

RECENT ADVANCES IN DIFFERENT ASPECTS OF TABLET COATING

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ABSTRACT

Coated tablets are defined as tablets covered with one or more layers of mixture of various substances such as natural or synthetic resins, gums, inactive and insoluble filler, sugar, plasticizer, polyhydric alcohol, waxes, authorized colouring material and some times flavoring material. Coating may also contain active ingredient. Substances used for coating are usually applied as solution or suspension under conditions where vehicle evaporates. The present paper reviews recent advances in different aspects of tablet coating.

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INTRODUCTION

In the process of tablet pressing, it is important that all ingredients be fairly dry, powdered or granular, somewhat uniform in particle size, and freely flowing. Mixed particle sized powders can segregate due to operational vibrations, which can result in tablets with poor drug or active pharmaceutical ingredient (API) content uniformity. Content uniformity ensures that the same API dose is delivered with each tablet. Some APIs may be tableted as pure substances, but this is rarely the case; most formulations include excipients. Normally, an inactive ingredient (excipient) termed a binder is added to help hold the tablet together and give it strength. A wide variety of binders may be used, some common ones including lactose powder, dibasic calcium phosphate, sucrose, corn (maize) starch, microcrystalline cellulose and modified cellulose (for example hydroxymethyl cellulose). Often, an ingredient is also needed to act as a disintegrant that hydrates readily in water to aid tablet dispersion once swallowed, releasing the API for absorption. Some binders, such as starch and cellulose, are also excellent disintegrants. Small amounts of lubricants are usually added, as well. The most common of these is magnesium stearate; however, other commonly used tablet lubricants include stearic acid (stearin), hydrogenated oil, and sodium stearyl fumarate. These help the tablets, once pressed, to be more easily ejected from the die.

Advantages and disadvantages

Variations on a common tablet design, which can be told apart by both color and shape. Tablets are easy and convenient to use. They provide an accurately measured dosage in a convenient portable package, and can be designed to protect unstable medications or disguise unpalatable ingredients. Coatings can be coloured or stamped to aid tablet recognition. Manufacturing processes and techniques can provide tablets special properties; for example enteric coatings or sustained release formulations.

Tablets sometimes cannot be used adequately in emergency cases. This is because the rate at which the active ingredient reaches the site to be treated may be too slow. Other routes of administration such as intravenous and intramuscular injections are more effective.

Some drugs may be unsuitable for administration by the oral route. For example protein drugs such as insulin may be denatured by stomach acids. Such drugs cannot be made into tablets. Some drugs may be deactivated by the liver when they are carried there from the gastrointestinal tract by the hepatic portal vein (the "first pass effect") making them unsuitable for oral use. Drugs which can be taken sublingually are absorbed through the oral mucosae, so that they bypass the liver and are less susceptible to the first pass effect. Bioavailability of some drugs may be low due to poor absorption from the gastrointestinal tract. Such drugs may need to be given in very high doses or by injection. For drugs that need to have rapid onset, or that have severe side effects, the oral route may not be suitable. For example Salbutamol, used to treat problems in the pulmonary system, can have effects on the heart and circulation if taken orally; these effects are greatly reduced by inhaling smaller doses direct to the required site of action.

Tablet properties

Tablets can be made in virtually any shape, although requirements of patients and tableting machines mean that most are round, oval or capsule shaped. More unusual shapes have been manufactured but patients find these harder to swallow, and they are more vulnerable to chipping or manufacturing problems.

Tablet diameter and shape are determined by the machine tooling used to produce them - a die plus an upper and a lower punch are required. This is called a station of tooling. The thickness is determined by the amount of tablet material and the position of the punches in relation to each other during compression. Once this is done, we can measure the corresponding pressure applied during compression. The shorter the distance between the punches, thickness, the greater the pressure applied during compression, and sometimes the harder the tablet. Tablets need to be hard enough that they don't break up in the bottle, yet friable enough that they disintegrate in the gastric tract.

