# RELYING ON TABLET PRESS TECHNICIANS

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*Many companies limit the adjustments that technicians can make to the tablet press during a production run, even though such adjustments are a normal part of tabletting. This article discusses what adjustments may be necessary and encourages manufacturing managers to support their tablet technicians.*

Over the last 3 decades, I've been on the front line of many pharmaceutical and nutritional manufacturing operations, both as a worker and as a consultant. It's no surprise that at each company, the best managers have the most production success. This article describes how to support and promote advanced press operation. Wise managers will recognize that room should be left for technicians to account for typical variation in the press, its tooling, the environment, and the product.

In tablet manufacturing, there is one clear objective: making a good tablet, and what actually comes off the tablet press reflects the activity of upstream operations. In that sense, a "bad" tablet is often destined to be so long before it reaches the press. Tablets are also affected by the processes that follow compression, including dedusting, coating, and packaging. Good tablets stem from good formulas and processes and well-trained technicians.

## Validation is not optimization

Many companies are plagued by troubled products. One day the product is running perfectly, and the next day it suddenly acts up and creates havoc. Because the problem is first observed at the tablet press, the technicians in charge of the press bear the bad news. Before shooting the messenger, try to understand what's happened and how to address it. The best way to do that is to talk with your technicians.

*Picking defect*

*These broken tablets are the result of poor compressibility.*

Many times, overcautious colleagues working in the regulatory and compliance areas—in the name of validation—impose unrealistic limitations that prevent technicians from making proper adjustments to the tablet press. Press technicians must be allowed to make adjustments. Otherwise they can't solve the problem and make the tablet meet final specifications. In fact, micro-managing tablet press operation may create more problems than it solves. Of course, a validated process demands that we follow guidelines to ensure reproducible results, but I'm going to let you in on a secret: Many products that are validated don't work. How can these products pass "validation" and yet not perform right in production? It's simple: Good and bad processes can both be validated. Validated does not mean optimized, only that we obtained reproducible results during (maybe) three production runs. The joke on validation thus becomes: The first result is luck, the second coincidence, and the third is validated.

Of course, making pharmaceutical or other tablets is no joke. It's serious business, and we want high quality time after time. So test the proposed validated procedures before they're executed. That may sound elementary, but I've seen people propose a validation procedure, document it, and then hand it off to production staff without ever testing it. Good managers wouldn't allow that to happen. Instead, they would work with their colleagues in regulatory compliance and with their technicians to avoid the implementation of unrealistic limitations. I suggest running the product more than three times. Then conduct at least three test runs to prove that the validation procedures really work, and have the production staff sign off on them.

## Are you a good manager?

Good managers share several traits. They are active in all areas of manufacturing. They invite communication

and actually listen to the people on the front line. They can take both the micro and macro view of problems. They know what their staff is capable of, and they know the strengths and weaknesses of each staff member. They help staff get better at what they do. And, key to manufacturing success, they understand how the many process variables affect tablet quality.

At many companies tablet press technicians (formerly known as operators) are forbidden from adjusting the very tablet press functions that they have been trained to use. It is not uncommon to hear, "Don't touch that," or "The mechanic does that," or "QA will not let us change that," and, the big one, "It was pre-set at the factory."

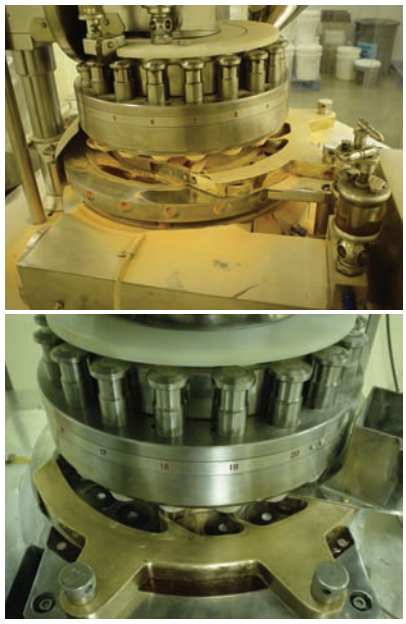
It's no surprise that, during production, all managers want their technicians to follow the procedures to the letter. At the same time, however, experience has shown that following the exact same steps each day will not always give you the same result. Why? Because each manufacturing step has some level of variation. Even the best raw materials are subject to variations from batch to batch and lot to lot. Add the variation within the process steps, and it's clear that the people running the tablet press must be allowed to adjust it to obtain the desired results. The other option is to have operators stop the press to search for the "right people" to adjust the press. Of course, stopping the press means downtime and lost production, and no one likes that.

