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WHITEPAPER

UNDERSTANDING THE IMPORTANCE OF PUNCH LENGTH AND CUP DEPTH

Manufacturing tablets to a uniform hardness, weight, and thickness requires tablet press punches of consistent length. We will describe how to understand punch length, how to measure it correctly, and how wear affects length and tablet consistency. We will also address the importance of specifying cup-depth tolerances.

Using rotary tablet press punches of consistent length is critical because their length directly relates to the uniformity of the hardness, weight, and thickness of compressed tablets. If you don't understand how length and cup depth affect tablet quality, you may attribute tablet defects to the wrong source. Thus, it is important to establish a punch inspection and maintenance program that will enable you to verify that all punch lengths and cups are within dimensional tolerances.

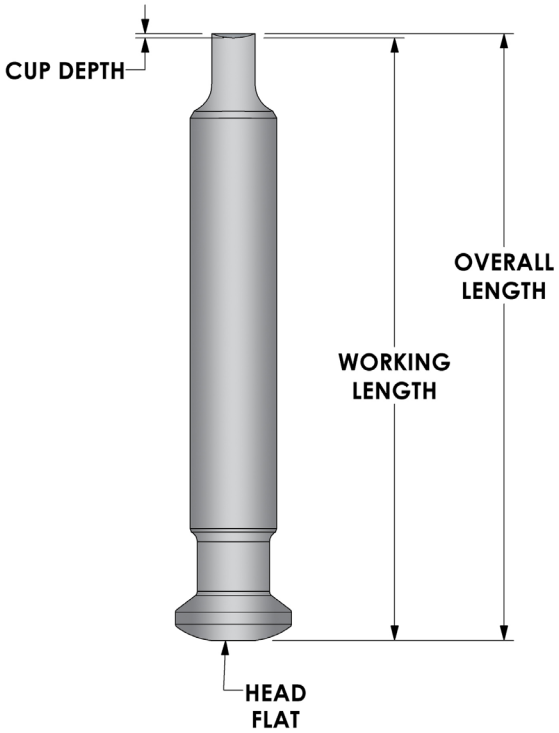

Figure 1. Cup depth, working length, overall length and head flat of a tablet press punch.

WORKING LENGTH

Punches are engineered and manufactured to consistent lengths. The working length of a punch is the distance from the head flat to the lowest measurable area of the punch cup. See Figure 1. The figure also illustrates the cup depth and the overall length, which is the distance from the head flat to punch tip. The punch tip comprises the cup and the land, as shown in Figure 2.

Understanding the working length leads to consistent overall tablet hardness, weight, and thickness, so it should be considered the most important dimension in a tool inspection program. If the working length varies, then tablet hardness, weight, and thickness will also vary.

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Working length consistency is the key. The working length of punches is engineered to a standard range of 0.002 inch (0.051 mm). This means that, within a set of punches, the difference between the working lengths of the longest and shortest punch is no more than 0.002 inch (0.051 mm). It is recommended that you periodically inspect the punches to ensure working lengths do not exceed that tolerance (or the range your company specifies). When inspecting to confirm a uniform working length, it is important you inspect the upper punches independent of the lower punches.

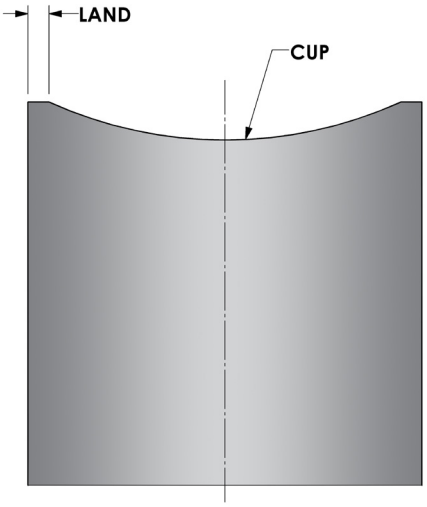


Figure 2.

