



# TEHCCEUTICALS

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

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## THE MANUFACTURING PROCESS

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### Objectives in learning

- Understanding the principles of the manufacturing process
- Designed for new employees, recent transfers, Managers, QA, R&D, Supervisors, Leads and Operators
- Gain a quick and comprehensive understanding of tablet manufacturing
- Get different departments on the same page



## TABLET AND CAPSULE MANUFACTURING

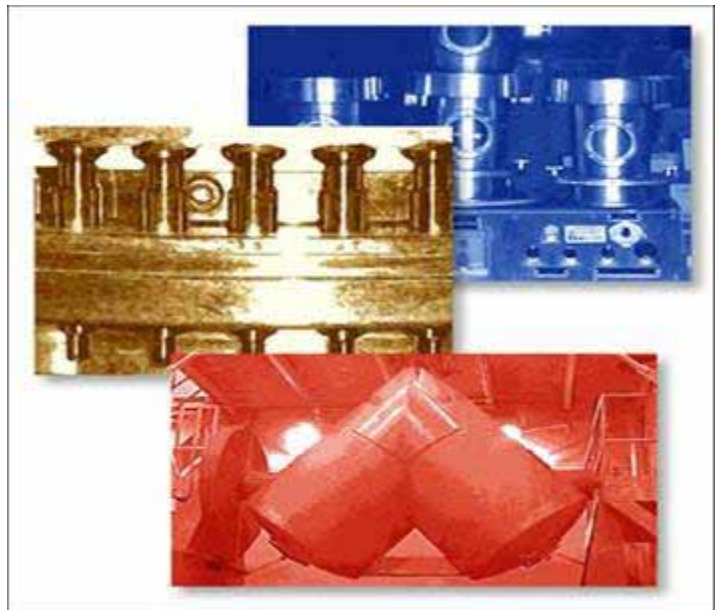
The Manufacturing Process was created for companies and individuals to gain a complete understanding of the basic requirements needed to make tablets and capsules.

The objective is that the reader will gain a quick, yet comprehensive understanding of solid dosage operations used in the manufacturing process.

The focus will be a step by step explanation of each unit dose operation, common equipment, and practical knowledge of each operation.

The main topics are Formulation, Blending, Milling, Granulation, Drying, Final Blending, Tabletting, Tablet Press Tooling, Coating, and Encapsulation.

Common tablet & capsule defects and problem solving are also part of the objective.



Designed for new & experienced employee training, the expectation is that having this information will create a common denominator; thus producing an opportunity for better communication between manufacturing groups. The company will no longer hear that the problem is the fault of another department.

The reader should be able to understand each unit of operation. They should understand how machines work and the usage of each piece of equipment and why one technology is preferred over another.

## SPECIALIZED TRAINING IN-PLANT AND PUBLIC SEMINARS

Michael Tousey has developed a complete series of training programs.

These programs can be presented for everyone involved in the manufacturing process. Operators, Leads, Man-

agers, R&D, Engineering, Maintenance, Quality Assurance, and packaging personnel will all be able to gain knowledge and a better communication method between departments. Each of the programs can be

tailored to meet the specific needs of the customers facility and application.

All training courses and seminars can include testing modules.

## UNIT DOSE OPERATIONS

Every separate manufacturing step is called a "Unit Operation". Weighing, Blending and Tableting are individual unit operations. A "Batch" of powder or granulation is processed in each unit operation. The objective is Batch to Batch Reproducibility in each Unit Operation. Unit Operations are determined by what manufacturing steps are needed to combine the active ingredient with other needed ingredients to make a quality finished product.

The three most common Unit Operation pathways are *Direct Compression*, *Wet Granulating*, and *Dry Granulating*. Which pathway is used depends on what is needed to

do to make a tablet out of the active ingredient.

