



TEHCCEUTICALS

*Providing quality consulting, training,
and equipment since 1989™*

Tablet Pro

A Tablet Making Training Resource for Tablet Making Professionals

- Learn the basics of tablet making
- Test your knowledge
- Create a basis for good communications
- Understand common nomenclature
- Differentiate between the granulation and the press operation
- Understand the roll of each department and keep communications open between them
- Learn how to fix and resolve common defects

Improving manufacturing skills within a company is critical to the success and key to **continuous quality improvement**.

Tablet Pro is exactly what our industry is about today; The methodology, documentation and mindset required to meet the needs of our changing industry.

This means that everyone connected to the manufacturing environment must comprehend the basics of Tablet Making. Managers and Supervisors must now understand the fundamentals of making tablets, because if they do not know the basics they cannot properly support the

Implementation!

Providing employee training is a key element in achieving continuous quality improvement.

Sending employees off or bringing someone into your facility is only one part of making training effective.

To assure your company that training will pay-off you must have a way to implement what is learned.

demands of the new production environment.

Every company has a simple objective...to make a quality product and to strive to maintain and improve that quality.

To improve tablet quality we need to completely understand how powder performs, how a tablet press works and be able to understand and control both to make a quality product.

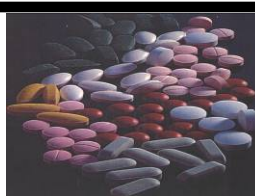
Trouble shooting and root cause analysis require a systematic approach, focusing on the key elements of tablet making. The only way to properly fix a problem is to know "how things

work".

The best manufacturing facilities are the ones that have open avenues to training and also exchange issues between departments. Realize that tablet quality is the report card for all unit operations before the tablet has been compressed.

This booklet is designed to help define the relationship of each department and help to define the basics and essence of making quality tablets.

Quality is the objective!



Be prepared to evaluate what has been learned and apply it in small amounts to your current manufacturing methods.

One of the best way to implement training is to establish a list of changes and improvements and evaluate the value and ROI (return on investment) for each change before moving on.

Also, be ready to answer questions. A good trainer will generate enthusiasm and this should generate questions. This is the sign of continuous improvement. Keep in touch with the trainer and get them to help answer the questions.

Remember that the objective is to improve quality through knowledge.

www.techceuticals.com

The Tablet Manufacturing Process

The tablet manufacturing process is the step by step, individual operations required to make powders into a tablet.

This is known as individual units of operation; or commonly referred to as Unit Operations.

Weighing, Blending and Tableting are unit operations in the tablet manufacturing process.

When a powder is first developed it may or may not naturally work well on a tablet press.

Powders must Flow and Compress in order to make a good tablet.

We may need to add many unit operations to make the powders perform.

Each different formula may have a different number of unit operations, which is based completely on the powders ability to Flow and Compress and then eject from the tablet press.

We also need the tablet to dissolve and then we need the dissolved particles to disintegrate. These are the factors that determine the number of unit operations required.

The Manufacturing process can be simple or complex dependant on the active ingredient

Unit operations

There are three basic ways to process powders for tablet making. Direct Blending, Wet Granulating and Dry Granulating.

Direct Blending: Weigh the powders, Blend the Powders and make tablets. Very few tablets can be made by this process.

Wet Granulating: a liquid is added and mixed into the powders, forming bonds between particles...much like gluing particles together. Once a bond is formed the excess liquid is removed through a drying step. This wet granulating technique is the most common way powders are processed for tablet making.

Dry Granulating: is compacting powders and then grinding them back up. Each time a powder is compressed it becomes more densely compacted. A more dense powder will flow better and compress more consistently. This process is used for products too light and fine to compress by Direct Blending and too sensitive for Wet Granulating.

Powder Flow

One of the most important concepts to understand in the tablet making process is powder flow.

Powders must flow evenly and consistently. Good powder flow is much like granulated sugar and bad powder flow is

much like powdered sugar. They are the same ingredient but yet the flow differently. Granulated sugar flows very evenly and consistently. Powdered sugar flows poorly in comparison.

The basis of achieving tablet

weight on a tablet press is through volumetric filling. This implies the need for excellent flow and it also requires that the product have uniform density. Changes in volume or density will result in tablet weight changes.



Powder Characteristics

Different powders have very different characteristics.

Some powders are very fine and dry, some are large and brittle, some soft and wet ...one thing for certain is they all compress differently from one another.

Comparing compression of powders to making a snowball is a good analogy. When snow flakes are large and wet they will compress into a snowball easily. However,



when the snow is very fine, light and fluffy the snow ball maker must hold the snow under pressure for an extended period time...relative to the dryness...until a snowball is formed.

Be careful not to over compress the snowball or it will fall back apart.

Making a tablet is much like making a snowball. The particle size, shape moisture content lend themselves to the quality of the tablet. Particles must be the same in relation to the other particles or compression of the particles will not be uniform.

Companies that make only one product learn quickly that there are variations batch to batch. These changes are due to the natures of the powders characteristics.

Many formulas cannot run as fast as a press can run.

