

# tablet tooling

MAXIMIZE THE RETURN ON YOUR TOOLING INVESTMENT  
WITH PROACTIVE MAINTENANCE

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*The condition of your tablet compression tooling is critical to manufacturing high-quality tablets that meet specifications. This article explains how proactive tooling maintenance can help extend tool life and maximize your return on investment.*

**T**ablet compression tooling is a significant investment. Although the costs to purchase and maintain a single set of punches and dies may represent only a small portion of production costs compared to the cost of a tablet press or fluid-bed dryer, tablet manufacturers typically buy many sets of tooling over a drug product's life cycle.

Excessively worn or improperly maintained tooling can be a tremendous liability to a production team because it will require frequent replacement, and the tablets produced may give consumers a perception of poor quality. Properly maintained tooling, on the other hand, will last longer and consistently produce high-quality tablets.

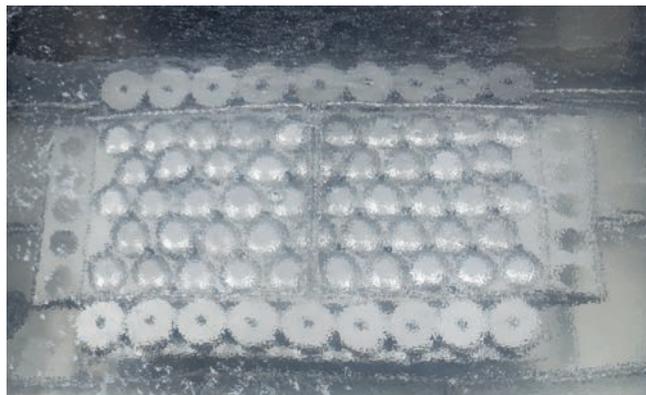
## Proactive tooling maintenance

One of the most common questions a tooling supplier hears from customers is, "How long should a set of tablet compression tools last?" The answer depends on many factors, including tablet configuration, the characteristics of the material being compressed, and the type of steel used to make the tooling. But independent of these factors, a proactive maintenance program can extend the life of your punches and dies and maximize the return on your tooling investment.

Proactive tooling maintenance can be divided into four main components: lubrication, cleaning, polishing, and handling and storage.

**Lubrication.** Improperly lubricated tooling causes excessive friction between the punch barrel and the press's punch guide during operation. This friction increases the punch's operating temperature, causing thermal expansion of the punch barrel and reducing the space available for lubrication between the punch barrel and the guide. This thermal expansion can lead to tool binding, which can damage the tooling and the tablet press and result in emergency production stoppages.

Tablet presses are typically equipped with automatic lubrication systems, but these systems can give operators a false sense of assurance that all necessary areas of the punches are adequately lubricated at all times. Some automatic lubrication systems require the centrifugal force generated during press operation to push the lubricant into distribution channels. As a result, lubricant may not have reached critical locations at press startup, which can cause premature wear to the punches and



**Photo 1:** Ultrasonic cleaning is a quick, easy, and safe method for thoroughly cleaning your punches and dies. damage mating press components, including the punch guides, keyways, cams, and pressure rollers.

You can ensure proper lubrication at startup by simply applying a food-grade barrel lubricant to the punch barrel and a food-grade grease to the punch head prior to tablet press setup and operation.

**Cleaning.** Dirty tools can also cause binding during operation. Keeping tools clean decreases the chance of premature tool wear and increases the effectiveness of lubrication, allowing the machine to run more efficiently and produce more tablets.

An ideal cleaning procedure is one that consistently cleans the tools but minimizes handling to reduce the potential for damage. Ultrasonic cleaning with an automatic dryer is optimal because it increases the tooling's exposure to the cleaning solution and requires minimal

handling. An ultrasonic cleaner uses high-frequency pressure waves to agitate a liquid (typically cleaning solution or water) and cause cavitation, which creates tiny bubbles that loosen and remove debris from the tool surface.

When used properly, ultrasonic cleaning is highly effective for removing traces of product and contaminants, as shown in Figure 1. The ultrasonic waves penetrate all tooling surfaces—including hard-to-clean areas such as key slots (not shown), cups, and die bores—and cause debris such as oil, grease, and biological residue to break up and disperse. However, when using an ultrasonic wash unit, it's critical to ensure that the tools are rinsed and dried thoroughly, because any cleaning solution residue or water left on the tool can corrode or discolor the surface.

The benefits of ultrasonic cleaning include:

*More effective cleaning.* Ultrasonic cleaners remove even tightly adhered material from tool surfaces and are more effective and thorough than manual scrubbing, which can be ineffective on heavily soiled tooling and can damage delicate tool surfaces.

*Reduced cost.* Not only does ultrasonic cleaning save labor costs, it also saves time. A typical ultrasonic cleaning cycle for moderately soiled tools can last less than 15 minutes and requires little supervision, which frees up staff for other tasks. The most important way ultrasonic cleaning can reduce costs, however, is by preventing the tool wear and damage often caused by manual cleaning.

*Reduced environmental impact.* Ultrasonic cleaning offers multiple environmental benefits compared to manual cleaning. Newer ultrasonic cleaners require much less energy and are more efficient to operate than older models, and the machines require less water per tool than manual cleaning. Also, the FDA-compliant ultrasonic cleaning solution is environmentally friendly and non-ozone-depleting.

