**REVIEW ARTICLE**

**Tablet Coating Technology: An Overview**

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**ABSTRACT:**
Tablet coatings must be stable and strong enough to survive the handling of the tablet. Modern tablet coatings are polymer and polysaccharide based with plasticizers and pigments included. Coatings are necessary for tablets that have an unpleasant taste, and a smoother finish makes large tablets easier to swallow, extend the shelf-life of components, controlled release, bioadhesive and sustained drug release. We were reviewed here pharmaceutical coating process, type of coatings, stability testing, quality control and advanced coating technology. This review concluded on Coating enhances the quality of products and controls the bioavailability of the drug which provides physical protection to facilitate handling. This includes minimizing dust generation in subsequent unit operations.

**KEYWORDS:** Tablet Coating.

**INTRODUCTION:**

Coating is the uniform deposition of a layer of material on or around a solid dosage form. This is the last stage in tablet formulation and it is done to protect the tablet from temperature and humidity constraints. It is also done to mask the taste, give it special characteristics, distinction to the product, and prevent inadvertent contact with the drug substance. The most common forms of tablet coating are sugar coating and film coating.

Although sugar-coating was popular in the past, the process has many drawbacks. Modern tablet coatings are polymer and polysaccharide based, with plasticizers and pigments included. Tablet coatings must be stable and strong enough to survive the handling of the tablet, must not make tablets stick together during the coating process, and must follow the fine contours of embossed characters or logos on tablets. Coatings can also facilitate printing on tablets, if required.

Coatings are necessary for tablets that have an unpleasant taste, and a smoother finish makes large tablets easier to swallow. Tablet coatings are also useful to extend the shelf-life of components that are sensitive to moisture or oxidation. Opaque materials like titanium dioxide can protect light-sensitive actives from photo degradation. Special coatings (for example with pearlescent effects) can enhance brand recognition. If the active ingredient of a tablet is sensitive to acid, or is irritant to the stomach lining, an enteric coating can be used, which is resistant to stomach acid and dissolves in the high pH of the intestines. Enteric coatings are also used for medicines that can be negatively affected by taking a long time to reach the small intestine where they are absorbed. Coatings are often chosen to control the rate of dissolution of the drug in the gastrointestinal tract. Some drugs will be absorbed better at different points in the digestive system. If the highest percentage of absorption of a drug takes place in the stomach, a coating that dissolves quickly and easily in acid will be selected. If the rate of absorption is best in the large intestine or colon, then a coating that is acid resistant dissolves slowly would be used to ensure it reached that point before dispersing.

The decision to coat a tablet is usually based on one or more of the following objectives:

- Protect the drug from its surrounding environment (air, moisture, and light), with a view to improving stability.
- Mask unpleasant taste, odor, or color of the drug.
- Increase the ease of ingesting the product for the patient.
- Impart a characteristic appearance to the tablets, which facilitates product identification and aids patient compliance.
Provide physical protection to facilitate handling. This includes minimizing dust generation in subsequent unit operations.

- Reduce the risk of interaction between incompatible components. This would be achieved by coating one or more of the offending ingredients.
- Modify the release of drug from the dosage form. This includes delaying, extending, and sustaining drug substance release.

Equipment Classification:

1. Pan Coating: Pan coating subclasses primarily are distinguished by the pan configuration, the pan perforations, and/or the perforated device used to introduce process air for drying purposes. Perforated coating systems include both batch and continuous coating processes.

- Conventional Coating System
- Perforated Coating System

Tablet coating pan

Tablet coating pan is used for sugar and film coating of tablets, pallets, granules etc. It consists of ellipsoidal shaped pan made of stainless steel sheet and mounted on the gear box shaft which is driven by an electric motor. The complete drive unit is enclosed in a sturdy cabinet. Hot air blower with flexible SS Pipe heaters is provided with thermostat control for fast drying. Heaters are interlocked with the blower motor therefore unless the blower is on, heater does not start. Available in Standard and GMP model with SS 304 or 316 contact parts.

The coating drum is supported from the rear by a cantilever support bearing. This design provides complete isolation of the mechanical drive system from the product processing area, ensuring maximum containment and facilitating cGMP compliance. The Signature Series is available with unique charging and discharging methods that virtually eliminate operator exposure especially critical in the processing of high potency compounds.

An integrated Wash-in-Place/Clean-in-Place system is an essential aspect of Glatt’s design. Coupled with a watertight housing, the WIP/CIP provides complete cleaning of the coating drum and interior housing. A set of hinged access doors on the left and right side of the housing provides easy access to the exhaust and inlet air connections for cleaning, inspection and maintenance. Pilot scale equipment is available at Glatt’s Ramsey New Jersey.

Multi-Drum Lab Perforated Pan Coater:

This lab coater is capable of handling up to four different sized pans – 30 in., 24 in., 20 in. and16 in. – providing maximum flexibility from 2 liter through 56-liter batch sizes. This system can be used for either clinical or feasibility testing. The unit is uniquely designed with an integrated air handling system that can be located either within the process room or in a separate mechanical area. Both sugar coating and aqueous film coating processes can be run within this single system.
2. Gas Suspension

Gas suspension subclasses primarily are distinguished by the method by which the coating is applied to the substrate.

- Fluidized Bed
- Spray Congealing/Drying

Fluid Bed process system

The fluidized bed coating process is a simple dipping process that can be either conventional or electrostatic. In the conventional fluidized bed process, the fluidized bed is a tank with a porous bottom plate. The plenum below the porous plate supplies low pressure air uniformly across the plate. The rising air surrounds and suspends the finely divided plastic powder particles, so the powder-air mixture resembles a boiling liquid as shown in Figure-4 Products that are preheated above the melt temperatures of the powder are dipped in the fluidized bed, where the powder melts and fuses into a continuous coating. High transfer efficiency results from little drag out and no dripping.

Figure-4 Illustration of the fluidized bed process.

The fluidized bed powder coating method is used to apply heavy coats in one dip, 3 - 10 mils (75 - 250 µm), uniformly to complex shaped products. It is possible to build a film thickness of 100 mils (2500 µm) using higher preheat temperatures and multiple dips.

