

SECTION 2

TSM Tooling Specifications and Design Options

The detailed drawings of punches and dies contained in this section represent the bulk of the TSM specifications. Although the nominal dimensions shown on these drawings have remained basically unchanged over the years, the tolerances for these dimensions and surface finishes of the tooling have changed, to some degree, as the equipment used to manufacture the tooling has improved. In some cases, the tolerances are based strictly on what is reasonably achievable using the existing equipment. In most cases, however, the tolerances are the result of careful consideration of what limits provide users with satisfactory tooling performance and also allow suppliers to provide tooling at a reasonable cost.

Note: The "Introduction" lists the revisions and additions, including those for tooling specifications, for this edition. This information is provided as bulleted items in the description of each section's content.

Effect of Tooling Dimensions on Tablet Manufacturing

The proper interaction between tools and the presses on which they are installed is the crux of determining the appropriate dimensions and tolerances for tablet tooling. Understanding how individual tooling dimensions affect the tablet manufacturing process is essential to appreciating the need for standardized dimensions and tolerances.

Cup Depth, Overall Length, and Working Length

Cup depth, overall length (O.L.), and working length (W.L.) are the dimensions that constitute the length of a punch; they can be the most critical dimensions in any tooling program (see Figure 5, page 16): The most critical dimension, W.L., is primarily responsible for the

final tablet thickness, hardness, and weight. The O.L. is a reference dimension and therefore does not have a specified tolerance.¹ A reference dimension is defined by the *Machinery's Handbook* as:

A dimension, usually without tolerance, used for information purpose only. It is considered auxiliary information and does not govern production or inspection operations. A reference dimension is a repeat of a dimension or is derived from other values shown on the drawing or on related drawings.²

The O.L. of a common punch consists of two tolerance dimensions (except for flat-faced tip configurations): the W.L. dimension, with a tolerance of $\pm .001$ inch [$\pm .025$ millimeter] and the cup depth, with a tolerance of $\pm .003$ inch [$\pm .075$ millimeter]. Combining these two tolerances yields a possible variation of $\pm .004$ inch [$\pm .10$ millimeter] for the O.L.¹

The major concern with the cup depth and W.L. is to maintain consistency within a set of lower and upper punches.¹ The most critical of the two dimensions is the working length (W.L.), or the length from head flat to bottom of cup (L.B.C.). Variations in the W.L. of lower punches translate directly into variations in tablet thickness and hardness. Large variations in W.L. of lower punches will cause variation in tablet weight. For lower-weight tablets (<100 mg), small variations in W.L. will cause variations in tablet weight.

Electronic weight-monitoring devices (force and thickness types) are affected by punch W.L.; the effect is more pronounced when the device is used to reject individual tablets of nonuniform weight and/or thickness than when used for actual weight control.

The W.L. of a new punch is measured directly, with the use of a pointed indicator tip positioned as closely as possible to the center or the lowest area of the punch cup. If the variation in length throughout the set is within the tolerance range, the W.L. need not be measured at the exact center of the punch cup, as long as each punch is measured at the *deepest point of the cup*. If embossing or a bisect is present, the indicator tip is positioned between the embossing characters or beside the bisect.

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