for example, often hear changes in the sound of the press and know that the product is sticking. Their first action might be to change the compression settings, such as by increasing the force, reducing tablet thickness, or decreasing pre-compression thickness. They may even slow the press. A good operator always pays attention to the tablet and the tablet press. The sooner you identify a sticking problem, the faster you can resolve it.

The p's and q's of tooling

Sticking and picking are usually the result of many factors, but because they happen on the face of the punch, it's easy to blame the tooling. And sometimes the blame is placed there correctly, especially in the case of picking.

Picking occurs on the letters, logos, and other designs of the punch face. Usually you'll find the picking within the "closed" numbers and letters that form "islands." These numbers are 0, 4, 6, 8, and 9. Some of the letters are A, a, B, b, D, d, e, P, p, Q, q, and so on. See Figure 2.

Tooling manufacturers know about these problematic numbers and letters and do a good job of making punch faces that prevent picking. You can even order tooling with a "pre-pick" feature. A pre-pick feature means that the punch face has islands that are not as deep as the rest of the embossing. Despite the shallower islands, the punch still makes a clean, legible indentation. Another strategy is to change the height and angle of the embossing. Doing so produces a tablet with the same appearance but without the picking problem.

Note that tablets destined to receive a coating will have lettering that is less severely angled, wider, and shallower than the lettering on non-coated tablets. Thus the design of coated tablets helps reduce sticking and picking.

The choice of steel and the degree of polish on the punch will also affect picking. Type D2 and Type 440C steel contain more chromium than other steels, which

reduces sticking and picking. High-chrome steels also allow you to achieve a mirror-like polish. Another option is to specify a chrome-plated finish for a hard-faced, wear-resistant surface. However, if the product is abrasive, the chrome-plated finish can wear away quickly. Ask your tooling supplier about these options.

In some cases, changing the tool design and its surface finish is enough to stop sticking and picking. But changing designs could well be a waste of time and money, because many products will stick and pick no matter what changes are made to the punch design.

Air entrapment. The act of compression can trap air in the concave cup of the punch face. The deeper the cup, the more likely it is to trap air. This trapped air creates a soft area on the very top of the tablet. In such cases, the granules don't know whether to stick to each other or to stick within the punch cup. It is similar to making a tablet that is too soft: The granules aren't sure where or what to stick to.

The solution here is to make certain the punch dwell time is correct and that air evacuation is adequate. The primary way to reduce entrapped air is to increase the force of the pre-compression stage so that there is less air to evacuate during final compression. You should also be certain that the tablet is compressed as high in the die as possible. This is referred to as the depth of upper punch penetration. The higher it is within the die, the easier and faster the air can escape during compression.

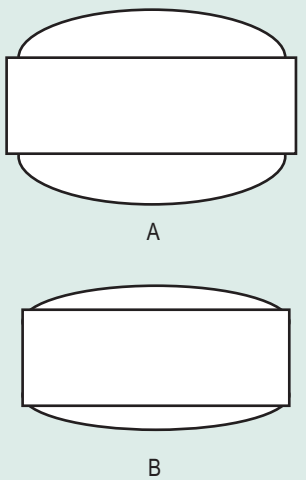
If those adjustments are not possible, consider using tapered dies to help get the air out. Talk with your tooling manufacturer. Tooling manufacturers are specialists and they can probably help you solve the problem by adding a taper.

Another possible solution is to specify a tablet shape that uses a compound radius. Doing so "flattens" the very top of the tablet, eliminating the air pocket. The change is slight but effective. Furthermore, it will not cause a noticeable change in the tablet shape or design. See Figure 3.

You may discover that new punches are more likely to entrap air than used punches simply because of their tighter clearances. Tight clearances are good, but they can cause air to escape more slowly during compression. With the old tooling, air escapes more quickly so particle-to-particle bonding is more likely. When customers tell me that brand new tooling gives them more hardness, sticking, and capping problems than the old tooling, I attribute the problems to the tighter clearances of the new tooling and a decrease in the evacuation of air.