Drying/Cooling: These are the most frequent applications of fluid beds. Different process systems are applied depending upon product, volatiles, operational safety and environmental requirements.

Spray Coating machine:

This is an attachment to the existing coating pan and most suitable for the rapid and uniform coating of Tablets, Granules and Pallets.

The system consists of a stainless steel 316 quality pressure vessel provided with SS jacket with electric heaters and thermostat control and provided with safety valve, pneumatic oscillating type stirrer fitted on the top of the vessel. Two Spray guns are mounted on a portable SS stand. The spray nozzles are operated with the help of a
pneumatic cylinder connected with digital timer and solenoid valves programmed for a sequential spray. The guns can be tilted at any desired angle. The vessel is filled with the coating solution and pressurized with oil moisture free compressed air to get uniform atomized conical spray over the tablet bed inside the coating pan. Capacity: 10/25/ 50/ 100 /150 liters.

3. Vacuum Film Coating: Although there may be differences in the jacketed pan, baffle system, or vacuum source, no vacuum film coating subclasses have been identified.

4. Dip Coating: Because of the custom design associated with this class of coating, no dip coating subclasses or examples have been identified.

5. Electrostatic Coating: Because of the custom design associated with this class of coating, no electrostatic coating subclasses or examples have been identified.

6. Compression Coating: Compression forces and amount of outer coating layer affecting the time-controlled disintegration of the compression-coated tablets prepared by direct compression with micronized ethyl cellulose.
Pharmaceutical Coating Process:

1. **Sugar Coating** - Deposition of coating material onto the substrate from aqueous solution/suspension of coatings, based predominately upon sucrose as a raw material.

2. **Film Coating** - The deposition of polymeric film onto the solid dosage form.

3. **Micro-encapsulation** - The deposition of a coating material onto a particle, pellet, granule, or bead core. The substrate in this application ranges in size from submicron to several millimeters. It is this size range that differentiates it from the standard coating described in the above two points.

4. **Compression Coating** - Compression forces and amount of outer coating layer affecting the time-controlled disintegration of the compression-coated tablets prepared by direct compression with micronized ethyl cellulose

Operating Principles:

a. **Pan Coating**: The uniform deposition of coating material onto the surface of a solid dosage form, or component thereof, while being translated via a rotating vessel.

b. **Gas Suspension**: The application of a coating material onto a solid dosage form, or component thereof, while being entrained in a process gas stream. Alternatively, this may be accomplished simultaneously by spraying the coating material and substrate into a process gas stream.

c. **Vacuum Film Coating**: This technique uses a jacketed pan equipped with a baffle system. Tablets are placed into the sealed pan, an inert gas (i.e. nitrogen) is used to displace the air and then a vacuum is drawn.

d. **Dip Coating**: Coating is applied to the substrate by dipping it into the coating material. Drying is accomplished using pan coating equipment.

e. **Electrostatic Coating**: A strong electrostatic charge is applied to the surface of the substrate. The coating material containing oppositely charged ionic species is sprayed onto the substrate.

f. **Compression Coating**: Compression forces and amount of outer coating layer affecting the time-controlled disintegration of the compression-coated tablets prepared by direct compression with micronized ethyl cellulose.

g. **Ink-Based Printing**: The application of contrasting colored polymer (ink) onto the surface of a tablet or capsule.

h. **Laser Etching**: The application of identifying markings onto the surface of a tablet or capsule using laser-based technology.

i. **Drilling**: A drilling system typically is a custom built unit consisting of a material handling system to orient and hold the solid dosage form, a laser (or lasers), and optics (lenses, mirrors, deflectors, etc.) to ablate the hole or holes, and controls. The drilling unit may include debris extraction and inspection systems as well. The sorting, orienting, and holding equipment commonly is provided by dosage form printing equipment manufacturers, and is considered ancillary in this use.

Coating Application Equipment:

The following types of equipment are used in the application of various types of coating. Each type has its own characteristics and are broken down as follows:

**Non-spray techniques**: -

- Dip Coating
- Flow coating
- Dip-Spin Coating
- Roll Coating (Direct and reverse)

**Spray Techniques**: -

- Conventional Air Atomization
- Airless Atomization
- Air-Assisted Airless Atomization
- High Volume, Low Pressure Air-Atomizing Spray
- Flame Spray Coating
- Fluidized Bed

**Electrostatics**: -

- Electrostatic spray
- Rotary Atomization

**Dip coating**

Dip coating refers to immersing a piece into a tank containing the coating material, removing the piece from the tank, and allowing it to drain. The coated piece can then be dried by force-drying or baking. Dipping is extremely dependent on the viscosity of the paint, is very messy, and may be highly hazardous. The viscosity of the paint in a dip tank must remain practically constant if the deposited film quality to remain high. Dip coating is well suited for high production painting of relatively simple shapes. Transfer efficiency is very high, all contact areas are coated, equipment requirements are low, and the process can be conveyorized and automated. Surface appearance tends to be poor-to-fair. The process is generally used to apply primers, not topcoats.

**Flow Coating**

In flow coating, the part is suspended, and the coating is poured over it. The excess material drips off and is collected for reuse. In a flow-coat system, 10 to 80 separate streams of coating material are directed to impinge on the parts. The streams flow out of drilled pipes or through short, crimped pipe outlets. Nozzles may be used, but they cannot be the atomizing type. Flow coating is usually used for large or oddly shaped parts that are difficult or
impossible to dip coat. Flow coating achieves a high paint transfer efficiency, often 90% and higher.

**Dip-Spin Coating**
In dip-spin coating, a wire basket containing up to 50 pounds of parts is immersed in a reservoir of paint. The basket is raised, the parts are allowed to drain, the basket is spun to remove excess paint, and the parts are dumped onto a mesh conveyor belt, then moved through a bake oven. The entire process is automatic. The main advantage is the extremely high production rate. Dip-spin coaters are designed to paint large-quantity batch loads of small parts, such as hairpins, clips, and fasteners. Some of the painted parts dumped on the conveyor may stick together in the oven, leaving paint voids when they are separated. These parts may be run through the process a second time to eliminate the defects.