Powders must *Flow*; making a tablet or a capsule requires the powders to be somewhat fluid. Good flow can be compared to granulated sugar. Bad flow can be compared to powdered sugar. Products must flow freely to achieve proper dosage. Tablet presses and encapsulation machinery do not actually weigh the individual dosage amount, they fill by volume.

Powders must *Compress*; Particles must lock together. Overly wet particles will cause *Sticking*. Overly dry particles will cause *Lamination*. Fine particles escape during *compression*.

Time under pressure is *Dwell time*. Tablet Press speed relates to compressibility and time under pressure. Tablets and capsules must also eject from the die after being compressed.



## THREE PRINCIPLE METHODS OF DEVELOPING POWDERS FOR TABLET MAKING

Tablets made by blending the dry powdered ingredients together, and then compressing into tablets is called "**A Directly Compressible Formula**". We are saying that the characteristics of these powders will blend together with the other ingredients and stay mixed. This combination of ingredients will flow, compress and eject from the tablet press. Furthermore, the tablet will have good hardness, friability, and will dissolve quickly.

If powders will not make a good tablet because they do not compress, don't flow well, are too fluffy or separate after blending, the particles need to be combined and attached using a pharmaceutical glue called a *binder*. When the binder is put into water or a solvent solution and is sprayed or metered into the powders this process is called "**The Wet Granulation Process**". The solids within the liquid solution form bonds between particles which are

maintained even after the liquid is dried and milled. There are many different types of binders that can be used.

All powders have a variety of characteristics; some may only require a very small amount of binder and some may require large amounts of binder. Many powders require some level of intense mixing while adding a liquid binder, actually comparable to kneading dough when making bread. Once the powder and binding solution are kneaded they are then milled for drying. The bonds that hold the particles together can withstand the milling process forming a uniform size "granule". If we accomplish these "unit operation" steps correctly (pre-blending, binder addition, milling, drying and final blending) the result is a compressible powder called a granulation.

A granulation is the formation of small agglomerates called

"granules". Each granule will contain a proper mix of the ingredients of the formula. We can control the final density of the granules by the amount of liquid binding solution and the mechanical energy created by the type of machine used. The machines used to blend powders and add liquid are called "granulators".

Some granulators have the ability to dry the excess moisture. Many granulators do not have the ability to dry the wet massed granulation; therefore the wet granulation must be moved to the next unit operation which is called *Drying*.

There are many types of Dryers that we will discuss later. When powders are sensitive to liquids, heat, or both, we must blend the powders with a pre granulated "dry binder". If the blended powders will not work with the addition of the dry binder and liquid, or heat cannot be used, then we

*The three principle methods of developing powders for tablet making are:*

*Direct Compression*

*Wet Granulating*

*Dry Granulating*

(Three Principle Methods continued)

must "Dry Granulate". The Dry Granulation method uses mechanical force to densify and compact powders together which forms dry granules. This compaction can be done on a tablet press using "slugging tooling". Slugging tooling or slugging punches & dies are a method to dry compact powders into granules.

The other method is to use a machine called a Roller Compactor or Chilsonator. This is basically the same kind of machine used to make the charcoal briquettes for our outside grill. The slugged or roller compacted powders are then milled, final blended and compressed on a tablet press. Of these three principle meth-

ods, the "Wet Granulation" method is the most common. It is also the most demanding and requires many unit operations.

In The Tablet & Capsule Process, we will discuss each of the principle methods and discover the unit operations required for each method. We will define each processing step and the common equipment types used in each unit operation.

The final goal is to make a quality tablet with the following attributes:

- Good Weight Control
- Good Thickness Control
- Good Hardness Control
- Good Ejection

- No Capping
- No Lamination
- No Sticking
- Good Friability
- Good Disintegration
- Good Dissolution

As we go through each unit operation we will refer to one of these three principle processing methods.

- Direct Compression
- Wet Granulating
- Dry Granulating



*"All formulas have a limit to how fast they can work on a tablet press. Even the best tablet press cannot improve this limitation without changes in the formula"*

## THE FORMULA

We have determined that a formula contains many ingredients other than just the active ingredient. The ingredients within the formula in addition to the active are called *excipients*.