Formula

The ingredients in a formula have a purpose. The main ingredient is known as the Active Ingredient. In pharmaceuticals it is known as the API (Active Pharmaceutical Ingredient). Nutritional Supplements refer to it as ANI (Active Nutritional Ingredient)

The other items in the formula are called Excipients as a category. There are many reasons for putting

items other than the API into a formula. We may want to enhance the hardness, increase or decrease disintegration, improve flow, reduce ejection pressure and a host of other reasons.

The formula has an important relationship with the type of tablet press or encapsulator it will be

used on. Many companies have purchased high speed presses to find out their own formula will not run as fast as the press can run. This is a common issue, why buy a faster press if the formula will not run as fast as your existing machine.

This is not a press issue it is a formulation issue.

Tablet Compression

Variations in powders will result in variation in the tablet, too much variation is considered a defect.

If powders do not flow with consistency than all tablets will not compress the same.

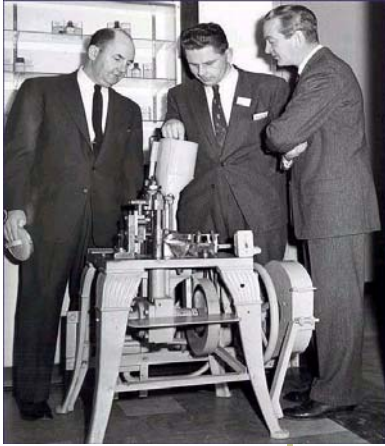
If the ingredients in the formula do

not function properly the formula must be changed.

Tablet compression is the event of squeezing powders together and driving the air from between the particles, resulting in a compressed tablet.



The Tablet press



1870 Wyeth Brothers, Invented the single punch press

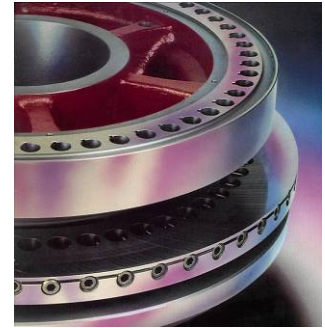
There are 2 basic types of tablet presses. Single punch and Rotary tablet presses.

A single punch tablet press has one station of tooling. It Typically operates at speeds from 1 -60 tablets per minute.

A rotary tablet press has multiple stations of tooling positioned on a rotary table. This rotary table is referred to as a turret. As the turret rotates

the tablet tooling is guided from one position to the next by cams.

The objective of the operator is to keep this turret clean and properly lubricated. A press that has been properly prepared can run without being stopped around the clock. What causes a machine to be stopped is a need for cleaning, repair and lubrication as a result of a formula that is dusty, sticky, or abrasive.



A rotary tablet press Turret

Rotary presses operate from 60-15,000 tablets per minute dependant primarily on the number of tool stations.

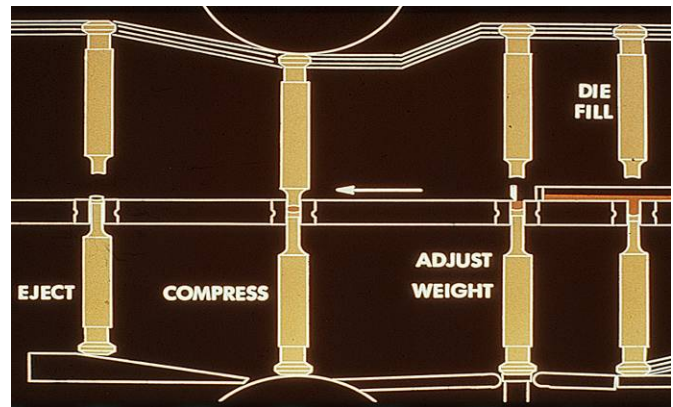
How a press operates

“A press must be cleaned and properly setup initially...whether it is manual or automated”

Rotary tablet presses all work on the same principle of operation with few exceptions.

The basics are adjust Weight, Compress and Eject within a speed range.

Understand these basic operation features and the impact that they have on the final tablet is the key to success.

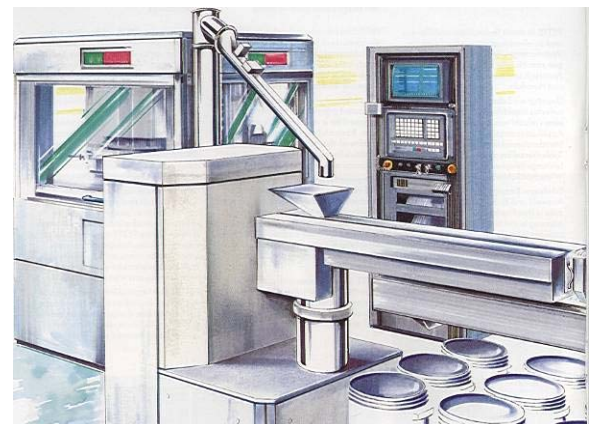


An automated press is capable of automatically monitoring and correcting itself through and entire batch of product, provided the press was setup , lubricated and cleaned properly

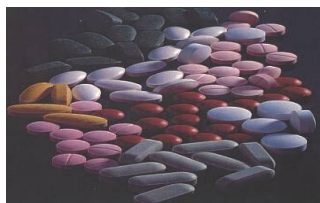
Manual or Automated

A press must be cleaned thoroughly and properly setup whether it is a simple manually operated press, or a very sophisticated automated press.