**Roll Coating (direct and reverse)**
Roll coating is the process of applying a coating to a flat substrate by passing it between rollers. Paint is applied by one or more auxiliary rolls onto an application roll, which rolls across the conveyed flat work. After curing, the coated substrate is then shaped or formed into the final shape without damaging the coating. Roll coating is divided into two types: direct and reverse roll coating. In direct roll coating, the applicator roll rotates in the same direction as the substrate moves. In reverse roll coating, metal feed stock is fed between the rolls as a continuous coil. The applicator roll rotates in the opposite direction of the substrate. Roll coating is limited to flatwork and is extremely viscosity-dependent. Physical properties should be checked often to ensure results of post forming. These tests should include adhesion, impact resistance, flexibility, and hardness.

**Conventional Air Atomization**
In conventional or air atomized spraying, the coating is supplied to a spray gun by siphon, gravity, or pressure feed. When the gun trigger is pulled, the coating flows through the nozzle as a fluid stream. Compressed air from the center of the nozzle surrounds the fluid with a hollow cone as it leaves the nozzle, breaking the coating into small droplets and transferring velocity to it. Additional jets of compressed air from the nozzle break up the droplets further and form an elliptical pattern. Conventional air spray is the oldest spray process. It offers the best control of spray patterns and degree of atomization. This system produces the finest atomization and, therefore, the finest finishes. Conventional spray will also spray the widest range of coating materials of the four techniques. Conventional spray has low transfer efficiencies, ranging from 30 to 70% and uses large amounts of compressed air (7 to 35 cpm at 100 psi). The paint-covered rollers have large surface areas that contribute to heavy solvent evaporation. This can pose a fire hazard from flammable solvents.

**Airless Atomization**
This is the fastest spray application method. It can deliver twice the amount of material as a compressed air system. This allows airless guns to be used advantageously on high-speed production lines or where surface areas are large. Transfer efficiency is higher than conventional spray because of reduced fog and overspray. The absence of blow air associated with the gun simplifies application. Airless atomization does not use compressed air directly to atomize the coating. Hydraulic pressure is used to pump the coating material through a small orifice (0.007 to 0.072 inch) in the nozzle at 500-4500 psi. As the coating leaves the nozzle, it breaks into small, finely atomized droplets that retain enough velocity to carry them to the work surface. The high velocity of the fluid stream and spray pattern as it exits the gun and hose is a potential hazard.

**High Volume, Low Pressure Air-Atomizing Spray (HVLP):**
HVLP is a type of air atomized spraying. HVLP guns operate at pressures of 0.1 to 10 psi at the air nozzle and use 15 to 30 cpm of air. However, there are many factors that affect overspray, most important of which is the manner in which the painter sets the air and fluid pressures, fan width, and gun-target distance. The low atomizing air pressure of an HVLP gun minimizes the amount of bounce-back paint fog and reduces the amount of atomized paint that is blown past a part as overspray. The higher transfer efficiency helps hold down operating costs by reducing paint waste. HVLP has higher transfer efficiency than conventional air spray, up to 65 to 75%. This results in lower material use (reduces costs), less spray booth maintenance and cleanup, and less hazardous waste. The droplet size is not as fine as conventional air atomization. To achieve good finish quality on some applications, additional polishing or coating reformulation may be necessary. However, if surface preparation is done properly, spray application should have good adhesion. HVLP may be too slow for some high-production lines. Increasing fluid flow to increase speed may reduce finish quality.

**Flame Spray Coating**
Flame spraying (combustion spraying) is a process that deposits finely divided metallic or nonmetallic materials onto a surface in a molten or semi-molten state. The material to be deposited is usually a powder, wire, or rod. It is fed at a controlled rate to the flame spray gun, which heats the material to the molten or semi-molten state with combustible gases or electricity. Compressed gas then propels the particles to the surface at a speed of 10 to 20 meters per second. The particles hitting the surface flatten and conform to the surface, forming the coating. Generally, no additional heating or curing is required. Applications include spraying wear-resistant coatings, spraying insulators, and protecting surfaces from corrosion. Thermal spray coatings are used on a wide variety of applications, from aircraft engine components and biomedical prostheses to bridges and pumps. The process is compatible with most surfaces. It has several advantages when coating...
thermoplastics: no primer is required; it covers sharp edges and welds well; the coating can be used as soon as it cools; there are no runs, drips, sags, or incomplete cure; coatings have high chemical, impact, and abrasion resistance. Flame-sprayed thermoplastics may have a slight orange peel appearance. Since the coating materials are solids, no solvents are used.

Electrostatic Spray
In electrostatic coating, the fluid is atomized, and then negatively charged. The part to be coated is electrically neutral, making the part positive with respect to the negative coating droplets. The coating particles are attracted to the surface and held there by the charge differential until cured. With an electrostatic spray gun, the droplets pick up the charge from an electrically charged electrode at the tip of the gun. The charged particles are given their initial momentum from the fluid pressure/air pressure combination. Electrostatic spraying offers high transfer efficiency (65% to 95%) and excellent edge coverage. The attraction between paint droplets and the part is strong enough to cause paint overspray that misses the part to curve back, which contributes to the high transfer efficiencies. Electrostatic application does not coat recessed areas (Faraday cages) as well as nonelectrostatic application. The charged droplets tend to be attracted to the sides of the recess and sharp edges instead of penetrating to the bottom. All electrically conductive materials near the spray area such as the material supply, containers, and spray equipment must be grounded to prevent static buildup. All hangers, conveyors, etc. must be kept clean to ensure conductivity to ground. Charges build up on ungrounded surfaces. Operators grounding out these surfaces may receive a severe electrostatic shock.