It is also important to measure correctly. Do not calculate the working length by subtracting the cup depth from the overall length, as that method can produce results showing some tools are out of specification when in fact they are not. The tolerances of the overall length and cup depth are greater than that of the overall length. Therefore, they cannot be used to calculate the working length, with its much tighter tolerance. The working length of the punches should be measured for deviation from punch to punch rather than from a calculated number. You should measure working length using a digital indicator mounted on a steel post fixed to a granite base. This is basic

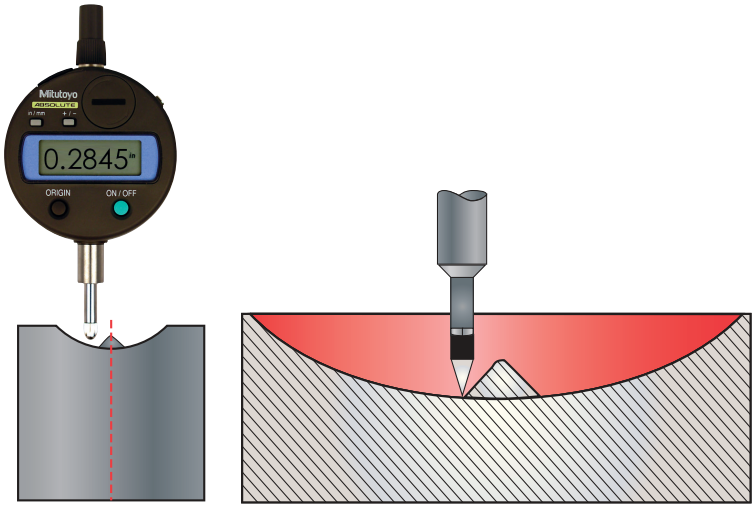


Figure 3. Measure working length from the deepest area of the cup that is accessible with the point of the digital indicator

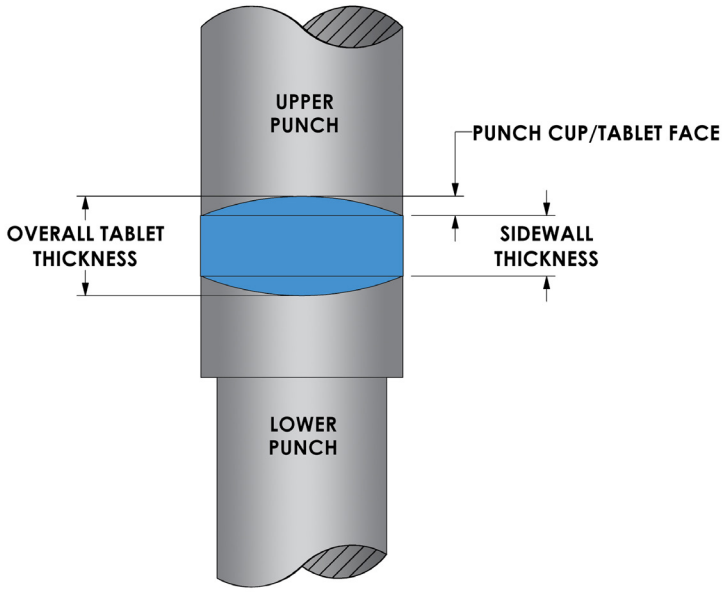
measuring equipment that costs less than $500 and provides the similar accuracy as elaborate systems that cost more than $50,000.

Whatever equipment you use, measuring the working length of punches that have embossing or a bisect at the lowest area of the punch cup is more complicated. In those cases, it is important to measure from the deepest area of the cup that is accessible with the tip of the indicator (Figure 3). Once you identify the lowest area of the cup, be sure you measure consistently from there as you check the entire set. Otherwise, you may have to "hunt and peck" for the lowest area of the cup on each punch.

Most reputable tooling manufacturers can provide a working-length matching report when they deliver a new set of punches. The matching report pairs each upper punch with a lower punch, from longest to shortest, and numbers them accordingly. Matched punch sets create the best possible consistency in tablet hardness and thickness, and a matching report offers helpful guidance during press setup.

