Guidelines for Using This Manual

Not for Distribution

Special Notice to Readers: Unless indicated otherwise, figures and text illustrations in the manual are not drawn to scale. Further, unless indicated otherwise, the dimensions listed in figures and tables are given first in inches, followed by the equivalent millimeters in brackets.

The first step in learning any industry is mastering its terminology. With this in mind, the Steering Committee has adopted a list of standard, industry-accepted terms for tablet manufacturing. An understanding of these terms will provide a foundation on which persons new to the industry can build a working knowledge of the basic tablet categories, tooling types, press operations, and tooling specification drawings. For those who have industry experience, the information in this section could be a useful reference for ensuring clear communication between production staff, tablet designers, tooling suppliers, and press manufacturers.

Tooling Terminology

The following definitions of the standard terminology for tooling (punches and dies) are illustrated in Figure 1 (page 3).

Abbreviations

IPT: Industrial Pharmaceutical Technology (obsolete term replaced with TSM)

TSM: *Tableting Specification Manual*

APhA: American Pharmacists Association (publisher of the *Tableting Specification Manual*)

EU: European union

FEA: Finite element analysis

kN: KiloNewton

kp: Kilopond

O.D.: Outside diameter

I.D.: Inside diameter

W.L.: Working length

O.L.: Overall length

General Terminology

Abrasion: The act of wearing of contact surfaces.

Alpha/Numeric Characters: A, B, C, etc./ 1, 2, 3, etc.

Anneal: A process of heating a steel followed by slow air cooling to change the steel's microstructure, usually to soften it.

Angle: A figure that is formed by two lines diverging from a common point.

Arc: A segment of a circle.

Axis: A straight line serving to orient a geometric object.

Barrel: The area between the neck and stem of a punch.

> **Barrel-to-Stem Chamfer:** The beveled area located between the barrel and barrel-to-stem radius. The chamfer allows for the proper insertion of the punches turret oil seals.
>
> **Barrel-to-Stem Radius:** The area at the junction of the barrel and stem, which provides a curved transition from the tip length to the barrel.

Bevel: The angle of a line that meets another at any angle other than a right angle.

Blend: To form a rounded surface at the point where two surfaces come together to form an angle.

Bore: To form a hole through an object.

Break (broken): To remove and round off a sharp edge.

Burr: A rough or raised edge.

Capping: A tablet defect in which air trapped during compression creates a layer of granulation with air between the granules, which in turn weakens the structure and allows a capping fracture (the tablet top and/or bottom curvature breaks off at or above the band).

Chamfer: A cut or bevel applied to an edge or corner.

Chipping: A defect in the tablet in which a piece has broken off the edge.

Clearance: The difference in size between interacting parts, which creates a working space between the parts and allows for their designed free movement.

Concave: Having a surface that is curved like the inner surface of a sphere.

Convex: Having a surface that is curved like the exterior surface of a sphere.

Concentricity: The measurement from a common center point.

Corrosion: A chemical reaction of contact surfaces, which causes pitting and discoloration.

Delaminate: A defect in a layered tablet in which the layers split apart.

Dimension: The numeric measured distance.

Ductility: The ease that metal flows during the high pressures of compression.

Finite Element Analysis (FEA): A sophisticated computer program that is capable of modeling complex shape configurations and performing accurate stress analyses to determine the maximum force loading that the punch tip can be subjected to and still permit infinite tableting cycles.

Flashing: A slight imperfection in a tablet in which the material has been compressed above the land in the clearance between the punch tip and the die bore, causing a raised edge.

Formulation: The result of bringing together all the ingredients in a recipe (see definition below) for a pharmaceutical, food, or nutritional product that is manufactured by blending (mixing) followed by compressing or molding the mixture of ingredients.

Force Tip Ratings: Maximum force loading that a punch tip can withstand and permit infinite tableting cycles. The rating is derived from a mathematical equation.

Granulation: Structure of the granules (particles) of the components of a pharmaceutical product after blending.

Hardening: A process of heating steel at high temperatures, then cooling it to transform the steel from a soft (annealed) condition to a hard condition.

Identification: The application of letters, numbers, and/or symbols to an object's surface.

Industrial Pharmaceutical Technology (IPT) section: The group who developed the first industry-wide tooling standards—the IPT standards—which were renamed the TSM standards.

KiloNewton: The unit of force use in measurement of the loading applied or subjected to in order to compress the tablet to the specified weight and thickness.

Kilopond: The unit of force used to measure the fracture point of a tablet.

Lubricant: A substance applied to moving parts to decrease the friction generated between them.

Milligrams: The unit of measurement used to determine tablet weight.

Oil: A common lubricant used on a tablet press during manufacturing.

Polishing Compound: Material that is used to assist in buffing the tip faces to remove built up residue.

Product: The final blended material that is to be processed into its final dosage form (tablet, capsule, vial, etc.).

Recipe: The formula and contents for the ingredients (active and inactive) and their quantities for a tablet.

Relief (Undercut): The area of increased mechanical clearance.

> **Tip Relief:** The undercut between the punch stem and the tip.
>
> **Bakelite Relief:** A special, designed undercut to prevent material buildup in the die bore.
>
> **European Dust Cup Relief:** A special, designed undercut on the punch barrel that allows attachment of a standardized dust cup with a precut hole that is standardized to the groove seal.

Rockwell Hardness: A measurement of the hardness of steel. The Rockwell C scale is customarily used for measuring tool steels.

Score: An embedded line in the tablet that allows the tablet to break when force is applied adjacent to the area. This term includes bisect and quarter-scores.