Rotary Atomization
Rotary atomizers are one of the possible methods of atomization used with electrostatic coating processes. Instead of air or fluid pressure, rotary atomizers use centrifugal force to atomize coating material. As a general rule of thumb, the faster the rotational speed, the greater the centrifugal force and the finer the atomization. Rotary atomizers are usually made from a high-quality steel and come in two basic shapes: disks and bells (cups). The combination of high rotational speeds and electrostatic charging voltage atomize the coating into extremely fine particles to ensure a high-quality finish. The disks are thin, relatively flat, and round. They come in two diameter ranges, depending on whether the rotational speed is low or high. Low-speed disks are 10 to 26 inches in diameter, and the high-speed disks are about 5 to 8 inches in diameter. Rotary bell atomizers are shaped like cups, truncated cones, or shallow sauce dishes. The bells range from about 1 to 5 inches in diameter. Parts must be electro-statically conductive and of simple geometry

Types of Coating:
Film Coating:
Film coating is a process that involves the deposition of a thin, but uniform, film on to the surface of the substrate. Film coating is a very flexible process that allows a broad range of products (e.g. tablets, powders, granules, nonpareils, capsules) to be coated. Film Coating essentially are typically applied continuously to a moving mass of product, usually by means of a spray technique, although manual application procedures have been used.

In the early years of film coating, the major process advantages result from the greater volatility of the organic solvents used; however, the use of such organic solvents has created many Potenial problems, including
1. Flammability hazards
2. Toxicity hazards
3. Concerns over environmental pollution
4. Cost (relating either to minimizing items 1 to 3 or to the cost of the solvents themselves)

Materials used for Aqueous Film Coating
- An ideal film coating materials should have the following attributes:
  - Solubility in solvent of choice for coating preparation.
  - Solubility required for the intended use, e.g., free water solubility, slow water solubility, or pH-dependent solubility (enteric coating)
  - Capacity to produce an elegant looking product.
  - Stability in the presence of heat, light air, and the substrate being coated. The film properties should not change with aging.
  - Essentially no color, taste or odor.
  - Compatibility with common coating solution additives.
  - Nontoxicity with no pharmacological activity, and ease of application to the particles or tablets.
  - Resistance to cracking, and provision of adequate moisture, light, odor, or drug sublimation barrier when desired.
  - No bridging or filling of the debossed tablet surfaces by the film former.
  - Ease on printing procedure on high-speed equipment.

The basic components of a film coating system are Polymers
As the tablet coating technique was changed from sugar coating to film coating, polymers like methyl cellulose, hydroxypropyl methylcellulose, (HPMC) ethyl cellulose etc. became the main coating materials in place of sugar. The higher viscosity grades of HPMC though provided film
with good tensile strength but produces films having poor adhesion with the core surface and very often one can easily peel-off the film from the tablet surface. The same HPMC when dissolved in water give rise to many other problems like -

- High solution viscosity
- Water is a poor solvent for HPMC as compared to organic solvents, therefore, solution preparation is difficult
- Water has much higher surface tension than organic solvents, material wetting is difficult resulting in poor film adhesion
- Films produced using water as solvent has poor mechanical properties like low tensile strength, higher modulus of elasticity and low film adhesion.

Therefore, the selection of correct polymer system is very critical for the success of aqueous coating formulation. By selecting the lower viscosity polymers, the solid content in the coating formulation can be increased which will result in lesser amount of water required which in turn can increase the coating speed. However, the lower viscosity HPMC produces the films with lower tensile strength. As described earlier the film produced by HPMC using water as solvent system may have poor film adhesion resulting in easy peel-off from the tablet surface. To overcome this problem some formulators have used the combination of HPMC and HPC. HPC provides better film adhesion to the substrate then HPMC, however, other mechanical properties of HPC are not comparable to HPMC, moreover, the cost of HPC is much higher then HPMC and thus makes the formulation economically non-viable. Various other polymers are also used in developing aqueous film coating formulations like Sod. CMC, PVA, PVP, Sod. Alginate, PEG etc. either alone or in combination

Solvent:
The primary function of a solvent system is to dissolve or disperse the polymers and other additives and convey them to substrate surface .All major manufactures of polymers for tablet coating provide basic physical-chemical data on their polymers. These data are usually helpful to a formulation. Some important considerations for an ideal solvent are as follow:

i. It should either dissolve or disperses the polymer system.
ii. It should easily disperse other coating solution components into the solvent system.
iii. Small concentration of polymers (2 to 10%) should not result in an extremely viscous solution system (>300 cps), creating processing problem.
iv. It should be colorless, tasteless, odorless, inexpensive, nontoxic, inert, and nonflammable.
v. It should have rapid drying rate (the ability to coat a 300 kg load in 3to 5 hours).
vi. It should have no environmental impact.

Widely used solvents are:-
Water,Ethanol,Methanol,Isopropanol,Chloroform,Acetone, Methylethyl-ketone, ethylchloride.

**Plasticizers:** The next most important component of the coating formulation is plasticizer. A wide range of plasticizers are available to the formulator such as phthalate esters, phosphate esters, other esters like citrates, stearates, olate, oils, glycerol, glycols etc. The important factor to be considered here are:

- Water solubility of the plasticizer: Hydrophobic plasticizers will create problems in solution preparation and can affect the D.T. and dissolution profile of the finished product.

- Water vapor transmission rate through the film: Higher concentration of plasticizer in the film generally tends to increase the water vapor permeability.

Concentration in the coating formulation: Higher concentration of plasticizer reduces the modulus of elasticity (a desired effect) and thus reduces the possibility of logo bridging but also reduce the tensile strength of the film (undesired effect).

- Film adhesion generally tends to increase with increased concentration of plasticizer.

- Higher concentration of plasticizer can lead to its bleeding (making the tablet surface feel oily) In most of the cases presence of plasticizer improves the gloss level in the finished product (depending on the quality and concentration of the plasticizer).

- Volatility of the plasticizer: Aqueous coating generally need higher drying capacity during the coating cycle due to less volatility of water, if the plasticizer is more volatile e.g. propylene glycol, much of the plasticizer may get lost during the coating process. Therefore, one needs to strike a balance between the desired and undesired effects of the plasticizer and optimize its concentration in the coating formulation. Many a time’s use of combination of plasticizer becomes necessary to achieve the most optimum results.

