

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

Dr.C.K.Dhanapal,Mr.Jailani.S



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

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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 experience from industry academia and regulatory agencies Pharmaceutical Manufacturing Handbook Shayne Cox Gad,2008-03-17 This handbook features contributions from a team of expert authors representing the many disciplines within science engineering and technology that are involved in pharmaceutical manufacturing They provide the information and tools you need to design implement operate and troubleshoot a pharmaceutical manufacturing system The editor with more than thirty years experience working with pharmaceutical and biotechnology companies carefully reviewed all the chapters to ensure that each one is thorough accurate and clear **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 **Industrial Pharmacy I (Theory)** Mr. Rohit Manglik, 2024-09-24 Explores industrial scale pharmaceutical manufacturing processes including tablet compression coating encapsulation and quality control measures Foundations of Industrial Pharmacy: A Comprehensive Textbook Dr.C.K.Dhanapal, Mr.Jailani.S, 2024-04-26 Dr C K Dhanapal Professor Department of Pharmacy Faculty of Engineering and Technology FEAT Annamalai University Chidambaram Tamil Nadu India Mr Jailani S Formulation dev R D Alpha Pharma Formerly Julphar Saudi Arabia Kingdom of Saudi Arabia **Indudtrial Pharmacy - I** Mr. Rohit Manglik, 2024-07-30 Examines the foundational aspects of pharmaceutical manufacturing formulation techniques and GMP regulations in industrial pharmacy **Pharmaceutics [GPAT] - Books [Study Notes] 7 in 1 Books with 2500+ Question Answer As Per Updated Syllabus** DIWAKAR EDUCATION HUB, 2022-04-01 Pharmaceutics GPAT Books Study Notes 7 Books with 2500 Question Answer As Per Updated Syllabus Design by Expert Faculties for Secure 152 Marks in Graduate Pharmacy Aptitude Test Asked 38 MCQ in Exam Highlights of Books As Per Updated Syllabus Graduate Pharmacy Aptitude Test 7 Booklets theory MCQ In Each Book given 4 Chapters in Details Total 28 Covered all 28 Chapters Ex Pharmacy Profession Introduction to Pharmaceuticals Introduction

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