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Cup depth and tablet consistency

Cup depth is the distance between the very tip of the punch and the lowest measurable point of the cup cavity. To establish proper tool inspection protocols and wear limits, you need to know about this dimension and how it affects the tablet.

Two standards for tablet compression tooling have been published by governed organizations. The first, originally published in 1971, is the "TSM." It appears in the American Pharmacists Association's *Tablet Specification Manual*. It defines the tooling format used primarily in the Americas. The other recognized standard, ISO 18084 International Tooling Standard, was published in 2005. It defines the EU tooling format. [*Editor's note:* For more information about how the different standards were developed, see the author's September 2010 Back Page article, "Combine the TSM and ISO tooling standards."]

In the TSM, cup depth tolerance is ±0.003 inch. But that's for newly manufactured tools, not in-process tools. ISO 18084 makes no reference to cup-depth tolerance or range.

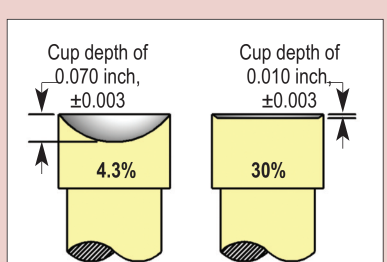
Cup depth is integral to overall punch length, and when its tolerance deviates from the standard, so does overall punch length. However, cup-depth variation does not affect the most critical tool length, known as "working length," which is more important than any other punch length dimension, even cup depth. How well punches remain within the given tolerance relates directly to the consistency of tablet weight, hardness, and thickness. According to the TSM, the working-length tolerance is a 0.002-inch TIR (total indicator reading). That is the allowable deviation within a set of upper or lower punches (not between upper and lower). The TSM does not specify a tolerance for overall punch length, which is a reference dimension. The take-home message is this: Do not measure all three of these punch dimensions (working length, overall length, and cup depth). One of these three dimensions is always the result of the other two. That's why overall length is defined as a reference dimension: It's the result of combining working length and cup depth.

The limits of the tolerance

Cup-depth tolerance was established for tooling manufacturers, not necessarily for tablet manufacturers to use as a basis for establishing a protocol to identify out-of-spec tooling. In fact, once tools are in service, it's better to apply an in-process range to maintain consistency among the different tablet products you make. Consider, for example, a flat-faced bevel-edge (FFBE) tablet that is 0.21875 inch in diameter, comprises a Schedule II API, and requires a 0.010-inch cup depth. If you adhered to the TSM tolerance, the cup depth could deviate by as much as 30 percent from its original value. Now imagine you also compress an over-the-counter (OTC) product that uses a 0.070-inch cup depth. In that case, the allowable deviation would be about 4 percent. Thus a tablet containing a controlled substance would get more leeway (allowable deviation) than a widely available OTC.

Figure 1

Adhering to TSM's 0.003-inch allowable cup-depth deviation can give widely different results when applied to deep and shallow cups.



Establish a limit

Once new tools enter production, they become in-process tools, and manufacturers should establish an appropriate standard deviation that accounts for tool service life and tablet consistency. A reasonable limit is a 15 percent decrease in cup depth from the original specification. Using that limit would keep all your products within the same allowable deviation, and they would be consistent regardless of the original cup depth.

A 15 percent limit would also allow you to polish and maintain tools with deeper cups without worrying about diminishing their service life. (Deep-cup tools typically wear more quickly than those with shallow or standard cups, which have a more robust design.) Furthermore, with an in-house standard, you can maintain the tools yourself, significantly reducing costs and increasing efficiency because the tools will remain in service longer. Furthermore, potent tablets made using shallower cups will be more consistent and closer to specification. T&C

[*Editor's note:* To comment on the Back Page, visit www.tabletscapsules.com.]

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