**Additives**
The properties and composition of other components of the film coating formulation also need to be considered and optimized to get the most desired effects without affecting the quality of the film. Various other components which could be used in coating formulation are –

- Pigments
- Opacifier
- Anti-tacking agent
- Film adhesion enhancer
- Sweeteners
- Flavors
- Anti foaming agent
The concentration and the properties of each of these excipients can affect the quality of the resulting film, e.g., the opacity of the film depends on the difference between the refractive index of the polymer and other components of the coating formulation. The lake colors used in film coating has refractive index similar to that of various polymers, thus the opacity of lake colors is very poor.

- The most commonly used anti-tack agent is Talc, which if used in higher concentration tends to settle down from the coating suspension, thus affecting the composition of suspension during the coating process. Further, it is poor pacifier and tends to produce translucent films.

- As the aqueous film coating need higher drying capacity, the volatile matter in the flavors used may get lost, changing the nature of the flavor. These volatile matters may also interact with other components of the coating formulation and can affect their properties. One, therefore, need to use specific flavors and incorporate them in the coating formulation in such a manner so that it does not affect the film quality.

It, therefore, once again a lot of balancing acts while developing the optimized coating formulation.

Colorants: - they are used to provide distinctive color and elegance to a dosage form. To achieve proper distribution of suspended colorants in the coating solution requires the use of fine powdered colorants (<10 microns). The most common colorants in use are certified Food and Cosmetic (FD & C) or Drug and Cosmetic (D & C) colorants. These are synthetic dyes or lakes of dyes. Lakes are derived from dyes by precipitating with carriers, e.g., alumina or talc.

Modified-Release Film Coatings:
Film coating can be applied to pharmaceutical products to modify drug release. The USP describes two types of modify release dosage forms. Namely those are delayed-release and those that are extended-release. Delayed-release products often are designed to prevent drug release in the upper part of the GI tract. Film coating used to prepare this type of dosage form is commonly called enteric-coating. Extended-release products are designed to extend drug release over periods of time, a result that can be achieved by the application of a sustained- or controlled-release film coating.

Enteric coating:
An enteric coating is a coating put on a pill or capsule so that it doesn’t dissolve until it reaches the small intestine. While the coating may make a pill easier to swallow and will mask bitter-tasting medicine, enteric coatings are primarily used because the drug is likely to cause stomach irritation or because its effectiveness might be reduced by stomach acids or enzymes. Enteric coatings work because they are selectively insoluble substances -- they won't dissolve in the acidic juices of the stomach, but they will when they reach the higher pH of the small intestine.

Some of the important reason for enteric coating is as follows:
1. To protect acid-labile drugs from the gastric fluid, e.g., enzymes and certain antibiotics.
2. To prevent gastric distress or nausea due to irritation from a drug, e.g., sodium salicylate.
3. To deliver drugs intended for local action in a concentrated from and bypass systemic absorption in the stomach.
4. To deliver drugs that are optimally absorbed in the small intestine to their primary absorption site in their most concentrated form.
5. To provide delayed-release component for repeat-action tablets.

An ideal enteric coating material should have the following properties:
1. Resistance to gastric fluids.
2. Ready susceptibility to or permeability to intestinal fluids.
3. Compatibility with most coating solution components and drug substances.
4. Stability alone and in coating solutions. The film should not change on aging.
5. Formation of the continuous (uninterrupted) film.
7. Low cost.
8. Ease of application without specialized equipment.
9. Ability to be readily printed or to allow film to be applied to debossed tablets.

Most enteric coatings won't dissolve in solutions with a pH lower than 5.5.

Enteric Coating Material:
Cellulose acetate phthalate (CAP)
CAP has been widely used in the industry. It has the disadvantage of dissolving only above pH 6, and possibly delaying the absorption of drugs. It is also hygroscopic and relatively permeable to moisture and gastric fluids, in comparison with some other enteric polymers. CAP films are susceptible to hydrolytic removal of phthalic and acetic acids, resulting in a change of film properties. CAP films are brittle and usually formulated with hydrophobic film forming materials or adjuncts to achieve a better enteric film.

Acrylic polymers:
Two forms of commercially available enteric acrylic resins are Eudragit L and Eudragit S. Both resins produce films that are resistant to gastric fluids L and S are soluble in intestinal fluids at pH 6 and 7, respectively. Others polymers
- Methacrylic acid copolymers
- Polymethacrylic acid/acrylic acid copolymer

Hydroxypropyl methylcellulose phthalate (HPMCP)
It is present in three commercially forms HPMCP 50, 55, and 55S (also known as HP-50, HP-55, and HP-55-S).
HPMCP is the trade name of hydroxypropyl methylcellulose phthalate. These polymers dissolve at a lower pH (at 5 to 5.5).

**Polyvinyl acetate phthalate (PVAP)**
PVAP is manufactured by the esterification of partially hydrolyzed polyvinyl acetate with phthalic anhydride. This polymer is similar to HP-55 in stability and pH-dependent solubility. It is supplied as ready-to-use or ready-to-disperse enteric systems.

Most enteric coatings are dissolved in organic solvents such as acetone, methanol, ethanol, isopropyl alcohol, ethyl acetate, methylene chloride, etc. and applied to the tablets or capsules. The coatings might be sprayed on or applied as a chemical vapor, or the tablets might be put in a rotating pan partially filled with the coating. The solvent evaporates, leaving the coating behind.

**Sustained-Release Coatings:**
The concept of sustained release formulation was developed to eliminate the need for multiple dosages, particularly for those drugs requiring reasonably constant blood level over a long period of time. In addition, it also has been adopted for those drugs that need to be administrated in high doses, but where too rapid a release is likely to cause undesirable side effects (e.g., the ulceration that occurs when potassium chloride is released rapidly in the gastrointestinal tract).

Formulation methods used to obtained the desired drug release rate form sustained-action dosage forms include
1. Increasing the particle size of drug
2. Embedding the drug in a matrix
3. Coating the drug or dosage forms containing the drug
4. Forming complexes of the drug with material such as ion-exchange resins

Material that have been found suitable for producing sustained-release coating include
1. Mixture of waxes (e.g., beeswax, carnauba wax) with glycerol monostearate, stearic acid, palmitic acid, glyceryl monopalmitate, and cetyl alcohol. These provide coating that are dissolved slowly or broken down in the GI tract.
2. Shellac and zein remain intact until the pH of gastrointestinal contents become less acidic.
3. Ethyl cellulose, which provides a membrane around the dosage form and remain intact throughout the GI tract. However, it does permit water to permeate the film, dissolve the drug, and diffuse out again.
4. Acrylic resins, behave similarly to ethyl cellulose as a diffusion-controlled drug-release coating material.
5. Cellulose acetate (diacetate and triacetate).

