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The 3 Most Common Defects

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Capping
Lamination
Sticking & Picking
Hardness variation
Thickness variation
Metal fragments
Black Spots
Erosion
Splitting
Chipping
Double Impressions







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The 3 Most Common Tablet Defects, and How To Prevent Them!

An experienced and trained technician can take a marginal product and produce a quality tablet, while an inexperienced, untrained tablet press attendant often cannot make the needed machine adjustments to overcome the variations of a product and optimize the quality of the tablets or correct common defects. The key is to understand the variables of the equipment and the process. Proper training and qualification are keys to producing quality products with minimal or no defects. When properly operated the tablet press is the report card for the success of all prior unit operations.

Any way you slice it, defects cost companies thousands of dollars in lost product, lost time, decreased productivity, increased downtime, increased machine cleaning, maintenance, and repair costs, and more. As a matter of fact, the average tablet manufacturing company has about $250,000 dollars lost to defects each and every year!

The most common tablet defects are; weight variation, friability variation, hardness problems, picking, sticking, capping, laminating, chipping, mottling, and double pressing or impressions. The top three are most common tablet defects are; Capping & Laminating , Sticking& Picking, and Hardness variation.

Defects can come from any of the unit operations upstream and from the tablet press. The raw materials may be of poor quality or do not meet specifications, causing excessive fines that lead to a host of defects. The formulation may be the source of defects if the materials do not compress well or the processing steps specified within the formulation fail to produce a powder with good flow, compressibility, and ejection properties. The processing & granulating of powders is often the source of defects. If the product ends up too wet, too dry, or fails to have good flow, compression, and eject the result is often blamed on the tablet press when it is often a formulating error or processing error. The milling process may produce too many fines, resulting in Capping, Black spots, Lamination, Hardness variation, and a host of other production related problems.

Though we spend a great deal of time discussing and establishing ways to prevent defects from occurring to begin with, we must also be prepared to solve the problem at the press and if necessary work back up stream to the source of the problem.

The focus of this discussion is to establish ways to resolve common defects at the tablet press, and to identify the root cause of each and ultimately resolve the defect before it reaches the tablet press. However, we understand all to clearly that in the heat of production you cannot stop the presses and send the product back to the drawing board, you must solve the problem at the press.

Let's take a look at the three most common defects and learn how to prevent them from costing your company precious profits.

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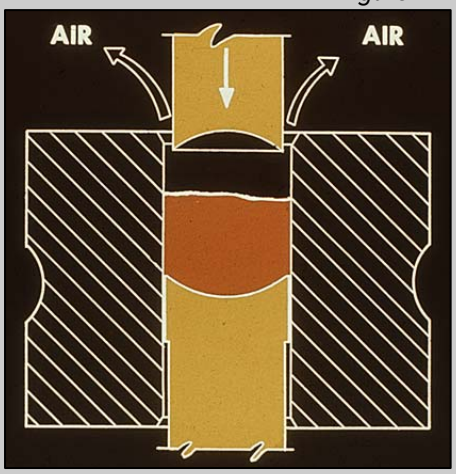
The 3 Most Common Defects - "Capping & Lamination"

Capping is when the top of the tablet fractures and/or breaks free from the rest of the tablet. (figure 1). Capping is often reported as being created by air being entrapped during compression. However it is truly defined as a lack of compressibility due to the collection of fines.

Figure 1



Figure 2



During compression, air is evacuated from between the granules allowing the granules to become locked together. The tablet press tooling (punches and dies) are designed to allow air to escape during compression along the upper punch tip as seen in figure 2. See the upper punch tip is smaller in diameter than the lower punch tip in order to allow and control the air evacuation.

Capping is not just air entrapment. During compression, air evacuation pushes the very fine, dry granules out with the air. The characteristics of fines (dry, light, dusty particles) do not want to lock together. These fines are pushed to the line of air evacuation during the compression event, which is the point between the cup and the tablet band. The result is lack of compressibility and the tablet cap will fracture.

This is why capping occurs on the top cap of the tablet only. If the lower cap breaks away from the rest of the tablet this would be referred to as lamination, which will be discussed later.

The faster the speed of the press the more likely capping will occur. Consequently slowing the press will often resolve the problem. However there are other fixes.

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"Capping & Laminating" ...continued

