In this article, experts describe the benefits of the Tableting Specification Manual to tablet manufacturers and equipment suppliers and discuss aspects of the manual that may be due for an update.

The Tableting Specification Manual (TSM), published by the American Pharmacists Association (APhA), is the authoritative reference for tablet and tablet tooling specifications in North America. In addition to tooling specifications, the TSM includes information on compression tooling terminology, tablet manufacturing, tooling and tablet design, tool steels, maintenance, and troubleshooting.

The manual was first published in 1971 and was initially referred to as the IPT Standard Specifications for Tabletting Tools, because it had been developed by the Industrial Pharmaceutical Technology (IPT) section of the APhA’s Academy of Pharmaceutical Sciences. The manual is currently in its 7th edition, which was published in 2006.

With pharmaceutical manufacturing and technology changing at an ever-increasing rate, we asked tableting experts about the TSM’s ongoing importance to the
industry and had them weigh in on aspects of the manual that might need to be updated in a future edition.

**What benefits does the TSM provide for manufacturers of tablet products and suppliers of tablet presses and tooling?**

Andrew Lapinsky, engineering and CNC programming manager, Elizabeth: The TSM is a great reference for the many users of tablet tooling across diverse companies within the healthcare industry. The nuances related to compression tooling can be daunting, and the TSM establishes a common vocabulary and principles for both experienced and novice users alike. Employee mobility and turnover across the pharmaceutical industry creates a demand for ongoing tablet manufacturing training. The TSM provides the foundation for establishing repeatable processes and cost-effective decision making within the industry.

Dale Natoli, president, Natoli Engineering, chairman for the TSM's 3rd edition, and steering committee member for the TSM's 7th edition: In general, the standards provide efficiency related to manufacturing processes, quality assurance, standard operating procedures, communications, training, cleaning, and storage. Also, tooling standards reduce variables when transferring a product from one manufacturing site to other, international sites.

Mark Rice, technical service manager, SMi: The TSM provides tablet manufacturers with a good resource for troubleshooting tablet press issues as well as aiding in tooling and custom parts design.

Luke Hoskin, technical sales manager, North America, I Holland: The TSM offers a clear and comprehensive guide to tabletting principles, which have been combined from a number of different influential industry sources. This ensures that the information is objective and specific to each subject area.

The TSM allows solid dose manufacturers to follow a common operating standard, helping to ensure interchangeability of tooling across the various tablet press types in use in North America. But the manual is not only useful for tablet press users in the Americas. Global users from time to time adopt a press made to TSM standards, so knowledge of the standard is helpful. The general information in the manual is also good to have available.

Nicola Pistillo, product manager, and Federica Giatti, compression technologist, IMA Active: From a tablet press manufacturer's point of view, TSM tooling requires a different cam configuration and assembly specifications compared to EU tooling, so the manual is a must for companies that supply equipment to both the European and US markets.

From a process point of view, there is no particular advantage to TSM tooling versus EU tooling. On the contrary, the existence of two standards covering the same tablet size represents an increased cost of ownership for pharmaceutical companies.

Mike Tousey, president, Techceuticals: The TSM standards allow for tooling interchangeability between tablet presses. The manual also provides information on troubleshooting, tablet designs to help strengthen tools and withstand formulation changes, logo design, and specific applications for coated and non-coated tablets. The standards also allow manufacturers to establish and track wear patterns and overcome them through tooling design, steel selection, or both. My TSM is always next to me, and I still have my first IPT manual from the 70s.

Todd Martin, senior tooling engineer, Wilson Tool International and contributor to the TSM's 7th edition: The TSM is the essential bible for tablet tooling in North America. I reference my dog-eared copy every day in my work. The standards and reference information allow for efficient design and manufacture of tooling. Consistent standards help end users purchase tooling that works in their machines, and press manufacturers rely on TSM standards to provide machines that fit our market.

**Do you believe the TSM is due for an update?**

Natoli: I do believe the TSM is due for an update. Even more so, the next edition has an opportunity to be the go-to publication, with more useful information including a reference for all tool features, modifications, and exclusive tool configurations.

Tousey: Yes, tablet presses have changed. The TSM is a good guide, but there is always room for improvement. I believe the TSM should be gone through from top to bottom and should include international standards as well and be considered a world book. Too many think it is just a North American book.

