



TECHCEUTICALS

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and equipment since 1989™

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MANUFACTURING NUTRITIONAL SUPPLEMENTS

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Objectives in learning

- Understanding the principles of the manufacturing nutritional supplements
- Designed for experienced & 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 RESOURCE & TRAINING SEMINAR

"Manufacturing Nutritional Supplements" was created to help companies understand the manufacturing environment needed to make tablets and capsules and to properly meet the new requirements of a rapidly changing industry.



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



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 under-



stand 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 are designed for everyone involved in the manufacturing of tablets & capsules. Operators, Leads,

Managers, R&D, Engineering, Maintenance, Quality Assurance, and packaging personnel will all be able to gain knowledge and a better communication method between departments. All programs can be tailored

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

These programs include root cause analysis, common defects and troubleshooting.



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

Direct Compression

Wet Granulating

Dry Granulating

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 to each other using 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

(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

These are the only methods used anywhere in the world.



"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.



GRANULE FORMATION IN THE WET GRANULATING PROCESS



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

Traditional granulating meant over wetting the powders with a liquid binding solution and mixing the liquid into the powders using a kneading action.

Once the solution was thoroughly mixed into the powders then they were removed from the mixer and spread out onto tray for drying, simply referred to as a traditional tray Drying Method. The drying process can take 24-72 hours dependant on the type of solution used and how much drying needed to take place along with the climate within the manufacturing area. Water based Solutions

take significantly longer than Solvent based solutions. However, both can present different challenges. Drying in an uncontrolled environment would result in different drying times and can greatly impact the success or failure of the drying event. Thus impacting the quality and consistency of the granules being formed. Water based solution This "traditional" method of forming granules is still in use today and in some cases has advantages over newer technologies.

Newer ways to form granules using the "wet granulation process" include the use of a

more precision mixing method, greater solution control delivery and conditioned air. Conditioned air meaning that the air is filtered and humidity and air volume are controlled to the point so that processing times and are greatly reduced. What takes 24 hours in a traditions tray drying method can be greatly reduced and in some cases the end point of the drying cycle can be achieved in under an hour. The key regardless of the process is to produce a quality product using a repeatable whereby the end product is predictable, time after time.

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.



Screens are used for classifying particle sizes and to remove unwanted lumps.



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:

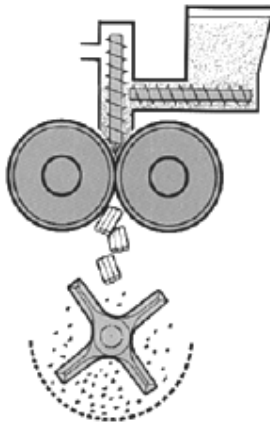
1. Granulate materials which are sensitive to heat and/or moisture.
2. Produce a uniform particle size range.

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

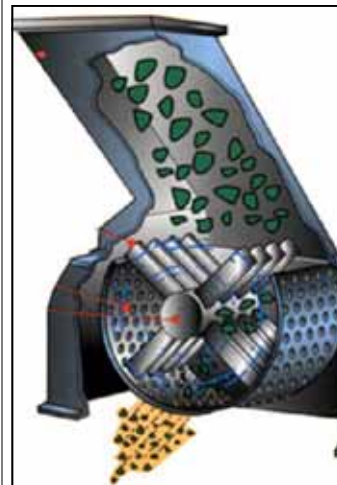
Generally we want to be as gentle with powders as possible. Some powders have high moisture content and they may be subject to compaction within the mill; others are very hard and friable and are subject to producing “fines”. Fines are powders that are very small and “dusty”, which will pass through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



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.