An improperly or poorly setup press will not produce quality tablets, will often break down and require more cleaning and maintenance and is less productive than one that is properly cleaned and setup.



Tablets...what's in them?



Tablets come in many shapes and sizes. A tablet contains active ingredients and other components. The Active Ingredient is commonly referred to as the API, active pharmaceutical ingredient. The other items found in the tablet formula

Tablets in all shapes, sizes, weights and hardness's. are called excipients. The problem with most API's is that they do not usually make a good tablet and need the help of excipients in order to make good reliable tablets.

Key Excipients:

Fillers: basically a bulking agent...to achieve the desired tablet size. This is usually a granulated powder.

Flow Agents: These are items designed to help powders flow with greater predictability

Binders: A binder helps lock the particles together and can be introduced as a powder or in solution.

Lubricants: A lubricant is used in the tablet formula in the form of a powder to help make it slick so the particles of powder do not stick to the machine, only to each other.

There are 13 classes of excipients used in tablet formulation.

“In real estate it is location, location, location...”

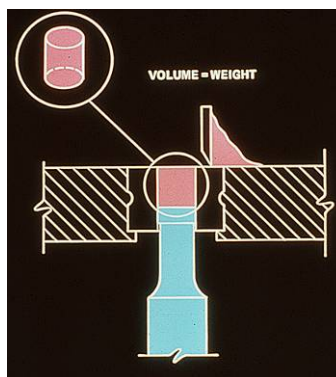
Tablet Weight is the Key

On the press tablet **Weight** is what determines potency of the tablet. High tablet weight means high potency and conversely low weight mean low potency, provided content uniformity is accurate. Therefore tablet weight control is critical.

A tablet press does not weigh powders, it fills volumetrically. In other words the volume created by posi-

tion the tooling for fill will determine the final tablet weight. Therefore if the powder density has variation then the final tablet weight will change even though the volume is the same.

Flow much be consistent to achieved consistent volumetric fill. each tablet will have variations.



on the press it is weight control, weight control, weight control”

Compression

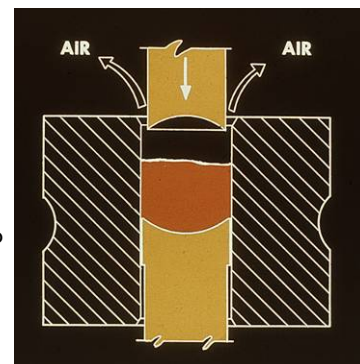
The tablet press tooling is made so that the air is evacuated via the top of the die around the upper punch tip. The upper punch tip is actually made slightly smaller than the lower punch tip to control air release.

One of the most common tablet defects is caused by improper air evacuation.

As the powder is compressed the air is driven from between the particles of powder. If the product has a high percentage of fine particles they get pushed with the air. Some of the particles escape and the rest will be pulled to the edge of the upper punch tip, which creates a layer of fine dry light particles that do not compress well and are not likely to hold together, and

they often split which is called Capping.

Air entrapment relates to tablet hardness, the difficult part is determining if the hardness variation is due to the press, formulation or both.



Air must be removed to make a good tablet

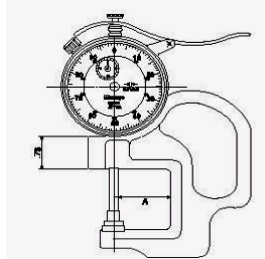
Tablet Testing



Tablets must be visually inspected

We need to test tablets as they are being made to assure that we are in control.

Tablet weight is critical as is thickness, hardness, friability, disintegration, dissolution and visual inspection.



Tablet Thickness Gauge

Thickness is an important physical attribute. On the press thickness variation may mean there is a variation in weight and hardness or both.

On the packaging floor, Bottle filling; thickness is important to allow for accuracy of count. A tablet that is too thick may not fit into the counting device, a tablet that is too thin may break, double-up and may also cause count accuracy issues.

Blister packaging machinery requires very tight tolerances in tablet thickness to achieve and maintain accurate filling, count and sealing of the blister.

Thickness is one of the main control features of a tablet press, the other is weight control and speed.

Tablet thickness is a critical attribute and should be controlled with accuracy.

Tablet Hardness

“Tablet Hardness changes rapidly after compression as the tablet cools”

Tablet hardness is the second most important physical attribute. A tablet that is too hard may not break up and dissolve into solution before it passes through the body.

A tablet that is too soft may break apart, not handle well, and can create other defects in manufacturing.

A soft tablet may not package well or may not stay together in transit.

Hardness changes over time. Tablet hardness off the tablet press and hardness 24 hours later may be entirely different due to the energy from compression. It is important the measure and monitor hardness changes on the manufacturing floor and over time.



Disintegration testing

Weight is the most important measurement.



Tablets must disintegrate before they dissolve. A disintegration tester will suspend tablets in a solution bath for visual monitoring of the disintegration rate.

The time it takes a tablet to break apart in solution is the first part of the objective. The other issue is how consistent are all tablets throughout the batch.

In some companies the tablet press operators are required to run this test, in others QA performs this duty.



Dissolution



Dissolution testing

The granulation process often uses coatings that will sustain dissolution. A common defect is that some of the particles are coated and the solution cannot penetrate the barrier.



