The Benefits of Tablet Tooling Standardization

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Tooling standardization in the tablet-manufacturing industry is a topic that has concerned tableting professionals for decades. I Holland, authors of the 1992 Eurostandard, the most widely adopted tooling standard globally, has been striving for some time to promote a consensus in this area.

Why was a standard needed?

Conception of the Eurostandard began in the 1970s when conversion from Imperial measurements (inches) to metric measurements (millimetres) first began to take effect, creating a recognized need to reduce variables in tooling specifications/standards set by original equipment manufacturers (OEMs).
As European tablet-press manufacturers started to gain ground in the 1980s against UK press manufacturer Manesty's former market domination, German DIN standards began to be applied to tablet tooling. DIN standards were designed for general engineering components, limits, and fits, but the clearances created by this system are not always appropriate for tablet tooling.

The incongruity occurs because the powder compaction process is different compared with typical mechanical processes that benefit from contact lubrication using general engineering components. The DIN system did not address the issues a dedicated tooling standard could have addressed.

In 1990, I Holland invited prominent tablet-press and tooling manufacturers to come together to formulate a dedicated standard. Unfortunately, however, there was little received interest—possibly because of fears of losing competitive advantages. Despite this setback, the first edition of the Eurostandard was developed and published in 1992. By the time the second edition was released in 1996, the Eurostandard had been adopted as the accepted standard for the vast majority of tablet-tooling markets outside North America.
Simultaneously, during the mid1990s, a group of French pharmaceutical companies and tooling manufacturers contacted the International Organization for Standardization (ISO), to investigate the possibility of establishing a European standard for tablet tooling. This exercise culminated in the formation of the internationally acknowledged ISO 18084.2005 (E) for punches and dies.

Seeking a global standard

Recent calls to combine legacy tooling standards and bring them in line with the internationally recognized ISO standard have become much more widespread. In today's global pharmaceutical marketplace, where many solid-dose companies have manufacturing plants around the world, there are numerous benefits to having only one standard for tablet tooling, including:

- Interchangeability between tablet presses of different manufacture both in plants and across locations worldwide
- Reduced tooling inventories, which can save costs
- Shorter lead times based on tooling-supplier rationalization
- Standardized procedures (e.g., procurement, operation, and maintenance)
- Standardized equipment and processes for validation and inspection
- Uniform quality and grade of tooling across all products and sites
- More international technical exchange for development and problem solving.

Given these benefits, it should come as little surprise that ISO 18084 is coming to be recognized as the right standard for the tablet-tooling industry. In fact, there is evidence that the ISO standard is being increasingly adopted among global pharmaceutical companies, for whom the benefits of rationalization are greatest.

In addition to the Eurostandard and ISO 18084, it should be noted that other tooling standards exist. For example, North America almost exclusively uses the Tablet Specification Manual (TSM) (formerly IPT) standard.