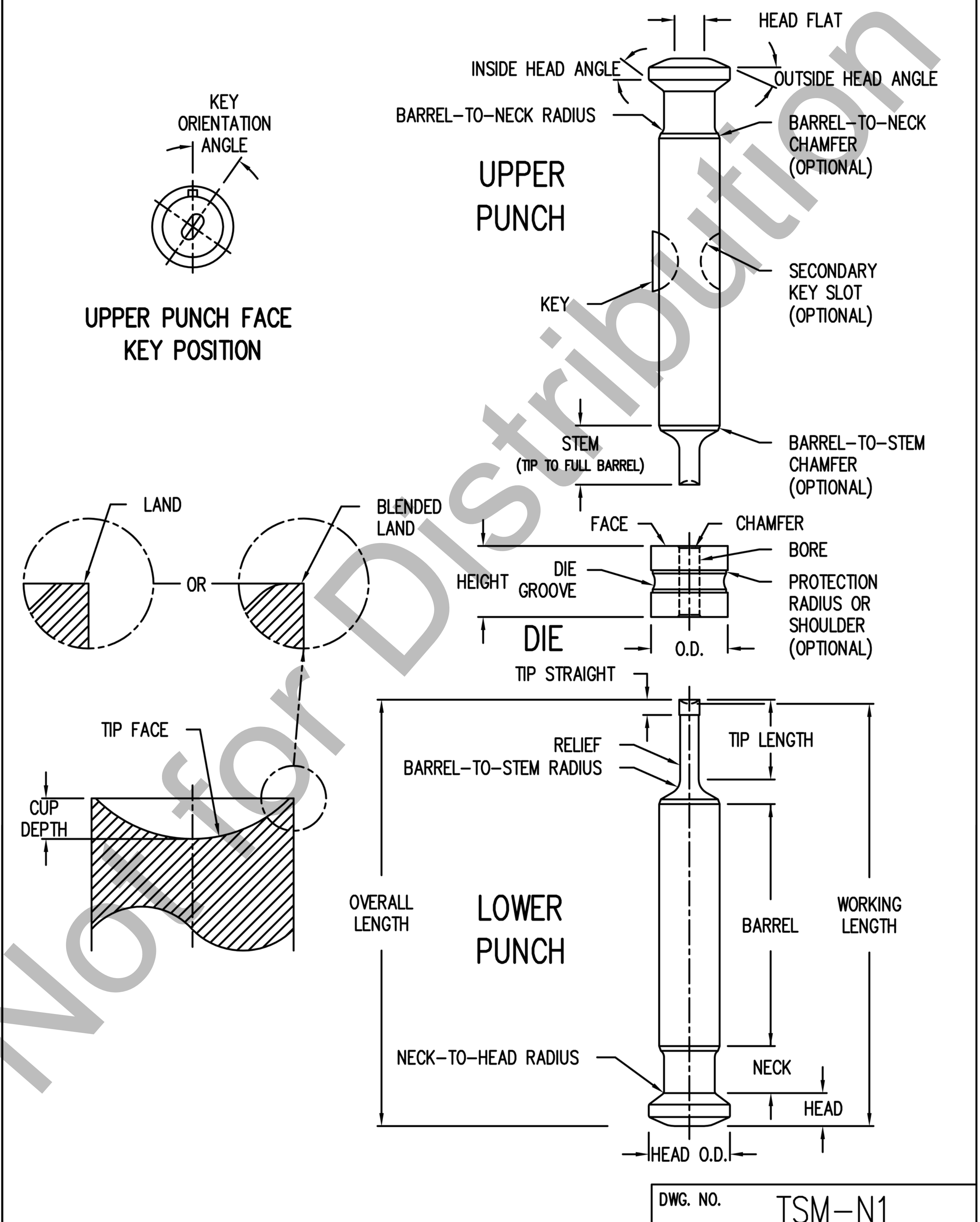
Sharp: Term used to describe a corner or edge that is not broken or rounded.

Soft Zone: The area on a tip face that receives unequal

Not for Distribution

© American Pharmacists Association

FIGURE 1. PUNCH AND DIE TERMINOLOGY



Not for Distribution

force during the compression cycle, which may result in a softer surface hardness of the tablet in the corresponding area.

Sticking: A tablet defect in which material adheres to the smooth surface of the punch tip face.

Surface Finish: The degree of smoothness required for a component, measured in microns.

Tableting: The function of compressing a volume of granular material into a hard form.

***Tableting Specification Manual* (TSM) Standards:** Standard specifications for tooling developed by the pharmaceutical industry, tablet press manufacturers, and the American Pharmacists Association for the U.S. market.

Tablet Specifications: The final parameters for weight, thickness, and hardness that are determined for any given tablet.

> **Tablet Thickness:** The combined height of the upper and lower punch tip cups and the band, along with the expansion of the materials after the compression of the tablet, determines the total thickness of a tablet.
>
> **Tablet Weight:** The amount of material specified for the tablet, which is determined by the final volume fill within the die.
>
> **Tablet Hardness:** The amount of force required to fracture a tablet, measured in kiloponds.

Taper: A gradual increase in the size of the die bore that extends from the point of compaction to the chamfer of the bore.

Tempering: A process of reheating and cooling steel that follows the hardening process. Tempering toughens the steel but reduces its hardness.

T.I.R.: The Total Indicator Reading obtained when measuring certain tooling dimensions with an instrument. The T.I.R. is the difference between the highest and lowest readings noted on the indicator dial during one complete rotation.

Tolerance: The authorized deviation from a tooling dimension measurement. The deviation allows for practicality of manufacturing tooling.

Tooling: The collective term for the upper punch, lower punch, and a die.

Tooling Compatibility: The ability to interchange tooling between different types of presses.

Tooling Steels: Steels used to manufacture tablet tooling.

Toughness: The ability to withstand great strain without breaking.

Wear Resistance: The ability to withstand abrasion.

Tablet Press Terminology

Cam Track: The mechanical track that guides the punches (lifting and lowering them into the dies) during a rotation of the press turret.

Compression: The function of pressing material together into a compact form.

> **Precompression:** The function during the tableting cycle in which the material is tamped to expel trapped air.
>
> **Main Compression:** The function during the tableting cycle in which the material is fully compressed to its specified form.

Die Lock: The die-fixing screw that secures a die in the machine die table.

Die Socket/Pocket: A recess (recesses) in the die table into which the die is secured. The recess allows positional location of the die.

Die Table: A component of the press's turret that contains recesses into which dies are placed.

Dwell Time: The length of time that compression tools (punches and dies) are subject to maximum compression force from the compression or precompression roller.

Ejection: The function of pushing the compressed tablet out of the die bore.

Fill: The function of granular material entering the die bore during the tableting process.