Pistillo and Giatti: It would be interesting to have an update that integrated some new developments in the market from tooling suppliers as well as tablet press manufacturers. The reality of the market has changed a lot since 2006.

Lapinsky: Yes, there have been advancements to rotary tablet presses, tablet tooling materials and coatings. These new specifications should be added.

Hoskin: Tablet manufacturing has come a long way in the last 14 years and there have been many innovations in tablet compression tooling and its associated maintenance and management. These considerations make some of the guidance in the TSM's 7th edition a little out of date.

Additionally, perhaps now would be the ideal time to bring the TSM into a digital format to work alongside the more traditional workbench document. At I Holland, we have introduced online training and believe this is the way forward to help tablet manufacturers improve their knowledge and skills. Putting the TSM into a similar format would allow those who follow the manual to access it with ease.

**Are any new tooling specifications needed?**

Pistillo and Giatti: Back in 2006, the steering committee was focused on the pharmaceutical market. However, there are new markets that need to be investigated. IMA is promoting tablet presses not only in pharma but in the chemical and other non-pharma...
industries, where tooling specifications are completely missing. Customers' requests need to be fulfilled not with TSM or EU punches but with product-specific tooling, such as IMA32.

Frederick J. Murray, president, Korsch America: Most of the machines listed in the document are old and, in many cases, have been replaced with newer models that are not referenced. There are also a number of European tool specifications, such as EU441 and FS12, which have no real equivalent in the TSM. In Europe, there is a different specification (DIN ISO 18084) to describe and define punch and die dimensions and tolerances and allow for exchangeability between presses from different suppliers. An effort should be made to bring all tool specifications into a single document if at all possible, and in the longer term, a process to harmonize tooling specifications should be considered.

With regard to current TSM standards, the upper key position on the punch barrel should be fully defined for all tool configurations. This can be a critical consideration, and the arbitrary placement of the key position can cause interference with the oil seal and risk lubricant contamination on the die table.

Martin: I would suggest adding BBS die specifications and updating the press tables as follows:
- Specify whether the press has punch seals;
- Specify key location range per model (X-min. and Y-max. from Table 4 on page 40);
- Specify upper punch penetration per model, and
- Specify minimum lower punch pull-down value.

Lapinsky: The common punch head configurations for type B and D punches should be reviewed for additions to the TSM domed head profile. There are one or two domed punch head profiles that are considered standard, but they have not been added to the TSM. These head profiles increase the punch head flat. A question should be asked if die segments need to be added to the standard TSM die line of (0.945", 1-3/16" & "D"). Also, information about automated polishing machines should be added.

Natoli: New tooling standards may not be required, but the manual should identify and explain innovative and accepted tooling options, such as extended head flats, special lower tip reliefs, and multi-tip tooling, that do not conform to the published standards relative to tablet press operation and product quality.

Hoskin: Tooling specification is very similar to a decade ago. However, as with all engineering refinement, incremental change is the driver. It is important to account for these incremental changes—for example, die segment technology and micro die tapers—in the manual.

Multi-tip tooling has advanced rapidly. As mass-production of tablets grows, multi-tip tooling is helping to transform the way tablets are produced by increasing production without requiring investment in new machinery or operator hours. Information on multi-tip setup procedures as well as general information on the setting of presses using this tooling is essential.

Jennifer McGonigle, director of operations, SMI: Specifications and an instructional section discussing the use of single and multi-tip tooling for minitablet production would be very beneficial.

Which existing specifications should be revised and how?

Tousey: There are many, including clearances, head flats, and tolerances. Also, many new copies of tablet presses have come out with new and different punch and die configurations. The steering committee would need to determine whether these presses should be included.

Martin: I would recommend the following revisions to existing specifications:
- Update Figure 37 to include D3 steel,
- Update Figure 40 (Quote/Order Form) to indicate a specific tool material (such as S7 or D2 steel) rather than "standard" or "premium;"
- Change the surface finish tolerance from "±" to a maximum value, as tools should not be rejected due to a surface finish that is too good;
- Correct the "BB" die O.D. dimension tolerance from +0.0005"/-0 to +0.005/"-0.0005;"
- Remove Note 3 regarding the Stokes GEM Supreme stem length—incorrect (B & D);
- Correct Table 3 (Standard Clearances) 5/32" metric value from 3.3970 millimeters to 3.969 millimeters; and
- Clarify 408 steel force rating (the text says 10 percent less than S7, while Figure 36 shows higher toughness than S7).