FIGURE 3

Using a compound radius to "flatten" the tablet (B) can help reduce sticking without noticeably changing the tablet shape.



Lubricating the right way

The function of a lubricant in the product formulation is to prevent powder from sticking to the punches, dies, and other metal components of the tablet press. A lubricant also facilitates the ejection of compacted tablets. It is not a liquid or oil, but a light, fine powder. Typically, lubricants account for a small percentage of the formula's content, from 0.25 percent to 2 percent. The most common lubricant in pharmaceutical formulations is magnesium stearate.

Despite the small particle size and the small quantity of the lubricants, they strongly affect your ability to make a good tablet. If they are not blended correctly in the mixture, they will not function as designed. There are two common errors when processing lubricants. The first error is neglecting to pre-screen the lubricants to remove the lumpy, over-size particles. The second error is failing to blend the lubricant evenly into the product formulation. The lubricant must be able to contact the metal parts to work correctly. However, it is better to under-blend the lubricant than to over-blend it. Over-blending will hide the lubricant within the other particles, rendering it useless.

If you run a press without lubricant, you may hear the powder squeaking as it compresses. You will also notice an increase in the force needed to eject the tablet. In fact, the increase may be so great that it damages the punches and the ejection cams. The absence of lubricant or the presence of incorrectly blended lubricant will also lead to sticking.

If you don't recognize that poor lubrication is causing the sticking problem, you or your colleagues are likely to blame the tooling. The next step in this misdiagnosis is to stop the press, remove the stuck products, and polish the punches before restarting the press. Because polishing the punches can provide short-term relief from sticking, you may repeat this cycle throughout the production campaign. By the time you're done, you'll have convinced yourself and your team that the tooling's loss of polish is the source of the problem. But that is incorrect.

True, polishing the punches can solve a sticking or picking problem temporarily, because many polishes act as mold-release agents. So the act of polishing did nothing more than work this mold-release agent into the surface of the punch. The satisfactory—but temporary—result is a successful production run. Then the product begins to stick again and you re-polish. Sometimes polishing does no

good whatsoever. Other times you might go for an hour or so before sticking resumes.

Some companies accept these short production runs as part of doing business. They expect some products to start OK, and then to stick eventually. They will remove the punches and polish them throughout the run. But ask your operator about the polishing routine. The secret that every press operator knows is that some polishing compound must remain on the punch tips for sticking to stop. They know not to clean the punch tips with isopropyl alcohol, as is standard. If they did, the sticking would return immediately. So is polishing really solving the problem? Not likely.

Even so, a combination of factors may convince you that poorly polished punches are indeed the source of the sticking. Recall that many sticking problems occur at startup, when all the metal components are clean and free of any lubricant. Thus, the punches are prone to sticking. The reaction of most operators when they see sticking is to stop the press, pull the punches, and polish again, even though the punches were just polished.

While they polish the punches, operators might give the press itself only a cursory cleaning. Excess powder is removed, but a thin dusting of the product is left behind. When the punches are re-installed, the press runs without sticking. Thus the operators walk away believing that polishing the punches solved the problem when the distribution of the lubricant within the product was actually the source of success.

To prevent sticking at startup, some companies routinely distribute lubricant by hand before tabletting. This puts a dusting on the press that prevents sticking at the start. Excess lubricant is gone after the first few press revolutions. Some people think this is unacceptable. But is it any less acceptable than not cleaning the punches after polishing?

Process-related sticking

Some sticking and picking relates to upstream processing. Improperly applying binders or poor drying of the product, for example, can make polishing the punches an hourly event at some companies.

Application of binder. During the granulation process, a liquid binder is often added to a powder blend, thus bonding (binding) the ingredients together to form granules. Binders are often called pharmaceutical glue, and to work as planned, the distribution must be even throughout the batch of product and the binders must be uniformly dried.

If binders are not distributed evenly and dried completely, some portions of the blend will contain concentrations of binder. In the drying process, these overly wet granules become dry on the outside, but not on the inside. This is called case-hardening.