The length of the lower punch is more critical than that of the upper punch. That's because the length of the lower punch largely determines how uniformly product (granulation) fills and doses in the die. (Product flow characteristics and lower punch binding also strongly influence the uniformity of die filling.) Deviations in the amount of product allowed into the die affect tablet hardness and weight.

Figure 4. The area between the two tablet faces is called the tablet sidewall.



CUP DEPTH

The cup depth is the distance from the tip edge of the punch to the lowest theoretical point of the cup. Some cup configurations have a varying depth, such as those used to manufacture tablets with scalloped edges. The cup determines the configuration and appearance of the tablet faces.

The area between the two tablet faces created by the die is called the tablet sidewall (Figure 4). It may also be referred to as the tablet gate or the tablet band. Although the sidewall is generally not inspected or measured, it is critical to tablet appearance and manufacturing. Ideally, the sidewall width will be well proportioned with the overall tablet thickness. This is important because a tablet with an excessively thick sidewall appears to be thicker overall, creating the perception that the tablet will be uncomfortable to swallow. An excessively thick sidewall also requires the tablet press to exert greater force to eject the tablet from the die.

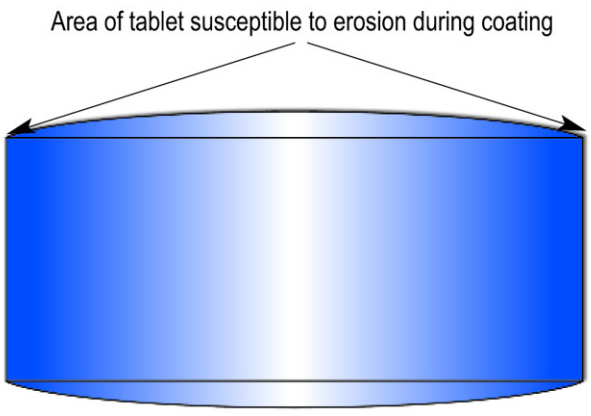
The width of the sidewall depends on the tablet hardness, weight, and thickness in relation to the cup depth. As the punch tip wears, cup depth decreases and sidewall thickness increases. Thus, if you compare two tablets of equal hardness and weight—the first tablet made with a shallow-cup punch and the second tablet made with a deep-cup punch—you'll notice that the first has a thicker sidewall. However, the shallow-cup tablet will be measurably thinner overall than the deep-cup tablet. But again, its wider sidewall makes it visually undesirable and unfavorable for manufacturing.

The wide sidewall of a shallow-cup tablet can also cause difficulties during film coating because the tablet may erode at the sharp corner where the shallow-cup radius and the vertical sidewall meet (Figure 5).

Most tablet press punches have a cup-depth tolerance of ±0.003 inch (0.076mm), which is published in the Tableting Specification Manual. This ±0.003-inch tolerance is widely accepted by the tablet compression industry and is used by tooling manufacturers worldwide. But while the published tolerance is adequate for most applications, it may be too liberal if you manufacture small-size tablets or too conservative if you manufacture large-size tablets.

To understand this point, consider a small-diameter, flat faced, beveled-edge tablet. Let's assume that this tablet is a Schedule II drug and that it requires a cup depth of approximately 0.010 inch (0.254 mm). If you adhere to the published cup-depth tolerance, the cup depth could range from

Figure 5. The wide sidewall of a shallow-cup tablet may create a sharp corner where the radius and the vertical sidewall meet.



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0.007 to 0.013 inch (0.178 to 0.333 mm). That means that you could create a total deviation equal to 60 percent of the desired cup depth.

Compare that to what occurs when manufacturing a larger modified-capsule tablet (such as a nutritional supplement). For this tablet, let's say the deepest part of the cup may be 0.060 inch (1.524 mm). Following the published standard, the acceptable range would be 0.057 to 0.063 inch (1.448 to 1.600 mm). Because the cup is deeper than the one used to make the small tablet, the percentage range of deviation is substantially less: 10 percent. That is a considerable difference, the importance of which is magnified by the fact that this small-diameter tablet is a Schedule II pharmaceutical product.