**Potential Advantages of Modified-Released Drug**
1) Avoid patient compliance problems.
2) Employ less total drug.
   • Minimize or eliminate local side effects.
   • Minimize or eliminate systemic side effects.
   • Obtain less potentiation or reduction in drug activity with chronic use.
   • Minimize drug accumulation with chronic dosing.
3) Improve efficiency in treatment.
   • Cure or control condition more promptly.
   • Improve control of condition (i.e., reduce fluctuation in drug level).
   • Improve bioavailability of some drugs.
   • Make use of special effects (e.g., sustained-release aspirin for morning relief of arthritis by dosing before bedtime).
4) Economic saving.

**Sugar coating:-**
Sugar coating is done by rolling the tablets in heavy syrup, in a similar process to candy making. It is done to give tablets an attractive appearance and to make pill-taking less unpleasant. However the process is tedious and time-consuming and it requires the expertise of highly skilled technician. It also adds a substantial amount of weight to the tablet which can create some problems in packaging and distribution. The sugar coating process involves several steps, the duration of which ranges from a few hours to few days. The basic sugar coating involves the following steps:
   o Sealing,
   o Subcoating,
   o Syruping (smoothing),
   o Polishing.
   o Printing

The tablet preferably has deep convex surfaces with thin rounded edges to facilitate sugar coating.

**Seal Coating:**
To prevent moisture penetration into the tablet core, a seal coat is applied. This is especially needed in pan-ladling processes, in which localized over wetting of a portion of tablet occurs. Without a seal coat, the over wetted tablets would absorb excess moisture, leading to tablet softening or disintegration and affecting the physical and chemical stability of the finished product. Zein is an alcohol-soluble protein derivative from corn that has also been used as an effective sealant.

**Subcoating:**
The subcoating is applied to round the edges and build up the tablet size. Sugar coating ca increase the tablet weight by 50 to 100%. The subcoating steps consists of alternately applying a sticky binder solution to the tablet followed by a dusting of subcoating powder and then drying.

**Syrup (Smoothing/Color) Coating:**
The purpose of this steps is to cover and fill in the imperfection in the tablet surface caused by the subcoating step, and to impact the desired color to the tablet. Dilute
colorants can be added to this phase to provide a tinted base that facilitates uniform coloring in later steps.

Polishing:
The desired luster is obtained in this final step of the sugar process. The tablet can be polished in clean standard coating pans, or canvas-lined polishing pans, by carefully applying powdered wax (beeswax or carnauba).

Printing:
To identify sugar-coated tablet (in addition to shape, size and color) often it is necessary to print them, either before or after polishing, using pharmaceutical branding inks, by means of the process of offset rotogravure.

Film Defects:
Variations in formulation and processing conditions may result in unacceptable quality defects in the film coating. The source of these defects and some of their probable causes are described in the following sections.

Sticking and Picking:
Over wetting or excessive film tackiness causes tablets to stick to each other or to the coating pan. On drying, at the point of contact, a piece of the film may remain adhered to the pan or to another tablet, giving a "picked" appearance to the tablet surface and resulting in a small exposed area of the core. A reduction in the liquid application rate or increases in the drying air temperature and air volume usually solve this problem. Excessive tackiness may be an indication of a poor formulation.

Roughness: A rough or gritty surface is a defect often observed when the coating is applied by a spray. Some of the droplets may dry too rapidly before reaching the tablet bed, resulting in deposits on the tablet surface of "spray dried" particles instead of finely divided droplets of coating solution. Moving the nozzle closer to the tablet bed or reducing the degree of atomization can decrease the roughness due to "spray drying." Surface roughness also increases with pigment concentration and polymer concentration in the coating solution.

Orange-Peel Effects:
Inadequate spreading of the coating solution before drying causes a bumpy or "orange-peel" effect on the coating. This indicates that spreading is impeded by too rapid drying or by high solution viscosity thinning the solution with additional solvent may correct this problem.

Bridging and Filling:
During drying, the film may shrink and pull away from the sharp corners of an intagliation or bisect, resulting in a "bridging" of the surface depression. This defect can be so severe that the monogram or bisect is completely obscured. This mainly represents a problem with the formulation. Increasing the plasticizer content or changing the plasticizer can decrease the incidence of bridging. Filling is caused by applying too much solution, resulting in a thick film that fills and narrows the monogram or bisect. In addition, if the solution is applied too fast over wetting may cause the liquid to quickly fill and be retained in the monogram. Judicious monitoring of the fluid application rate and thorough mixing of the tablets in the pan prevent filling.

Blistering:
When coated tablets require further drying in ovens, too rapid evaporation of the solvent from the core and the effect of high temperature on the strength, elasticity, and adhesion of the film may result in blistering. Milder drying conditions are warranted in this case.

Hazing/Dull Film:
This is sometimes called bloom. It can occur when too high a processing temperature is used for a particular formulation. Dulling is particularly evident when cellulosic polymers are applied out of aqueous media at high processing temperatures. It can also occur if the coated tablets are exposed to high humidity conditions and partial salvation of film results.

Color Variation:
This problem can be caused by processing conditions or the formulation. Improper mixing, uneven spray pattern, and insufficient coating may result in color variation. The migration of soluble dyes, plasticizers, and other additives during drying may give the coating a mottled or spotted appearance. The use of lake dyes eliminates dye migration. A reformulation with different plasticizers and additives is the best way to solve film instabilities caused by the ingredients.

Cracking:
Cracking occurs if internal stresses in the film exceed the tensile strength of the film. The tensile strength of the film can be increased by using higher-molecular-weight polymers or polymer blends. Internal stresses in the film can be minimized by adjusting the plasticizer type and concentration, and the pigment type and concentration.