Hoskin: There are now many more options in terms of punch head forms to increase desirable features such as dwell time without slowing down press speed or upsizing punches. Also, new innovations in tool steel, coatings, and treatments have been specifically tailored to provide wear and corrosion resistance or improve anti-stick properties. These developments have changed tablet manufacture significantly by addressing challenging formulations or production issues and have improved tableting efficiency.

Other procedures that should be updated and added to include anti-stick guidance and tooling maintenance. Planned, professional tooling maintenance, management, and storage is fundamental to achieving optimal equipment efficiency and tablet output.

Natoli: The standard TSM angled head configuration should be eliminated in lieu of the domed head for extended tooling life and smooth tablet press operation.

Lapinsky: Tables 5-8, which cover interchangeable tooling for rotary tablet presses, should be updated to indicate the newer tablet presses in the market. There is a need to add tolerances to the seal groove formation. This would help establish a profile of size range to ensure that all tool manufacturers' European dust cup reliefs (seal grooves) meet the TSM specifications. Also, bisects should be categorized as functional or non-functional, and more information from the FDA should be added to that section.
**Pistillo and Giatti**: Tooling specifications might need to be revised to include analysis of new technologies applied to force calculation—such as finite element method (FEM)—that include the effects of the material and coating on the final result.

Regarding tablet press specifications, new companies and tablet press models are in the market. Also, tablet presses that use centrifugal force feeding, such as the IMA Comprima, have not been taken into account.

Compatibilities between materials in contact with the formulation and the most recognized APIs should be revised. It might be interesting to have suggestions for coatings/tip materials depending on the API or excipient characteristics as well as advice for handling abrasive compounds. The same approach could be used for the troubleshooting section, which could include more discussion covering the most commonly found tablet defects.

**Should any new topics be added to the TSM?**

**Martin**: I would recommend adding the following:
- Guidance on the proper take-off position for different tablet shapes (keying angle for polygons);
- A new section on minitablet tooling;
- FEA guidance for determining force ratings (such as Von Mises versus maximum principal stress, mesh size, and endurance limits);
- Include maximum force values for punch head profiles;
- Include guidance on which presses need keyed rounds to prevent double impressions (from insufficient anti-turning between pre- and main compression).

**Tousey**: I would like to see a comprehensive section on wear issues. There are significant differences between older tablet presses and current machines that should be recognized and defined in the TSM. For instance, lower punch diameters have changed, but the TSM doesn’t explain that the change has to do with the introduction of punch seals and may not benefit companies using older machines. The original smaller diameter barrels allowed more clearance to reduce the potential for binding. The distinction should be clear, so manufacturers that have some older machines and some newer machines will understand how changing to “current” standards may impact performance.

The TSM is an important tool; too many manufacturers rely solely on the tooling supplier to interpret their application and their vintage and mix of tablet presses. This has a direct impact on tablet quality and productivity.

**Natoli**: New topics that would be beneficial for a new edition include:
- A more comprehensive and updated troubleshooting guide;
- A better understanding of clearances between the tablet compression tooling and the tablet press;
- A better understanding of clearances between the punch tip and the die; and
- Recognizing exclusive tool configurations as an alternative to standard dies.

**Pistillo and Giatti**: A study comparing the characteristics of tablets compressed using TSM punches to tablets compressed using EU punches would give users an idea of the effective advantages of each standard on the tableting process. Insight into multi-tip tooling applications is missing as are studies comparing blend feeding systems, which strongly affect tablet quality. Also, external lubrication technology is now available, fulfilling market requests to help ease challenging processes and meet the needs of the trend toward continuous manufacturing.

**Hoskin**: Continuous manufacturing is a big area of change in tableting and should certainly be addressed, including best practices, solutions, and technology to help with implementation. Examples of this are tool steel and coating choices that should be used for continuous tabletting and specialized tooling that can help achieve more reliable run times. Other topics that deserve space are tooling maintenance programs and management systems and scientific research relevant to tablet manufacture.


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