"The main purpose of the final blend is to distribute the lubricant"

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

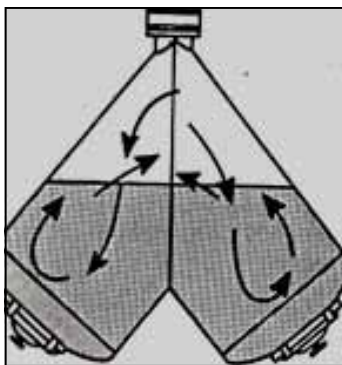
Materials go from an unmixed state to a state of relative homogenous consistency. Achieving a homogenous blend is accomplished through a combination of time and mechanical energy. Given enough time, components will pass from an unblended state to a relatively homogenous blend and back to an unblended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

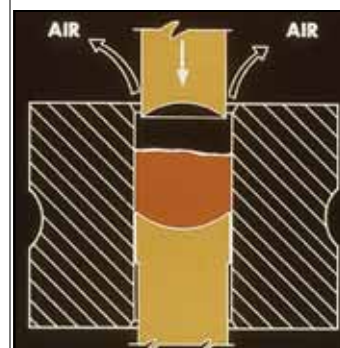
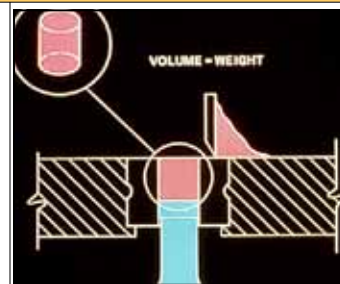
is the same for each application. The final granulation to be compressed must have three basic characteristics, all of which are critical: Flow, Compress and Eject.

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.

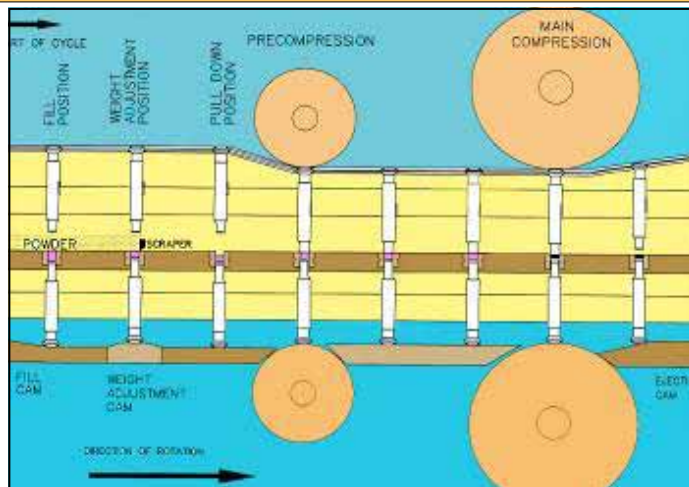
“During compression the air evacuation forces fine particles to the edge of the tablet, since “fines” will not compress, the result is Capping”

COMPRESSION

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.



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 Nutritional 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 is it an 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.

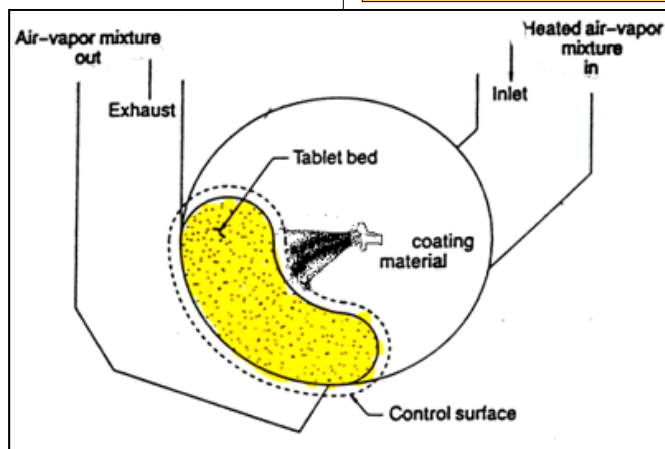
The solution is pumped into the guns and the air combines with the solution for atomization into a very fine mist.

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

Veggie Caps & 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. Or instead a gravure roll a flat plate is used in the case of the PAD printer.

All offset printing, regardless of equipment manufacturer, is accomplished in this manner. Gravure rolls & flat

plates 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.

UNDERSTANDING GMP REGULATIONS



Reading the GMP regulations in their entirety is challenging. Yet every company that manufactures, packages, and/or labels a pharmaceutical, nutritional, or dietary supplement must understand and apply these regulations to their business in order to be in compliance. Short of reading the regulations word for word, there is a way to summarize what they say. While this won't tell you each segment your quality system must cover or which documents you need, it will give you a condensed understanding of what compliance with GMP is all about.