Punch Guides: The bores in the turret that hold the punches, allowing them to ride through the cam track. The guides control the punch barrel's surface, thus ensuring the punch's alignment with the die.

Punch Tip Deflection: The total tip movement within the punch guide due to the clearance between the barrel and the punch guide bore at the point where the punch is about to enter the die bore.

Punch Entry: The distance within the die at which the tablet is compressed.

Not for Distribution

© American Pharmacists Association

Scrape Off: The function of removing excess granular material from top of the die bore to allow for the exact measure volume fill on the tablet press turret during the tableting process.

Station: A punch guide position within the tablet press turret, which consists of an upper punch, a lower punch, and a die.

Tableting Cycle: The process of compressing a tablet, which includes the fill, scrape off, compression, ejection, and take-off functions.

Tablet Press: The equipment used to mechanically compress granular material into a hard form.

Rotary Tablet Press: Equipment that uses a rotating turret to cycle the tooling through the tableting cycle.

Single Stroke Press: Equipment that uses a stationary table and eccentric cam to cycle the tooling through the tableting cycle.

Take-Off: The function of removing the compressed ejected tablet from the tablet press turret during the tableting process.

Turret: The rotating device in a tablet press, composed of the cam track and die table, which holds and aligns the tooling through the tableting cycle.

Punch Terminology

Barrel: The area between the neck and stem of a punch.

Barrel-to-Neck Chamfer: The beveled area located between the barrel and barrel-to-neck radius. The chamfer can reduce wear of punch guides.

Barrel-to-Neck Radius: The area at the junction of the barrel and neck, which provides a smooth transition from the barrel to the neck.

Barrel-to-Stem Chamfer: The beveled area located between the barrel and barrel-to-stem radius. The chamfer allows for the proper insertion of the upper or lower punch into the oil seal.

Barrel-to-Stem Radius: The area at the junction of the barrel and stem, which provides a curved transition from the tip length to the barrel.

Bellows: A pleated sealing device that contracts and expands upon application and removal of pressure. A bellows covers the extended portion of the punch barrel, providing a better seal and, thus, better protection from lubrication contaminating the product.

Cup: The depression or cavity within the punch tip.

Compound Cup: A cup design in which multiple arcs are generated from the cup's center point across the cup's diameter, minor or major axis.

Standard Cup: A cup design in which a single arc is generated from the cup's center point across the cup's diameter, minor axis, or major axis.

Flat-Faced Bevel-Edged (F.F.B.E.): A cup configuration consisting of an angle between the cup's and the tablet's flat face and a land. A 30° bevel is preferred to maximize the strength of punch edges. When the bevel is first applied, its contact area with the tablet face is a sharp beveled edge.

Flat-Faced Radius-Edged (F.F.R.E.): A cup configuration similar to F.F.B.E. consisting of a radius between the cup's and the tablet's flat face and a land. The radius from the tablet's periphery or land should not exceed the comparable 30° bevel used for the F.F.B.E. design to ensure the strength of punch edges.

Cup Depth: The distance from the cup's lowest point (usually the center point of the cup) to its highest point (usually the highest point of the land). This measurement does not include identification embossing and debossing.

Cup Radius: A single arc generated from the tablet's center point across the tablet's diameter, minor axis, or major axis.

Fluted Barrels: Punch barrels with machined grooves that prevent build up of material in the punch guides.

Head: The end of the punch that guides and positions it through the tablet press's cam track.

Head Angle, Inside: The area of the head that is in contact with the work portion of the cam track—that is, the pull-down cam for lower punches and the lifting cam for the upper punches.

Head Angle/Radius, Outside: The area of the head that is in contact with the tablet press cams and has the initial contact with pressure rollers.

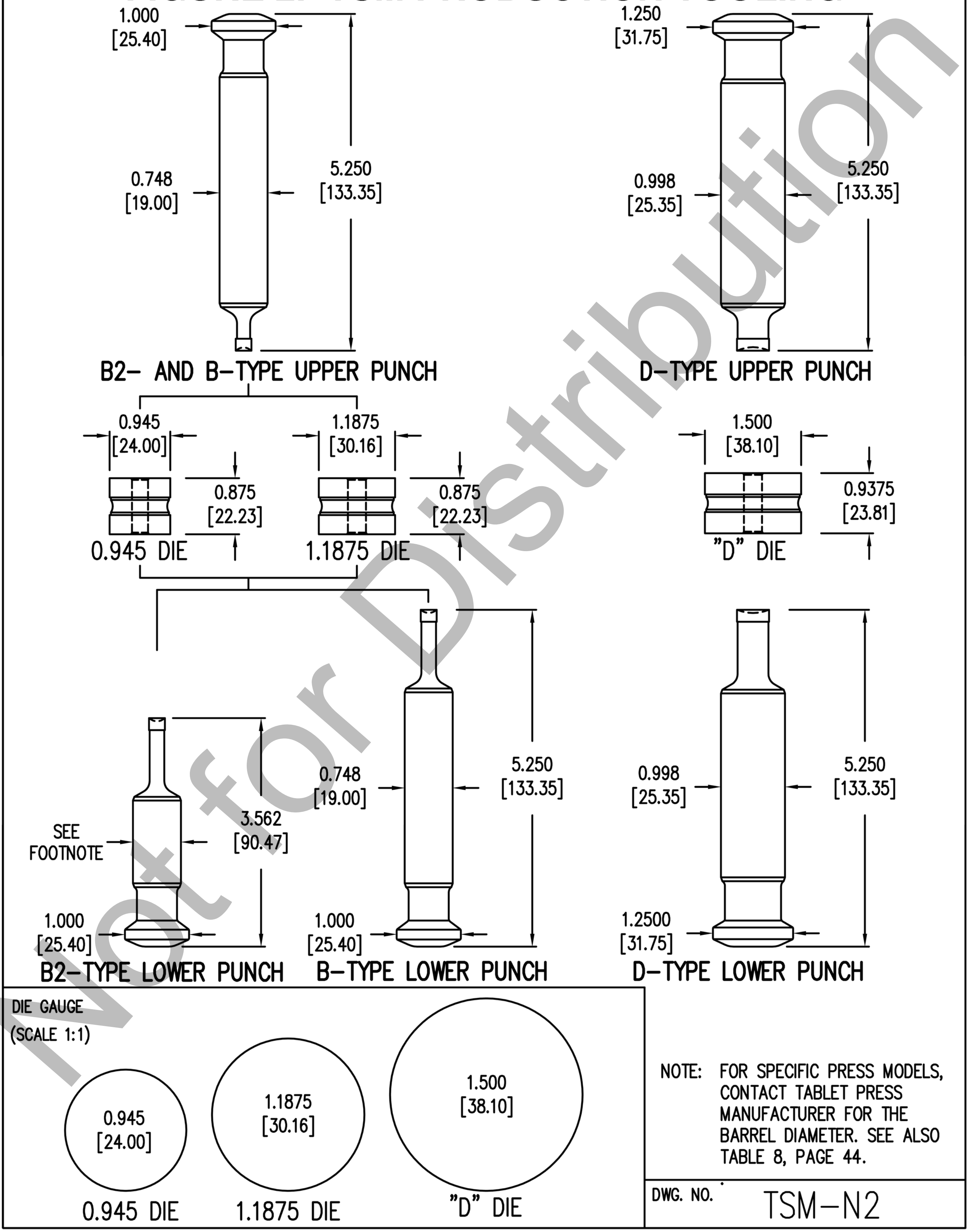
Head Flat: The flat area of the punch head.