Tests for Coated Tablets:
I. Water vapor permeability
II. Film tensile strength
III. Coated tablet evaluations:
   i) Adhesion test with tensile-strength tester: Measures force required to peel the film from the tablet surface.
   ii) Diametral crushing strength of coated tablet: Tablet hardness testers are used. This test gives information on the relative increase in crushing strength provided by the film and the contribution made by changes in the film composition.
   iii) Temperature and humidity may cause film defects. Hence studies are to be carried out.
iv) Quantification of film surface roughness, hardness, and colour uniformity. Visual inspection or instruments are used. Resistance of coated tablet on a white sheet of paper. Resilient films remain intact, and no colour is transferred to the paper; very soft coating are readily “erased” from the tablet surface to the paper.

**Coated Tablet Evaluation**

Once the preliminary screening of formulation variables has been accomplished, the candidate coating must now be studied under tablet coating conditions. Frequently, these studies are conducted on placebo tablets or on a group of placebo tablets with a limited number of drug tablets. The drug tablets must be of essentially the same shape, size, and density as the placebos, so that their patterns of movement in the coating pan are comparable. Obviously, there should be some distinctive tablet feature to permit separation of the tablets and allow evaluation of the two coated tablets. The technique of coating two different tablets at the same time has merit only if the surface properties of the two are equivalent. If two formulations, one having a hydrophilic surface and the other a hydrophobic surface, are aqueous-coated, the coating may preferentially adhere to one of the formulations.

Evaluation of the quality of coating on a tablet involves studying not only the film per se, but also the film-tablet surface interactions. A number of test methods can be employed.

1. Adhesion tests with tensile-strength testers have been used to measure the force required to peel the film from the tablet surface. Rowe has been a prolific investigator in the area of film coating evaluation and the factors affecting film strength.

2. Diametral crushing strength of coated tablets can be determined with a tablet hardness tester. Obviously, the resistance of the uncoated tablet to crushing will be a major factor in the test results. With this test, one is seeking information on the relative increase in crushing strength provided by the film and the contribution made by changes in the film composition.

3. The rate of coated tablet disintegration and/or dissolution must also be assessed. Unless the coating is intended to control drug release, the coating should have a minimal effect on tablet disintegration or dissolution.

4. Stability studies must be conducted on coated tablets to determine if temperature and humidity changes will cause film defects. Exposure of coated tablets to elevated humidity and measurement of tablet weight gain provide relative information on the perfection provided by the film.

<table>
<thead>
<tr>
<th>Pharmacopoeias</th>
<th>TYPE OF TABLET</th>
<th>TESTS TO BE PERFORMED</th>
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<td>Labeling of inactive ingredients</td>
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Table no.2 Comparison of Different Pharmacopoeial Quality Control Tests:
Quality Control of Coated Tablet:
The most important aspects of coated tablets that must be assessed from a quality-control standpoint are appearance characteristics and drug availability. From the appearance standpoint, coated tablets must be shown to conform, where applicable, to some color standard, otherwise the dispenser and the consumer may assume that differences have occurred from previous lots, signifying a changed or substandard product. In addition, because of the physical abuse that tablets, both in their uncoated and coated forms, receive during the coating process, it is essential to check for defects such as chipped edges, picking, etc, and ensure that they do not exceed predetermined limits.

Often, to identify the products, coated tablets may be imprinted (particularly with sugar-coated tablets) or bear a monogram (commonly seen with tablets that are film coated). The clarity and quality of such identifying features must be assessed. The failure of a batch of coated tablets to comply with such preset standards may result in 100% inspection being required or the need for the batch to be reworked.

Batch-to-batch reproducibility for drug availability is of paramount importance; consequently each batch of product should be submitted to some meaningful test such as a dissolution test. Depending on the characteristics of the tablet core to be coated, tablet coatings can modify the drug release profile, even when not intended (unlike the case of enteric- or controlled-release products). Since this behavior may vary with each batch coated (being dependent, for example, on differences in processing conditions or variability in raw materials used), it is essential that this parameter be assessed, particularly in products that are typically borderline.

The in vitro performance of the coated product is evaluated by disintegration and dissolution testing. A standard disintegration test measure the time required for the tablet to break up into particles small enough to fall through a 10-mesh screen. Dissolution testing measure the amount of active drug in solution over time. A description of the standard equipment and method use for each test is given in the USP/NF. Standards of acceptance for drug products can be found in the USP/NF or the code of Federal Regulation, Title 21.

To be a valid quality control method, the in vitro test should be discriminating. This means that it should be sufficiently sensitive to reflect variation in the product caused by improper processing or by the effect of storage and aging. For this reason, modification of the media and rates of agitation are commonly adjusted to accommodate each specific product.

Ideally, the in vitro performance should reflect in vitro performance. This correlation is rare, owing to the difficulty of devising an in vitro testing method to mimic the complex and dynamic nature of the physiologic system. Drug availability can be affected by apparently minor changes in the concentration of ingredients in either the core or film formulation. Therefore, for most drug products, bioavailability testing remains the only valid assessment of the product’s in vitro performance.

Additional testing of coated tablets may also include tests for mechanical strength and for resistance to chipping and cracking during handling. Methods and devices for these tests are similar to those used for uncoated tablets.

Stability Testing of Coated Tablet:
The stability-testing program for coated products varies depending on the dosage form and its composition. Many stability-testing programs are based on studies that have disclosed the conditions a product may encounter prior to end use. Such auditions usually are referred to as normal and include ranges in temperature, humidity, light, and handling conditions. The conditions to be employed in modern stability-testing programs often conform to the guidelines established by the International Committee on Harmonization (ICH).

Limits of acceptability are established for each product for qualities such as color, appearance, availability of drug for absorption, and drug content. The time over which the product retains specified properties, when tested at normal conditions, may be defined as the shelf life. The container for the product may be designed to improve the shelf life. For example, if the color in the coating is light-sensitive, the product may be packaged in an amber bottle and/or protected from light by using a paper carton. When the coating is friable, resilient material such as cotton may be incorporated in both the top and bottom of the container, and if the product is affected adversely by moisture, a moisture-resistant closure may be used and/or a desiccant may be placed in the package. The shelf life of the product is determined in the commercial package tested under normal conditions.