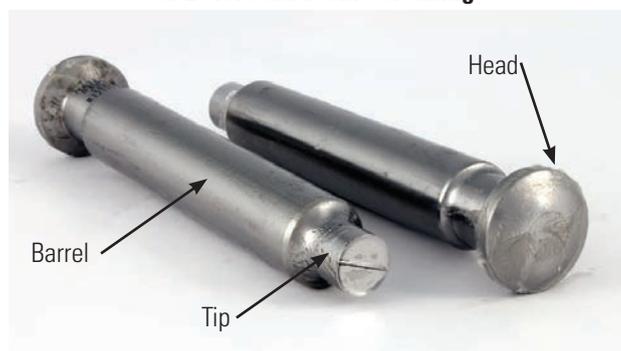
*Validated cleaning process.* Most pharmaceutical companies operate under very strict regulations and audit procedures requiring that all product contamination is removed from all tablet press components, including tooling. Ultrasonic cleaning can allow a company to validate the process by swabbing the clean tools and verifying that, when the ultrasonic cleaning steps are followed, the tooling is free of contaminants and the process is repeatable.

**Polishing.** Over time, tooling loses its luster and can develop nicks, scratches, and a wear pattern commonly called a J-hook, in which excessive wear around the perimeter of the punch cup creates a thin, sharp edge that curls inward. These imperfections can cause tablet defects such as capping, in which the top or bottom portion of the finished tablet separates from the tablet body; lamination, in which the finished tablet separates in horizontal layers; sticking, in which a portion of the compressed formulation adheres to the punch surface and breaks away from the tablet; and picking, which is similar to sticking but occurs within the letters, logos, or designs embossed on the punch cup surface. Often, companies will replace tooling when these tablet defects

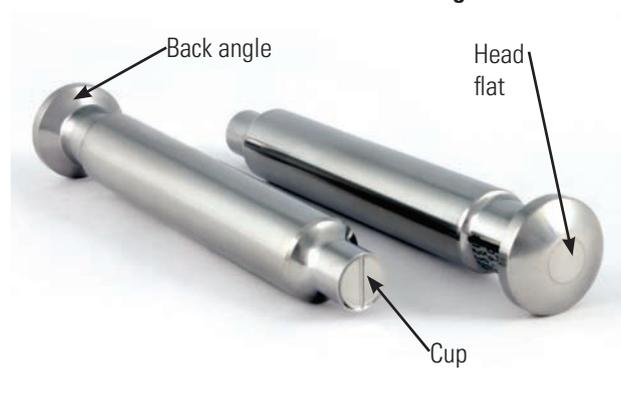
**FIGURE 1**

**Typical tablet punch**

**a. Before ultrasonic cleaning**



**b. After ultrasonic cleaning**





**Photo 2:** Using an unsewn cotton wheel to manually polish tools often doubles their usable life.

begin to appear, but in many cases, proper polishing will allow a company to place previously unusable tools back into service.

The best method for polishing punches is to use a large, unsewn cotton buff wheel. Unlike automated polishing, the cotton-wheel method also refurbishes the punch, which can often double the tool's usable life. Manual polishing refurbishes the punch cup, restores land (the thin flat area around the perimeter of the punch cup), and repairs minor damage to the punch head, back angle, and barrel. However, only a well-trained and experienced tooling technician should perform this procedure, because an inexperienced technician could destroy a set of tools by over polishing the punches. Great care should be taken to ensure that only a small amount of material is removed during polishing.

**Handling and storage.** A surprising number of tools need to be replaced each year due to punch-tip damage caused by mishandling. Nicks and dings on and around the punch tip are commonly known to cause black specs and product discoloration in tablets as well as capping, lamination, and other visual defects. The costs of such mishandling "accidents" by tablet compression technicians add up, but you can minimize them by implementing a systematic tooling handling and storage procedure.

Proper handling and storage can be as simple as using tooling storage bins available from your tooling supplier. These bins separate individual tools and keep them from striking one another during transport and storage. Other handling solutions include racks and cabinets that protect the tools during transport and storage. It's also a good idea to use a desiccant pack inside the sealed tooling storage box or drawer to minimize surface damage from moisture.

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### Beyond proactive maintenance: Resizing tool lengths

The critical punch dimension for ensuring consistent tablet production is the *working length*. Working length is the distance between the surface of the punch head flat and the deepest point in punch cup. The working lengths of each punch in the set must be within the tolerance range determined by internal standard operating procedures (SOPs) to ensure that the tablets produced by all the tools in the tooling set meet the required parameters.

Visually inspect and measure each punch after cleaning and before transferring the tooling into storage. In most cases, punches that are out of spec with respect to working length can be lightly machined and put back into service. If the working length of your tooling is out of spec, contact your tooling supplier to discuss repair options.

Proper lubrication, cleaning, polishing, handling, and storage can help maintain the integrity of your tablet compression tooling and ensure consistent and efficient tablet production while prolonging tool life and reducing downtime. By implementing a proactive tooling maintenance program, you're not only protecting your company's investment and reducing variable costs, you're helping to maintain or increase production output and improve tablet quality.

T&C

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