

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

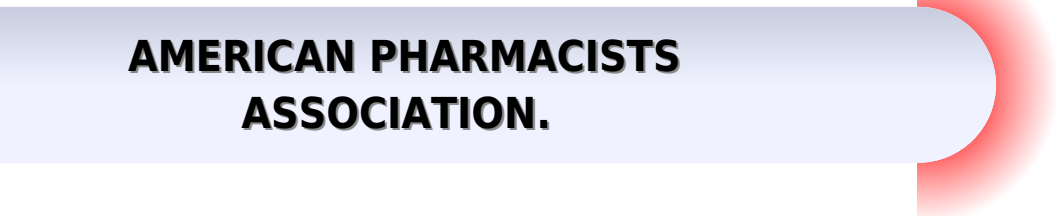
The major concern with the cup depth and W.L. is to maintain consistency within a set of lower and upper punches.¹ The most critical of the two dimensions is the working length (W.L.), or the length from head flat to bottom of cup (L.B.C.). Variations in the W.L. of lower punches translate directly into 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.

Tableting Manual Tsm

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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) are a resource that can help your team utilize this guide to enhance performance and improve quality.

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 research and development of oral dosage forms. Tools and approaches of preformulation, investigation, formulation, process design, characterization, and scale-up in pharmaceutical sciences and technologies. New developments, challenges, trends, opportunities, intellectual property issues, and regulations in solid product development. The first book ever that provides comprehensive and in-depth coverage of what's required for developing high-quality pharmaceutical products to meet international standards. It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market, including the most updated science and technologies, practice applications, regulation, intellectual property protection, and new development trends, with case studies in every chapter. A strong team of more than 50 well-established authors/co-authors of diverse background, knowledge, skills, and

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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 ADVANCED PHARMACEUTICS Dr Shekhar Verma,Dr Rupesh Soni,Mr. Arpan K

Tripathi,Dr.Chatlapelli Kishore, *Pharmaceutical Dosage Forms - Tablets* Larry L. Augsburger,Stephen W. Hoag,2008-06-03 The ultimate goal of drug product development is to design a system that maximizes the therapeutic potential of the drug substance and facilitates its access to patients *Pharmaceutical Dosage Forms Tablets Third Edition* is a comprehensive treatment of the design formulation manufacture and evaluation of the tablet dosage form With over 700 i

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Kumar Yadav,Mr. Khemkaran Ahirwar,2022-10-19 The pharmaceutical business strives to find develop produce and distribute medications that are both safe and effective for their intended use in a therapeutic setting As a field of study industrial pharmacy focuses on all aspects of the pharmaceutical life cycle including research and development product design production quality control and retail distribution Industrial Pharmacy is a book written with the express purpose of reshaping readers basic understanding of the many common dosage forms now in use Over ninety percent of commercially available formulations are traditional Pharmacy students at all levels might benefit from learning the fundamentals of drug delivery system design and production This book is written in a straightforward manner so the reader can easily understand Industrial pharmacy also known as pharmaceuticals is not limited to a single field of study Instead it calls for expertise in a wide range of disciplines including chemistry pharmaceuticals biological sciences biochemical and more This book includes number of topics like Preformulation Studies Chemical Properties Physical properties Formulation of tablets Compression and processing problems Tablet coating Quality control tests Capsules Parenteral Products Preformulation factors and essential requirements Containers and closures selection Ophthalmic Preparations and many more **Pharmaceutics**

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1. Understanding the eBook Tableting Manual Tsm
 - The Rise of Digital Reading Tableting Manual Tsm
 - Advantages of eBooks Over Traditional Books
2. Identifying Tableting Manual Tsm
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Tableting Manual Tsm
 - User-Friendly Interface
4. Exploring eBook Recommendations from Tableting Manual Tsm
 - Personalized Recommendations
 - Tableting Manual Tsm User Reviews and Ratings

- Tableting Manual Tsm and Bestseller Lists
- 5. Accessing Tableting Manual Tsm Free and Paid eBooks
 - Tableting Manual Tsm Public Domain eBooks
 - Tableting Manual Tsm eBook Subscription Services
 - Tableting Manual Tsm Budget-Friendly Options
- 6. Navigating Tableting Manual Tsm eBook Formats
 - ePub, PDF, MOBI, and More
 - Tableting Manual Tsm Compatibility with Devices
 - Tableting Manual Tsm Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Tableting Manual Tsm
 - Highlighting and Note-Taking Tableting Manual Tsm
 - Interactive Elements Tableting Manual Tsm
- 8. Staying Engaged with Tableting Manual Tsm
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Tableting Manual Tsm
- 9. Balancing eBooks and Physical Books Tableting Manual Tsm
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Tableting Manual Tsm
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Tableting Manual Tsm
 - Setting Reading Goals Tableting Manual Tsm
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Tableting Manual Tsm
 - Fact-Checking eBook Content of Tableting Manual Tsm
 - Distinguishing Credible Sources

13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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