The tablet is composed of the Active Pharmaceutical Ingredient (that is the active drug) together with various excipients. These are biologically inert ingredients which either enhance the therapeutic effect or are necessary to construct the tablet. The filler or diluent (e.g. lactose or sorbitol) is a bulking agent, providing a quantity of material which can accurately be formed into a tablet. Binders (e.g. methyl cellulose or gelatin) hold the ingredients together so that they can form a tablet. Lubricants (e.g. magnesium stearate or polyethylene glycol) are added to reduce the friction between the tablet and the punches and dies so that the tablet compression and ejection processes are smooth. Disintegrants (e.g. starch or cellulose) are used to promote wetting and swelling of the tablet so that it breaks up in the gastro intestinal tract; this is necessary to ensure dissolution of the API. Super disintegrants are sometimes used to greatly speed up the disintegration of the tablet. Additional ingredients may also be added such as coloring agents, flavoring agents, and coating agents. Formulations are designed using small quantities in a laboratory machine called a Powder Compaction Simulator. This can prove the manufacturing process and provide information for the regulatory authorities.

TABLET COATING

Coated tablets are defined as tablets covered with one or more layers of mixture of various substances such as natural or synthetic resins ,gums ,inactive and insoluble filler, sugar, plasticizer, polyhydric alcohol, waxes, authorized colouring material and some times flavoring material . Coating may also contain active ingredient. Substances used for coating are usually applied as solution or suspension under conditions where vehicle evaporates.

Many tablets today are coated after being pressed. 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 photodegradation. 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 gastro-intestinal 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 and dissolves slowly would be used to ensure it reached that point before dispersing. The area of the gastro-intestinal tract with the best absorption for any particular drug is usually determined by clinical trials.

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. Coating is also performed for the following reasons:

- Controlling site of drug release
- Providing controlled, continuous release or reduce the frequency of drug dosing
- Maintaining physical or chemical drug integrity
- Enhancing product acceptance and appearance
- Protects the tablet (or the capsule contents) from stomach acids
- Protects the stomach lining from aggressive drugs such as enteric coated aspirin
- Provides a delayed release of the medication
- Maintains shape of the tablet

Aspects of tablet coating

1. Therapy

- Avoid irritation of oesophagus and stomach
- Avoid bad taste
- Avoid inactivation of drug in the stomach
- Improve drug effectiveness
- Prolong dosing interval
- Improve dosing interval
- Improve patient compliance

2. Technology

- Reduce influence of moisture
- Avoid dust formation
- Reduce influence of atmosphere
- Improve drug stability
- Prolong shelf life

3. Marketing

- Avoid bad taste
- Improve product identity
- Improve appearance and acceptability

Tablet Coating Process

Many solid pharmaceutical dosage mediums are produced with coatings, either on the external surface of tablets, or on materials dispensed within gelatine capsules. Coating serves a number of purposes:

- Protects the tablet (or the capsule contents) from stomach acids
- Protects the stomach lining from aggressive drugs such as enteric coated aspirin
- Provides a delayed release of the medication
- Helps maintain the shape of the tablet

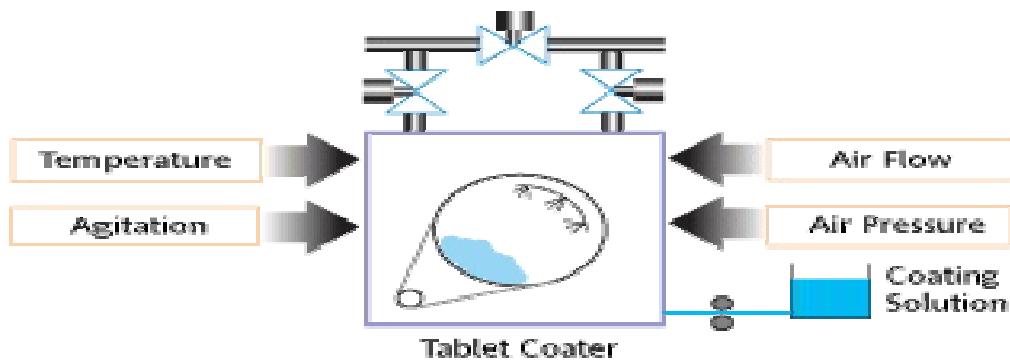
Ideally, the tablet should release the material gradually and the drug should be available for digestion beyond the stomach. The coating can be specially formulated to regulate how fast the tablet dissolves and where the active drugs are to be absorbed into the body after ingestion.