Excipients are needed to make a good quality tablet at the required tablet press speed. They help the flow, compressibility and the ability

of the tablet to eject from the tablet press without falling apart. Excipients also enhance the hardness, disintegration, appearance, color, taste, and the overall performance of the tablet.

As stated previously, a formula that is designed on a slow speed tablet press may not work on a high speed press. Even the best tablet press with all the best design features may not be able to

compress a formula at any speed. Each formula has a limit to how fast it can be compressed. In order to increase the speed, the formula must be changed.



## WHY GRANULATE?

- To improve powder flow.
- To improve compressibility.
- To reduce fines.
- To control the tendency of powders to segregate.
- To control density.
- To capture and fuse small quantities of active material.

The average tablet press speed in the pharmaceutical industry produces 3,000 tpm (tablets per minute) or 50 tablets per second. Tablet press speeds can exceed 10,000 tpm or 166 tps.



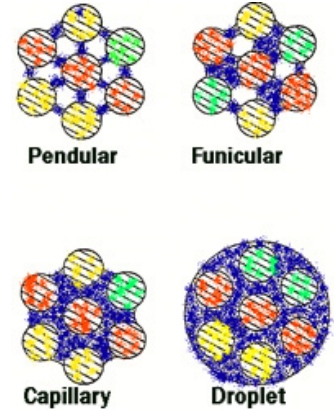
## GRANULE FORMATION IN THE WET GRANULATING PROCESS

Most of the early research in granulating took place in pans and drums and some of the theory and knowledge gained using that equipment is not directly applicable in all technologies. There are however at least three theories which have been accepted by academics as applicable. These three mechanisms are:

- (1) Nucleation
- (2) Transition in the funicular and capillary stage
- (3) Ball growth. In nucleation, the formation starts with loose agglomerates or single particles which are wetted by

the binding solution and form small granules by pendular bridging. Continued addition of binding solution and tumbling action consolidates and strengthens the granules through the **funicular stage** and into the **capillary stage**. In this transition stage the granules continue to grow by one of two mechanisms: (1) single particle addition and (2) multiple granule formation.

Theoretically, at the end of the transition stage there are a large number of small granules with a fairly wide size distribution.



*Wet Granulating is the most common processing method used in pharmaceutical manufacturing*

## WET GRANULATING PROCESS STEPS

In the **pre-mix** step the powders to be granulated are added and mixed prior to the introduction of the binder. In the **wet massing** step the binder is added to the mixture and the components are massed to a predetermined end point.

In the **drying** step the wet mass is dried to a predetermined end point, commonly measured with a test called

the "LOD" or loss on drying test. The finished granulation is then **milled** to reduce the size of any caked material into a standardized particle size distribution. This distribution is usually measured using a series of screens lined up top to bottom from largest screen to a pan to collect the dust.

In the **final blend**, the lubricant is added to the granula-

tion producing the final blend. Granulation is actually caused by a complex interaction of several variables and knowledge of each is necessary to control the granule formation process. If we establish which variables are critical to granule formation, we will have the basis to control granule growth for a reproducible process.

## HOW GRANULES ARE TESTED

There are four standardized tests which are commonly performed on either milled or finished granules:

1. LOD- water content
2. Bulk Density, mg/ml
3. Particle Size Distribution
4. Angle of Repose, flow gradient.

Two of the four tests, **Loss on Drying (LOD)** and **Particle Size Distribution**, are commonly performed by operators on the production floor. In some cases, the operator only performs the LOD and the other three tests are performed in the laboratory. The practice varies depending on the situation.



**Moisture Balance for checking LOD...Loss on Drying**



# DRY GRANULATING

Dry granulating, also called Slugging, Chilsonating or Roller compaction, involves the pressing of mixed powders into an object to be re-ground into a precise powder. This action increases particle density, improves powder flow and captures fines.

