capsule filling

The role of tooling in finished capsule quality

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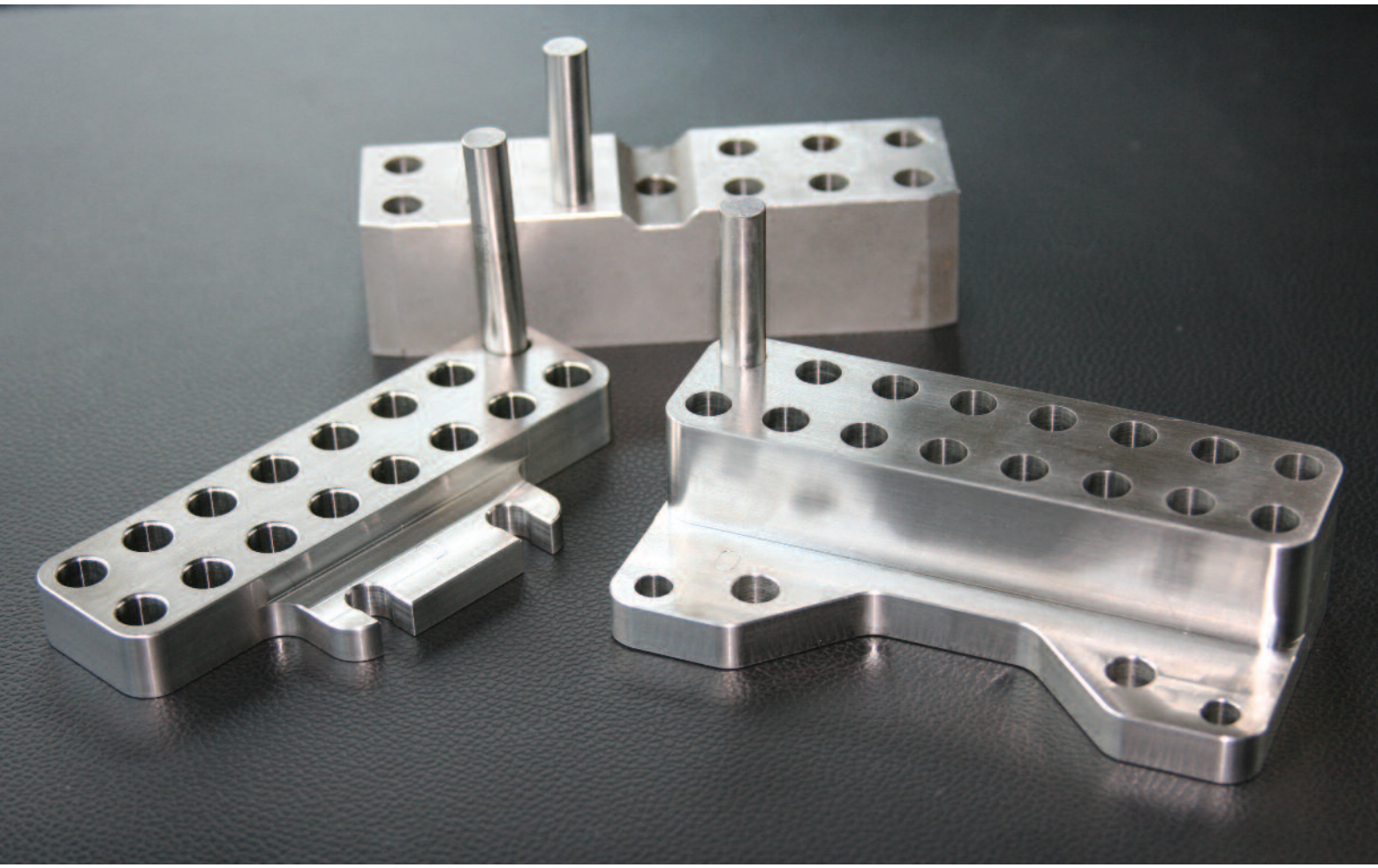


This article describes how the tooling and capsules interact and how worn tooling can degrade productivity and quality.

