Review Article

An Overview: Aqueous Film Coating Technology on Tablets

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ABSTRACT
Tablet coating is perhaps one of the oldest pharmaceutical processes still in existence. Earlier, Sugar coating was adopted for pharmaceutical as from confectionary industry. But as it was tedious process and required skilled manipulation, film coating was started to be preferred over sugar coating. Development of film coating was mainly based on solutions of different polymers in various organic solvents. All these solvents are toxic in nature. Nobody ever was concerned about the problems like material cost, toxic effects due to coating or pollution etc. In today's competitive business environment, any cost saved will improve the market viability and success of any product. Therefore, left with no other choice but to eliminate the use of organic solvents and to start using water as the solvent system for tablet coating. The main focus of this review is, to study various aspects of aqueous based film coating.

Keywords: Aqueous film coating, Film formers, Opadry II, Coating Process parameters.

INTRODUCTION
All drugs have their own chracteristic, like some drugs are bitter in taste or have an unpleasant odor, some are sensitive to light or oxides, some are hygroscopic in nature[1, 2, 3]. Because of this reasons, tablet coating is the choice of option to solve such problems in conventional dosage form. During the middle of 19th century sugar-coating process was a skilled manipulative operation and could last for even five days. The operator must be highly skilled for such coating. In the last 25 years, tablet coating has undergone several fundamental changes. Many modifications were advocated to improve the basic process and film coating chosen in place of sugar coating and after that, the researchers were moved towards to the organic solvent based coating to overcome problem occurred with sugar coating.

Tablet film coating is performed by two types, one is aqueous film coating (generally water is used as a solvent) and non aqueous film coating (generally organic solvents are used). Some problems are associated with the non aqueous film coating like safety of employees (as most of the solvents are dangerous, smell, and they are not good to breathe), atmospheric pollution etc. But key problem is with the approval of the regulatory authority[4].

High quality aqueous film coating must be smooth, uniform and adhere satisfactorily to the tablet surface and ensure chemical stability of a drug.

Tablet as a dosage form
A tablet is a pharmaceutical dosage form. It comprises a mixture of active substances and excipients, usually in powder form, pressed or compacted into a solid**.** Tablets Dosage form is one of a most preferred dosage form all over the world. Almost all drug molecules can be formulated in a tablet and process of manufacturing of tablets is very simple and is very flexible. One can administer 0.01 mg to 1 gm of a drug dose by oral route of administration, by formulating as a tablet.

Tablet Coating
Coating is a process by which an essentially dry, outer layer of coating material is applied to the surface of a dosage form in order to confer specific benefits that broadly ranges from facilitating product identification to modifying drug release from the dosage form. After making a good tablet, one must often coat it[4,5,6].

Coating may be applied to a wide range of oral solid dosage forms, including tablets, capsules, multiparticulates and drug crystals. When coating composition is applied to a batch of tablets in a coating pan, the tablet surfaces become covered with a tacky polymeric film. Before the tablet surface dries, the applied coating changes from a sticky liquid to tacky semisolid and eventually to a nonsticky dry surface. The entire coating process is conducted in a series of mechanically operated acorn-shaped coating pans of galvanized iron stainless steel or copper. The smaller pans are used for experimental, developmental, and pilot plant operations, while the larger pans for industrial production[5,6].

Necessity of Tablet Coating [1, 2, 3]

- A number of reasons can be suggested, like:
- The core contains a material which has a bitter taste in the mouth or has an unpleasant odour.
- Coating will protect the drug from the surroundings with a view to improve its stability.
- Coating will increase the ease by which a tablet can be ingested by the patient.
- Coating will develop the mechanical integrity; means coated products are more resistant to mishandling (abrasion, attrition, etc.)
- The core contains a substance which is incompatible in the presence of light and subject to atmospheric oxidation, i.e. a coating is added to improve stability.
- The core alone is inelegant.
- The active substance is colored and migrates easily to stain hands and clothes.
- The coated tablets are packed on high-speed packaging machine. Coating reduces friction and increases packaging rate.
- Coating can modify the drug release profile, e.g., enteric coating, osmotic pump, pulsatile delivery.

