

REVIEW ON TABLET MANUFACTURING MACHINES AND TABLET MANUFACTURING DEFECTS

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ABSTRACT:

From the hundreds of years tablets manufactures have developed materials and processes that can produce compressed tablets containing a precise amount of an active pharmaceutical ingredient at high speed and at relatively low cost. The easy of manufacturing, convenience in administration accurate dosing & Stability compared to oral liquids, tamper proofness compared to capsules, safe compared to parenteral dosage forms makes it popular and versatile dosage form. A tablet press also known as tablet compression machine or tableting machine is used to compress Pharmaceutical powder formulations into tablet form, creating tablets of uniform size, shape and weight. Tablet defects can come from any of unit operation upstream and from the tablet press. The processing and granulation of powder is often the source of defects. The article focuses on the review of various manufacturing machinery used for compression of tablets. It pin points the possible causes of these defects and offers advice on preventing and fixing the source of problems.

KEYWORDS: Tablets, Compression, tablet defects, tablet press.

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INTRODUCTION

The equipment employed in tablet manufacturing is referred as Tablet Press Or Compression Machine. It is used to compress the powder material or granules into tablets. The tablet press is a high speed mechanical device. It compresses the ingredients into the required tablet shape with extreme precision¹. It can make the tablet in many shapes, although they are usually round or oval. Also, it can press the name of the manufacturer or the product into the top of the tablet. Tablet punching machines work on the principle of compression. A tablet is formed by the combined pressing action of two punches and a die².

Types of tablet press machines

Tablet press machines in current use are mainly two types,

- Single stationary tablet press
- Multi stationary tablet press

SINGLE STATIONARY TABLET PRESS:

A single stationary tablet press machine is the simplest tableting equipment .It may also called as Single Punch Or Eccentric Press. It uses a single tooling station that has a die and a pair of upper and lower punches. It can be operated by hand or by an electric motor. The compression force is exerted by the upper punch only during the compression step the lower punch is stationary³.



Fig.1: Single stationary tablet press

Parts of single stationary tablet press

The basic components of an eccentric press

are

- > Hopper
- > Die cavity
- > Punches
- ➢ Cam track
- Tablet adjuster
- Ejection adjuster

Hopper

It is the place where the granules or powder mixtures are poured into prior to tableting or

compression .It is connected to feed shoe. The hopper can be filled manually or by using mechanical equipment during subsequent tableting⁴.

Die cavity

Die cavity is where the powder or granules are compressed into tablets. The die determines

- \succ The diameter of the tablet
- \triangleright Size of the tablet
- > To some extent the thickness of the tablet⁵.

Punches

This comprises of upper and lower punch. They compress the powder into tablets of various shapes within the die^{6} .

Cam track

This guides the position or movement of the punches 7 .

Tablet adjuster

This is used to adjust the volume of the powder to be compressed and so determines the weight of the tablet⁸.

Ejection adjuster

This facilitates the ejection of the tablet from the die cavity after compression⁹.

Process

In production of tablet using single punch upper punch compresses the powder into the tablet where as lower punch ejects the tablet.The events involved in tablet production can be divided into three stages,

- Filling.
- ➤ Compression.
- Ejection.



THE SEQUENCE OF EVENTS INVOLVED IN THE FORMATION OF TABLET

Fig. 2: Sequence involved in formation of tablet

Filling

In this stage upper punch is raised from the die cavity using upper cam and the lower punch drops to create a cavity in the die¹⁰. The feed shoe moves over the die cavity and the granules or powder fall into the die cavity under the influence of gravity from the hopper¹¹.

Compression

The feed shoe moves out of the way and the upper cam forces the upper punch into the die cavity¹². The upper

punch descends to compress the granules or powder mixture into tablets by progressive reduction of porosity of the die content and forcing the particles into close contact with one another resulting in formation of tablet¹³.

Ejection

The upper punch retracts and while the lower punch also moves upward to eject the compressed tablet¹⁴. The whole events repeat over and over again unit. The feed material is exhausted.

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Advantages

- Single punch structure is rational and small.
- Easy to operate and it operates at high utilization ratio.
- It can manufacture odd shaped products with a diameter of up to 20mm.
- It is an ideal for development of tablets and small batch production¹⁵.
- It utilizes a high amount of pressure to reduce weight variation between tablets.
- Maintains low noise level.

Disadvantages

- Not suitable for large scale production¹⁶.
- Wastage of powder is high.
- Time consuming process.

MULTI STATIONARY TABLET PRESS

One of the most popular equipment, in the pharmaceutical industry, due to high production capacity and cost saving benefits¹⁷. Multi stationary tablet press is also called as "ROTARY PRESS". The name rotary press is due to rotating tableting assembly.



