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REVIEW ON AQUEOUS FILM COATING ON TABLET DOSAGE FORM

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ABSTRACT

Film coating is the process of application of a thin, uniform layer or film of polymeric material on the surface of the tablet. Tablet coating is one of the oldest pharmaceutical processes still in existence. Now days different organic and aqueous solvents are used in coating. There are various polymers from different chemicals characteristics are used for film coating; e.g. vinyl polymers, cellulose ethers, silicones etc. But many of the organic solvents are toxic in nature and causes problem in coating. Use of water over organic solvent is economic. Polymers and solvents are one of the important parts of coating. Coating also alters release of medicament and solubility. The main aim of review is to understand advantages and problems in aqueous film coating.

KEYWORDS: Aqueous film coating, Polymers, Solvents, Coating process parameters.

INTRODUCTION

The process of applying thin layer or film of polymer on tablet, capsule or pellet is essential for to protect the tablet from moisture, temperature, some are sensitive to light, oxidation. Coating helps in masking the bitter taste and unpleasant aroma. It modifies release and swallowing of tablet. Coating also improves appearance of tablet. Coating with different dyes helps in identification of tablet.

Aqueous film coating is environmental and economic and safe over the organic or non-aqueous film coating. No discussion on tablet coating would be completed without a brief

historical review of pharmaceutical coating to provide an appropriate perspective to evolutions in the coating process that have occurred over the past thousand years. Rhazes mentioned coated pills in Islamic drug literature. French publications in the 1600s described coating as a masking the taste of medicines.

In 1953, a dramatic change was made in tablet coating when Abbott Laboratories marketed the first film coated tablet. In 1950s, De. Dale Wurster patented an air suspension coater that efficiently applied film coating compositions. In 19th century sugar coating process was a skilled manipulative operation and could last for even seven years. The process was expensive.

The principle of tablet coating is relatively simple. Coating is the choice of option to solve such problems; because it increases cost of pharmaceutical dosage form. There are three primary components involved in tablet coating.

1. Tablet properties.
2. Coating compositions.
3. Coating process.

- Coating equipment.
- Parameters of coating process.
- Facility and ancillary equipment.
- Automation in coating processes.

Tablet film coating is performed by two ways, one is aqueous film coating (water as solvent) and another is non-aqueous film coating (organic solvents). High quality aqueous film coating must be smooth, uniform and adhere satisfactorily to the tablet surface and ensure chemical stability of drug. During the coating process tablet are exposed to high temperature and humidity variations which results in penetration of water inside the tablet core. Penetrated water can causes risk of degradation of moisture -labile drug.[1, 2, 3]

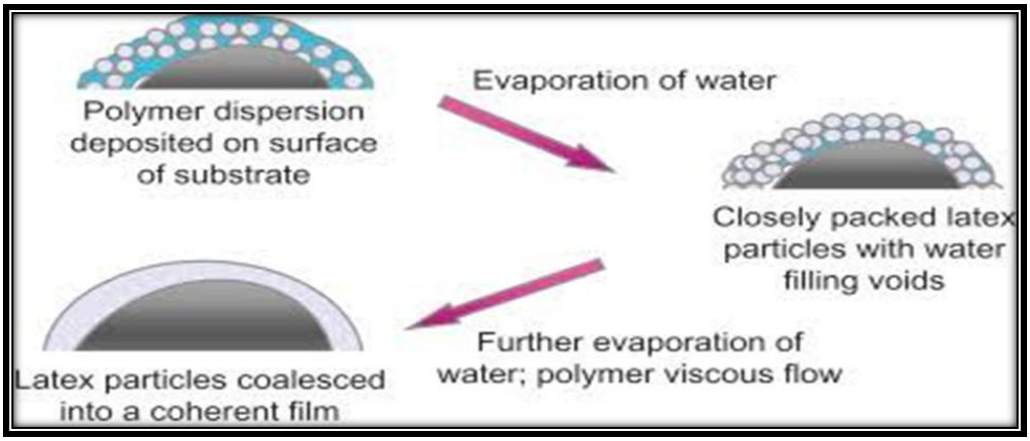


Fig-1: Mechanism of aqueous film coating.