Many people want to know just what is GMP? GMP stands for Good Manufacturing Practices. GMP really means the planning, design, processes, equipment, and people put into place to ensure that the finished products produced result in the same quality product, each and every single time. Most GMP requirements are somewhat vague in that they state the minimum requirement for compliance. This allows each company to decide how to best implement the necessary controls. While providing some compliance flexibility, it also requires that the manufacturer fully understand and

interpret the requirements. Another important concept of GMP compliance is that the regulations are in place not only to encourage companies to make safe, pure, and effective products, but to protect the consumer from purchasing and using products that are possibly adulterated, misbranded, or generally unsafe. Since we are all consumers, it is easy to see why GMP compliance is so important.

BEING PREPARED FOR THE FDA

“A company must produce products that are safe, pure and effective”

The FDA expects companies to fully understand their processes. They must take proactive steps to produce these products so that they are safe, pure, and effective. Their products must not be adulterated or contaminated. This means using a quality approach to reduce or eliminate the chance of products being contaminated, having mix-ups, or errors in any of the processes it takes to produce the product. The central nervous system of this is the Company Quality System. This is the system by which a company employs a philosophy and techniques to define the specifications and requirements needed to produce a quality product. Quality must be built into the product by designing it into each process, from the specifications of raw materials through the storage of the finished product prior to distribution. While this is no small undertaking, this is exactly the proactive steps the FDA expects and companies must use in order to be in compliance and to be as cost effective and productive as possible.

THE QUALITY SYSTEM



One of the most critical points of the Quality System is having all the people and processes in the company be fully integrated with each other. This is especially important for the Quality Team. The Quality Team interacts with every aspect of the organization from new product development through customer

complaints. If the Quality Team lacks the understanding of any part of the process, true Good Manufacturing Practice will suffer. It is not enough to have procedures for performing tests, taking samples, and verifying specifications; the Quality Team must understand how the processes work so that every-

one is fully onboard with the efforts of producing quality products. The Quality System must be part of the company culture and not a tool used just for the Quality Team.

TRAINING IN YOUR FACILITY

Manufacturing Nutritional Supplements is a in-house training seminar that will provide each participant with a comprehensive knowledge of the complete manufacturing process. It will provide the tools for improving skills for everyone related to the tablet & capsule 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 machine attendants into "Professional Operators". It is all about improving skills within a company which 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 Nutritional Supplement 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 be on the same page. Managers and Supervisors must now understand the fundamentals, because if they do not know the basics they cannot properly support the demands of the new manufacturing environment.

We will cover Trouble shooting and root cause analysis and utilize a systematic approach to all elements of manufacturing nutritional supplements. 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 ideas between departments. Tablet & capsule quality is the report card for all unit operations and represents the company long after it has left the manufacturing floor. This 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 tailored to meet the needs of the customer. We guarantee that this course will be both educationally beneficial and enjoyable.

Michael D Tousey, Technical Director & Owner

Manufacturing Nutritional Supplements

Topics & Schedule

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

- Introduction to The Manufacturing Process
- Unit Operations
- Principles cGMP's
- The three key Principles of Preparing Powders
- What's in a Formulation and Why
- Granulating, Milling, and Blending

Day 2 8:00am - 4:00pm (this is a suggested schedule only)

- Quality Systems
- Tablet Compression & Tooling
- Film Coating
- Printing
- Encapsulation
- Root Cause Analysis, 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 *RE-SCHEDULES* training without a minimum 15 day written notice, Techceuticals reserves the right to charge the Customer for the resulting travel and/or accommodation rebooking 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."

Please call us for a quote to come to your facility, or request dates for our next public course in your area.

Techceuticals
365 Red Cedar Street, Suite 202
Bluffton, SC 29910
Phone: 843 815 7441
Fax: 843 815 7446
Email: sales@techceuticals.com



Mike Tousey

Dear Valued Customer,

Please join us at our next public seminar or invite us into your facility for one of the most rewarding training programs your manufacturing team will experience. Call me directly for a quote.

I have been involved in the industry since 1973 and have provided training to 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



TEHCCEUTICALS

*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 2nd shift from 3pm until 10 pm and then present the same information to 1st 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.

www.techceuticals.com