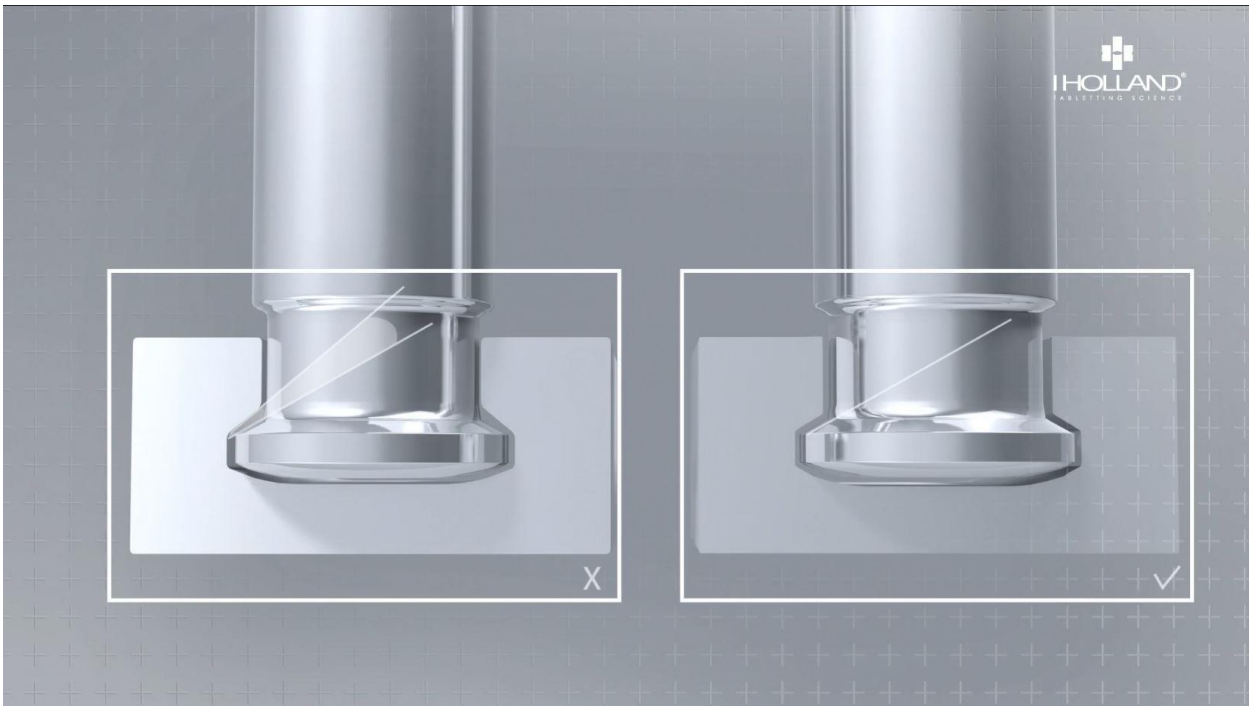

Figure 1: Variations in the profile of the head form.

While punch and die configurations are similar across all standards, there are several key differences. Figure 1 demonstrates variations in the profile of the head form, including head radius/angle, dwell flat, head thickness, head length, and under-head (cam) angles.
The ISO/Eurostandard "domed" head incorporates a radius that blends into the "dwell flat," which gives a smoother lead onto compression rollers, reducing wear on both tooling and the tablet press. This feature also ensures sufficient dwell time for optimized granule compaction and allows the tablet manufacturer to produce a quality product. Version 7 of the TSM also recommends that all new punches adopt this domed head shape.

Variations found between the ISO/Eurostandard and TSM under head cam angles (Figure 1) result in incompatibility of tooling between European and TSM tablet presses, meaning that interchangeability is restricted and that tooling inventories increase.

Nominal punch length

The nominal (overall) punch length is a reference length governed by the dimensions of the tablet-press turret (Figure 1 shows the differences across the standards). This means that a Euro/ISO standard length punch cannot be used in a TSM tablet press and vice versa. Standardization of overall punch length would ensure compatibility across all tablet presses and reduce the cost of tooling inventory for tablet manufacturers.

Keying angles/turret rotation

All shaped and multi-tipped upper punches need to be fitted with an antiturn key to ensure correct alignment into the die. The positioning of this key relative to the tablet shape is important on high-speed presses to optimize ejection and take-off of the tablet from the press. As a result of the different turret rotations, this positioning becomes a challenge. Most modern tablet presses use a turret that rotates in an anticlockwise direction (e.g., IMA, Fette, Korsch and Kilian machines), while others rotate clockwise (e.g., Cadmach and Manesty machines). In addition, there are wide variations in keying angles between tablet-press manufacturers (see Figure 2).