Basic principles involved in 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. Coating may be a type which influences the release pattern of the drug as little as possible and does not markedly change the appearance of the formulation. Coating may modify release of drug with specific requirement and release mechanism adapted to body function in the digestive tract. It may be color coating which provides insulation. Incorporation of another drug or formula adjuvant in the coating to avoid chemical incompatibilities or to provide sequential drug release is also possible. Through coating, improvement of the pharmaceutical elegance by use of special colors and contrasting printing is also possible. Primary components involved in tablet coating are tablet properties, coating process, coating equipments, parameters of the coating process, facility and ancillary equipments, and automation in coating processes, etc[5,6].

Coating Process Design and Control

In most of the coating methods, the coating solutions are sprayed onto the tablets as the tablets are being agitated in a pan, fluid bed, etc. As the solution is being sprayed, a thin film is formed that adheres directly to each tablet. The coating may be formed by a single application or may be built up in layers through the use of multiple spraying cycles. Rotating coating pans are often used in the pharmaceutical industry. Uncoated tablets are placed in the pan, which is typically tilted at an angle from the horizontal, and the liquid coating solution is introduced into the pan while the tablets are tumbling. The liquid portion of the coating solution is then evaporated by passing air over the surface of the tumbling tablets. In contrast, a fluid bed coater operates by passing air through a bed of tablets at a velocity sufficient to support and separate the tablets as individual units. Once separated, the tablets are sprayed with the coating composition[4,7].

The coating process is usually a batch driven task consisting of the phases like, 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, and unloading.

A modern tablet coating system combines several components like a coating pan, a spraying system, an air handling unit and a dust collector.

Fundamentals of Film Formation

In the pharmaceutical industry, polymeric films are generally applied to solid dosage forms using a spray-atomization technique. The polymer is dissolved or dispersed in aqueous or organic solvents prior to spraying. The solid cores are often preheated in the coating equipment prior to initiation of the coating process. This pre-warming stage is especially important in the coating of soft gelatin capsules. The coating solution or dispersion is atomized with air into small droplets, which are then delivered to the surface of the substrate. Upon contact, the atomized droplets spread across the substrate surface.

The solvent may penetrate into the core, causing surface dissolution and physical mixing at the film–tablet interface. As the solvent begins to evaporate, the polymer particles densely pack on the surface of the solid. Upon further solvent evaporation, the particles flow together due to the cohesive forces between the polymer spheres, a process known as coalescence. Heat is generally added to the coating equipment to facilitate solvent evaporation and film formation. Immediately following the completion of the coating process, coated solids are generally stored at temperatures above the glass transition temperature of the polymer to further promote coalescence of the film and ensure a homogeneous distribution of the plasticizer[8].

Aqueous film coating

Aqueous film coating is applied as a thin polymeric film to the surface of a tablet. Film coating can protect the tablet from light, temperature and moisture; mask undesirable taste or odor; improve the appearance; provide tablet identity; facilitate swallowing and control or modify the release of the drug. Aqueous coating of oral solid dosage forms has rapidly replaced solvent-based coating for safety, environmental and economic reasons.

Film-coating of tablets is a multivariate process, with many different factors, such as coating equipment, process conditions, composition of the core tablets, shape of tablets, coating liquid, etc. which affect the pharmaceutical quality of the final product. High quality aqueous film coating must be smooth, uniform and adhere satisfactorily to the tablet surface and ensure chemical stability of a drug[9].

Mechanisms of Film Formation

Aqueous film coating applications are either solutions or dispersions, depending on the water solubility of the film former polymers. Film formation from the polymer solution occurs through a series of phases. When the polymer solution is applied to the surface of the tablet, cohesion forces form a bond between the coating polymer molecules. To obtain high cohesion, the cohesive strength of the polymer molecules must be relatively high and continuous surface of the film material must coalesce. Coalescence of adjacent polymer molecular layers or surfaces occurs through diffusion. When most of the water evaporates, the viscosity of the solution increases (gelation) and leaves the polymer chain in close proximity to each other and deposit over a previous polymer layer. If there is adequate cohesive attraction between the molecules and sufficient diffusion and coalescence upon the more complete evaporation of the residual water, the individual polymer chains align themselves to form a cohesive film[10].