Head O.D.: The outside diameter of the punch head. The O.D. extends the effective area of contact between the cam and both the inside head angle and the outside head angle/radius.

Hooked Tip: A defect of the punch tip caused by wear in which the edge curls inward toward the punch face.

Not for Distribution

FIGURE 2. TSM PRODUCTION TOOLING



Not for Distribution

© American Pharmacists Association

Interchangeable Upper Punches: Keyed punches that can be inserted into any station in a press turret because of the precise positioning of the key in relation to the punch tip.

Key: A device that is inserted into the punch barrel and protrudes into the turret guide, thus preventing the rotational movement of the punch, which allows for precise alignment of the punch tip to the die bore.

Woodruff Key: A half-round key that is pressed into a broached machined groove in the punch barrel.

Hi-Pro Woodruff Key: A half-round key with side tabs that is pressed into a broached machined groove in the punch barrel.

Fixed Parallel Key: A standard flat key that is screwed into the broached machined groove in the punch barrel.

Keying Angle: The relationship of the key and the punch tip shape to allow for proper ejection of the tablet.

Land:

Land, Tablet: A narrow plane perpendicular to the tablet's band, which creates a junction between the band and the cup radius.

Land, Tip: The area between the edge of the punch cup and the O.D. of the punch tip.

Land, Blended: The broken edge between the land and the tip face.

Length:

Working Length (W.L.): The 1ength of the punch from the bottom of the cup to the head flat. The working lengths of the upper and lower punches control tablet thickness and weight.

Overall Length (O.L.): The total punch length as measured from the head flat to the end of the tip.

Neck: The relieved area between the head and barrel, which provides clearance for the cams.

Oil Cups: A circular cup inserted onto the punch stem to collect excess lubrication and prevent it from dripping down the punch onto the tip.

Oil Seals: Seals that are placed into the upper and lower punch guides to prevent lubrication from exiting the guides and material from entering them.

Punch: A rod-shaped tool, usually made from steel, which is used in producing tablets and other hard products. The collective description for the device includes the head, neck, barrel, stem, and tip. The face of the tip forms the mold surface for producing detail (logo, company name, identification code, etc.) on the tablet face. (See "Tablet Terminology" in Section 3.)

Lower Punch: The punch inserted into the turret below the die.

Upper Punch: The punch inserted into the turret above the die.

Radius: A line segment that joins the center point of a sphere with any point on its surface.

Corner Radius: The curvature used to eliminate sharp corners on peripheral surfaces where two lines or curves meet.

Barrel-to-Stem Radius: The corner radius located between the punch barrel and the stem.

End Radius: The radius located at either end of an oval-shaped tablet.

Neck-to-Barrel Radius: The corner radius located between the punch neck and the barrel.

Neck-to-Head Radius: The corner radius located between the punch neck and the inside head angle.

Seal Groove: A groove on the punch barrel that secures a sealing device, such as an oil/dust cup or bellows, which prevents possible contamination of the product during the precompression and compression phases.

Stem: The area of the punch opposite the head, beginning at the tip and extending to the point where the full diameter of the barrel begins. If a chamfer is present, the barrel usually reaches its full diameter just above the chamfer.

Tip: The end of the punch that is compatible with the die bore. The tip determines the size; shape, profile, and identification of the tablet

Tip Engraving, Debossing: An engraving identification that is depressed into the tip face below its surface (see Section 3).

Tip Engraving, Embossing: An engraving identification that protrudes above the surface of a tip face (see Section 3).

Tip Face: The area within the cup's periphery.

Tip Land: The area between the edge of the punch cup and the O.D. of the punch tip.

Tip Length: The straight portion of the stem that is effective inside the die bore. On lower punches, the tip length allows vertical movement within the

Not for Distribution

die bore for the metering of volume, compression of granulation, and ejection of the tablet

Tip Straight: The area of the tip length that extends from the end of the tip to the tip relief.

Die Terminology

Die: A tool that serves as the mold in which the product is compressed to form the desired peripheral (outer) size and shape of a tablet.

Die, Lined (Insert): A die fitted with an insert made from a much harder, more wear-resistant material, such as tungsten carbide or a ceramic.

Die, Tapered: A die in which the size of the bore gradually increases from the point of compaction of the granulation to the chamfer of the bore.

Die Bore: The cavity within the die where the tablet is compressed. The cavity's shape and size determine the same for the tablet.

Die Chamfer: Entry angle on the die bore edge.

Die Groove: The groove around the outer periphery of the center of the die, which allows the die to be fixed in the tablet press.

Die Height: The overall height of the die, which is compatible with the height of the die sockets in the tablet press.

Die O.D.: The outside diameter of the die, which is compatible with the diameter of the die sockets in the tablet press.

Die Protection Radius: The undercut area between the die groove and O.D.