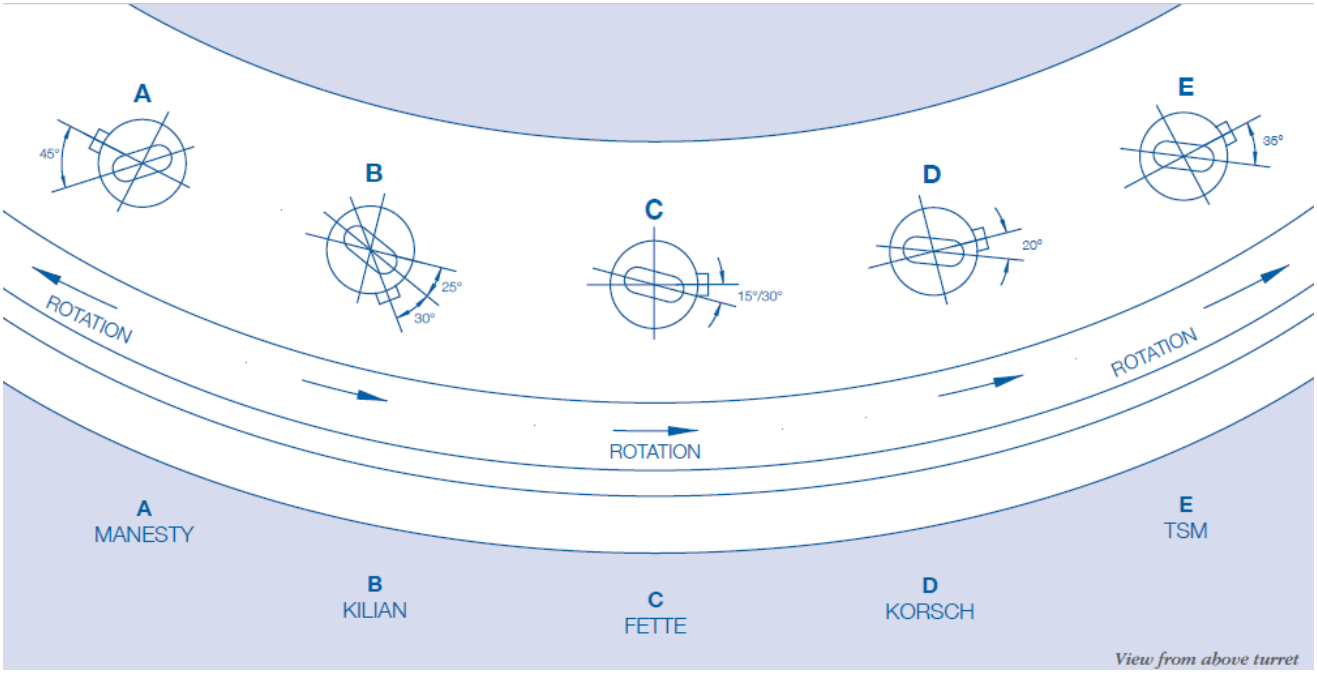

Figure 2: Variations in keying angles between tablet press manufacturers.

These variations in angle and rotation cause problems with the correct presentation of the tablets to the take-off plate and in ejection, which can cause tablet breakage. To ensure the correct key position of shaped or multi-punches, the set of tools must be specially manufactured to suit the type of machine, which increases costs and potential inventory. Currently, there is no move to create or agree on a universal position on keying angles/turret rotation. This will need to be agreed upon and driven by major tablet-press manufacturers.

Clearances and tolerances

Unlike typical mechanical processes, powder compaction inevitably results in granule coming between the lower punch tip and die bore, resulting in resistance. Consideration should be given to the clearance between such surfaces.