Case-hardening can occur even when binder is added correctly but drying was too rapid. Removing the moisture too quickly causes some binder to move to the granule's exterior. This migration of binder to the granule surface creates a hard shell around other material that may not be completely or evenly dry. This phenomenon leads to two possible causes of sticking: entrapped moisture and concentrated binder on the granules' surfaces. Slowing the drying process will sometimes eliminate both problems.

Changing the way you add binders or dry a granulation is easier said than done. Nonetheless, scrutinize all the steps of your methods to find and prevent problems. After all, proper granulating is a fundamental issue when sticking is the problem. Some of you may opt to polish the punches again and again instead of addressing the true cause. Or, sometimes a company buys new punches. The new punches may work better than the old ones, but often only because the new punches are very polished. As discussed earlier, new punches may create a bigger problem because their tighter clearances lead to air entrapment.

Milling. Many times mills are viewed as ancillary pieces of equipment that you just roll into a vacant room to perform a quick task. That attitude raises questions: Is this milling step controlled and predictable? Will the operators mill a batch on Monday at 8 a.m. the same way they do on Friday at 4 p.m.?

Overly fine particles, known as fines, often exhibit poor compression characteristics and may cause sticking. The fines are usually the result of milling friable powders incorrectly or at inconsistent feed rates. With too many of these dust-like particles in the product formulation, it won't flow or compress well. The fines also create a dusty atmosphere and cause tablet-to-tablet weight fluctuations. Furthermore, fines can get trapped within the logos and lettering on the punch face, especially if the punch design was made to handle a different particle size range.

Non-friable powders can also cause problems. Especially problematic are the powders that are readily compressible, because they can compact during the milling step. Furthermore, some products may re-agglomerate if they are stored too long. In that case, they will need to be de-agglomerated in a low-shear mill before going any further in the process. Products that have re-agglomerated flow poorly and cause weight fluctuations which, in turn, create hardness variations that increase the potential for sticking and picking.

Pinning the problem on R&D

Why do products compress into a tablet well in the lab but not on the production floor? We have all had this question at some time. More accurately, you might think that if only the product development team and the R&D people had developed the product correctly, we wouldn't have sticking, picking, or other problems on the production floor.

There may be some truth to such thinking, but you should understand that identifying operational differences between lab and production equipment is difficult, especially when the product is still under development. Because of scale-up problems, many companies use production-capacity machines when developing products.

The substitution of critical ingredients during product development can also hamper scale-up success.

Scale-up. Some machines scale up better than others, and changing the batch size or a machine's capacity may or may not give your product its intended attributes. Scale-up guidelines are general, and they don't always work. I've seen plants that use identical or comparable processing machinery to make the same product, but the properties of the products at each plant differ. You can attribute these differences to environmental factors, the skill of the people who work at the plant, or both. There is still a lot of art in the science of tablet making.

Ingredient substitution. Many of the ingredients in tablet formulations are expensive, especially in the pharmaceutical industry. Therefore, sometimes a company substitutes a cheap ingredient for an expensive one during product development. Or the company may not have enough of the active pharmaceutical ingredient to make tablets and to perform all the developmental tests. In that case, the company will again use a substitute.

If the substitute doesn't have the exact attributes of the true ingredient, then test results can lead you in the wrong direction. Time and storage conditions may also cause the ingredient to behave one way in the lab and another way on the plant floor. This may include more fines, de-mixing at the tablet press, and heat sensitivity, all of which may cause sticking.

Conclusion

The one conclusion you should draw from this article is that a sticking or picking problem can have one or several causes. Polishing the punches during a production run is a temporary fix, not a long-term solution. Environmental factors can affect how well a tablet will form. Some products are so sensitive to temperature and humidity that they may compress differently or not at all with the slightest change in the environment.

If you're the troubleshooter in charge of solving a sticking problem, evaluate the problem at the press and work upstream from there. Study all the process variables and record as much data as possible. Finally, if you make a change, try to make just one change at a time. This will help you link each change to a result. **T&C**

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