

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.

Tsm Tableting Specification Manual

James Swarbrick



Tsm Tableting Specification Manual:

Tableting Specification Manual AMERICAN PHARMACISTS ASSOCIATION.,2025-08 The Tableting Specification Manual TSM is the pharmaceutical industry's guide for tablet tooling specifications in North America. In addition to tooling specifications, TSM includes information on terminology, tablet manufacturing know-how, tablet design, tool steels, tool interchangeability, maintenance, and troubleshooting. The contributions come from a team of volunteers, each possessing years of experience and valuable knowledge with a willingness to share. Tablet press tooling, tablet presses, and the tablet making industry continue accelerating rapidly. Advances in machining technologies to manufacture tooling and tablet press components for optimized performance have paved the way for improved tablet making capabilities. Other advancements in areas such as tablet simulator technology provide greater insight into controlling tablet attributes with increased understanding. The culmination of this is improved product development, greater scalability, more predictable performance, and continually improving tablet quality. This new 8th edition provides a resource for tablet manufacturing professionals unlike anything else. It is essential to remember that while this text governs tooling standards for North America, it also serves as a guide for supporting tablet manufacture. The best way to use TSM is to fully understand your current capabilities and improve and enhance those needs. Our guidance is to work with the tooling suppliers and the tablet press Original Equipment Manufacturers (OEMs). They are a resource that can help your team utilize this guide to enhance performance and improve quality. *Tableting Specification Manual* American Pharmaceutical Association. Tableting Specification Steering Committee, 2003. A guide to the design of and specifications for tablet tooling, the design of tablets, and the appropriate compression forces for various types of tooling. It provides explanations and supporting illustrations for inspection and maintenance of tooling. It can be used as a reference on US manufacturing specifications for tablets and tablet tooling.

Tableting Specification Manual American Pharmacists Association, 2006. This is the most comprehensive guide about the design of and specifications for tablet tooling, the design of tablets, and the appropriate compression forces for various types of tooling. The manual provides detailed explanations and supporting illustrations for inspection and maintenance of tooling. Two troubleshooting charts identify common tablet production problems and their remedies. **Developing Solid Oral Dosage Forms** Yihong Qiu, Yisheng Chen, Geoff G.Z. Zhang, Lirong Liu, William Porter, 2009-03-10. *Developing Solid Oral Dosage Forms* is intended for pharmaceutical professionals engaged in research and development of oral dosage forms. It covers essential principles of physical pharmacy, biopharmaceutics, and industrial pharmacy, as well as various aspects of state-of-the-art techniques and approaches in pharmaceutical sciences and technologies, along with examples and/or case studies in product development. The objective of this book is to offer updated or current knowledge and skills required for rational oral product design and development. The specific goals are to provide readers with Basics of modern theories of physical pharmacy, biopharmaceutics, and industrial pharmacy and their applications throughout the entire process of

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comprehensive treatment of the design formulation manufacture and evaluation of the tablet dosage form With over 700 i

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