The Dry Granulating method is used over other technologies for one or more of the follow reasons:

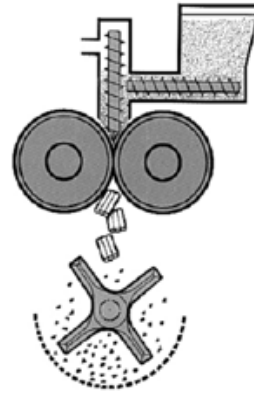
1. Granulate materials which are sensitive to heat and/or moisture.
2. Produce a uniform particle size range.

3. Improve flow properties.
4. Control dust.
5. Control bulk density.
6. Produce uniform blends
7. Control particle hardness.
8. Improve wetting or dispersion rates.

Powders can be compacted using a tablet press; this is called Slugging. Once slugging is completed or powders are compacted on a Chilsonator or Roller Compactor, they are milled.

It is best to Mill densified powders using a low shear mill for best results. Using a

high shear mill may over-mill or result in an over production of fine particles.



# MILLING

Milling equipment is used to *Improve flow, reduce segregation, enhance drying, and limit wide particle size distribution.*

Milling machinery used in the preparation of tablet & capsule formulations can be categorized as to their mechanical energy; Low, Medium or High energy mills will impart a force on the powders called

shear force. Therefore, milling machinery is defined by Low, Medium and High shear applications.

Some milling machines allow for changes in the type of mechanical action used to reduce the powder to the proper final particle size range. Mills can be used to de-lump powders without actual particle size reduction.

Often different mills are used within different unit operations throughout the complete manufacturing process: At weigh-up for de-lumping, before blending for proper particle size distribution, after wet granulating to enhance drying, and after dry granulating to prepare powders for final blending and tablet compression.

*“Fines” are small dust like particles, that do not flow or compress well and also contribute to lower yields and more frequent cleaning.*

# MILL APPLICATION

Generally we want to be as gentle with powders as possible. Some powders have high moisture content and they may be subject to compaction within the mill; others are very hard and friable and are subject to producing “fines”. Fines are powders that are very small and “dusty”, which will pass through a 200 mesh screen.

Fine dusty particles

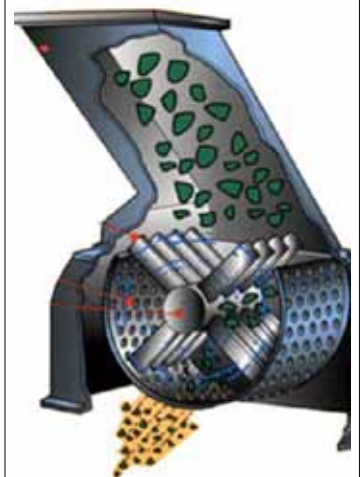


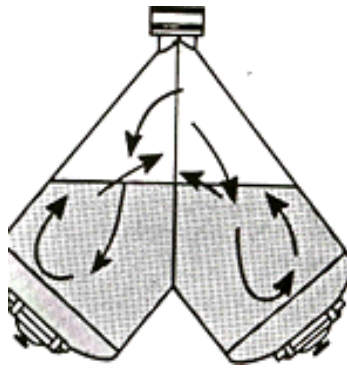
impede the flow, do not compress well and can become air born. The air born dust can be witnessed on filters, walls, cabinets and machine components. Besides affecting yields, the dust will combine with oil and grease on the tablet press causing the punches to become tight, requiring more frequent cleaning cycles.

Common milling

equipment: Low Shear Mills; Oscillators and Comils. Medium Shear Mills; Quick Sieves and Hammer Mills. High Shear Mills; Pulverizes and Hammer Mills.

Many companies do not have designated milling rooms which requires moving single mills from location to location. In this event, you must always check motor rotation before operating any milling equipment.