Tablet as a dosage form

Tablet is a pharmaceutical dosage form. It comprises a mixture of pharmaceutical active ingredients (APIs) and other additives, commonly in powder form, pressed or compacted into a solid. Tablet 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 0.01mg to 1 gm of a drug dose by oral route of administration, by formulating as a tablet. Ingredients used in tablet dosage forms are mentioned in table no: 1

Sr. No	Name of ingredients	Examples
1.	Diluents	Lactose, dextrin, starch, sucrose, etc.
2.	Binders	Carboxymethylcellulose, ethylcellulose.
3.	Disintegrators	PVP, Alginate, cellulose, starch 5-20%.
4.	Lubricants & glidants	Talk, calcium stearate, stearic acid, etc.
5.	Colouring agents	Sunset Yellow, Amaranth, Brilliant blue. etc.
6.	Sweetening agents	Sucrose, liquid glucose, sorbitol, etc.
7.	Flavouring agents	Ethyl vanillin, peppermint oil, etc.

Coating is a process by which an essentially dry, outer layer of coating material (tablet) is applied to the surface of dosage form in order to confer specific benefits that broadly ranges from facilitating product identification to modifying drug release from dosage form. The tablet should release medicament gradually and the drug should be available for pharmacological action. The coating process can be specially formulated to regulate how fast the tablet dissolves and where the active drugs are to be absorbed into the body after administration. Coating may be applied to wide range of oral solid dosage forms, including tablets, capsules, pills, multiparticulates and drug crystals. The complete coating system is conducted in a chain of routinely operated acorn formed coating pans of galvanized iron

stainless steel or copper.[4-6] The smaller Pans are used for experimental, developmental and pilot plant operations, the larger pans for industrial production.[4, 5, 6]

Objectives of coating

- To mask the taste, odour, or colour of drug.
- To provide physical and chemical stability.
- To protect drug from gastric environment of stomach with an acidic resistant enteric coating.
- Facilitate the swallowing of dosage form.
- To protect them from storage environment (air, moisture and light).
- To improve esthetic qualities of product.
- Improve appearance and provide product identity.
- Improve product stability.
- To improve pharmaceutical elegance by use of special colours and contrasting printing.
- Facilitating handling, particularly in high speed filling.

Disadvantages of coating

1. Tablet coating increases the cost of formulation.
2. Coating may causes changes in properties of formulation.
3. Uneven coating of polymer dispersion changes the surface smoothness.

Basic principle involved in 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 colour 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 colours and contrasting printing is also possible. Primary components involved in tablet coating are tablet properties, coating process, coatin, equipment, parameters of the coating process, facility and ancillary equipment, 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 **a**ir handling unit and a dust collector.

Film formation mechanism

Aqueous film coating application is 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 polymers solution is applied to the surface of tablet, cohesion forces from a bond between the coating polymer molecules .To obtain high cohesion, the cohesive strength of polymer molecules must be relatively high and continues surface of the film material must coalesce. Coalescence of adjacent polymer molecular layer or surfaces occurs through diffusion. When most of the water evaporates, the viscosity of the solution increased (gelatin) and leaves the polymer chains in close proximity to each other and deposited 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. Film formation from dispersion occurs when polymeric particle coalesces to form a continuous film.

Making it more complex mechanism compared to film formation from solution. The coalescence of aqueous polymer dispersion deposited on the surfaces of a tablet into continuous film is initiated by water evaporation. As water evaporates, dispersed polymer particles are pushed into a closely packed, ordered array with water filling the voids. After the polymer particle comes into a contact with each other, they must deform and fuse in order to coalesce into 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 occurring through particle interfaces, making the film more homogeneous.

Film formation, i.e. coalescence is complex process and dependent on coating and storage conditions, coating polymer molecular weight and particle size, coating liquid constituents and properties like viscosity and surface tension. In the aqueous film coating technology first of all droplets are formed and after wetting and spreading the coating material finally coalescence is takes place.[8, 10, 11, 12]