## Variation is unavoidable

Raw material variations may occur from environmental conditions, as well as variations within the materials themselves. Particle size, moisture content, density, age, aeration, static electricity, and many other metrics play a role. These physical variations can affect how well the granulation flows and compresses and how well the tablet ejects. Thankfully, every modern press has controls to account for these variations.

That's one reason that you want well-trained tablet press technicians who can to react to changes throughout the entire batch. As these expert technicians learn to associate the characteristics of the batch with the process, they will get better and better at making the product behave as it should on the tablet press. Note that I'm talking about trained technicians, not tablet press attendants, who typically only check tablet weights and hardness while watching for defects like capping, sticking, and the appearance of black and/or gray specks on the tablets. Attendants are would-be technicians in need of training.

I also recognize that some products are very demanding, challenging even the best technicians. I also acknowledge that it's fairly easy to find technicians who lack experience and cannot distinguish a powder problem from a press problem. But an outright ban on adjustments isn't the answer, and I oppose writing up procedures in such a way that machine features cannot be changed or adjusted. After all, some tablet press functions require adjustment simply to account for the machine's range of operation. These include punch penetration, pre-compression force, feeder speed, and turret speed. Add ingredient and process variation to the mix and the case is made: Technicians need to be able to react using the tools at hand to bring the final product back to the target specification.



*Excessive powder on the die table is a symptom of non-optimized weight control. The photo below shows what it looks like after cleaning.*

So why are technicians so frequently handcuffed? It stems from poor training. Many knowledgeable technicians are forbidden from making changes without involving people from the maintenance, quality, and regulatory groups. I've been asked to solve problems at many companies and suffered from the same restrictions placed on the technicians. I hear, "You're not allowed to change that setting," even when adjusting the setting is normal and meant to help solve the problem. So be wary of products that are "validated" with limitations. How can it be validated if it's not repeatable? Solving tabletting problems requires changing the press settings, at the discretion of the technician. This should not be put up for a vote across departments.

Let's look at the basics of the tabletting process and some tablet press functions. The discussion may shed some light on why it's important to have good, knowledgeable managers to help technicians do what they're paid to do: Fine-tune and optimize the press settings to make the best possible tablet.

**Blend variation.** So-called "properly blended" ingredients can be one of the biggest factors in determining how well products flow and compress. The objective of blending many ingredients together is to achieve complete content uniformity. That task becomes more difficult if the ingredients change or their properties change. In fact, even if the blend is perfect, the different characteristics of each powder may cause the blend to vary once it's on the tablet press. Such variation can affect flow, compression, and ejection. That, in turn, can affect tablet weight, thickness, and hardness, which may cause disintegration and dissolution to vary. Next thing you know, the QA people say something like, "Can't you control your press?" The operator then might respond with, "Hey, can't you control the blend better?" The folks in charge of blending then say, "If you could give me more consistent powders I could give you a better blend." And so on.

When troubleshooting material-related problems, it's easy to say the formula is the problem. That may be, but how is it "wrong?" There are many good formulas that are just not put together correctly. It's analogous to having a dozen people follow the same recipe but not creating the same dish. Certainly, they'd be similar, but without a written procedure for each cooking step, the outcome is not wholly predicable. That's why technicians need to be able to adjust the press: to offset the variation in the blend. Likewise, just because you lay out clothes for a young child doesn't mean he or she will don all the garments or, if the child does, maybe not in the correct order. Maybe the socks end up over the shoes. Here's the point: Ingredients must be added properly and in the correct order or you will encounter problems and defects. Well-trained technicians with the support of their manager might be able to save such batches. This would be an impossible task for poorly trained operators or well-trained technicians who lack their manager's support.

**Filling the die.** Getting powders to flow uniformly into the dies is an important skill. Without consistent filling, compressibility changes and thus the force required to compress the tablet varies. In that case, the technician has a choice: Slow the press, adjust pre-compression, adjust punch penetration, or change the feeder speed. How do technicians know whether they've responded correctly? They perform weight checks. Under normal circumstances, weights are checked every 30 minutes or so. But weight must be checked much more often if any variation is discovered. In fact, the behavior of some products is so unpredictable that they may require continuous weight monitoring. In short, the greater the variation of the ingredients and blend, the more often press technicians must check (and adjust for) tablet weight.

**Keeping powder in the die.** If we've optimized die filling and tablet weight is under control, that means we've also optimized the feeder speed, turret speed, and scrape-off function. Now it's time to ensure that compression occurs without the powders being "splashed" or pushed out of the die.