Fig. 3: Multi Stationary Tablet Press

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Parts of rotary press

The basic components of rotary press are

- > Hopper
- Die cavity
- > Punches
- ➢ Feed peddle
- ➢ Lower cam track
- ➤ Cam track
- Capacity control
- ➢ Take off blade
- Discharge chute
- > Pre compression roller
- Main compression roller
- ➢ Ejection cam

Hopper

It is the place where powder mixture or granules are poured into prior to tableting.

This is connected to feed shoe. The hopper can be filled manually or by using mechanical equipment during subsequent tableting¹⁸.

Die cavity

It is the place where the powder or granules are compressed into tablets. The die cavity determines

- \succ The diameter of the tablet.
- \triangleright Size of the tablet.
- ➤ To some extent the thickness of the tablet¹⁹.

Punches

Punches compress the powder into tablet of various shapes within the die cavity. It comprises of upper punch and lower punch²⁰.

Feed peddle

This plays an integral role in high speed rotations where it forces the material into the dies.

Lower cam track

During the filling stage, lower cam track guides the lower punch to ensure the die cavity is over

filled. This allows for easy or accurate adjustment of the system²¹.

Cam track

Cam track guides the movement of both upper and lower punches to ensure precise movement.

Capacity control

During the filing stage, capacity control adjusts lower punch track to ensure that appropriate quantity remains within the die prior to compression²².

Take off blade

This is fitted in front of the feeder housing and it deflects the tablets down the discharge chute.

Discharge chute

This is where the tablet passes through for compression after being deflected by takeoff blade²³.

Pre compression rollers

This roller gives the granules an initial compression force to get rid of excess air that might be entrapped in the die.

Main compression roller

This roller applies the final compression force to the punches needed for the formation of $tablet^{24}$.

Ejection cam

This guides the lower punch upwards facilitating the ejection of tablet from die cavity after compression²⁵.

Process

The events in tablet production are classified into three stages

- ➤ Filling
- Compression
- ➢ Ejection



Fig. 4: Working of Multi Station Tablet Press

Filling

In this method the upper punch is raised from the die using upper cam amd lower punch drops to create a cavity in the die. Then the material to be compressed is placed into the several dies simultaneously from the hopper²⁶.

Compression

Like in case of single punch tablet press it punches that exert required magnitude of force to transform powder or granules into tablets. During this process rollers and cam track that control these punches by guiding their movement as the tablet rotates. Next lower cam guide and pulls lower punch to the bottom of the dies. This action allows the particular die to be overfilled with powder.

As lower punch raises excess powder is removed by the swipe blade which then pushes the material on coming die. After this lower punch drops then upper punch penetrates the die and contact the upper surface of the powder and compression process begins. In this press there is a pre compression step in which both the punches are forced by pre compression rollers to squeeze the powder to form a tablet within the die. As the tablet rotates, so the punches are engaged by the main compression rollers which are substantial rolls, exerting a massive force on the powder. Both punches have forces applied and both move to compress the tablet [unlike the single tablet press in which only the upper punch moves during the compression step]²⁷.

Ejection

After the full compressive force has been applied, the upper punch is withdrawn by the upper cam, and the lower punch also rises to bring the tablet above the surface of the die. At this point the tablet is fully formed and is swept off the die table from the feed frame towards a chute and container located beneath the die table to catch the tablets. The lower punch will then be engaged by the pull down cam to be withdrawn to the bottom of the die, and the whole process starts again²⁸.

Advantages

- Cost efficient than single punch tablet press.
- Suitable for continuous operations where bulk production can be done within hour.
- It is automated thus eliminating human intervention.
- Accurate tableting process.
- Independent control of both tablet hardness and weight.
- It decreases the wastage of valuable formulation in non specific tablets.
- Less time consumption process.
- > Suitable for large scale production.
- Number of production batches can be increased²⁹.

Disadvantages

- Cleaning is difficult.
- \blacktriangleright Noisy due to high compression pressure³⁰.

TABLET MANUFACTURING DEFECTS

During tablet manufacturing some problems may arise due to defects in formulation or compression machine or both. The following are the defects that occur during tablet manufacturing

1.Due to excipients

- Sticking
- Picking
- Binding
- Mottling
- Chipping

2.During process

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- Capping
- Lamination
- 3. Due to machine
 - Double impression

Due to excipients

Sticking

Sticking means adhering of tablet material to the walls of the die cavity.

Causes

- Granules are not dried properly.
- > Too little or improper lubrication.
- Too much binder.
- Oily or waxy material.
- Too soft or weak granules.
- Greater concavity of the punches.
- Due to low compression pressure.
- Fast compression³¹.





Punch face affected by *Sticking*

Tablet face affected by *Sticking*

Fig.5: Punch faces on sticking

Remedies

- By increasing the compression pressure.
- By slow downing the compression process.
- By reducing concavity of the punches.
- By drying the granules properly.
- > By increasing or changing the lubricant.
- > To reduce or use another binder.
- > To modify mixing process. Add an absorbent.
- \blacktriangleright To optimize the amount of binder³².