Tablet dissolution is an important test to make certain that the API goes into solution.

A dissolution test is basically taking water samples over time to determine the active is available for absorption into the body.

Tablet Defects

Tablet defects can come from many places. Contaminated raw materials, poor cleaning techniques, operating machinery incorrectly, and just plain old poor formulation are all common issues.

The most common defects are tablet weight, hardness and thickness.

Also, some common visual defects

include: capping, laminating, sticking & picking, black or grey spots and chipped tablets.

Many defects can come from process, manufacturing, packaging and poor handling. Criteria boards with acceptable and unacceptable examples should be used to assure product quality.



Lubricant

A lubricant is a very small part of the overall formula but a very valuable part of the performance of the product and tablet. A poorly lubricated formula will not flow well, it will allow particles to stick to the punches and pick out the lettering and numbers on the tablet.

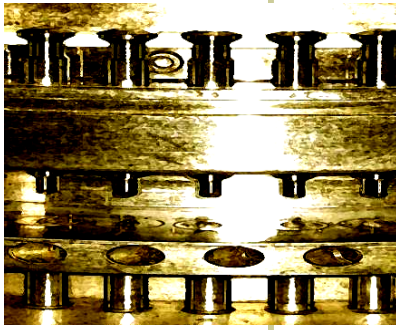
Materials will extrude and create flash and gum up the punch tips.

The tablet press is the report card for everything that happens upstream. A poorly blended product is often not discovered until it reaches the tablet press. An experienced operator can adjust for changes in the granulation, but there are only so many things they can do.



Extrusion and buildup on the punches indicate a lubrication problem.

Tooling

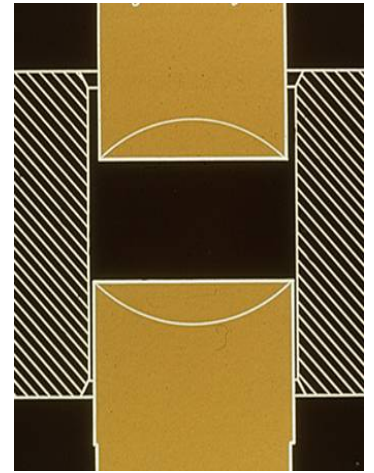


A set of punches and dies are often referred to as tooling. A station of tools consists of an upper punch, lower punch and die.

The job of the upper punch is to control compression position within the die. Most modern tablet presses have adjust upper punch entrance which means that the machine can be adjusted to control how far the punch enters the die. Typically a good place to

start is around 3mm upper punch penetration into the die. If the upper punch is set too high the product maybe pushed out of the die before the upper punch enters the die. Many machines allow punch entrance as deep as 6mm. The problem with being too deep in the die is that air may become entrapped contributing to a capping issue.

Notice that the upper is smaller in diameter than the lower.



Punch function is often not understood

The Lower Punch



The job of the lower punch is more complex than that of the upper. The upper punch only controls penetration depth into the die.

1. The lower punch first overfills the die with too much powder.
2. Then to achieve final and proper tablet weight the lower punch is moved up to allow the scrapper to sweep

the excess powder off the surface of the die table.

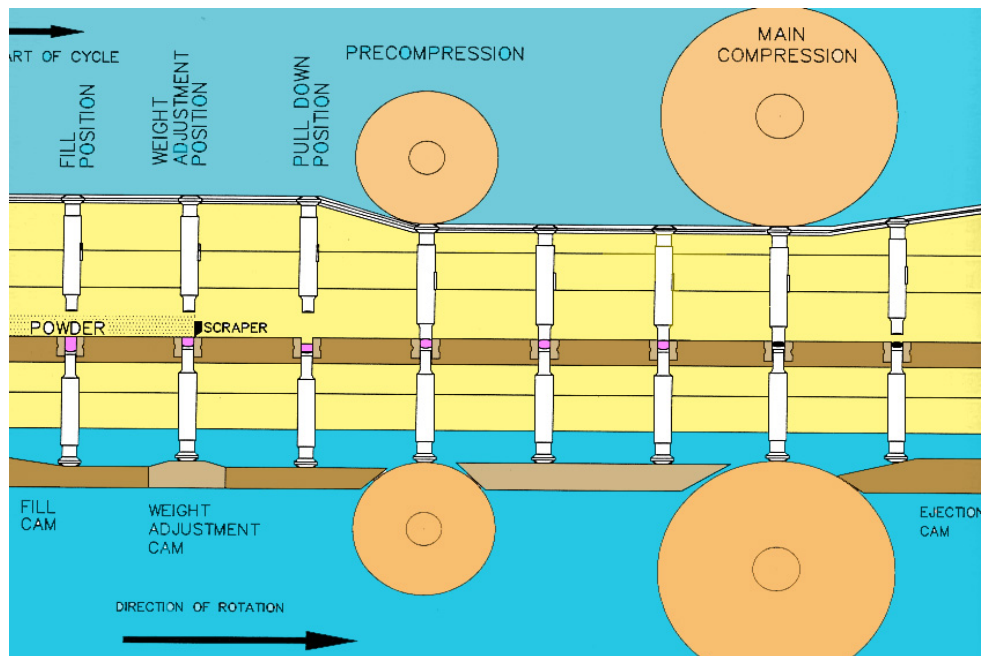
3. Then the powder in the die is moved downward into the die which is called **under fill** to prevent the effects of centrifugal force from slinging powder back out of the die. This feature is not found on all rotary presses.
4. Pre-compression is a feature found on most modern

tablets presses. It's designed to help tamp the powders together lightly compressing the powder and driving the air out of the die prior to final compression.