The stability of the product also may be tested under exaggerated conditions. This usually is done for the purpose of accelerating changes so that an extrapolation can be made early, concerning the shelf life of the product. Although useful, highly exaggerated conditions of storage can supply misleading data for coated dosage forms. Any change in drug release from the dosage form is measured in vitro, but an in vivo measurement should be used to confirm that drug availability remains within specified limits over its stated shelf life. This confirmation can be obtained by testing the product initially for in vivo availability and then repeating at intervals during storage at normal conditions for its estimated shelf life (or longer).

Interpretation of stability data for coated, modified-release products should be undertaken with extreme care, since the diffusion characteristics of polymeric films can change significantly under exaggerated temperature conditions. This change may be confounding when trying to predict...
their diffusion characteristics under more moderate conditions and thus can prove misleading when predicting shelf life.

When elevated-temperature stability studies are conducted on products coated with aqueous polymeric dispersions (latexes or pseudo latexes), the data obtained might be more indicative of morphological changes that have occurred in the film. Such changes may result from partial destruction of the film when coated material adheres together in the container and subsequently is broken apart; additionally, these changes might result from further coalescence of the coating (which can occur when the coating is not coalesced completely during the coating process).

Stability tests usually are conducted on a product at the time of development, during the pilot phase and on representative lots of the commercial product. Stability testing must continue for the commercial product as long as it remains on the market because subtle changes in a manufacturing process and/or a raw material can have an impact on the shelf life of a product.

Of particular note is the growing interest in Process Analytical Technology. This has resulted in bringing many analytical procedures out of the laboratory and closer to the manufacturing process with which they may be associated. The desire here is to introduce, ideally as an on-line control function, specific analytical techniques that can be used to enhance the quality of the final coated products. One example is the use of near infrared techniques that can be used to analyze coated product in such a way that, for example, product moisture contents, drug contents, amount of coating applied, and even, to some extent, drug release rates can be predicted before that product is discharged from the coating process.

Another advance involves the increasing acceptance of continuous film coating processes. Current continuous processes are based on the concept of a stretched side-vented coating pan, where uncoated product is introduced at one end, passes by a whole bank of spray guns, and emerges from the other end fully coated. The advantages of this type of process include:

1. Increasing output (typical outputs are in the range of 500 to 1000 kg h⁻¹), compared to common batch processes which might coat a 250 kg batch in one to two hours, while a 500kg batch might be coated in three to four hours.
2. Reducing residence time in a process where product is typically exposed to stressful conditions (attrition, high humidities and temperatures) from several hours to about 15 minutes.
3. Improving uniformity of distribution of coating materials.

Continuous coating processes of this type are usually reserved for coating large-volume products where desired applied coating levels are in the range of 3—4% (based on the tablet core weight).

Currently, most coating processes involve the spray application of liquid coating systems where solidification of the coating is achieved through solvent removal (i.e., drying), and distribution of coating materials is facilitated through constant motion of the material being coated. A more revolutionary approach to film coating, also based on a continuous process, involves the electrostatic deposition of powder coating systems to the surface of tablets (and fusing the coating through application of heat) using principles that are based on electro photography (photocopying). Tablets are coated individually one side at a time. The advantages of this type of process are:

1. No solvents (aqueous or organic) are used.
2. The coating is deposited onto tablets in a much more precise manner than can be achieved with any other existing pharmaceutical coating process.
3. Novel imaging can be achieved.
4. Tablet surfaces can be only partially coated, thus facilitating applications involving novel drug delivery.
Another example of a new technology is the "Delsys AccuDep System" (Sarnoff Corporation, Princeton, NJ), which uses electrostatic deposition of pure drug substance onto a film substrate. Dosing is controlled by applying an electrostatic charge to spots on the film so that a cloud of oppositely charged drug particles deposits the target dose at point-of-charge neutralization. The drug-loaded film is laminated to seal the deposited doses, which can then be punched out and encapsulated or embedded in a tablet. The dosage process itself is excipient-free, but edible films are required as a substrate, and conventional excipients would be used for subsequent encapsulation or embedding in a tablet. The low levels of drug loading that are possible with this method make it best-suited for potent compounds.

The "LeQtradose" (Phoquis, Kent, UK) process uses electrostatic dry powder coating of conventional tablets to provide visually distinct coated tablets, but the coating could also be used to precision-load placebo tablets with low drug doses, provided the drug is not affected by the hot annealing process used to seal and bond the deposited powder coatings onto the tablet. The film formers must be electrostatically chargeable and thermally annealable.

"Three Dimensional Printing" (Aprieca Pharmaceuticals, Langhorne, PA, under license from the Massachusetts Institute of Technology) uses the precision of ink-jet printing with multiple print layers to build three-dimensional constructs in which the loading and spatial distribution of a drug is precisely controlled, together with a similar control of barrier materials to modify release in a programmable manner. Diffusion path lengths, the diffusivity of the polymers used, the thickness of the diffusion barriers, and the number of barriers can be varied. This system offers wide latitude in drug loading and excipient choice.

CONCLUSION:
Coating enhances the quality of products. The coating is applied to a dosage form that already in functionally complete. Coating controls the bioavailability of the drug. By the coating the drug are protect from its surrounding environment. Coating is applied to those products which has unpleasant taste and odor. Coating is done for improving the identity of the products. Coating minimizes the cross contamination due to dust elimination. It reduces the risk of interaction between in compatible components. It improves the robustness so coated products are more resistant to mishandling. Coating protects the drug by encapsulation which is inactivating by enzymes and decomposes by bacteria. Delayed-released (enteric coating) product often are designed to prevent drug release in upper part of gastrointestinal tract. Delayed-released product include repeat action tablet where time release is achieved by a barrier coating Extended-release (sustained-release) product are designed to extend the release over a period of time. The concept of sustained release formation was developed to eliminate the need of multiple dosage regimens. Extended-release products include any dosage form that maintains therapeutic blood or tissue level. Modified drug are receptor targeting drugs. They decrease the both local and systemic side effects. Minimization of accumulation in body tissue in with chronic dosing.

REFERENCES:

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