Many factors can affect the end-use properties of pharmaceutical tablets:

- Chemical composition
- Coating process
- Drying time
- Storage and environmental monitoring

Coating process design and control

Tablet coating takes place in a controlled atmosphere inside a perforated rotating drum. Angled baffles fitted into the drum and air flow inside the drum provides means of mixing the tablet bed. As a result, the tablets are lifted and turned from the sides into the centre of the drum, exposing each tablet surface to an even amount of deposited/sprayed coating.



The liquid spray coating is then dried onto the tablets by heated air drawn through the tablet bed from an inlet fan. The air flow is regulated for temperature and volume to provide controlled drying and extracting rates, and at the same time, maintaining the drum pressure slightly negative relative to the room in order to provide a completely isolated process atmosphere for the operator.

Tablet coating equipment may include spray guns, coating pan, polishing pans, solution tanks, blenders and mixers, homogenizers, mills, peristaltic pumps, fans, steam jackets, exhaust and heating pipes, scales and filters. The coating process is usually a batch driven task consisting of the following phases:

- Batch identification and Recipe selection (film or sugar coating)
- Loading/Dispensing (accurate dosing of all required raw materials)
- Warming
- Spraying (application and rolling are carried out simultaneously)
- Drying
- Cooling
- Unloading

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.

In comparison to sugar coating, film coating is more durable, less bulky, and less time consuming. But it creates more difficulty in hiding tablet appearance. One application of film-coating is for enteric protection, termed enteric coating. The purpose of enteric coating is to prevent dissolution of the tablet in the stomach, where the stomach acid may degrade the active ingredient, or where the time of passage may compromise its effectiveness, in favor of dissolution in the small intestine, where the active principle is better absorbed.

Basic principle of tablet coating

Tablet coating is the application of coating composition to moving bed of tablets with concurrent use of heated air to facilitate evaporation of solvent.

- Insulation which influences the release pattern as little as possible and does not markedly change the appearance.
- Modified release with specific requirement and release mechanism adapted to body function in the digestive tract.

- Colour coating which provides insulation or is combined with modified release coating.

Type of tablet coating process

1. Sugar coating

Compressed tablets may be coated with coloured or uncoloured sugar layer. The coating is water soluble and quickly dissolves after swallowing. The sugar coat protects the enclosed drug from the environment and provides a barrier to objectionable taste or odor. The sugar coat also enhances the appearance of the compressed tablet and permit imprinting manufacturing's information. Sugar coating provides a combination of insulation, taste masking, smoothing the tablet core, colouring and modified release. The disadvantages of sugar coating are the time and expertise required in the coating process and thus increases size, weight and shipping costs.

Sugar coating process involves five separate operations:

- Sealing/Water proofing: provides a moisture barrier and harden the tablet surface.
- Subcoating: causes a rapid buildup to round off the tablet edges.
- Grossing/Smoothing: smoothes out the subcoated surface and increases the tablet size to predetermine dimension.
- Colouring: gives the tablet its colour and finished size.
- Polishing: produces the characteristics gloss.

Sealing/Water proofing

The seal coat provides a moisture barrier and hardens the surface of the tablet in order to minimize attritional effects. Core tablets having very rapid disintegration rates conceivably could start the disintegration process during the initial phase of sugar coating. The sealants are generally water-insoluble polymers/film formers applied from an organic solvent solution. The quantities of material applied as a sealing coat will depend primarily on the tablet porosity, since highly porous tablets will tend to soak up the first application of solution, thus preventing it from spreading uniformly across the surface of every tablet in the batch. Hence, one or more further application of resin solution may be required to ensure that the tablet cores are sealed effectively. Common materials used as a sealant include Shellac, Zine, Cellulose acetate phthalate (CAP), Polyvinylacetate phthalate, Hydroxypropylcellulose, Hydroxypropylmethylcellulose etc.