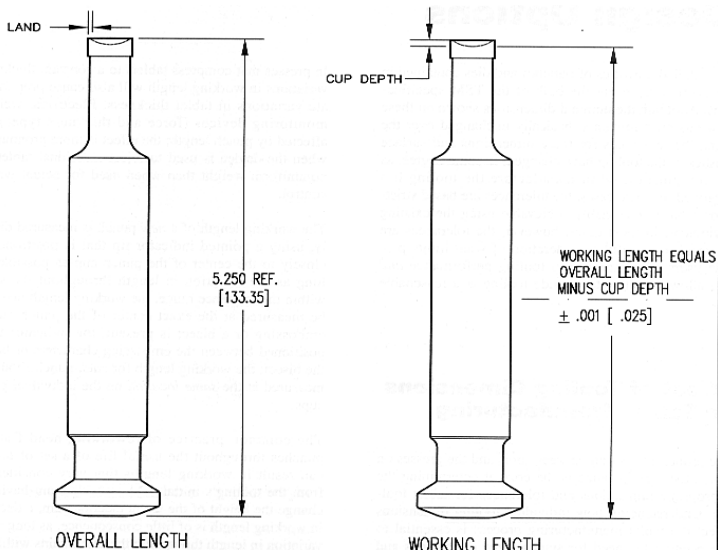
5. Main compression is where the final tablet is compressed.

6. Ejection is achieved by simply pushing the tablet up out of the die.

A good operator will be able to define each key area of this slide



Punch Length



Working Length: The most important dimension of the tooling is the working length variation within a set of punches. Working length is the distance from the bottom of the cup to the head flat. Working length is controlled to a very tight specification. Variations in this specification will result in weight, thickness and hardness variation. All companies should have the ability to inspect this dimension. When tooling is new the allowable variation is .002". Using tooling with variations over .005"

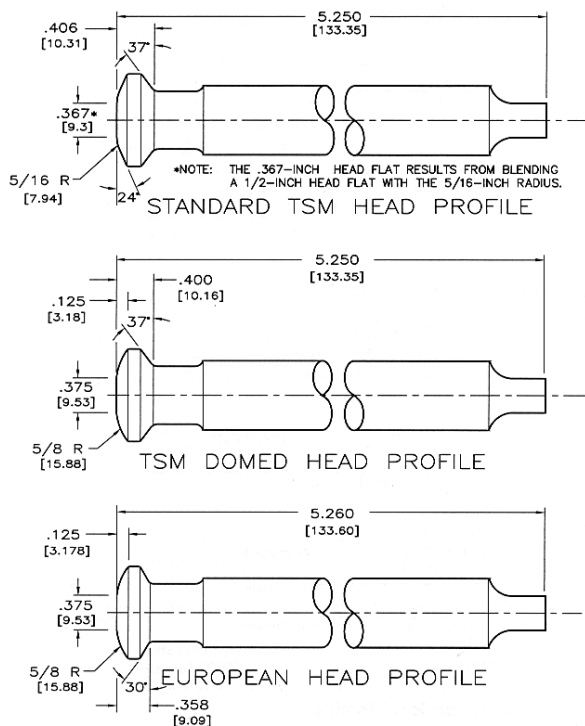
would be considered extreme. This variation must be maintained within the entire set. All upper punches must be the same length and all lowers must be the same as each other with the set. Uppers and lowers need not be the same.

Overall length: The distance from the Cup edge (land) to the head flat is called the working length. This dimension is not critical to the success of the tablet. It is acceptable for new tooling to have punch variations in the overall length by as much as .006" when new.

Head Configurations

In the world of tablet press tooling there was a Standard tool head design and a different design used on European tooling. This meant that the tooling and cams used on a machine in the US was different than the tooling and cams used in Europe and the rest of the world. From this we have learned more about tooling and have been able to compare the benefits of each design.

From that design a third design has been developed called the TSM Domed Head design. This design will not work into a Eurocam machine. It offers a larger more consistent head flat design and a radiused outside bevel for improved transition onto the pressure rolls. This design is becoming a standard and has proven to be a superior design.

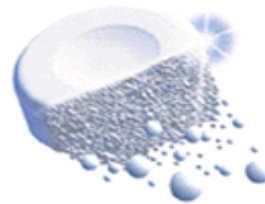


TSM



The TSM is an excellent guide to understanding tooling and the tooling influence on the compression operation. This manual has been put together but industry professionals that include Tablet press manufacturers, Tooling manufacturers, Tablet manufacturing companies. This group has put together the best reference available for tooling specification, terminology,

and machine interchangeability. TSM is an excellent resource for new and experienced professional that work with tablet compression. Every company should have several copies in key departments and should reference this technology when ordering, inspecting, polishing, cleaning and repairing tooling.



Dwell Time



Dwell time is the actual amount of time that the powder is under pressure.