Tablet Manufacturing

Producing a tablet with a unique design often increases a product's recognition among consumers. Although tablets can be produced in a variety of shapes and sizes, limitations as to their configuration do exist. The limiting factors are usually related to characteristics of the tooling and the press used to produce the tablets. Some categories of tablets are easier to manufacture and comprise the majority of tablets on store shelves.

Tablet Categories

Definitions of tablet terminology are based on the geometric properties of the most common tablet shapes; therefore, these definitions are placed in Section 3, "Tablet Design." For the scope of this section, tablets are broadly categorized as either "rounds" or "shapes." Figures 22–25 in Section 3 are cross-referenced in the following text to illustrate examples of the tablet categories.

Round Tablets

Round tablets include primarily convex and flat-faced tablets (see Figure 22, page 52). Frequently, industry people use the term *concave* to describe both the concave surface of a punch cup and the surface of the tablet produced. Technically, the punch cup is usually a concavity and therefore produces a tablet with a convex surface; however, convex cups that produce concave tablets do exist.

Convex tablets can be further categorized according to their cup depth. Figure 23 (page 54) shows convex tablets with shallow, standard, deep, extra-deep, and modified-ball cup depths. Flat-faced tablets can be further categorized as flat-faced plain, flat-faced bevel-edged, and flat-faced radius-edged (see Figure 25, page 56).

Shaped Tablets

Tablets that have geometric configurations other than those listed for rounds are referred to as shapes (see Figure 25). Figure 24 (page 55) uses three common geometric configurations to illustrate the terminology for shaped tablets. To produce a tablet with a particular configuration, the tablet shape is reproduced in the tooling used to manufacture the tablets. Before the method of reproduction can be discussed, a thorough understanding of tablet tooling is required.

Modern Tablet Tooling

The function of tablet tooling is to produce tablets with predetermined physical characteristics, such as shape, thickness, weight, and hardness. To achieve this, the die cavity, or bore, is filled with a granulation or powder to a depth that is determined by the position of the lower punch. The lower punch's position determines the amount of granulation used in each tablet. The upper punch tip is then guided into the bore and force is applied to the punch heads, thereby compressing the material into a tablet. The tablet's shape is determined by the configuration of the die bore and the punch tips. The tablet's thickness and hardness are determined by

Not for Distribution

 © American Pharmacists Association

the amount of compression force applied to the punch heads, whereas its weight is determined by the amount of granulation loaded into the die before compression.

The basic design of tablet punches and dies used in rotary tablet presses has changed very little since these presses were first marketed in the late 1800s. Only minor changes, such as refinements to the head and tip radius, tighter tolerances, and higher surface finishes, have been made. In the U.S. tablet industry, three types of punches and three types of dies are used predominantly in production presses to produce large quantities of tablets for market distribution.

Punches

Punches are classified according to their overall length, barrel diameter, and the O.D. of the punch head. These dimensions, as well as the other specifications for tablet tooling, are nominal: that is, each dimension has a specified measurement, but its actual measurement after the tool is produced may vary from its specification. The allowable variance from a nominal dimension, called its tolerance range, is discussed later in this section under "Tooling Specifications."

The punches most commonly used in production presses are the B-type and D-type punches (see Figure 2, page 6). B2-type punches are used predominantly in a few older models of presses that are no longer being manufactured. During the research stage of a new tablet design, F-type punches and dies (not pictured) and a single-station laboratory press are used to determine the approximate amount of compression force and granulation needed to produce a tablet with the desired physical characteristics.

B-Type Punches have a reference overall length of 5.250 inches [133.35 millimeters] and a head O.D. of 1 inch [25.40 millimeters]. These dimensions are the same for the upper and lower punches. Although the barrel diameter of a B-type punch is often said to be 3/4 inch [19.05 millimeters], the specified barrel diameter for the upper—and now the lower—punch is 0.7480 inch [19.00 millimeters].

B2-Type Punches usually have a barrel diameter of 3/4 inch [19.05 millimeters]. Table 8 (pages 44–49) lists barrel diameters of B2-type punches for specific press models). This punch has a head O.D. of 1 inch [25.40 millimeters]; however, the overall lengths of the upper and lower punches differ. The upper punch is 5.250 inches [133.35 millimeters] long, whereas the lower punch is 3.562 inches [90.475 millimeters] long.

D-Type Punches have the same reference overall length as B-type punches (5.250 inches [133.35 millimeters]), but the head O.D. of D-type punches is 1.250 inches [31.75 millimeters]. Again, D-type punches are often said to have a barrel diameter of 1 inch [25.40 millimeters]; however, the specified barrel diameter for the upper—and now the lower—punch is 0.9980 inch [25.35 millimeters].

Dies

Dies are classified according to their outside diameters (see Figure 2, page 6).

The 0.945 Die, as the name indicates, has an O.D. of 0.945 inch [24.00 millimeters]. This size die can be used with B- and B2-type punches. The die is commonly referred to as a "BB die."

The 1.1875 Die, sometimes referred to as the "1 3/16 die," has an O.D. of 1.1875 inches [30.16 millimeters] and also can be used with B- and B2-type punches. This die is commonly referred to as a "B die."

The "D" Die, which has an O.D. of 1.500 inches [38.10 millimeters], is used with D-type punches.

Comparison of Shaped and Round Tooling

Not surprisingly, punches and dies used to manufacture round tablets are often called "round tooling," and punches and dies used to manufacture shaped tablets are called "shaped tooling." After the geometric configuration of a tablet has been determined by the designer, the desired configuration is reproduced in the punch tips and die bores.

The upper punch for a shaped tablet has a device called a key that is inserted into a slot in the barrel and projects above the barrel's surface (see Figure 1, page 3). The key prevents the punch from rotating as it is lifted vertically from the die bore so that the punch can re-enter the die bore at the proper alignment. Because round configurations are usually unaffected by rotation of the upper punches, round punches seldom require a key. However, if a round lower punch is embossed, a key is sometimes used to prevent punch rotation and possible distortion of the embossing during tablet ejection.

Regardless of the tablet shape and the type of tooling used, the basic press operations are the same.

