ISSN: 0975-766X
CODEN: IJPTFI
Review Article

Available Online through
www.ijptonline.com

PHARMA TOOLING: AN OVERVIEW

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Received on 10-08-2019 *Accepted on: 29-09-2019*

Abstract:

Tablet tooling, usually made from hardened and tempered tool steel, is subjected to a highly demanding process. The tooling is rotated through a cam track system at high speeds, exerting high friction forces. High cyclic compaction force is also applied to the punch heads via the precompression and main compression rollers to form what can sometimes be aggressive granules and powders into the final tablet. The delicate punch tips are extremely vulnerable to accidental damage at various stages of this process. This article highlights the basic thing about procurement of tools and real-life examples of the more common types of damage or wear to the tooling and explains how these problems could be avoided.

Keywords: Tooling, Compression, corrosive elements, Terminology & specifications, Embossing.

Introduction:

Our experience through the years (with applications from pharmaceutical to industrial) has shown us that quality tablet compression tooling can't be produced without the use of quality raw materials, manufactured to strict specifications. All pharmaceutical tooling is formed from high-nickel, high-chrome shock steel that must meet strict requirements before we will ever consider it.

Keeping abreast of today's latest equipment, techniques and processes is no easy task. Not only do we invest continuously in new technology; employees are constantly undergoing training and honing of their skills. We take genuine pride in the work we do and the equipment we use. Matching the finest machinists with the finest machinery makes for an unbeatable combination. And the Production R&D Department redesigns and modifies machinery to further improve and speed production.

Materials and Methods:

Definition of Tablets

Tablets can be defined as Solid Pharmaceutical Dosage form containing drug substances with or without suitable diluent and prepare either by compression or molding methods.

There are various types of Tablets and abbreviations used in referring to them are as follows.

Compressed Tablet	Controlled Release tablets.
Sugar-Coated Tablets (SCT)	Tablets for Solution.
Film-Coated Tablets (FCT)	Effervescent tablets.
Enteric-Coated Tablets (ECT)	Compressed Suppositories or inserts.
Multiple Compressed tablets (MCT)	Buccal and Sublingual Tablets.

Types of Tablets

Compressed Tablets: These tablets are formed by compression and contain no special coating. They are made from a powdered, crystalline or granular material, alone or in combination with binders, disintegrants, lubricants, diluents and in many cases, colorants.

For different types of tablets as per their usage, market requirement, elegance etc.

Basics of Tablet tooling. (Terminology & specifications)

- Tablet compression machines are made in keeping in view the type of dies and punches will be used on them, the dies and punches and their setup on compression machine is called tooling, it is classified as B and D mainly.
- The B tooling dies and punch can be further having specifications as BB and D tooling can also be dies and punches can be utilsed on B tooling machine which is called as DB
- Mainly there are two standards, ad D and B, in US specification provided by Tableting Specification Manual (TSM) is followed where as in Europe European standard known as the EU, or “Euronorm” standard is. There is not much difference in both the specifications but both are very different.

Punch

1. **Head**: The end of the punch that guides it through the cam track of tablet machine during Rotation.

2. **Head flat (Dwell Flat)**: The flat area of the head that receives the compression force from Rollers (in upper punches) and determines the weight and ejection height (in lower punches).

3. **Outside head Angle**: The area gets in touch with the roller prior to head flat, while Compression.

4. **Inside Head Angle**: This is the area, which pulls down the lower punches after ejection and lifts the upper punches after compression.

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

6. **Barrel:** This area guides the punch (while going up and down) with reference to turret guides.

7. **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 the chamfer is present, the barrel usually reaches its full diameter just above the chamfer.

8. **Tip:** This determines size, shape & profile

9. **Tip face:** This area of punch is where the tablet is formed. Good surface finish is required here to get quality tablets.

10. **Working length:** This distance between bottom of the cup and the head flat is called as working length which determines weight and thickness of the tablet.

11. **Overall length:** Distance between top of the cup and the head flat.

12. **Key Angle:** The relationship of the punch key to the tablet shape. The keys position is influenced by the tablet shape, take-off angle, and turret rotation.

13. **Domed Heads:** Increases the dwell time and hence help to achieve the better tablet hardness.

14. **Dwell time** – The time punches spend below the pressure roller while rotating in the machine.

15. **Clearance:** Die bore dia – punch tip dia = Clearance.