Often overlooked, the design and condition of tooling play critical roles in producing high-quality filled capsules. The issue is often overlooked because there are few if any industry standards for manufacturing empty capsules or the equipment that fills them. That makes the job of consistently manufacturing good filled capsules more difficult. But with a firm grasp on the technical specifications that your capsule supplier uses and a better understanding of capsule tooling, you can improve your capsule filling operation.

If you asked a group of tabletting professionals to specify the diameter of a "B" size punch bore, every one of them would answer 19 millimeters. The response would be uniform because manufacturers of tablet press tooling and tablet presses adhere to a standard. However, if you asked a capsule filling professional to specify the diameter of a size 0 upper capsule bore, you'll get either a blank stare or a lengthy and confusing answer.

That's why, even as a capsule specialist, I applaud the people who pioneered the American Pharmacist Association's Tableting Specification Manual (TSM). It outlines the dimensions and other specifications of tablet press tooling, including the bore size required to accommodate "B" size punches. To institute these specifications, industry professionals—many of whom are competitors—met and agreed on the standards. The meetings continued over the years, and the current TSM (seventh edition) includes many changes and improvements. Today, two similar standards are also used: Eurostandard and ISO 18084:2005, and it's possible that all the three standards will merge [1].

Standard specifications promote the consistent manufacture of tablet presses and tools. Their greatest benefit, however, accrues to the companies that manufacture

tablets because they are provided equipment and tooling whose dimensions are identical and consistent from one tool and tablet press supplier to another.

In the capsule filling industry, standardization is limited to the identification of basic capsule sizes, and the most common range from size 000 to size 5. However, no published standard defines exactly what the sizes must be, so equipment suppliers must try to engineer their tooling to fit capsules of all the mainstream suppliers. Or, alternatively, the capsule suppliers must make their products meet the specifications of various tooling suppliers. Either way, with no exact standard, there is a risk of mismatching the tools and the capsules.

Consider a manufacturer that has just purchased several high-speed capsule fillers to handle demand for its new product. As the machines fill the capsules, it becomes apparent that a large percentage of empty capsules are not separating and instead go straight to waste, thereby causing excessive losses of both capsules and powder. Eventually, someone finds that the bore of the upper capsule tool is slightly undersized, causing the cap to pinch the body and preventing it from releasing and separating properly. What to do? Given the investment, changing capsule fillers isn't an option, and the manufacturer also has a long-standing commitment to buy from its capsule supplier. The only options are to purchase custom tooling or to somehow alter the capsule design, a

The cap and body segments as they appear when assembled.

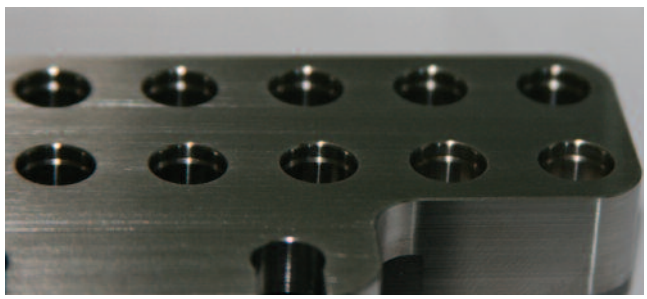
complex undertaking. Either approach would be costly and time consuming. Yet if there had been a standard in place for the capsules and/or the tooling, the entire problem would likely have been avoided.

As the number of suppliers of capsules, equipment, and tooling increases, the risk of problems also grows. Many manufacturers have on their shelves tooling that will not work with capsules from certain suppliers. There are also many boxes of capsules gathering dust in warehouses because the dimensions of the capsules are incompatible with the manufacturer's filling equipment. The ensuing challenge then is to educate everyone who fills capsules to understand the interaction between the tooling and the capsules. Only then will they be able to decide whether to change or add capsule suppliers, purchase new capsule fillers, and/or specify non-OEM tools. A good understanding of the issues will also help manufacturing personnel to better care for the tooling.