Subcoating

Subcoating is the actual start of the sugar coating process and provides the rapid buildup necessary to round up the tablet edge. It also acts as the foundation for the smoothing and colour coats.

Table: Binder solution formulation for subcoating

	%W/W	%W/W
Gelatin	6	3.3
Gum acacia (powdered)	8	8.7
Sucrose (powdered)	45	55.3
Distilled water	to 100	to 100

Table: Dusting powder formulation for subcoating

	%W/W	%W/W
Calcium carbonate	40.0	-
Titanium dioxide	5.0	1.0
Talc, asbestos free	25.0	61.0
Sucrose(powdered)	28.0	38.6
Gum acacia (powdered)	2.0	-

Table: Suspension subcoating formulation

	%W/W
Sucrose	40.0
Calcium carbonate	20.0
Talc, asbestos free	12.0
Gum acacia(powdered)	2.0
Titanium dioxide	1.0
Distilled water	25.0

Grossing/ smoothing

The grossing/smoothing process is specifically for smoothing and filing the irregularity on the surface generated during subcoating. It also increases the tablet size to a predetermined dimension. If the subcoating is rough with high amount of irregularities then the use of grossing syrup containing suspended solids will provide more rapid buildup and better filling qualities. Smoothing usually can be accomplished by the application of a simple syrup solution (approximately 60-70 % sugar solid). This syrup generally contains pigments, starch, gelatin, acacia or opacifier if required. Small quantities of colour suspension can be applied to impart a tint of the desired colour when there are irregularities in coating.

Colour coating

This stage is often critical in the successful completion of a sugar coating process and involves the multiple application of syrup solution (60-70 % sugar solid) containing the requisite colouring matter. Mainly soluble dyes were used in the sugar coating to achieve the desired colour, since the soluble dye will migrate to the surface during drying. But now a day the insoluble certified lakes have virtually replaced the soluble dyes in pharmaceutical tablet coating. The most efficient process for colour coating involves the use of a pre dispersed opacified lake suspension.

Polishing

Sugar-coated tablets needs to be polished to achieve a final elegance. Polishing is achieved by applying the mixture of waxes like beeswax, carnuba wax, candelila wax or hard paraffin wax to tablets in polishing pan.

2. Film Coating

Film coating is more favored over sugar coating.

Table: Comparison between film coating and sugar coating

FEATURES	FILM COATING	SUGAR COATING
Tablet: Appearance	Retain contour of original core. Usually not as shiny as sugar coat type	Rounded with high degree of polish
Weight increase because of coating material	2-3%	30-50%
Logo or 'break lines'	Possible	Not possible
Process Operator training required	Process tends itself to automation and easy training of operator	Considerable
Adaptability to GMP	High	Difficulty may arise
Process stages	Usually single stage	Multistage process
Functional coatings	Easily adaptable for controlled release	Not usually possible apart from enteric coating

Process description

Film coating is deposition of a thin film of polymer surrounding the tablet core. Conventional pan equipments may be used but now a day's more sophisticated equipments are employed to have a high degree of automation and coating time. The polymer is solubilized into solvent. Other additives like plasticizers and pigments are added. Resulting solution is sprayed onto a rotated tablet bed. The drying conditions cause removal of the solvent, giving thin deposition of coating material around each tablet core.

Process details

Usually spray process is employed in preparation of film coated tablets. Accela cota is the prototype of perforated cylindrical drum providing high drying air capacity. Fluidized bed equipment has made considerable impact where tablets are moving in a stream of air passing through the perforated bottom of a cylindrical column. With a smaller cylindrical insert, the stream of cores is rising in the center of the device together with a spray mist applied in the middle of the bottom. For fluidized bed coating, very hard tablets (hardness > 20 N) have to be used.

Basic process requirements for film coating

The fundamental requirements are independent of the actual type of equipments being used and include adequate means of atomizing the spray liquid for application to the tablet core, adequate mixing and agitation of tablet bed, sufficient heat input in the form of drying air to provide the latent heat of evaporation of the solvent. This is particularly important with aqueous-based spraying and good exhaust facilities to remove dust and solvent laden air.