Not for Distribution

TABLE 1. ROTATION DIRECTION OF TABLET PRESSES	
PRESS TYPE	**DIRECTION OF ROTATION**
CADMACH	CW
COURTOY	CCW
HATA	CCW
FETTE	CCW
KIKUSUI	CCW
KILIAN	CCW
KORSCH	CCW
MANESTY	CW
RIVA	CW
STOKES	CCW (Gem Series); CW (all other models)
VECTOR	CCW
NOTE: CW = CLOCKWISE; CCW = COUNTERWISE.	

Rotary Tablet Presses

Major advancements in the tablet industry have occurred with new models of rotary tablet presses: their speed has increased; a precompression stage has been added to the production cycle; and, in some presses, computer technology automatically adjusts the powder fill mechanism for lower punches to maintain the proper tablet weight. The engineering of these presses was designed around the basic configuration of TSM tooling to ensure that tablet manufacturers could continue to use their existing inventory of tooling. All presses have designated positions at which certain steps in the production of a tablet occur. The following description of these positions is supported by Figures 3 and 4 (pages 11 and 12). These figures show the production cycle of a press that rotates counterclockwise. Table 1 lists the direction of rotation for presses of major manufacturers.

Fill Position (Die Fill)

At the fill position, the lower punch is pulled down by the fill cam as the die is passing under the feed frame. The pulling down of the lower punch creates a slight vacuum and a void in the die bore. Initially, the combined effect of the vacuum and the void allows loose powder to flow into the die bore. As the die continues its pass under the feed frame, the powder continues to flow into the bore under the force of gravity. The powder can be brought over the die by either a gravity feeder as just described (material flows without a mechanical aid) or by a mechanical feeder (material is actively pushed over the die by rotating paddles).

Typically, the position of the fill cam remains fixed for the entire production run and can only be readjusted or changed manually. Keeping the fill cam at a fixed position allows each die to be filled with the same amount of powder. After the die bore has been filled, the lower punch is transferred to the weight-adjustment cam.

Weight-Adjustment Position

The weight-adjustment cam next raises the lower punch, which pushes excess powder out of the filled die. After the die leaves the area of the feed frame, a spring-loaded, knife-edged blade scrapes the surface of the die and removes any excess powder.

The highest vertical position reached by the weight-adjustment cam regulates the amount of powder expelled and the amount of powder remaining in the die, thus determining the final weight of the tablet. Increasing the highest vertical position of this cam will expel more powder, resulting in a lighter tablet; likewise, decreasing the cam's highest vertical position will expel less powder, resulting in a heavier tablet. On manual presses, a manual handwheel controls the position of the weight adjustment cam; on automated presses, a computer-controlled feedback loop sets the cam's position.

Pull-Down Position

Newer press models have a pull-down position, which allows the lower punch to be pulled down slightly so that the top of the powder column in the die bore is below the surface of the die table. Simultaneously, the upper punch is lowered by the lowering segment of the upper cam track. The lowering of the powder column prevents any powder from being blown out of the die as the upper punch enters the die bore, thus preventing variations in tablet weight. When the upper punch enters the die, precompression begins.