However, the mechanism of film formation is fundamentally different when using aqueous polymer dispersions instead of organic polymer solutions: Once the latter are sprayed onto a surface, the organic solvent evaporates, the polymer chains approach each other and finally form a continuous homogeneous film. In contrast, upon spraying aqueous polymer dispersions onto the dosage form's surface, water evaporates, the polymer particles approach each other and – under appropriate conditions (in particular temperature, presence of sufficient amounts of water and/or other plasticizers) – coalesce to form a homogeneous polymeric film. In practice, it is often difficult to assure complete film formation during coating. That is why generally a thermal after-treatment (curing) is performed, in order to complete polymer particle coalescence[11].

Film formation from dispersion occur when polymeric particle coalesce to form a continuous film (Fig.1), making it a more complex mechanism compared to film formation from solution[7].

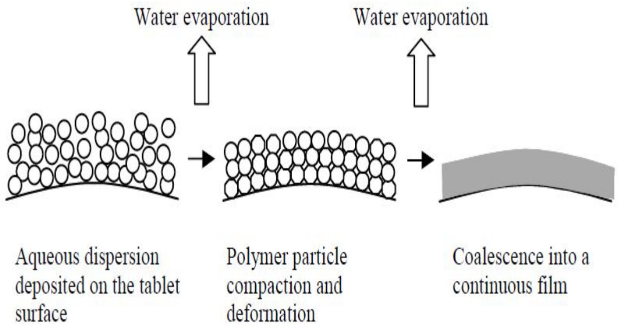

Fig 1: Film formation from aqueous polymeric dispersion[7]

The coalescence of aqueous polymer dispersion deposited on the surface of the tablet into continuous film initiated by water evaporation. As water evaporates, dispersed polymer particle are pushed into a closely packed, ordered array with water filling the voids. After the polymer particles come into contact with each other, they must deform and fuse in order to coalesce into a film. Coalescence will occur when the promoting forces are greater than the resistive forces of the particles. The forces promoting particle coalescence include capillary pressure (water-air interfacial tension), as well as particle-air and particle-water interfacial tension. Finally, the coalescence of the polymer particles is further complemented by inter-diffusion of polymer chains (autohesion) occurring through particle interfaces, making the film more homogeneous.

Film formation, i.e. coalescence, is a complex process and dependent on coating and storage conditions, coating polymer, polymer molecular weight and particle size, coating liquid constituents and properties like viscosity and surface[12].

Since coalescence only occurs above a minimum film formation temperature (MFT) of coating polymer, temperature and water evaporation are considered to be major process-related factors affecting the properties of coatings[7].

Coating equipment[14]

Before few years different types of coating pans are used for coating like conventional coating pans, manesty accelacota, driam (driacoater), butterfly coater etc. Now a days the side-vented, perforated pan-coater is the most commonly used coating device of tablets. In equipment, spray nozzle, number of spray nozzle, pan size, etc may also affect the quality of final product. Its air flow system through a perforated pan ensures rapid and continuous drying conditions. The low evaporation capacity of water requires high drying efficiency of aqueous film-coating equipment.

Process parameters

Spray rate

The spray rate is an significant parameter since it impacts the moisture content of the formed coating and, subsequently, the quality and uniformity of the film[7,15,16]. A low coating liquid spray rate causes incomplete coalescence of polymer due to insufficient wetting, which could effect in brittle films[7]. A high coating liquid spray rate may result in over wetting of the tablet surface and subsequent problems such as picking and sticking[7,15]. If the spray rate is high and the tablet surface temperature is low, films are not formed during the spraying but the post drying phase, and rapid drying often produces cracks in the films[7].

Atomizing air pressure

In general, increasing the spraying air pressure decreases the surface roughness of coated tablets and produces denser and thinner films[17,18,19]. If spraying air pressure is excessive, the spray loss is great, the formed droplets are very fine and could spray-dry before reaching the tablet bed, resulting in inadequate droplet spreading and coalescence[19]. If spraying air pressure is inadequate, the film thickness and thickness variation are greater possibly due to change in the film density and spray loss. In addition, with low spraying air pressure big, droplets could locally over wet the tablet surface and cause tablets to stick to each other.