Materials used in film coating

- Film formers, which may be enteric or nonenteric
- Solvents
- Plasticizers
- Colourants
- Opaquant-Extenders
- Miscellaneous coating solution components

Film formers

Ideal requirements of film coating materials are summarized below:

- Solubility in solvent of choice for coating preparation
- Solubility requirement for the intended use e.g. free water-solubility, slow water-solubility or pH -dependent solubility
- Capacity to produce an elegant looking product
- High stability against heat, light, moisture, air and the substrate being coated
- No inherent colour, taste or odor
- High compatibility with other coating solution additives
- Nontoxic with no pharmacological activity
- High resistance to cracking
- Film former should not give bridging or filling of the debossed tablet
- Compatible to printing procedure

1. Film formers

Hydroxy Propyl Methyl Cellulose (HPMC)

It is available in different viscosity grades. It is a polymer of choice for air suspension and pan spray coating systems because of solubility characteristic in gastric fluid, organic and aqueous solvent system. Advantages include: it does not affect tablet disintegration and drug availability, it is cheap, flexible, highly resistant to heat, light and moisture, it has no taste and odor, color and other additives can be easily incorporated. Disadvantage includes: when it is used alone, the polymer has tendency to bridge or fill the debossed tablet surfaces. So mixture of HPMC and other polymers/ plasticizers is used.

Methyl Hydroxy Ethyl Cellulose (MHEC)

It is available in wide variety of viscosity grades. It is not frequently used as HPMC because soluble in fewer organic solvents.

Ethyl Cellulose (EC)

Depending on the degree of ethoxy substitution, different viscosity grades are available. It is completely insoluble in water and gastric fluids. Hence it is used in combination with water-soluble additives like HPMC and not alone. Unplasticized ethyl cellulose films are brittle and require film modifiers to obtain an acceptable film formulation. Aqua coat is aqueous polymeric dispersion utilizing ethyl cellulose. These pseudolatex systems contain high solids, low viscosity compositions that have coating properties quite different from regular ethyl cellulose solution.

Hydroxy Propyl Cellulose (HPC)

It is soluble in water below 40°C (insoluble above 45°C), gastric fluid and many polar organic solvents. HPC is extremely tacky as it dries from solution system. It is used for sub coat and not for colour or glass coat. It gives very flexible film.

Povidone

Degree of polymerization decides molecular weight of material. It is available in four viscosity grades i.e. K-15, K-30, K-60 and K-90. Average molecular weight of these grades is 10000, 40000, 160000 and 360000 respectively. K-30 is widely used as tablet binder and in tablet coating. It has excellent solubility in wide variety of organic solvents, water, gastric and intestinal fluids. Povidone can be cross-linked with other materials to produce films with enteric properties. It is used to improve dispersion of colorants in coating solution.

Sodium carboxyl methyl cellulose

It is available in medium, high and extra high viscosity grades. It is easily dispersed in water to form colloidal solutions but it is insoluble in most organic solvents and hence not a material of choice for coating solution based on organic solvents. Films prepared by it are brittle but adhere well to tablets. Partially dried films of are tacky. So coating compositions must be modified with additives.

Polyethylene glycols (PEG)

Lower molecular weights PEG (200-600) are liquid at room temperature and are used as plasticizers. High molecular weights PEG (900-8000series) are white, waxy solids at room temperature. Combination of PEG waxes with CAP gives films that are soluble in gastric fluids.

Acrylate polymers

E is cationic®. Eudragit®, it is marketed under the name of Eudragit E is freely soluble in gastric fluid up to pH 5 and®co-polymer. Only Eudragit expandable and permeable above pH 5. This material is available as organic solution (12.5% in isopropanol/acetone), solid material or 30% aqueous RL®dispersion. Eudragit & RS are co-polymers with low content of quaternary ammonium groups. These are available only

as organic solutions and solid materials. They produce films for delayed action (pH dependent).

2. Solvents

Solvents are used to dissolve or disperse the polymers and other additives and convey them to substrate surface.