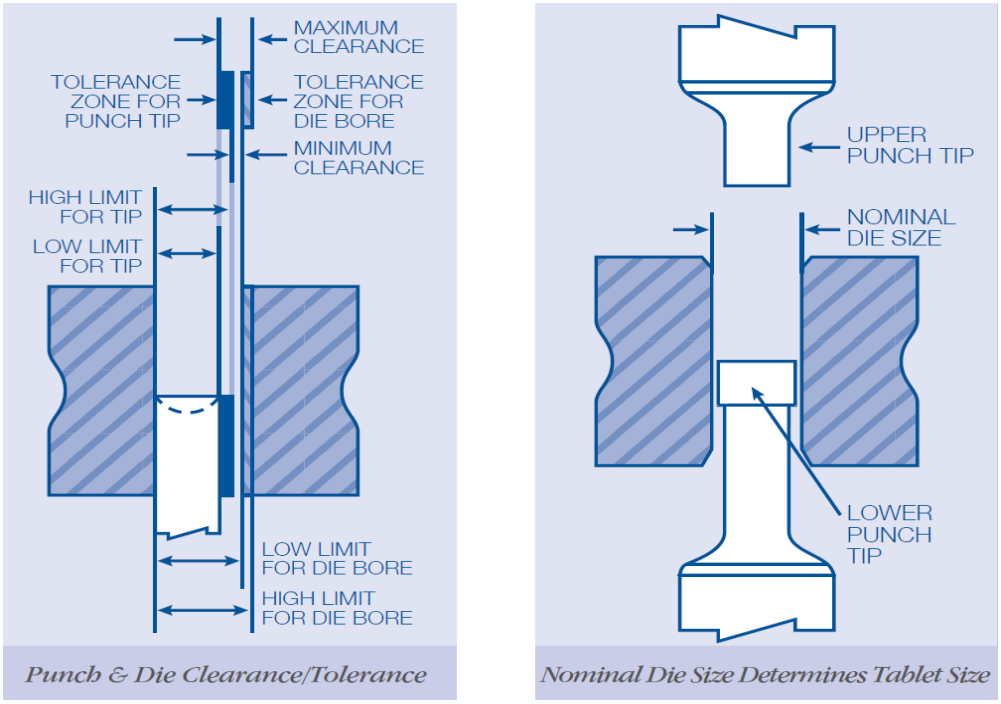

Figure 3: Clearances and Tolerances

Lower punch tip to die bore clearance

Clearances and tolerances (see Figure 3) are critical to ensure accurate functionality of the tooling, and reduce wear of tooling and press components. The clearances between the punch tips and die bores are important to ensure good, problem free tablets and to eliminate problems such as capping (see Figure 4). The ISO standard stipulates the use of DIN Norm for tolerances, adopting the same size and clearance for both upper and lower punches irrespective of tablet size. This also creates a wider variation in clearance between the lower punch tip and die bore regardless of granule size, which can cause granule leakage past the lower tip, resulting in potential wear and damage to tooling and press parts.

Figure 4: A typical example of capping

Upper punch tip to die bore clearance

ISO adoption of DIN Norm on upper punches also results in insufficient clearance leading to rejected tablets through capping. To counter this, all dies have to be tapered at both ends to enable air to escape from the tablet. This requirement increases tooling costs for the tablet manufacturer.

The Eurostandard and the TSM standard avoid these issues by adopting customized clearances, which offer advantages over ISO standards, although there are differences between the two. The Eurostandard adopts a tighter clearance range to help improve general operation and product yield.

Conclusion

Although there are other small variations between the standards, such as seal groove configuration, these variations do not prevent interchangeability and are not detrimental to the running of the tablet press. All of these differences are surmountable.

In recognition of the need to eliminate these variables and specifically take into account the sensible and efficient provisions for cross-platform/press compatibility laid out in ISO 18084, the Eurostandard has been updated to make it compatible with the ISO standard.

A single global tooling standard should be highly desirable for the industry; however, even if tablet press manufacturers could be convinced that it is in their commercial interest to adopt it, it will take time for these changes to evolve. Leading tablet-press manufacturers are always seeking to innovate and move the industry forward so tooling standards will always require revision.

In turn, this means that high quality tooling suppliers will always need to retain the ability to solve complex problems and preserve the skill set within their workforce to manufacture tooling that is compatible with any press worldwide.

In conclusion, I Holland believe that calls for the standards laid out in ISO 18084:2005(E) to be adopted globally should be fully endorsed. However, the Eurostandard already represents a comprehensive global standard because it is the most widely adopted tabletting tooling standard today and is compatible with ISO.