16. **Hardness:** Usually measured in HRC (Rockwell 'C' scale) and optimum readings are as follows:

Steel	**Hardness**
OHNS O1	58-59
HCHC D2	59-60
HCHC D3	61-62

Die Terminology:

1. **Die.O.D**.: The outside diameter of the die, which is compatible with the die pockets in the press.

2. **Die Height:** The overall height of the die.

3. **Die Bore**: The cavity where the tablet is made. The Cavity's shape and size determine the same form of tablet.

4. **Chamfer:** Entry angle of the die bore.

5. **Taper dies:** dies with tapered bore on one or both sides. They are used for easy ejection of tablets (mainly for double layered tablets.

7**. Die Groove:** The groove around the periphery of the die, which allows the die to be fixed in the press.

8. **Lined (Insert) Dies:** Dies fitted with a linear insert made from a much harder, more wear resistant material such as tungsten carbide and ceramic.

There are following types of Tooling available:

- 'B' –Tooling
- 'D' – Tooling
- 'BB' –Tooling
- 'DB' – Tooling

Type Of Tooling	**Punch Length (mm)**	**Punch Diameter.(mm)**	**Die Diameter.(mm)**	**Height of dies (mm)**	**Max. Tab. size (mm) Round/Capsule**
B	133.6	19	30.15	22.22	16/19
D	133.6	25.4	38.1	23.82	25/25
BB	133.6	19	24.0	22.22	13/14
DB	133.6	25.4	30.15	23.22	19/19

Inspection of punches and their parameter

Inspection of punches and dies to be done after receiving of a new punch set and after compression of two million tablets per subset.

Tip diameter of punches

- Check the tip diameter with the help of a Vernier caliper.
- Check and set the zero reading of the Vernier caliper.
- Place the punch tip in a vertical position.
- Check the fine setting of the Vernier caliper and record the reading.

- The readings should be within ± 0.1 mm of the standard dimension.

Difference in height of the punches

- Set the dial gauge of the inspection kit at zero position with the help of the standard punch height 133.60mm.
- Keep the punches one by one inside the punch holder over the metal pad of the inspection kit and check the difference in deflection from the zero position.
- The difference should not be more than ±0.08 mm of the standard dimension.

Body diameter of punches

- Check the body diameter with the help of a Vernier caliper.
- Check and set the zero reading of the Vernier caliper.
- Check the fine setting of the Vernier caliper and record the reading.
- The standard dimensions and limit are as in table.

Embossing of punches

Visually check the embossing & Record the observation.

Difference in concentricity of punches

- Keep the punch over a 'V' block pad horizontally by keeping the magnet on and set the dial
- gauge at zero position over the punch body.
- Rotate the punch in the clockwise direction, take two readings each from the punch (one from the top and one from the bottom of the punch body) and record the observations in Annexure I.
- The deflection should be within ± 0.05 mm of the standard dimension.
- Keep the punch over a 'V' block pad horizontally by keeping the magnet ON and set the dial
- gauge at zero position over the highest point on tip diameter.
- Rotate the punch in the clockwise direction and record the observations in Annexure I.
- The deflection should be within ± 0.025 mm of the standard dimension.

Go and No-Go of punch head.

- Take "B" or "D" type tooling "Go-No Go" punch head tester for checking punch head.
- Move the punch head through "go" side of punch head tester it should pass easily.

- Move the punch head through "no go" side of punch head tester & it should not pass through it.
- Record the observations.

Outer diameter of dies

- Set the dial gauge of the inspection kit at zero position with the help of the standard die master piece.
- Keep the dies horizontal position one by one over the metal pad (V BLOCK) of the inspection kit and check the outer dimension deflection from the zero position.
- Record the reading.

Height of the die

- Set the dial gauge of the inspection kit at zero position with the help of the standard die master piece.
- Place the dies in vertical position one by one over the metal pad of the inspection kit and check the height deflection from the zero position.
- Record the reading.

Difference in concentricity of dies

- Keep the die over a 'V' block in horizontal position and set the dial gauge at zero position over the die body.
- Rotate the die in the clockwise direction, take two readings each from the die (both side) and
- Record the observations in Annexure II.
- The deflection should be within ± 0.05 mm.

Preventing tablet tooling problems

Tooling can be damaged by poor handling or problems in process design or material choice.

Figure 1: Damage to punch-tip land area can be caused by poor handling.