Ideal requirements

- Should be either dissolve/disperse polymer system
- Should easily disperse other additives into solvent system
- Small concentration of polymers (2-10%) should not in an extremely viscous solution system creating processing problems
- Should be colourless, tasteless, odorless, inexpensive, inert, nontoxic and nonflammable
- Rapid drying rate
- No environmental pollution

Mostly solvents are used either alone or in combination with water, ethanol, methanol, isopropanol, chloroform, acetone, methylene chloride, etc. Water is more used because no environmental and economic considerations. For drugs that readily hydrolyze in presence of water, non aqueous solvents are used.

3. Plasticizers

Combination of plasticizer may be used to get desired effect. Concentration of plasticizer is expressed in relation to the polymer being plasticized. Recommended levels of plasticizers range from 1-50 % by weight of the film former. Commonly used plasticizers are castor oil, PG, glycerin, lower molecular weight (200-400 series), PEG, surfactants, etc. For aqueous coating PEG and PG are more used while castor oil and spans are primarily used for organic-solvent based coating solution. External plasticizer should be soluble in the solvent system used for dissolving the film former and plasticizer. The plasticizer and the film former must be at least partially soluble or miscible in each other.

4. Colorants

Colorants can be used in solution form or in suspension form. To achieve proper distribution of suspended colorants in the coating solution requires the use of the powdered colorants (<10 microns). Most common colorants in use are certified FD & C or D & C colorants. These are synthetic dyes or lakes. Lakes are choice for sugar or film coating as they give reproducible results. Concentration of colorants in the coating solutions depends on the colour shade desired, the type of dye, and the concentration of opaquant-extenders. If very light shade is desired, concentration of less than 0.01 % may be adequate on the other hand, if a dark colour is desired a concentration of more than 2.0 % may be required. The inorganic materials (e.g. iron oxide) and the natural colouring materials (e.g. anthrocyanins, carotenoids etc) are also used to prepare coating solution. Magenta red dye is non absorbable in biologic system and resistant to degradation in the gastro (opaque colour concentrate for film coating) and@intestinal track. Opasray

(complete film coating concentrate) are promoted as achieving less®Opadry lot-to-lot colour variation.

5. Opaquant-Extenders

These are very fine inorganic powder used to provide more pastel colours and increase film coverage. These inorganic materials provide white coat or mask colour of the tablet core. Colorants are very expensive and higher concentration is required. These inorganic materials are cheap. In presence of these inorganic materials, amount of colorants required decreases. Most commonly used materials are titanium dioxide, silicate (talc & aluminum silicates), carbonates (magnesium carbonates), oxides (magnesium oxide) & hydroxides (aluminum hydroxides). Pigments were investigated in the production of opaque films and it was found that they have good hiding power and film-coated tablets have highlighted intagliations.

6. Miscellaneous coating solution component

Flavors, sweeteners, surfactants, antioxidants, antimicrobials, etc. may be incorporated into the coating solution.

Enteric coating

This type of coating is used to protect tablet core from disintegration in the acid environment of the stomach for one or more of the following reasons:

- To prevent degradation of acid sensitive API
- To prevent irritation of stomach by certain drugs like sodium salicylate
- Delivery of API into intestine
- To provide a delayed release component for repeat action tablet

Polymers used for enteric coating are as follow

Cellulose acetate phthalate (CAP)

It is widely used in industry. Aquateric is reconstituted colloidal dispersion of latex particles. It is composed of solid or semisolid polymer spheres of CAP ranging in size from 0.05 - 3 microns. Cellulose acetate trimellitate (CAT) developed as an ammoniated aqueous formulation showed faster dissolution than a similar formulation of CAP. Disadvantages include: It dissolves above pH 6 only, delays absorption of drugs, it is hygroscopic and permeable to moisture in comparison with other enteric polymer, it is susceptible to hydrolytic removal of phthalic and acetic acid changing film properties. CAP films are brittle and usually used with other hydrophobic film forming materials.