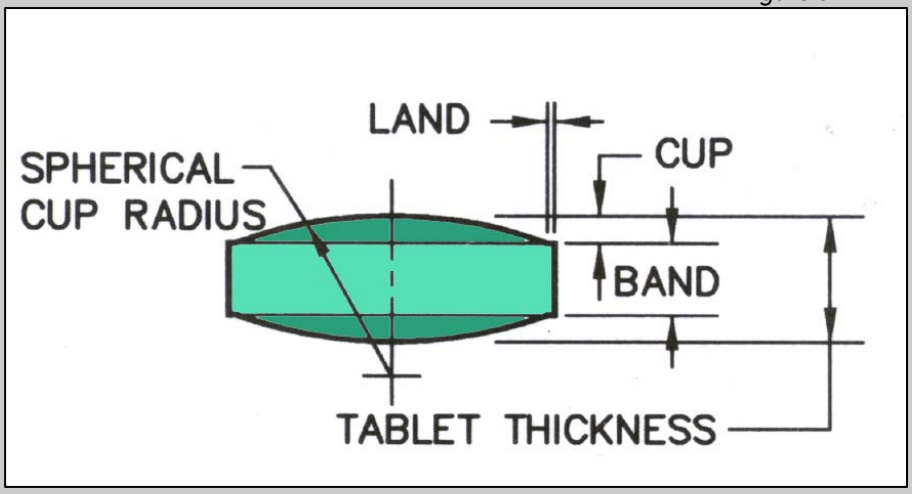
Poor formulation and bad processing can contribute to capping. Blends that are too dry are prone to capping since there is insufficient moisture to help the particles lock together. Formulas that do not contain enough binder will cause capping due to the particles inability to bind or lock together. Poor blending may introduce air, breakdown granules, or over blend the powders. Under mixing may produce powder segregation and this can causes capping.

Capping is one of the most common tablet defects and it can be simple to correct and proper diagnosis of the root cause of the capping problem is critical to correcting and eliminating capping. A key step to resolving capping is to increase dwell time. This will allow the particles more time to lock together. All other issues associated with capping must be systematically evaluated in order to correct the problem.

Lamination is when the tablet splits apart anywhere except at the upper cap. While similar to capping, lamination can happen anywhere in the tablet. Capping takes place exclusively along the top cap of the tablet. This distinction is critical for correctly diagnosing this problem and proper trouble shooting to correct the problem. Lamination is often blamed on over compressing. Too much compression force flattens out the granules and they no longer lock together.

Lamination can also occur when groups of fine and light particles do not lock together. These groups of fine and light particles simply will not compress well. Reducing thickness and increasing dwell time will give the fine and light particles more of a chance to lock together and eliminate lamination. Dwell time can be increased by adding pre-compression or slowing the machine speed down. Either of these methods allows the granules more time under pressure to lock together. Machining a taper into the die will also help eliminate both capping and lamination.

Figure 3



TSM: Tablet Specification manual is a very through guide to tablet press tooling. There is no better resource as it is put together by industry professionals, manufacturers of press, tooling and tablets. Contact the publisher: AphA the American Pharmacists Association or any press or tooling manufacturer for the most recent version.

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Lets take a look at the order of correction for eliminating Capping.

Step 1: Punch Penetration: If your tablet press is equipped with adjustable punch penetration, reducing the upper punch penetration depth into the die will often allow for better air evacuation and will often solve the problem. Rule: pre-compression penetration does not have to be the same as the setting for the main–compression penetration, but it should never be deeper.

Step 2: Pre-Compression: Most modern presses now have pre-compression. Which is a tool designed specifically for higher speed presses. This tool can be compared to having 4 wheel drive on a vehicle, 4 wheel drive is not always needed, and so it is with pre-compression. Pre-compression is designed to be used two different ways. If the granulation to be compressed has dry dusty fines and caps it is used to lock the smaller particles in place so they cannot migrate during final compression, it is best to use light force. If the product does not have a "fines" issue but needs more dwell time than pre-compression can be used to "hit it twice" and really extended the dwell time, then using higher force is recommended.

Step 3: Slow the press down: decreasing the tablet presses speed increases the amount of time the tablet as under pressure, which is known as dwell time. Extending the dwell time allows more time to evacuate air between particles, provides more time for the particles to lock together, which results in better and more controlled tablet hardness. However if too much dwell time or two much pressure is applied to small dry, fine particles and you exceed the ability for those particles to stay locked together than those particles will laminate. In solving a capping problem greater dwell time oftentimes is a solution hence slowing the press down. At the same time extending dwell time for product that laminates will net a poor result. It's like walking a fine line; one step to one side and there's not enough pressure to hold the particles together, and one step to the other side and that there's too much pressure and the result again is lamination.

Step 4: Tooling design; there is much that can be done in the design of tooling and help solve capping and lamination problems. Using dome head tools extends dwell time, designing cup depth and radius will provide easier and quicker air release during compression. Also, adding a taper to the die will assist in air evacuation during compression to reduce the tendency the cap. The taper also reduces each action force which is a common contributor to lamination. also, proper care and maintenance of tooling can eliminate potential faux causes of capping and laminating; such as j-hooking, premature punch tip wear and compression wear rings within the die.

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The 3 Most Common Defects - "Sticking & Picking"

Sticking occurs when granules attach themselves to the faces of tablet press punches. Picking is a more specific term that describes product sticking within the letters, logos, or designs on the punch faces. Whether it's sticking or picking, the result is a defective tablet. To salvage the batch, visual inspection of the tablets may be required. . This can slow production and decrease yields, but sometimes there is no alternative. Once the batch reaches the compression department and is put on the press the operator must adjust the tablet press to for the characteristics of the product. If a company makes one and only one product day in and day out it is not always the same, there are many variables and reasons that a product is never the same. There also variables in the tablet press, tooling, and setup, operation, and cleaning up. Sometimes, the punch face design and embossing can be modified to eliminate the problem. Other times, granules are not dried properly. They become case hardened during the drying cycle, which means that the granules are wet on the inside buy dry and hard on the outside. During compression, these granules break open and the wet product sticks to the punch faces. If this occurs, the drying process must be improved.