The cap seat, near the bottom of the upper tool, is where the edge of the capsule rests once inserted.

Identifying tool wear

Another common issue related to mismatched tooling and capsules stems from normal tooling wear. Many ingredients that go into capsules are abrasive and, over time, wear the tooling to a point where the tool no longer supports the capsules, which causes joining defects. The problem is often misdiagnosed as a capsule quality issue, and I've fielded a few of those calls. Other times, instead of discussing the issue with Capsule Supplier A—whose products have worked well for years—the manufacturer suspects the supplier's quality has declined and begins to favor Capsule Supplier B. In reality, it is more likely that the condition of the tooling has changed, and the filler now runs better with a capsule that has dimensions that accommodate worn tooling. But that often goes unnoticed and the manufacturer will instead pressure Capsule Supplier A to change its manufacturing criteria to accommodate the tooling. That can cause major problems for capsule suppliers, especially when the manufacturer is a large-volume customer. When in doubt, try this the next time your tooling begins to deteriorate: Replace the tooling and keep the tighter-specification capsule that had been working well. You'll notice a big rebound in performance and productivity.

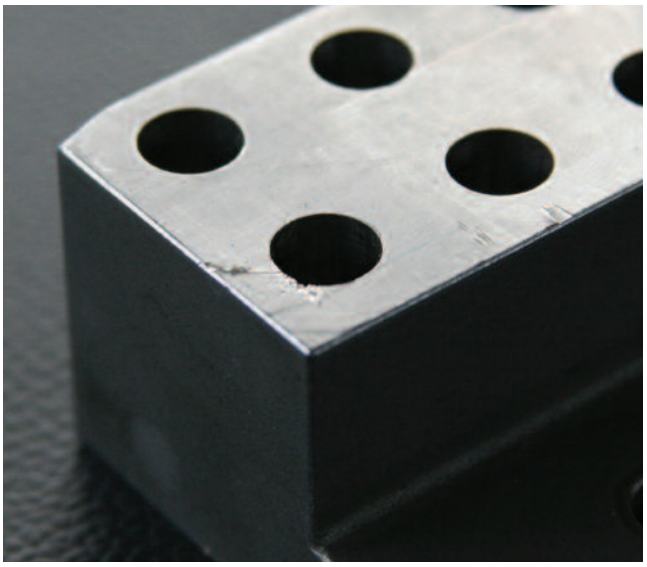


Inverted upper tool shows the body passage.

Also recognize that flip-flopping between capsule suppliers to accommodate tool wear can hurt your relationship with valuable suppliers. It's better to learn how to recognize worn tooling and budget for replacement.

Upper and lower tooling must stabilize without restricting

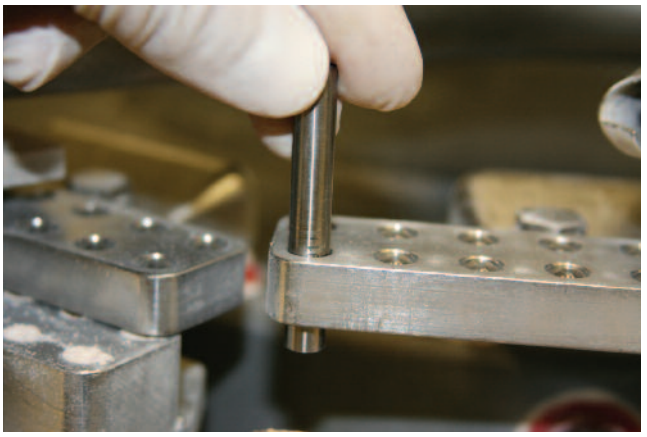
To understand how tooling affects filled-capsule quality, let's examine two pieces of tooling in detail: the



The lower tool is easily damaged, especially at its top surface.