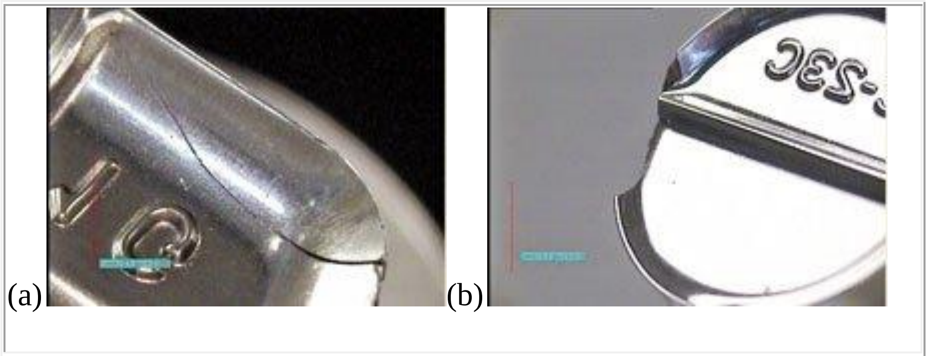

Figure 2: Punch-tip edges show (a) cracking and (b) piece of tip edge broken away.

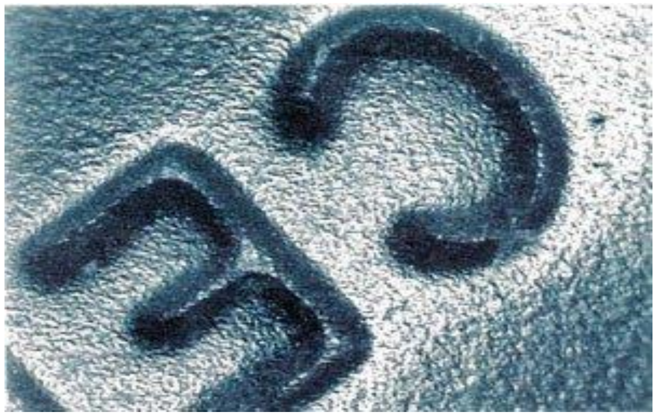

Figure 3: Agressive granules cause pitting and abrasion.

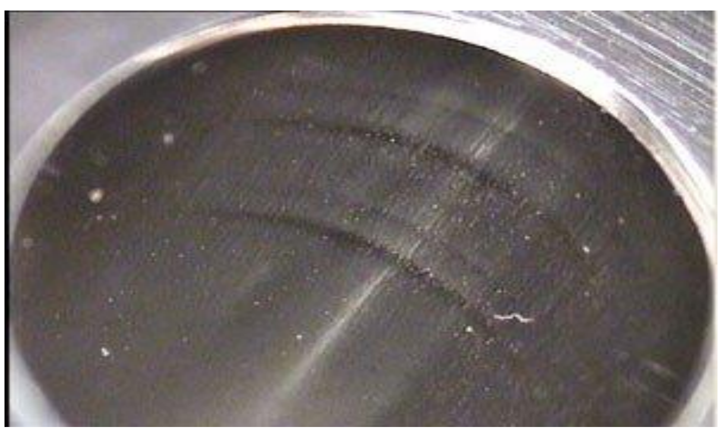

Figure 4: Die-bore wear appears as a double ring.

Figure 5: Punch head wear and damage.

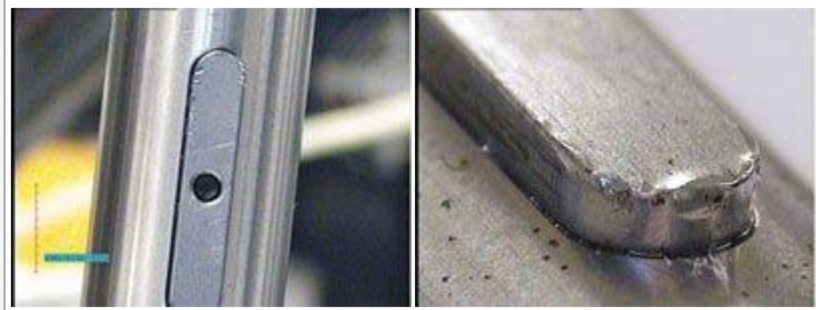

Figure 6: Close-up view of handling damage to punch keys.

Conclusion

The problems discussed in this article are quite common, although the damage is not always to the extent shown in the images in this article. Damage and wear to tooling result in time-consuming and costly mistakes. If the correct procedures are put in place at the beginning of the process and the correct quality tooling is used, problems like the ones discussed will simply not happen. Employing good care and maintenance practices with both the tooling and the tablet press is crucial.

Acknowledgements

The authors would like to thank Dr. H. B Mishal and Prof A.V Kotkar for their technical input and discussions in preparing this review paper.

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