*“The main purpose of the final blend is to distribute the lubricant”*



## POWDER FLOW & BLENDING

There are at least ten (10) different variables that can contribute to the success or failure of powder flow on a tablet press. In addition to the well studied particle size, shape and distribution. There are also particle surface texture, cohesivity, surface coating, particle interaction, static electricity, recovery from compaction and wear/attrition while in the holding container.

These other non-traditional measurements, studied and appreciated, shed significant light on flow issues heretofore not fully understood:

*Particle size*

*Size distribution*

*Shape*

*Surface texture*

*Cohesivity*

*Surface coating*

*Particle interaction*

*Electro-static charge*

*Compaction recovery*

*Wear/attrition characteristics*

Most powders, without the aide of granulation and flow agents, simply cannot flow at speeds required for high speed tableting. All powders have the capacity to form bridges, create rat holes and stick to contact surfaces. To some extent, most powder mixes exhibit some degree of each problem situation above. The issue becomes critical when any or all of the situa-

tions begin to affect unwanted change in powder flow. Bottom line: Recognize that a “good” final blend is often viewed as such because it has good content uniformity and potency, not by its ability to flow.

However, good flow is imperative to attaining a good tablet. Understanding powder characteristics will contribute to accurate blending practices.

### FINAL BLEND

The final blend represents the result of the formulating, granulating and lubrication effort. The reason we test blends is to optimize blend time, demonstrate lack of segregation after blending is completed, and confirm that specified blend conditions produce acceptable uniformity during validation.

An individual powder or finished blend may flow very well under one set of circumstance and not flow well at all under another. Notice that under *Powder Flow* we see attributes of the powder itself while under *Powder Process* we see what may happen under different processing circumstances.

The message here is for management to be aware of these potential issues on the pro-

duction floor.

*Powder Flow*; Flow rate, Compaction and flow, Hysteresis and flow, Wall Friction performance, Vertical shear, Tensile Strength

*Powder Processing Segregation*: Attrition, Over-processing, Post-storage/transportation time.

### UNIFORM BLENDING

Materials go from an unmixed state to a state of relative homogenous consistency. Achieving a homogenous blend is accomplished through a combination of time and mechanical energy. Given enough time, components will pass from an unblended state to a relatively homogenous blend and back to an unblended state.

Blend studies determine the optimum endpoint. All blends

have a unique pathway to their optimum state of uniformity. Because under blending and over blending fall on either side of the optimization curve, the symptoms are somewhat similar; and include Content Uniformity problems, Weight and Hardness variation.

The most common blenders used for final blending are the V blender, the double cone blender and the tote blender.

All use low shear tumble blending as the most effective way to achieve good mixing with a variety of powders and granules.

# TABLET COMPRESSION

While an experienced operator can take a marginal granulation and make a good quality tablet, an inexperienced operator (not fully understanding tablet press operation) will be unable to produce a quality tablet.

Understanding the machine operation and being able to identify the difference between a machine issue and a granulation issue is important. Operators should be qualified, tested and certified in the operation of a tablet press.

While tablet presses are used for many applications, the basis of formula development

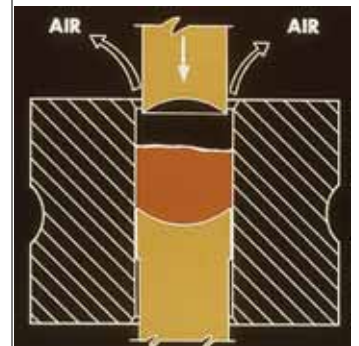
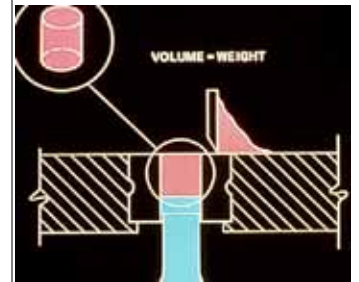
is the same for each application. The final granulation to be compressed must have three basic characteristics, all of which are critical: Flow, Compress and Eject.