To eliminate excessive cup-depth deviation, consider specifying the tolerance as a percentage of the desired cup depth. For example, specifying a tolerance range of 20 percent of the desired cup depth for the first cup (0.010 inch deep) changes the range from 0.007 to 0.013 inch (.0178 to 0.330 mm) to 0.009 to 0.011 inch (0.229 to 0.279 mm). Cup depth inspection is simple and uses the same basic measuring instruments used to inspect the working length: a digital indicator mounted on a steel post fixed to a granite base.

OVERALL LENGTH

The overall length is the least important length dimension of the punch. It is the distance from the punch tip to the head flat. The overall length is a reference dimension that comprises two or more critical dimensions, the working length and the cup depth. Since both working length and cup depth are manufactured to a specific tolerance, there is no need to assign a tolerance to the overall length. As long as the working length and the cup depth are confirmed to be within the acceptable range, then the overall length will be consistent and you don't need to inspect it. However, the overall length of the lower punch is somewhat critical when it comes to setting the punch height for uniform tablet take-off, which is important to minimize the potential for tablet damage.

However, if your company's standard operating procedures require inspection of the overall length, use the same basic equipment that you used to inspect the working length and cup depth. Of course, you must establish a tolerance range and a pass-fail policy.

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A WORD ABOUT PUNCH WEAR

With normal use, punches show the most wear at their tips, which reduces the cup depth. It follows, then, that tip wear also reduces the overall length of the punch, although it does not affect the critical working length. Any wear of the head flat (not as common as punch-tip wear) will further reduce the overall length, as well as reduce the working length. Head flat wear does not affect cup depth.

Normal maintenance of the cup face, tip, and head can also affect punch length. Polishing the face using fine abrasives, hard felt bobs, or stiff brushes can alter critical lengths. Likewise, if you use hard cotton bobs and/or stiff brushes with abrasive compounds to remove product adhered to the face or to remove surface discoloration or pits (typically the result of compressing abrasive products), you will eventually deepen the punch cup and thereby possibly alter the critical working length.

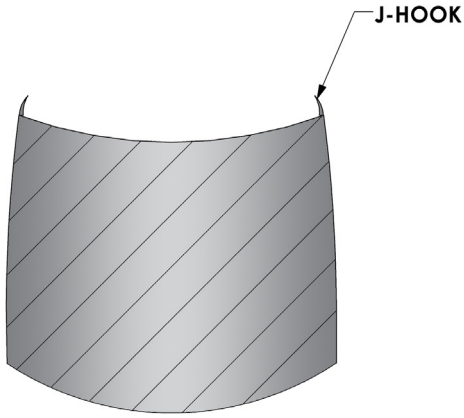

Figure 6. When the land of the punch tip wears, it becomes very thin and may form a J-hook.

Wear can also occur at the land (Figure 2), which is the narrow flat area located at the perimeter of the punch tip. The land is subject to abrasion during compression and is commonly the first area of the punch to wear. When the land wears, the tip edge becomes very thin, even razor sharp, sometimes causing a condition referred to as J-hooking (Figure 6). J-hooks normally occur on the upper punch tip and are a common cause of tablet capping and lamination. Polishing the punch using a soft cotton wheel and a polishing compound will remove any J-hook and restore the land. While polishing and restoring the land will prolong the useful life of your punches, it will eventually reduce the cup depth and overall length.

CONCLUSION

Uniform tool length is critical for maintaining tablet consistency and smooth press operations. The most important dimension of the punch related to tablet quality is the working length, followed by the cup depth, and then the overall length. To achieve the highest level of tablet uniformity, most reputable manufacturers of tablet compression tooling can provide a working-length matching report. Setting up the tablet press in the sequence of the supplier's matching report will provide the best scenario for tablet consistency.