Picking

In this the upper surface of the tablet picked to either of the punches that causes eroding of the tablet surface.



Fig.6: Picking effects

Causes

- > Due to engraving or embossing of the tablets.
- Due to rough edges if the punches.
- Due to excess binder.
- Due to excess of moisture.
- > Due to presence of sticky material 33 .

Remedies

- By increasing the surface area of the tablet or decreasing the size of the symbols.
- > By polishing the punches with chromium.
- By adding adequate binder.
- By proper drying.
- ➢ By adding adsorbents and replacing the sticky materials³⁴.

Binding

The tablet material is sticked within the die cavity which is difficult to take out the tablet from the punches.

Causes

- > Due to insufficient or improper lubricant.
- Too moist granules.
- Too coarse granules.
- > Too hard granules for the lubricant to be effective.
- Granular material too warm.
- Due to poorly finished dies.
- Rough dies due to abrasion, corrosion.
- Due to undersized dies.
- > Too much pressure in the tablet press.



Fig.7: Binding Effects

Remedies

- > To dry the granules properly.
- To increase or change lubricant.
- ➢ To reduce granular size.
- > To modify granulation and reduce granular size.
- > To reduce temperature.
- \succ To polish the dies properly.
- To investigate proper size.
- \blacktriangleright To reduce pressure³⁵.

Mottling

It is term used to describe uneven distribution of the colour on a tablet which is non elegant in appearance.



Fig. 8: Mottling effects

Causes

- A coloured drug used along with colourless or white coloured excipients.
- A dye migrates to the surface of granulation while drying.
- Improperly mixed dye, especially during Direct Compression.
- > Improper binding of a coloured binder solution.

Remedies

- To use appropriate colorant.
- To change the solvent system, change the binder, reduce the drying temperature and use a smaller particle size.
- Mix properly and reduce size if it is of a larger size to prevent segregation.
- To incorporate dry colour additive during powder blending step, then add fine powdered Fig. 8:

adhesives such as Acacia and Tragacanth and mix well and finally add granulating liquid³⁶.

Chipping

It is defined as breaking of tablet edges while the tablet leaves the press or during subsequent handling.

Causes

- Sticking on punch faces.
- Due to too dry granules
- > Too much binding causes chipping at bottom.
- > Due to groove of die worn at compression point.
- > Barreled die [center of the die wider than ends.
- Edge of punch face turned inside or inward.

Remedies

- To dry the granules properly or increase lubrication.
- > To moisten the granules.
- > To optimize binding or use dry binder.
- > To polish open end, reverse or replace the die.
- > To polish the die to make it cylindrical.
- ➤ To polish the punch edges.
- ➢ To reduce concavity of punch faces, Use flat punches³⁵.



Fig.9: Chipping effect

During process

Capping

Capping, means when the upper or lower segment of the tablet separates horizontally during ejection from the tablet press, or during subsequent handling.

Causes

- Large amount of fines in the granulation.
- Low moisture content.

- Insufficient amount of binder or improper binder and lubricant.
- Poorly finished dies.
- Deep concave punches.
- Lower punch remains below the face of die during ejection.
- ➢ High turret speed.

Remedies

- Remove some or all fines through to mesh screen.
- \succ Moisten the granules.
- Increasing or change the type of binder and lubricant.
- To polish the die properly.
- ➢ To use flat punches.
- To make proper setting of lower punch during ejection.
- > To reduce speed of turret 35 .



Fig. 10: Capping effect

Lamination

Lamination is the separation of a tablet into two or more distinct horizontal layers.

Causes

- > Too much of hydrophobic lubricant.
- Rapid relaxation of the peripheral regions of a tablet, on ejection from a die.
- Rapid decompression.

Remedies

- Modify mixing process. Add adsorbent or absorbent.
- Use a less amount of lubricant or change the type of lubricant.

- > Use tapered dies, i.e. upper part of the die bore has an outward taper of 3^0 to 5^0 .
- > Use pre compression step. Reduce turret speed and reduce the final compression pressure³⁶.





Due to machine

Double impression

Due to free rotation of punches which have some engraving or monogram on the punch faces. During his free travel the punch rotates and at this point, the punch may make a new impression on the bottom of the tablet, resulting in double impression.

Cause

Free rotation of either upper punch or lower punch during ejection of a tablet.

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Remedies

- Use keying in tooling i.e. inset a key along side of the punch, so that it fits the punch and prevents punch rotation.
- Newer presses have anti turning devices, which prevent punch rotation³⁶.

CONCLUSION

This article has covered all the critical aspects of pharmaceutical tablet press machines. It includes definition, types, working principle to quality regulations, among other aspects. Defects in tablets can arise during process, storage and transport. These defects, causes and measures to overcome these defects have been discussed and the same could be minimized and prevented.

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