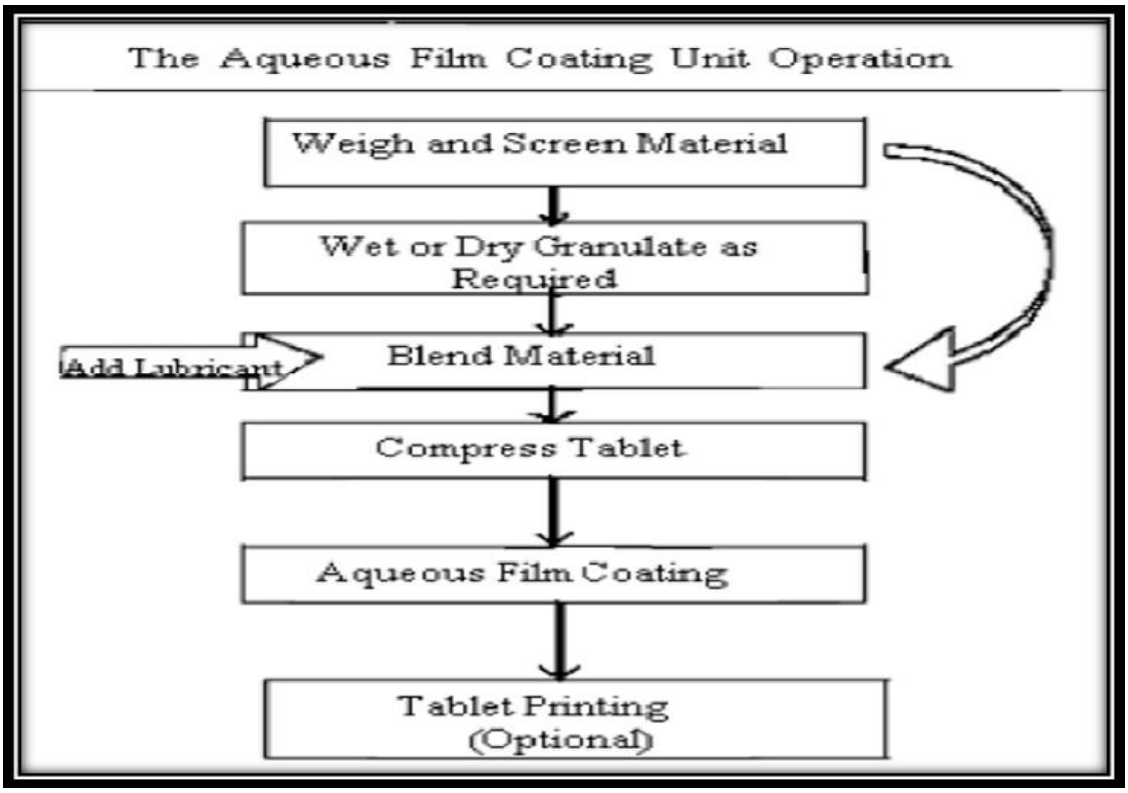


Fig. 2: Aqueous Film Coating Unit Operation.

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 odour; 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]

The process of the coating according the engineering success according to the Myths. Film coating of tablet is a multivalent process with many different factors, such as coating equipment, process conditions, composition of the core tablet and coating liquid, which affect the pharmaceutical quality of the final product. The side vented, perforated pan coater is the most commonly used coating device of tablets. Its airflow 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.

Traditionally the level of instrumentation and automation of coating equipment has been low and subsequently, the coating process difficult to control. To improve the reproducibility and predictability of coating process and quality and safety of the final coated product, demand for instrumentation and automation of coating equipment in the pharmaceutical industry are increased. The reduction of the product costs has become an important factor a requirement for efficient production. An automated film coating process and a critical process parameter monitoring system would provide a useful tool for controlling process and for understanding the phenomena during the process. High quality aqueous film coating must be smooth, uniform and adhere satisfactorily to the tablet surface and ensure chemical stability of a drug.

Advantages of aqueous film coating

1. Minimized weight increased.
2. Reduction in processing times.
3. Increases process efficiency an output.
4. Increases flexibility in formulation.

5. A simplified process.

Aqueous film coating material

Film formers

The film former is major ingredient in a coating formulation. As no polymer has all of the physical and chemical properties, such as chemical stability, chemical inertness, strong tablet adherence, flexibility, and printability, to meet the various application needs, the coating compositions must be formulated with plasticized polymers or mixtures of polymers to achieve the desired tablet coating. The polymers can be divided into essentially two classes: aqueous soluble polymers and water-insoluble (sustained release) or pH-dependent (enteric) soluble polymers.

The most commonly used water-soluble coating polymers are hydroxypropylmethylcellulose (HPMC), other cellulose derivatives and polyvinylpyrrolidone. Recently, new rapid release coating material has been introduced, such as amylose starch. Water-soluble coating materials dissolve completely in the gastrointestinal tract and do not modify the drug release characteristics of the dosage. These polymers are usually applied as aqueous solutions.[13,14]

- **Commonly used aqueous-soluble polymers**

1. Hydroxypropyl methylcellulose

The polymer is prepared by reacting alkali-treated cellulose first with methyl chloride to introduce methoxy groups and then with propylene oxide to introduce propylene glycol ether groups. The resulting products are commercially available in different viscosity grades. This polymer is a material of choice for air suspension and pan spray coating systems. The reason for this widespread acceptance includes.