How do you solve sticking problems that the press;

1) Change compression force: increasing compression force with over granulated products creates sticking, an not enough compression causes the particles stick to the punches rather than to themselves.
2) If the product is picking, solving the problem usually involves increasing pressure to that the particles walked to each other rather than to this within the lettering On the punch face.
3) Extending dwell time through the use of pre-compression or slowing the press speed will often have the same result in allowing the particles to stick to each other rather than to the faces of tooling.
4) Make sure the punch faces are polished.
5) Make certain the lubricant is mixed properly, and not over mixed which will result in rendering the lubricant ineffective.

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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. 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.

To overcome sticking on the press, increase hardness by making the tablet thinner and increase dwell time to make the wet granules adhere to other granules, rather than adhering to the punch faces. Another cause for sticking and picking is when a blend is incomplete. This means the lubricant in the formula is not protecting the granule from sticking to the punch cup surface. Poor final blending is usually the cause of this and must be corrected. If all else fails, the punch cup surfaces should be polished to remove the sticking and picking defects. 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.

Products with granules that are highly compressible form excellent tablets. However, they are also prone to sticking to the punch faces. If this is the problem the problem will most likely worsen over the course of the production run. Powders that are super-sensitive to compression will compact even as they flow through the hopper and into the feed frame. If the powder compacts before it reaches the die cavity, the bulk density of the formulation increases, reducing the 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 aggravate the product's tendency to stick. This is why the sticking gets worse as the run progresses.

An experienced tablet press operator will most likely know how to overcome this situation. When sticking is a problem, they quickly increase compression and make very hard tablets for a few revolutions. This is known as "shocking the press" and it can work extremely well. The reason is somewhat straightforward, the increased compaction forces cause the granules to bind with the tablet and pull the stuck granules away from the punch face. Caution must be exercised when using this method to shock the press. If the punches are overloaded, they may become damaged or possibly break.

This is a classic example of how experienced, trained, and qualified operators produce consistent, defect-free tablets. A good operator pays close attention to their press and the tablets being produced. The sooner you identify a sticking or picking problem, the faster it can be resolved.

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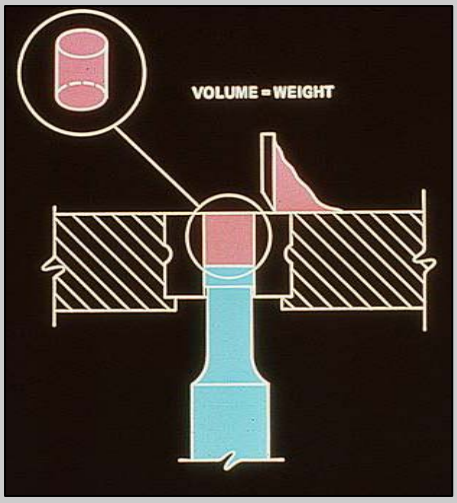
The 3 Most Common Tablet Defects, and How To Prevent Them!

Tablet hardness variation is one of the most common tabletting defect and complaints among consumers. A soft tablet causes problems at the press, makes it difficult to film coat with any consistency, cause problems in packaging and can be the cause of a recall.

Solving the problem at the press is the first step and then work back up stream.

1) Weight Control; controlling tablet weight is often the key to tablet hardness control. The more fluctuation in tablet weights the greater the variation in tabletting hardness. When we speak about weight control accuracy is everything. We don't mean within the range of acceptable variation, we mean accuracy at target weight. A lighter weight tablet results in a softer tablet, a heavier weight tablet results in a harder tablet. Nine granulating blends of various powders up and have big variation in bulk density. if the Bulk density has variation been the die fill will not be the same each and every time and will result in a wider weights fluctuations.





2) Scraper blade & Die fill; the figure on the right demonstrates the die fill after the scraper blade is scraped off the excess powder prior to file compression. The scraper blade is often overlooked as aware item and must be replaced on a regular basis. For brace of products this could mean changing the scraper blade on a daily basis for other products that could mean that the creeper blade can last for months or longer to its very product dependent and dependent on how well the scrapper blade is installed and cared for.



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A MESSAGE & INVITATION

I have been involved in the pharmaceutical industry since 1973 and have provided consulting & training to pharmaceutical and nutritional companies throughout the world. Everyone within the manufacturing facility from management to the operator, including R&D, QA, Tech Services, Maintenance, Supervisors, and Leads will benefit from our consulting & training programs. The goal is to have everyone exposed to the same information, to create a common denominator and to open communication. Companies that participate in our programs are encouraged to use our training materials to improve their own in-house training programs.

You're invited to visit our website for technical tips, published articles, and many other resources. Please visit us at: www.techceuticals.com If you would like to discuss this information with me in person, please contact me.

Sincerely,

Michael D Tousey

Technical Director/CEO



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