The key factors to controlling dwell time are **punch head flat diameter, number of compression points** and **rpm**. To increase dwell time, simply slowing the machine down will provide more dwell. Conversely increasing rpm will decrease dwell time.

It is important to recognize that all products are not dwell sensitive. Some products will

recompress well at any given speed, others are very sensitive to even the slightest change.

The punch head flat diameter is a contributing factor that is often overlooked. Look at the photo here on the left, you can see the many different diameters of head flats in this one set of tooling.

Most up to date machines have pre-compression and main-compression stations which

means that the tablet is being compressed twice. Using pre-compression with a dwell sensitive powder will allow increased speed without sacrificing dwell.

The bottom line is tablet hardness is (for most products—not all) directly effected by dwell.

Companies should be able to inspect tooling in-house

Head profile

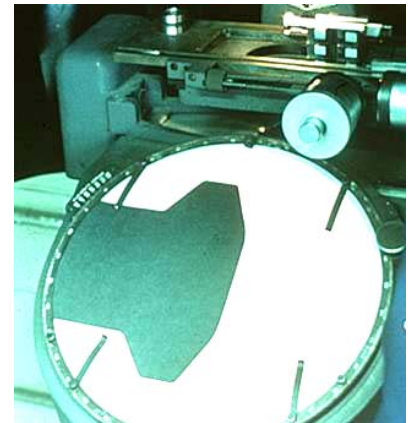
The head of a punch is designed to match and follow the contour of the cams on the tablet press.

It is important to be able to visually monitor wear of the punch head and the corresponding cams.

The difference between a good

operator and a great tablet press operator is the ability to look at wear of the cams and punches and be able to take corrective action to prevent further damage.

Most companies use a simple gauge called a Go-No-Go gauge to determine acceptable punch head wear.

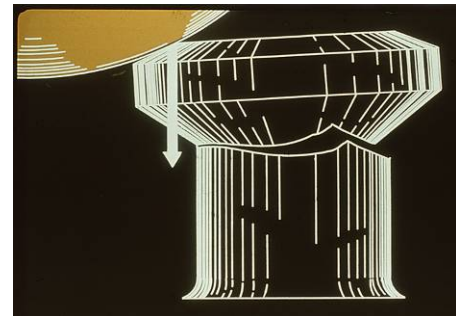


The inspection process

Tablet press tooling must be checked in-house. Tooling inspection should take place when the tools are first received from the vendor and then re-checked on a regular basis.

If the product is abrasive causing advanced wear, then inspection should occur with

great frequency. Products with a history will allow for less frequent inspection. Two inspections must take place after each cleaning; visual and working length. The operator must inspect tools before they are installed in the press and when removing the from the press for cleaning.



Common Defects

Making tablets batch after batch without an occasional defect would be unusual. Some products start up with problems and end with them. Tablet to tablet weight variations create tablet defects. Consistent tablet weight is essential to making a good tablet. Without good and consistent weight control, solving other defects will be difficult (if not impossible) because of how a tablet press operates. Some of the most common tablet defects are:

- Weight variation

- Friability variation
- Picking & Sticking
- Capping
- Laminating
- Chipping
- Mottled
- Double pressing

Often problems with compression can be associated with many root causes. One very common issue is machine start up. The tablet press is cold. The steel is cleaned and

bare metal can allow granules to stick to these metal surfaces. The reason a lubricant is in the product is to prevent granules from sticking. Many companies are very accustomed to a double start up. The first one distributes powders which begin to stick, especially to the punches and to the die table. The operator will often remove the stuck granules and then at second start up no sticking occurs because the working surfaces are now protected by the lubricant.



Tablet Defects

Defects can be solved, if you know where to look

Picking & Sticking

Picking and Sticking occurs when granules stick to the punch faces during compression. Sometimes the punch face design and debossing can be modified to eliminate the problem. Other times granules are not dried properly. They become case hardened during the drying process, which means that the granules are wet on the inside.

During compression these granules break open and the wet product sticks to the punch faces. If this occurs, the drying process must be improved. To overcome sticking on the press, increase hardness by making the tablet thinner and increase dwell time to make the wet granules adhere to other granules rather than the punch face.

Also, if a blend is incomplete this could mean that the lubricant in the formula is not protecting the granule from sticking to the punch cup surface. If all else fails polish the punch cup surface.



Sticking occurs when particles adhere to the punch face

Weight, Hardness and Friability

Tablet weight is the key to controlling hardness and friability. Controlling tablet weights within a tight range will contribute to better tablet hardness and friability.

Many variables can influence weight fluctuations. The key weight control factors are product uniformity in particle size and density, proper tablet press set-up, and control of

flow rates into the die cavity.

However, the importance of weight control cannot be over emphasized. Weights must be uniform in order to trouble shoot most other tablet defects.

Friability testing is done by tumbling tablets to see how well they will withstand the tumbling action which replicates typical handling

situations. This test is done to make certain that the tablet does not fracture or break apart. Too much friability means that the tablet chips or fractures break away from the rest of the tablet.