A tablet press can be fully automated to the point that it can be operated in a lights out operation. This puts all the emphasis on the cleaning and proper set up of the machine. This is also true of a non automated machine. The emphasis is on cleaning and proper setup.

With few exceptions, rotary tablet presses operate the same basic way. Many machines have very advanced features that may provide

better compression and weight control at high speed.

However, understanding the basics of compression is the key to understanding all tablet presses. The tablet press is the report card on all previous unit operations; the tablet press is only half responsible for the final tablet quality, the formula and powder preparation operation is the other half. A good press cannot improve a bad formula.



## TABLET WEIGHT CONTROL

Having consistent flow of a granulation provides the needed avenues to control tablet weights. Consistent tablet weight will result in repeatable tablet hardness. Tablet hardness is a function of tablet thickness and tablet weight.

A given volume of granulation compressed to a specific

thickness will result in a given hardness. Though excipients play a large roll in the dissolution rate of a tablet, so does tablet hardness.

A tablet press and tools will not improve a granulation. If used correctly though, the press and tools can be used to maximize the granulation and maintain a consistently

hard tablet with acceptable disintegration & dissolution rates.

The three most important variables of making a good tablet are; weight control, weight control and weight control.

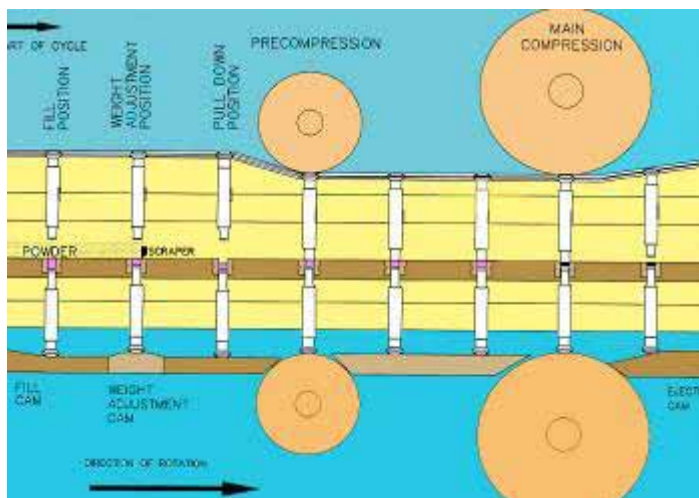
*“During compression the air evacuation forces fine particles to the edge of the tablet, since “fines” will not compress, the result is Capping”*

The compression cycle on a rotary tablet press:

- Overfill the die = die fill.*
- Adjust the volume of fill = weight adjustment.*
- Compress the tablet = remove the air.*
- Eject = push the tablet from the die.*

When setting up the tablet press; Adjust Tablet Weight, Adjust Thickness, Balance weight & thickness and machine speed, to get proper Hardness.

## COMPRESSION



## TABLET COATING



Once a good tablet is made, we often need to add a coating. The coating can serve many purposes; it makes the tablet stronger and tougher, improves taste, adds color, and makes the tablet easy to handle and package.

The coating can be a thick sugar based coating or a very thin film. Most pharmaceutical tablets are coated with a thin film coating. This coating is sprayed as a solution (a mixture of solids in a liquid).

For many years the liquid was a solvent such as alcohol or some other quick drying solvent. The use of solvents can present problems in handling, operator safety, solvent recovery and the odor of the tablet

can smell like the solvent, which is not a desirable attribute.

In general, many manufacturers have moved to a water based solution instead of using a solvent. This presents a challenge in applying and quickly removing this water based solution so it does not disrupt the integrity of the tablet.

Tablet film coating equipment has evolved to enhance this drying capability. Essentially a tablet coating system is much like a fancy clothes dryer. The water based solution is sprayed in a very fine mist so as to dry almost immediately as it reaches the tablets. As the water dries it

leaves the solids as a thin film on each tablet.

The coating system continuously supplies hot air, at the same time pulling air through small holes in the coating drum. The drum is commonly referred to as the coating pan, with small holes called perforations. This process can take as little as 30 minutes or it can take several hours.