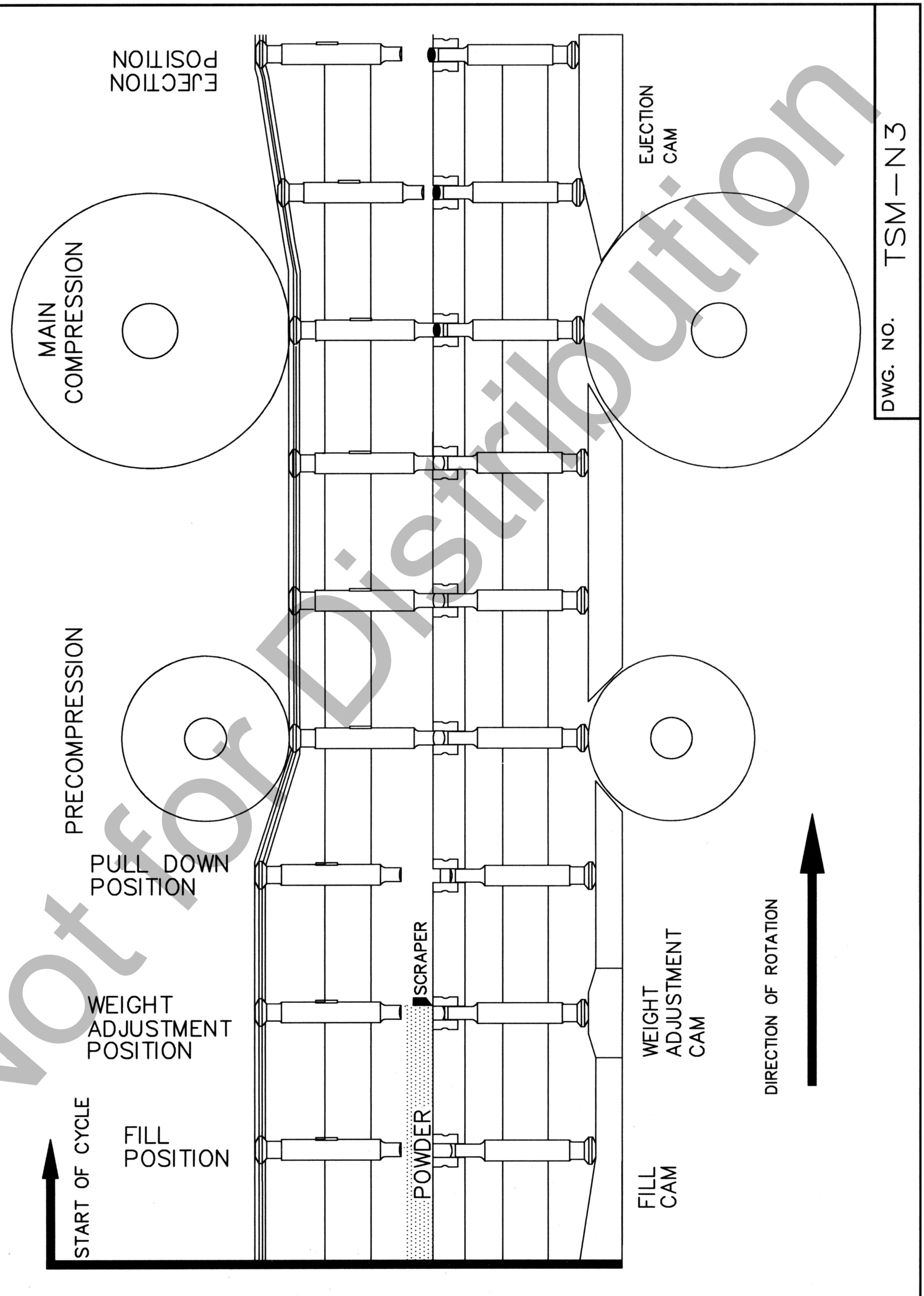
Precompression Position

During precompression, loose powder is consolidated in the die by the removal of any air trapped in the powder column and by the physical orientation of the powder particles. Typically, precompression forces tend to be less than the main compression forces. In presses where the fill cam can be automatically adjusted, the precompression position can be monitored for automatic control of tablet weight. The "tablet" formed at this step is now ready for main compression.

Not for Distribution

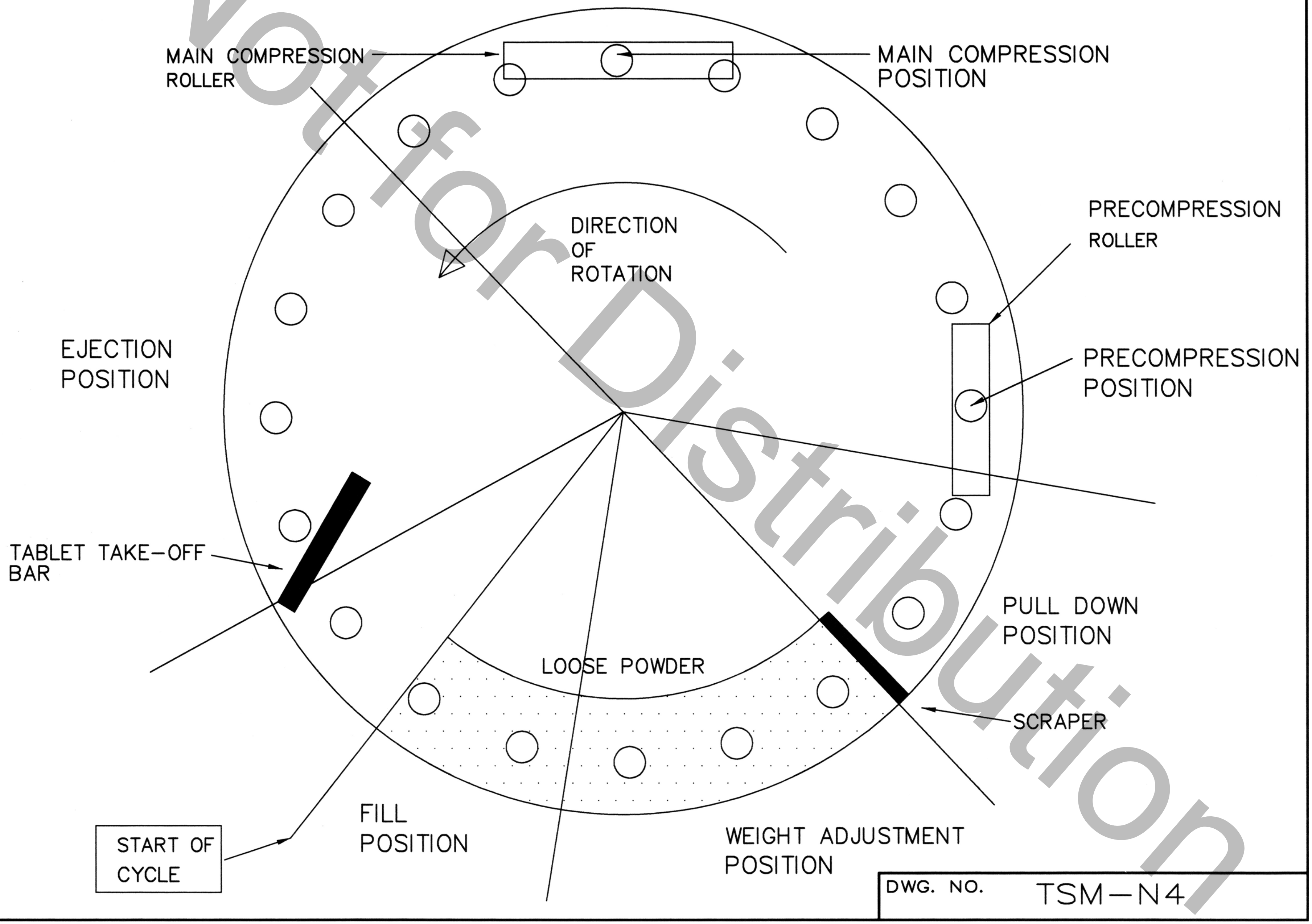
© American Pharmacists Association

FIGURE 3. ROTARY TABLET PRESS CYCLE



Not for Distribution

FIGURE 4. TOP VIEW OF TABLET PRESS CYCLE



Not for Distribution

© American Pharmacists Association

Main Compression Position

The main compression step gives a tablet its final characteristics. The final tablet thickness is determined by the distance between the punch rollers, which determines the distance between the punch tips. Again, in some presses, the main compression position can be monitored for automatic weight control.

Tablet Ejection and Take-Off Position

Before reaching the full ejection position, the upper punch is lifted out of the die bore while the lower punch is being pushed up by the ejection cam, thereby pushing the tablet out of the die. At the full ejection position, a tablet take-off bar located above the die table guides the tablet off the table.

The successful completion of each stage of tablet production depends on how well the tablet tools work with each other and within the tablet press. Making sure that tooling and presses conform to TSM specifications can eliminate many production problems. Understanding specification drawings is critical in determining if a tool conforms to TSM specifications.