Capping & Lamination



Capping

Capping is often referred to as air entrapment. During compression, air is evacuated from between the granules to allow the granules to lock to one another. If the “air” does not escape during the compression process the top of the tablet (the tablet cap) wants to come off. The tooling (punches and dies) are designed to allow air to escape during compression along the upper punch tip and die wall. This is why capping occurs on the top “cap” of the tablet. Capping is not just air

entrapment. During compression air evacuation pushes the very fine dry granules out with the air. It is these dry and light particles that do not want to lock together, resulting in tablet “caps” wanting to come off the tablet.

Lamination is when the tablet splits apart anywhere except at the upper cap. Lamination is often blamed on over compressing. Too much compression force flattens out the granules and they no longer lock together.

Lamination can also occur when groups of fine and light particles do not lock together. These groups of fine and light particles simply will not compress well. Reducing thickness and increasing dwell time will give these particles more of a chance.

Dwell time can be increased by adding pre-compression or slowing the machine speed down. Machining a taper into the die will help eliminate capping and lamination.

Capping is one of the most common defects which has many root causes

Chipping

Many tablets are sensitive to chipping after compression. First make certain that the punch tip edges are not damaged. Some punch tip designs are more sensitive to damage from handling than others. Once confirmed that the chips are not being created by damaged punches then make certain that the “take off blade” is set correctly for proper ejec-

tion off the machine. If the blade is too high it will allow the tablet to wedge under the blade causing chipping. If the tablet is friable the tablet can become chipped as the tablet travels off the press, down the tablet chute, through the tablet metal detector, tablet De-duster and finally into the collection bin.

Transferring finished tablets

must be done carefully. Many times investigations into chipped tablets discover poor handling and transfer of tablet bins from compression to storage and then onto the packaging floor. Packaging machinery can also cause chipping.

Double impressions



Double Impressions are caused by punches twisting and jumping

Double Impressions will happen on a tablet press when the punches are allowed to twist or jump. Round punch tips want to twist naturally due to the rotation of the press. Double impressions usually occur on the bottom of the tablet from the lower punches. It usually means that the lower punch retainers are loose and

the punches are jumping during compression.

Make certain the lower punch retainers are clean and not worn. They do need to be replaced often. When a machine starts up it is cold. As it warms up, lower punch retainers can become loose and may need to be tightened to pre-

vent double impressions. Therefore, it is important to check them often at start-up.

Also, many newer machines now use punch seals. As seals become worn they will allow the punches to bounce or twist during compression.

Fines



Ask any operator what they would rather do; run a press or clean-it. The answer is usually that they would rather run it.

A press can run as long as it stays clean and the tooling is lubricated.

Fines can create weak areas in the tablet

Another way to say this is that dust is what causes us to stop and clean the machine. If we had a formula with very little dust the machine would run cleaner and longer because the dust was not present and therefore unable to make the machine dirty.

Many companies must stop the press and perform partial or complete cleanups in the middle of a batch. This immediately tells us

that they have contamination issues and the lubricant on the punches or lack of lubricant is the issue due to variations in fine dusty products...also commonly referred to as Fines.

Fines are the dust in the formula that can cause capping, dust can become airborne and land on the lubricant and dry it up, resulting in possible black specks on the tablet.

Fine particles that become airborne are enemies of the press

Tablet Press Operation

Lets run a press. It must be clean and set up correctly before we can begin.

Step 1: Rotate the machine by hand or in jog mode as the powder is first introduced.

Step 2: Adjust tablet weights into an acceptable range, keep in mind

we are in jog and weights will drop as speeds increase, so set the weight on the high side of your target.

Step 3: Adjust final tablet thickness by raising the lower main pressure roll.

Step 4: Adjust speed to accept-

able expected speed as defined by your SOP's.

Step 5: Add Precompression as needed to achieve hardness range and achieve proper compression.

Step 6: Make final adjustments to weight, thickness and speed to attain final hardness.

Batch variations and changes

When a machine starts-up the operator must understand that the tablet press is cold. As the press runs it will warm-up. If a press becomes too warm the product may stick to the die table resulting in densified material which will migrate into the tablet creating a visual defect, a gray or dark spot. As the product runs on the press

some segregation usually takes place. Fines migrate one way and larger particles another. At some point these groups of fines or large particles will enter the die causing a big increase or decrease in weight or compressibility. If a group of fine particles enter a die cavity the result maybe capping. The point is that segregation is not only possible, but it is very likely with prod-

ucts that have a wide variety of particles sizes with various densities. A poorly blended batch will result in many variation on the tablet press. Remember that the tablet press is the report card for how well the product was prepare for the press.

What are GMP's and SOP's

Good Manufacturing Practices are guidelines designed to assure consistency and reproducibility in manufacturing.

GMP or cGMP; Current Good Manufacturing practices are federally regulated by the FDA.

The FDA is the Food and Drug Administration. They have established a Code of Federal Regulations (CFR).

It is required by the FDA that each employee is responsible to follow and practice GMP's.

The manufacturing company can be held accountable for the employee not following the requirements of the GMP. Therefore companies have established SOP's; Stand Operating Procedures.

Standard Operating Procedures are written instructions

for the employee to follow and sign. The employee must understand that their signature assures that they have completed the SOP step by step and has not changed any step.

If an employee changes a step, an explanation must be written as to why, and a deviation must be recorded by the company.

**Safety should
always be our
number 1 concern**

General employee procedures

The employee is required to follow procedures at all times.