Inlet air temperature

The inlet air temperature affects the drying efficiency (i.e. water evaporation) of the coating pan and the uniformity of coatings[17]. High inlet air temperature increases the drying efficiency of the aqueous film coating process and a decrease in the water penetration into the tablet core, decreases the core tablet porosity, tensile strength and residual moisture content of coated tablets[17,20]. Too much air temperature increases the premature drying of the spray during application and, subsequently, decreases the coating efficiency[16,21]. Measuring the pan air temperature helps to manage the optimum conditions during the coating process and, consequently, enables predicting possible drying or over wetting problems which may result in poor appearance of the film or may have unfavorable effects on the moisture and heat sensitive tablet cores[22].

Rotating speed of pan

It is well documented that increasing the rotating speed of the pan improves the mixing of tablets[21,22,23,24,25]. The pan speed affects the time the tablets spend on the spraying zone and, subsequently, the homogeneous distribution of the coating solution on the surface of each tablet throughout the batch. Increasing the pan speed decreases the thickness variation and increase the uniformity of coatings[7,21,24]. Too much rotating speed of the pan will cause the tablet to undergo unnecessary attrition and breakage.

History of Aqueous Film Coating

Initially, aqueous processes were met with skepticism because of the longer process time and the inferior appearance of the coated product. A few desired release functions were obtainable only with organic solvent–soluble films. However, the development and introduction of latex and pseudo latex materials as well as improvements in equipment design have broadened the spectrum of aqueous coating. With correctly selected equipment and processing conditions, it is now possible to apply water-based films to small particles without agglomeration or to tablets containing superdisintegrants without core penetration and dissolution of the tablet surface.

Until about 1950, sugar was the first choice as a coating agent for pharmaceutical preparations and much time and efforts were spent in perfecting the sugar coating techniques. Nobody ever was concerned about the problems like material cost, toxic effects due to coating or pollution, etc. because the solvent used was always water. However, sugar coating technique was time consuming; affecting the productivity and the quality of finished product was dependent on the skills of operator. Many a times the companies had to reschedule their production plans due to the non-availability of skillful coating operator. These problems led to the development of film coating technique which was mainly based on solutions of different polymers in various organic solvents. Almost all of these solvents are toxic in nature[26].

Aqueous film coating systems have been widely used for many years and offer substantial advantages over organic solvents. Traditionally, organic solvents had been used to dissolve the polymer but modern techniques rely on water because of significant drawbacks. Below lists some of the problems associated with organic solvents, are related to environment, safety, financial, solvent residues, etc.

Venting of untreated organic solvent vapour into the atmosphere is ecologically unacceptable and removal of gaseous effluent is expensive. Organic solvents are also a safety hazard as they are toxic, explosive and fire hazard is also involved.

The hazards associated with organic solvents necessitate the need for building flame and explosive- proof facilities. In addition, the cost of their storage and ingredients are relatively expensive. The organic solvents are expensive and are likely to become more expensive in future. For a given process, the amount of residual organic solvent in the film must be investigated. Thus, stringent regulatory controls are existing[8]. The cost of insurance of the manufacturing facility is now very high if one uses the organic solvents. The best alternative to overcome these adverse situations is to revert back to water as the solvent medium for tablet coating[26].

As the level of understanding regarding the toxic effects of organic solvents is increasing, industrial hygiene rules and Food and Drug Administration (FDA) regulations are being tightened world over, limiting the use of these solvents and exposure of workers to these solvents.

Although these formulated aqueous enteric coating systems were advancement from traditional solvent systems, they required the separate addition of plasticizers, detackifiers, pigments, and other process aids.

Another area of concern is the cost of these solvents, which can only be expected to increase in coming times. In today's competitive business environment's any cost saved will improve the market viability and success of any product[27].

We are, therefore, left with no other choice but to eliminate the use of organic solvents and start using water as the solvent system for tablet coating. Like any other system, aqueous film coating has some disadvantages.

The main reason for using organic solvents was to avoid possible decomposition of active ingredients and many other process related problems such as over wetting, picking and sticking, etc. which may occur with aqueous coating systems. However, research and experience of industry has indicated that the decomposition of active ingredients and possible coating difficulties are not so serious issues in actual applications and all such problems can be sorted out by scientific evaluation of the reasons for these problems. Most of these problems could be categorized as material related problems, coating instrument related problems and coating process related problems.