Tablets must be tough enough to tumble while the solution is added. The solution is distributed from tablet to tablet during the tumbling and drying process. The spraying, distribution and drying all takes place at the same time.

*Tablet Coating  
Art or Science?*

## COATING EQUIPMENT

Tablet coating equipment combines several technologies and is commonly referred to as a coating system. This system consists of the coating pan, spraying system, air handling unit, dust collector and controls.

The coating pan is really a drum within a cabinet, allowing for control of air flow, air temperature and controlled solution application.

The spraying system consists of spraying guns, a solution pump, tank & mixer and air lines.

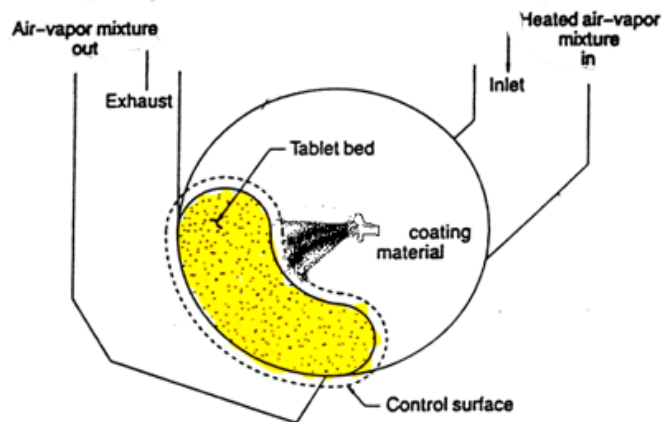
The solution is pumped into the guns and the air combines with the solution for atomization into a very fine mist.

The air handling unit (AHU) is basically a way of heating and filtering the air. Dehumidifica-

tion and/or humidification maybe be needed depending on your location and application requirements.

The Dust Collector collects the dust during the preheat and tumbling cycles and the Controls connect all of the components creating a complete coating system.

## THE COATING PROCESS



Tablets are loaded into the coating pan, creating a bed of tablets. There must be enough tablets to attain good mixing, but not too many or the tablets will spill when the door is opened. Consistent batch sizes are important to attain consistent results.

The tablet bed is tumbled slowly, as the warm air is introduced; the dust collector pulls the dust off the tablets and into a collection bin.

When the tablet bed temperature reaches the proper temperature the spraying can begin. Once tablets have an initial base coating the spray rate can be increased.

The controls are monitored by the operator or computer, recording data frequently. Tablet defects can occur if the temperature, spray rate and air volume are allowed to fluctuate.

## ENCAPSULATION

Commonly referred to as a capsule filler, the encapsulation machine has the ability to fill many different products. Powders, granulations, liquids, tablets and capsules can be filled into a two piece capsule.

Encapsulation machinery technology varies a great deal from one manufacturing to the next. Not all machines can fill a wide variety of products; most are designed to handle free flowing powders much like powders that are prepared for a tablet press.

The capsule filler must first position all of the incoming capsules into an upright position (rectification), separate the cap from the body (top from bottom), attain the proper fill volume (capsule

weight), and then the product filled body is rejoined with the cap and ejected from the machine. Some capsule filling machines have the ability to compress or tamp the powder for proper filling volume and weigh control.

Encapsulators can be defined as 1) Hand operated 2) Semi Automatic 3) Automatic. The Hand Operated capsule filler requires the operator to organize the capsules in the correct position, separate the cap from the body, and fill & close the caps (basically the hand filler is a holder for the capsule body).

There are exceptions and some hand operated fillers assist the operator with separation and closing functions. The Semi automatic machine

requires the operator to move rings (capsule holder rings) from the rectifier to the filling and closing stations allowing for production up to 25,000 capsule per hour.

Automatic machines with speeds up to 90,000 per hour can be divided into two categories: Continuous and Intermittent operation.