Tooling Specifications

A tool that conforms to specifications has been machined to meet specific dimensions within a designated range called a tolerance range. Dimensions have been specified for all components of the punches and dies shown in Figure 1 (page 3). The specifications drawings for standard punches and dies (Figures 8–11 and 14–16; pages 25–28, 31–33) list these dimensions first in inches, followed by the equivalent millimeters placed in brackets. For specifications of radii, an "R" follows the measurement. If the specification is a reference dimension, the abbreviation "REF." follows the measurement. An explanation of reference dimensions follows the discussions of tolerances and clearances—two other dimensional specifications that affect the proper manufacturing and operation of tablet tooling.

Clearances

If tablet tools are to work properly, there must be enough space between interacting parts to allow them to function without making forced contact. This working space is called clearance. For example, punch tips must be allowed to enter and leave the die bore without making forced contact with the die bore wall. The amount of clearance between interacting parts is affected by the tolerance range of tooling dimensions.

Tolerances

Producing tooling that match specifications exactly would be accomplished only at great expense to tooling manufacturers and ultimately to the companies that purchase the tooling. For that reason, tolerances, or allowable deviations, have been established for tooling specifications. These permissible deviations from specified dimensions, established in cooperation with leading tooling and press manufacturers, ensure that tools can be purchased at a reasonable price and that they will operate properly in the press to produce good-quality tablets.

Specifically, a tolerance is given as a range with an upper limit that determines how much a dimension can be exceeded and a lower limit that determines how much a dimension can be reduced. For example, a tooling dimension that has the specification 1 1/32 [26.19 millimeters] inches ±1/32 inch [0.794 millimeter] can vary from a high value of 1 1/16 inches [26.99 millimeters] to a low value of 1 inch [25.40 millimeters] and still be considered to meet specifications.

The tolerance range for a particular specification immediately follows the dimensional value. The range is given either as a number preceded by a plus and minus sign (±) or a set of numbers, one of which is preceded by a plus sign, the other by a minus sign. If a tolerance range is not listed next to the dimensional value, the appropriate tolerances can be found in the block located in the lower right corner of each specification drawing. For dimensions given as a fraction, the appropriate tolerance range is the value labeled as "fractional." The same rule applies to dimensions given as decimals and angles.

The tolerance block also lists the acceptable tolerances for concentricity of die bores, punch tips, and punch heads. Concentricity refers to the placement of one tooling element in the center of another larger element (i.e., the two tooling elements share the same axis). The tolerance is given as a T.I.R., or total indicator reading. Indicator readings measure the form or location of one surface with respect to another. The surface relationships of concern here are the die bore to the O.D.; the punch head to the barrel; and the punch tip to the barrel. The instrument used to measure concentricity, called a comparator, has a readout dial that indicates any deviations in concentricity as measured by a pointer attached to the dial. The T.I.R. is the difference between the highest and lowest readings

Not for Distribution

recorded during one complete rotation of a punch or die.

Reference Dimension

A reference dimension is derived from, or is the result of, other toleranced dimensions that are machined first. For example, the die groove diameter for a 0.945-inch [24.00 millimeters] die is given as a reference value of 27/32 inch [21.43 millimeters] ±.015 inch [.381 millimeter] (see Figure 14, page 31). When making this die, the die groove width (1/4 inch [6.35 millimeters] ±.015 inch [.381 millimeter]) and the protection radius (3/16 inch [4.76 millimeters] ±.015 inch [.381 millimeter]) are machined, or "worked to," first. When these dimensions have been achieved within their specified tolerance ranges, the resultant die groove diameter should fall near its reference dimension.

Comparison of U.S. and International Tooling Specifications

Presently, there are two major "standards" of tooling on the international market: the U.S. TSM and the EuroStandard. Figure 21, (page 50) shows the TSM flat-head (angled) punch and the EU19, which has a domed punch head. Besides the illustrated head configurations, the most significant differences in punch specifications are those for overall punch length and inner head angle. Also shown for the two standards of B-type tools are the correlating differences in die specifications.

As noted on Figures 8–11 (pages 25-28), domed heads are preferred for new TSM punches. A large number of flat-head TSM punches currently are being used for existing products; these punches will continue to be available. Figures 6 and 7 (pages 23 and 24) give detailed illustrations of the dimensional and configurational differences of flat-head and domed punch heads. Flat-head punches have an outside head angle, whereas domed heads have a radius. Domed heads, which were developed by European tooling manufacturers, increase the dwell time during the tablet compression stage.

Standardization—Its Purpose and Advantages

Since the first edition of the *Tableting Specification Manual* was published almost a quarter of a century ago, many U.S. tablet press manufacturers have voluntarily redesigned their presses to conform with the specifications. International press manufacturers also are realizing the economic advantages of making their presses compatible with TSM tooling. Tablet manufacturers, especially those with international production facilities, have compelling reasons for preferring presses that meet TSM standards.

Advantages of Standardized Tooling

Standardizing tablet tooling offers the following economic and procedural advantages:

- A uniform quality of tooling can be achieved.
- Tooling suppliers can produce tooling more economically by standardizing their fabrication equipment and manufacturing procedures, and by producing batch quantities of frequently ordered tooling.
- Tooling suppliers can fulfill orders faster by carrying an inventory of standard sizes of round tooling.
- Procedures for purchasing tooling can be simplified.
- Tablet manufacturers can use tooling interchangeably in presses purchased from different manufacturers.
- Tablet manufacturers can reduce their tooling inventory.
- Tablet manufacturers can use standard inspection equipment and validation procedures.
- Multinational pharmaceutical companies can interchange tools and discuss tooling technicalities on the same level.
- Press manufacturers can be sure that their machines will perform well with standard TSM tooling.

Problems of Nonconformance to Specifications

Using tools that do not conform to dimensional specifications can affect tablet quality, press performance, and tablet production rate. Nonconformance of tooling to specifications also can (1) reduce the life of punches, (2) impair the efficient operation of machinery, and (3) cause severe damage to tools and presses.

The remaining sections of this manual provide the necessary information to determine whether a new tool conforms to TSM specifications. The reader also will find detailed guidelines on tablet design, standard operating procedures for procuring and inspecting tooling, and step-by-step instructions for maintaining tools—an important function in protecting tooling and presses.

Not for Distribution

© American Pharmacists Association