A damaged lower tool will often cause the capsule body to sit high.

Because the capsule body cannot descend into the tool, its edge is crushed over during filling. This critical defect is called a body fold.



Use pin gauges to check for wear of the cap seat, body passage, and body seat.

upper-capsule (cap) bore, and the lower-capsule (body) tool, as shown in the photo on page 23 and below. (Note: All the photos here show segments, which are the tooling for Bosch machines. Machines from IMA would use bushings, while other capsule fillers may use rings.)

Following the capsule rectification step, the empty capsule is transferred to tooling that acts as a carrier, holding the cap and the body of the capsule separately. Depending on the machine type, the capsule is transferred to either upper and lower segments, upper and lower rings, or upper and lower bushings. Regardless of the carrier type, each tool has independent bores to house the caps and bodies.

The upper tool. In the upper, or cap, tool, two areas are critical to success: the cap seat and the body passage. The cap seat is a visible ring located near the bottom of the tool, and that is where the cut edge of the capsule rests when inserted into the tool. See the photo top right. The purpose of the cap seat and its sidewalls is to hold the cap securely and level at the center of the bore, particularly during capsule closing. As the cap seat wears or if it becomes damaged, the cap may shift during closing, creating joining defects.

Deeper within the upper tool, beyond the cap seat, the bore narrows significantly to form the body passage, through which the capsule body passes during separation and by which it re-enters when the capsule halves are joined. See the photo below. The body passage is a critical point and must be maintained in prime condition for good joining. Unfortunately, this is another area subject to wear as fill material is pushed up through the passage during closing. Some very abrasive fills, such as a calcium-magnesium combination, can wear out this area within a few months as the granules gradually abrade the metal. Once the body passage is worn, the bore widens enough for the capsule to misalign during closing. To protect the body passage from premature wear, ensure that the fill material forms a slug that moves cleanly through the passage before the capsule is closed.

The lower tool. The lower, or body, tool usually suffers damage from operator handling. See the image at the top of the next page. Damage from handling often occurs at the top surface of the tool, which is generally flat, with no

chamfer or lead-in to the bore. That makes it susceptible to damage when operators allow it to contact other metal parts during disassembly and cleaning. For this reason, it is imperative that this tool not be stacked and it be handled carefully during cleaning. If the tool is damaged, it is usually visible because metal is pushed over the edge of the bore, restricting the movement of the capsule into the tool. As a result, during the filling operation, the capsule body is restricted and sits high in the tool (photo on next page, center). Its edge will then be crushed over, and the dose will be deposited atop the cut edge, as shown on the next page, bottom. This is called a body fold and is considered a critical defect.

To address the maladies described above, ask your tooling suppliers to provide the criteria for damaged or worn-out tools, and periodically measure them. For example, Bosch sells a go/no-go kit for inspecting its tools. For checking capsule bores, an instrument called a pin gauge is used. If a kit is not available for your capsule filler, ask the equipment supplier to inform you about the acceptable range for wear. With that information, you can buy pin gauges from an industrial supplier such as McMaster-Carr or Grainger and make your own go/no-go kit. To analyze your tooling, you should measure the cap seat, body passage, and body seat of every bore in your tool set. Then compare those measurements to the acceptable ranges that your equipment supplier provided. Always replace tooling that falls outside the recommended wear tolerance. Just one worn or damaged hole may prompt defects to reach an unacceptable level.

By understanding how tooling design and condition affect your process, you can run a better capsule filling operation. When in doubt, don't hesitate to contact your capsule supplier. Most reputable suppliers are happy to provide technical assistance. *T&C*

Reference

1. For a discussion of the genesis of these tooling standards and the prospects for unifying them, see "Combine the TSM and ISO standards" by Dale Natoli on page 64 of T&C's October 2010 issue.

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