The intermittent motion machine is divided into segments. Each segment indexes from each machine function; rectify, fill, tamp, close and eject.

The automatic machine is a continuous operation somewhat comparable to a rotary tablet press in that the rotation is continuous and does not start and stop.



*“Capsules are sensitive to temperature and moisture variations”*

## CAPSULE CARE

Gelatin capsules that are old and improperly stored can dry out and become brittle; they have a rather high defect rate when compared, say, to finished tablets. Even with all the quality check points many capsules are unusable by the time they reach the production floor. Just ask any process operator and they will tell you about the impact that

defective capsules have on production rates. Even on the semi-automatic model 8 machinery defective capsules can slow production rates significantly. Common Capsule defects include: Dented, cracked, split, over size caps, and empty capsules after the filling cycle.



## PRINTING TECHNOLOGY

The principle of operation in printing is the successful transfer of the image from a surface to the object. In the case of tablets the transfer is made from the ink pot to the gravure (or design roll) roll, to the rubber roll to the tablet.

All offset printing, regardless of equipment manufacturer, is accomplished in this manner. Gravure rolls should be inspected for defects before they are used on the production floor. As an example,

using a jeweler’s glass to inspect the ink retaining screens is recommended before the roll is placed in use. Rolls received with incomplete or missing screens will not be able to hold ink in the impression cavities and the image cannot be transferred to the rubber roll. If this occurs, you will have unknowingly introduced defectively printed tablets into the batch.

Most equipment manufacturers recommend using a 50-

50 mix of n-butanol and isopropyl alcohol as both an ink thinning and cleaning agent. All ink manufacturers supply recommended specific gravity ranges for their inks.

Controlling the ink viscosity is critical throughout the entire batch.

## COMMON TABLET 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

*Good tablet weight control must be attained before trouble shooting other tablet defects.*



- 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**

## WEIGHT, 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 & 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.

## PICKING AND STICKING

Picking & 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**

# CAPPING AND LAMINATING

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 & 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 & 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



**Capping**

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



**Punch tip edges are easily damaged, usually from poor handling practices, rarely from operation.**

*The tablet press punches are designed to allow air to escape during compression along the upper punch tip.*

## 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 cor-

rectly for proper ejection 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 deduster 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 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 prevent 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.



Double Impressions are caused by punches twisting and jumping during compression



**Extreme chipping and breakage**

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*Mike Tousey*

I have been involved in the pharmaceutical industry since 1973 and have provided 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 training programs.

The goal is to have everyone exposed to the same information, to create a common denominator and to open communication between departments.

Companies that participate in our programs are encouraged to use our training materials to improve their own in-house training programs.

If you would like to discuss this information with me in person, please contact me.

Sincerely,

Michael D Tousey  
Technical Director/Owner  
Techceuticals



**TECHCEUTICALS**

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

## PACKAGING TRAINING

*Solid Dose Packaging Training covers each component of the packaging line, setup, operation, cleaning, changeover, covering a wide variety of applications. Each packaging line component item is discussed separately: Unscrambler, Bottle Cleaner, Counter/Fillers, Cottoner, Capper, Induction Sealer, Retorquer, Body/Neck Bander, Labeler, Over-wrapper, Cartoning and Conveyors. We will also discuss line integration, inspections stations and troubleshooting. Many different*

*types of applications will be covered in detail. We will*



*focus on Bottles (plastic & glass), Caps, Cotton, Labels, Coding, Shrink wraps, Inserts, Outserts, and bundlers. We will discuss line speed, machine flow and process and the roll of the operator. Supervisor function and line management*

*will be main topics.*

*This is a multiple shift training session; we will provide the program based on your shift requirements. Often we present this program to 2<sup>nd</sup> shift from 3pm until 10 pm and then present the same information to 1<sup>st</sup> shift from 8am to 3pm on the following day. This is a classroom lecture series presented to managers, supervisors, tech services, quality control, leads, maintenance and operators.*

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