Acrylate polymers

Eudragit®L & Eudragit®S are two forms of commercially available enteric acrylic resins. Both of them produce films resistant to gastric fluid. Eudragit®L & S are soluble in intestinal fluid at pH 6 & 7 respectively. Eudragit®L is available as an organic solution (Isopropanol), solid or aqueous dispersion. Eudragit®S is available only as an organic solution (Isopropanol) and solid.

Hydroxy propyl methyl cellulose phthalate

HPMCP 50, 55 & 55-s (also called HP-50, HP-55 & HP-55-s) is widely used. HP-55 is recommended for general enteric preparation while HP-50 & HP-55-s for special cases. These polymers dissolve at a pH 5-5.5.

Polyvinyl acetate phthalate

It is similar to HP-55 in stability and pH dependent solubility.

Enteric sugar coating

In this the sealing coat is tailored to include one of the enteric polymers in sufficient quantity to pass the enteric test for disintegration. The sub coating and subsequent coating steps are then as for conventional sugar coating.

Enteric film coating

Enteric polymers are capable of forming a direct film in a film coating process. Sufficient weight of enteric polymer has to be used to ensure an efficient enteric effect. Enteric coating can be combined with polysaccharides, which are enzyme degraded in colon e.g. Cyclodextrin & galactomannan.

Controlled release coating

Polymers like modified acrylates, water insoluble cellulose (ethyl cellulose), etc. used for control release coating.

Specialized coating

1. Compressed coating

This type of coating requires a specialization tablet machine. Compression coating is not widely used but it has advantages in some cases in which the tablet core cannot tolerate organic solvent or water and yet needs to be coated for taste masking or to provide delayed or enteric properties to the finished product and also to avoid incompatibility by separating incompatible ingredients.

2. Electrostatic coating

Electrostatic coating is an efficient method of applying coating to conductive substrates. A strong electrostatic charge is applied to the substrate. The coating material containing conductive ionic species of opposite charge is sprayed onto the charged substrate. Complete and uniform coating of corners and adaptability of this method to such relatively nonconductive substrate as pharmaceutical is limited.

3. Dip coating

Coating is applied to the tablet cores by dipping them into the coating liquid. The wet tablets are dried in a conventional manner in coating pan. Alternative dipping and drying steps may be repeated several times to obtain the desired coating. This process lacks the speed, versatility, and reliability of spray-coating techniques. Specialized equipment has been developed to dip-coat tablets, but no commercial pharmaceutical application has been obtained.

4. Vacuum film coating

Vacuum film coating is a new coating procedure that employs a specially designed baffled pan. The pan is hot water jacketed, and it can be sealed to achieve a vacuum system. The tablets are placed in the sealed pan, and the air in the pan is displaced by nitrogen before the desired vacuum level is obtained. The coating solution is then applied with airless spray system. The evaporation is caused by the heated pan, and the vapour is removed by the vacuum system. Because there is no high-velocity heated air, the energy requirement is low and coating efficiency is high. Organic solvent can be effectively used with this coating system with minimum environmental or safety concerns.

Equipments

General types of equipments are

- Standard coating pan
- Immersion sword system
- Immersion tube system

Perforated pan system e.g., Accela cota system

- Hicoater system
- Glattcoater system
- Driacoated system

Fluidized bed coater

CONCLUSION

Coating Systems and pharmaceutical coating films are extensively used by pharmaceutical companies for coating solid oral dosage forms:

- To protect against deterioration by environmental factors like sunlight, temperature variations, moisture, environmental gases etc.
- To facilitate swallowing
- To mask taste and odour
- To increase shelf-life
- To enhance aesthetic appeal and brand image
- To facilitate product identification during manufacture and prevent wastage during packing and handling
- To provide immediate release, specific release, sustained release, controlled release and targeted drug delivery properties
- To provide enteric release properties for release in the intestinal tract
- To facilitate identification of oncological drugs

Coating Systems are dry blend concentrates of polymers, plasticizers, pigments, opacifiers, glidants, binders, antitacking agents, antifoaming agents, surfactants, fillers and extenders. Polymers constitute a major component of the film coating system and our systems are based on Hydroxy Propyl Methyl Cellulose (HPMC), Poly Vinyl Alcohol (PVA), Sodium Alginate (SA), Cellulose Acetate Phthalate (CAP), Hydroxy Propyl Methyl Cellulose Phthalate (HPMC-P), Methacrylic Acid Co-polymer Type 'C'. Likewise, pigments constitute a very critical component for visual distinction and our systems are based on Lake Colors, Natural Colors, Aluminium Lakes, FD&C Aluminium Lakes and Pharmaceutical grade Titanium Dioxide (TiO₂).