Personal hygiene; this means being physically clean (body and clothing). The employee is required to keep their hands washed, keep their body hair, nasal and oral discharge (sneezing and coughing) controlled.

Jewelry: generally not accepted to be worn in the manufacturing areas including rings, watches, brochettes, earrings including any exposed body jewelry.

Clothing: must be clean at all times. Pockets are generally not acceptable above the waste line, shirt pockets must be sewn shut .

Footwear: Street clothes and shoes should remain separate from the clothing and footwear within the manufacturing environment.

Food, drinks and medications are not allowed on the manufacturing floor. The only exception is in the case of immediate first aid requirements.

Safety

No job is worth getting hurt for.

Most unit operations have some level of danger.

Wet floors, cleaning chemicals, ladders, doors, fork lifts, material handling equipment, stor-

age vessels and machinery all carry the potential for personal injury.

Always follow procedures, wear safety glasses and protective foot wear, respiratory and safe breathing apparatus when required.

Remember machines don't have a brain...use your own!

Be safe and think safety at all times.

Training in your Facility

Tablet Pro is a in-house training seminar that will provide each participant with a comprehensive knowledge of the complete tablet making process. It will provide the tools for improving tablet making skills for everyone related to the tablet making process. This includes Managers, Supervisors, R&D, QA & QC, Technical Services, Maintenance, Operators and anyone specifically involved in the tablet making process. This course will benefit everyone involved with formulation, weighing, blending, milling and all areas of powder preparation. It will also greatly benefit those involved in post compression operations such as coating, tablet printing and packaging. This course is design to turn new & experienced tablet press attendants into "Professional Operators". It is all about improving tablet making skills within a company is critical to the success and key to continuous quality improvement.

This course will cover theory, methodology and documentation and the mindset required to meet the demands of today's tablet making environment. We incorporate cGMP's into all of our presentations as well as safety and proper procedure protocol. Everyone connected to the manufacturing environment must comprehend the basics of Tablet Making. Managers and Supervisors must now understand the fundamentals of making tablets, because if they do not know the basics they cannot properly support the demands of the new production environment.

We will cover Trouble shooting and root cause analysis and utilize a systematic approach to all elements of tablet making. The only way to properly fix a problem is to know "how things work". We believe the best manufacturing facilities are the ones that have open avenues to training and exchange issues between departments. Tablet quality is the report card for all unit operations and represents the company long after it has left the manufacturing floor. The presentation is done in a lecture style classroom setting using PowerPoint. Every participant will receive a comprehensive manual and a certificate of completion. This session will be uniquely tuned for the customer.

We guarantee that this course will be both educationally beneficial and enjoyable.

Technical Director & Owner

Michael D Tousey

Tablet Pro

Topics & Schedule

Day 1 8:30 am - 4:00pm (this is a suggested schedule only)

- The Tablet Manufacturing Process
- Unit Operations
- Powder & Granulation Flow
- What's in a formulation and why
- Tablet Compression basics

Day 2 8:30am - 3:00pm (this is a suggested schedule only)

- How a Press operates
- Tablet Compression
- Tablet Press Tooling
- Troubleshooting & Defects
- Summary / Q&A

Date: **Customer to request specific dates**

Price: Call for Pricing. Our fee includes the instructors' travel and living expenses, plus training manuals and training certificates for each participant.

Terms: 50% with Order, Balance at completion prior to lecturers' departure. Customer agrees to provide written notice of **CANCELLATION** on or before 15 days prior to first day of scheduled training to avoid 25% cancellation fee. In the event that Customer **RESCHEDULES** training without a minimum 15 day written notice, Techceuticals reserves the right to charge the Customer for the resulting travel and/or accommodation re-booking penalties.

Class Room: Customer to provide adequate location for lecture style training. Other items needed are: white board or large pad easel, projector screen.

Certificates: Customer to provide a complete list of participants for personalized "Certificates of Completion."

365 Red Cedar Street, Suite 202 ~ Bluffton, SC 29910

Phone: 843-815-7441 ~ Fax: 843-815-7443

sales@techceuticals.com ~ www.techceuticals.com



*Providing quality consulting, training,
and equipment since 1989™*

TECH TEAM LEADER



Mike Tousey

AN INVITATION FROM MIKE TOUSEY

I have been involved in the pharmaceutical industry since 1973 and have provided consulting & training to pharmaceutical and nutritional companies throughout the world. Everyone within the manufacturing facility from management to the operator, including R&D, QA, Tech Services, Maintenance, Supervisors, and Leads will benefit from our consulting & training programs. The goal is to have everyone exposed to the same information, to create a common denominator and to open communication. Companies that participate in our programs are encouraged to use our training materials to improve their own in-house training programs.

You're invited to visit our website for technical tips, published articles, and many other resources. Please visit us at: www.techceuticals.com If you would like to discuss this information with me in person, please contact me.

Sincerely,

Michael D Tousey

Technical Director/CEO



www.techceuticals.com

TECHCEUTICALS

365 Red Cedar Street, Suite 202

Bluffton, South Carolina, USA 29910-4519

Phone: 843 815 7441 Fax: 843 815 7446

E-mail: sales@techceuticals.com Web: www.techceuticals.com