Effect of Residual Moisture

One should keep in mind that water is less volatile than organic solvents, and will require much better drying capacity resulting in higher energy cost to the coating process. However, exceptions do exist in optimized film coating formulations which have a very low affinity for water, and therefore, can be run at lower temperatures, higher spray rates. Ideal Cures Pvt. Ltd. has developed few such products (under INSTACOAT range of products) which dries faster and the whole coating process can be completed in the same or sometimes little less time as compared to organic solvent based coatings. The use of organic solvents raises the possibility of residual solvent in the finish product which is increasingly becoming a concern to the regulatory agencies due to their adverse effects on the consumer health[26].

Current trend of aqueous film coating in pharmaceutical oral solid dosage forms

Aqueous coating technology remains the main option for film coating of oral solid dosage forms. This is irrespective of the purpose of the film-coating applications, i.e. for conventional and modified-release film coatings. The main reasons for its continued popularity are the environmental limitations of organic solvents used, recent advances in the formulation of aqueous film–coating materials, as well as major improvements made in the coating machines and their ancillaries. Aqueous coating systems are widely used for conventional film-coating systems (immediate release), enteric film-coating systems (delayed release), and barrier membrane controlled release film-coating systems (extended release) [28].

Opadry formulations provided numerous advantages versus the use of individual raw materials including the reduction of the number of raw materials for QC testing, reduced dispersion preparation time, consistent color-matched formulations, good processibility, excellent appearance on tablets, and good mechanical film properties. Opadry formulations have enjoyed widespread, successful use globally and are still found on a great variety of marketed products. However, one drawback of the Opadry formulations is that dispersion solids must be kept in the range of 10% to 15% by weight in water to achieve processible dispersion viscosities of 300 to 600 centipoises. In order to increase productivity, by decreasing coating time and/or increasing spray rate, the Opadry II family of products comprising HPMC and polysaccharides, was introduced in the 1980s. With Opadry II, processible dispersions can be obtained at 20% rather than 10% to 15% solids, which allows for the productivity increase as well as increased adhesion[29].

The most significant recent advances in the development of fully formulated aqueous film coatings have been the introduction of new film coatings based on polyvinyl alcohol (PVA) and sodium Carboxymethylcellulose (NaCMC). Film coatings comprising these polymers offer the formulator the same or greater production conveniences afforded to them when using Opadry formulations containing Hydroxypropoxymethylcellulose (HPMC) and also provide functionality previously unrealized. PVA-based films are known to have relatively low moisture vapor and oxygen permeability. On the other hand, NaCMC-based films have low oxygen permeability but relatively high water vapor permeability. Another important feature of NaCMC-based films is that, when formulated and applied properly, they are very glossy. NaCMC-based film coatings therefore offer the possibility of both enhanced functionality and aesthetics[29].

Opadry aqueous moisture barrier (AMB) and Opadry II 85 series are two proprietary families of PVA-based products that were commercialized in the mid to-late 1990s. The Opadry AMB formulation was optimized to provide the lowest moisture vapor transmission rate (MVTR) possible while still affording all the conveniences of fully formulated film-coating systems. It is supplied as a color-matched system and can be readily dispersed into water at the 20% solids level. Owing to the inherent tackiness of the PVA polymer, the maximum achievable spray rates obtained with Opadry AMB are not as high as those of HPMC-based Opadry II film coatings. The Opadry II 85 series family of products was developed to address this. Opadry II 85 series products offer MVTR almost as low as Opadry AMB but can be applied at significantly higher spray rates[30].

Film coatings based on PVA and NaCMC offer the formulator new functional benefits. It is now possible to coat moisture-sensitive cores, using aqueous coating processes, and preserve them through the use of PVA-based coatings. NaCMC based coatings provide demonstrable oxygen barrier properties and also excellent aesthetic characteristics.

CONCLUSION

On the basis of the studies carried out till date, it is focusing that aqueous film coating technology is now a days very important in the field of pharmacy particularly in formulation development and the aqueous based coating and its various aspects which are giving the more benefits over the organic coating, which leads to non-toxicity, cost effectiveness and non hazardous to environment.

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