Sugar Coating

- The sugar coating involves several steps like, sealing, subcoating, colour coating and printing
- Sugar coating process yields elegant and highly glossed tablet.
- Newer techniques utilize spraying systems and varying degree of automation to improve coating efficiency and product uniformity.
- Film coating is deposition of a thin film of polymer surrounding the tablet core.
- Film coating is more favored than sugar coating because weight increase is 2-3%, single stage process, easily adaptable to controlled release, it retains colour of original core, high adaptability to GMP, automation is possible, etc.
- Accela cota and fluidized bed equipments are widely used for film coating.
- Basic formula is obtained from past experience or from literature and modifications are made accordingly. Common modifications are to alter polymer-to-plasticizer ratio or addition of different plasticizer/polymer. Experimentation of this type can be best achieved by fractional factorial study.
- Materials used in film coating include film formers, solvents, plasticizers, colorants, opaquant-extendors, surfactant, anti oxidant, etc.
- Widely used film formers are Hydroxy Propyl Methyl Cellulose (HPMC), Methyl Hydroxy Ethyl Cellulose (MHEC), Ethyl Cellulose (EC), Hydroxy Propyl Cellulose (four grades available i.e. K-15, K-30, K-60 and K-90), Sodium®(HPC), Povidone carboxy methyl cellulose, Polyethylene glycols (PEG) and Acrylate polymers (Eudragit®, Eudragit®RL, Eudragit®RS, Eudragit®E) are used for film coating. Eudragit®L & S are used for enteric coating. Eudragit®RL, Eudragit®RS, Eudragit®S are available as organic solution and solid while Eudragit®L and Eudragit®E are available as organic, solid or aqueous dispersion.
- Quality of film can be modified by plasticizer. Commonly used plasticizers include PG, glycerin, low molecular weight PEG, castor oils, etc. Castor oil and spans are more used for organic-solvent based coating solution while PE and PEG are used for aqueous coating.
- FD & C or D & C certified colorants are used. Lakes are choice for film coating as they give reproducible results. Opaspray® (opaque colour concentrate for film coating) and Opadry® (complete film coating concentrate) are promoted as achieving less lot-to-lot variation.
- Colorants are expensive and higher concentration is required. So materials like titanium dioxides, silicates, and carbonates are used to provide more pastel colours and increase film coverage.

Enteric Coating:

- Enteric coating is used to protect tablet core from disintegration in the acid environment of stomach to prevent degradation of acid sensitive API, prevent irritation to stomach by certain drugs, delivery of API into intestine, to provide a delayed release components for repaet action etc.
- Several kinds of enteric layer systems are available like one layer system and two-layer system. Polymers used for enteric coating are cellulose Acetate Phthalate (CAP), Acrylates (Eudragit®L and Eudragit®S, Hydroxy Propyl Methyl

Cellulose Phthalate (HPMCP50, HPMCP55 & HPMCP 55s) and polyvinyl acetate phthalate.

Enteric sugar Coating

- Here sealing coat is modified to comprise one of the enteric polymers in sufficient quantity to pass the enteric test for disintegration. The sub coating and subsequent coating steps are then as for conventional sugar coating.
- Enteric polymers are capable of forming a direct film in a film coating process. Sufficient weight of enteric polymer has to be used to ensure an efficient enteric effect
- Enteric coating can be combined with polysaccharides, which are enzymatically degraded in colon. For example, Cyclodextrin & Galactomannan.

Controlled release coating:

- Polymers like modified acrylates, ethyl cellulose, etc are used for the same

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