During tabletting, compression squeezes the powder, causing its particles to lock together as the interstitial air escapes through the clearance between the die wall and punch tip. Worn upper punch tips allow air to escape more quickly than new ones do, and that fact explains why capping—a defect in which the tablet separates after ejection due to unrelieved mechanical stress—occurs more often with new tooling than with worn tooling. Less escaping air can also lead to less brilliant, slightly softer tablets. Controlling how much air escapes will often improve tablet appearance, lock the particles together better, and thus eliminate any capping while improving the hardness and glossy appearance.

In fact, the best solution to capping is to compress the powder lightly using pre-compression or by decreasing turret speed. That method locks the particles together, so that when the remaining air is pushed from the powder, it includes only a minimal amount of dusty fines. The goal is to tamp the powders lightly to prevent fine particles from migrating and causing a defect. Turret speed should be adjusted in conjunction with the amount of clearance between the die wall and punch tip, the punch depth penetration, and the force of pre-compression.

*Powders that form lumps make tabletting a real challenge. Also, inconsistent powders make inconsistent tablets.*

**Upper punch tip clearance.** When specifying or adjusting the upper punch tip clearance, you might consult the Tableting Specification Manual (TSM) [1]. The TSM provides a standard recommended clearance, which is a mechanical clearance based on proper punch entrance into the die. But you don't have to abide by that standard. You

can specify the clearance you want based on the characteristics of the powder. If capping is a major concern, you might consider specifying upper punches that have more tip clearance, which could eliminate capping by increasing air release. The most common way to increase clearance is to use a tapered die. When working on capping and air-release problems, keep in mind that the upper punch penetration into the die should be as shallow as possible. If powder escapes during compression, an operator has just two options: slow the press or change the penetration depth of the upper punch.

**Pre-compression.** Some manufacturers specify the correct tablet thickness at pre-compression. But since there's really no way to check pre-compression thickness except during set-up, I'd recommend not making this specification. After all, what use is a specification that cannot be checked in real time? The better way to monitor pre-compression is to use a tablet press that can monitor and adjust pre-compression force based on changes to the die fill. If your company doesn't have pre-compression force monitoring and control, then watch the pressure rolls and adjust pre-compression force so that there is just enough force to make the pressure rolls turn evenly. If the pre-compression force is too low, the rolls will not turn smoothly, and the poor rotation will cause premature damage to the punches and roll.

**Ejection.** Once the tablet is compressed, it must be ejected without damage. One potential source of damage here is die-wall friction, which relates directly to the lubricant within the formula. (See next section.) To make ejection easier, slow the press down and make the tablet high in the die (reduce punch penetration). By minimizing punch penetration, the tablet travels the shortest possible distance toward ejection. You might also consider adding a taper to the die and making certain that the die is not worn and that it does not have compression rings.

**Formula lubrication.** All tablet formulas need a lubricant, most commonly magnesium stearate. The lubricant is blended into the powder and serves as a mold release agent due to its fine, slick surfaces that prevent the powder (tablet) from sticking to the punch and die surfaces. Just because it is present in the blend doesn't mean it will work correctly. If the lubricant is over-blended, it will not help with ejection and it could affect tablet hardness.

The amount of lubricant within a blend should relate to the percentage of fines. The higher the percentage of fines in the blend, the more lubricant is needed. All things being equal, I suggest that you reduce the percentage of fines before increasing the amount of lubricant. Fewer fines will make the lubricant more effective and will reduce or eliminate sticking and picking. By the way, poor lubricant blending can actually increase ejection forces, and the technician will once again be forced to react by adjusting the press.

## Conclusion

Good managers recognize good technicians and help them develop their skills so that they can make the necessary adjustments to the tablet press. Some others will impose unwarranted restrictions and thus limit the ability of their technicians to solve everyday problems. I see it all the time. I suggest that managers empower their tablet press technicians and stop relying on mechanics or others to take action. Too often, quality or regulatory groups impose unrealistic limitations that prevent or inhibit expert operators from making changes.

My one caveat: Make your tablet press technicians experts. Have them discuss each function of the tablet press and demonstrate what effect each adjustment and feature of the press has on the final tablet. Everyone favors raising the bar on quality to make a better tablet, but that effort cannot succeed if improper limitations are imposed. *T&C*

## Reference

1. *Tableting Specification Manual*, 7th edition. American Pharmacists Association, Washington, DC, 2006. Copies are available for purchase at *Tablets & Capsules'* website: www.tabletscapsules.com.


*Removing the feeder reveals that too much powder remains on the turret, which leads to overworking the powder and an increase in fines.*

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