1. Solubility characteristics.
2. Non-interference with tablet disintegration and drug bioavailability.
3. Flexibility, absence of taste, odour.
4. Stability in heat, air, light.

Aqueous film coating using HPMC has proven complex and more sensitive to changes in the process compared to those of organic solvent coating. In aqueous coating the water evaporation capacity is lower, which requires compensating adjustments to other coating parameter, such as air, temperature, flow rate of coating solution and spraying air pressure. The increased use of aqueous based film coating has clearly increased the amount of coating

defects. If the coating conditions during aqueous film coating using HPMC were better characterized, these problems could be avoided. Most of the other polymers become tacky during their drying cycle. This limits the quantity of even the low-viscosity grades that can be used, as it is difficult to spray viscous compositions, and they do not spread adequately on the sprayed surface to produce a smooth coating.[15,16]

2. Methyl hydroxyethylcellulose

This polymer is prepared by reacting alkali-treated cellulose first with methyl chloride and then with ethylene oxide. A wide variety of viscosity grades are available. Because of its structural similarity to Hydroxypropyl methylcellulose, this polymer is expected to have similar properties. It is marketed in Europe, but it is soluble in fewer organic solvents, it is not used as frequently as Hydroxypropyl methylcellulose.

3. Povidone

Povidone is a synthetic polymer consisting of linear 1 -vinyl-2-pyrrolidinone groups. The degree of polymerization results in materials of various molecular weight ranges. Povidone is usually available in four viscosity grades identified by their K values, Which approximate K-15,K-30,K-60, and K-90. The average molecular weight of these grades are 10,000, 40,000 160,000, and 360,000 respectively. The most common uses of Povidone in pharmaceuticals (frequently K-30) are as a tablet binder and a tablet coating. It has excellent solubility in variety of organic solvents and water.

4. Hydroxyproylcellulose

This material is manufactured by treatment of cellulose with sodium hydroxide, followed by reaction with propylene oxide at an elevated temperature and pressure. It is soluble in water below 40^0C (insoluble above 45^0 C), gastrointestinal fluids and many polar organic solvents. This polymer is extremely tacky as it dries from a solution system and may be desirable for a sub coat, but not for a flexible films. It is usually not used alone, but it is used in combination with other polymers to improve the film characteristics.

5. Polyethylene glycols

Polyethylene glycols (PGE) are manufactured by the reaction of ethylene glycol with ethylene oxide in the presence of sodium hydroxide at elevated temperature and under pressure. In addition to their other uses in formulations, they are used in film coating for which a wide variety of molecular weights are available. The materials with low molecular

weights (200 to 600 series) are liquid at room temperature and are used as plasticizers for coating solution films. The materials with high molecular weights (series 900 to 8,000) are white, waxy solids at room temperature.[15, 16]

Solvents

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

1. It should either dissolve or disperse the polymer system.
2. It should easily disperse other coating solution components into the solvent system.
3. Small concentrations of polymers (2 to 10%) should not result in an extremely viscous solution system (>300cps), creating processing problems.
4. It should be colourless, tasteless, odourless, inexpensive, nontoxic, inert and non-flammable.
5. It should have a rapid drying rate (the ability to coat a 300 kg load in 3 to 5 hours).
6. It should have no environmental impact.

The most widely used solvents, either alone or in combination are water, methanol, isopropanol, chloroform, acetone, methylethylketone, and methylene chloride. Because of environmental and economic consideration, water is the solvent of choice; however, several polymers cannot be applied from aqueous system.[15]

Plasticizers

The next most important component of the coating formulation is plasticizer. A wide range of plasticizers is available to the formulator such as:

A. Phthalate esters.
B. Phosphate esters other esters like citrates, stearates, sebacate, oleate, adipate.
C. Oils, glycerol, glycols etc.

Films prepared from pure polymers frequently are brittle and crack on drying. To correct this deficiency, the polymer can be chemically modified or other ingredients can be added to make the film more pliable. Plasticizers can be classified into two categories:

- Internal politicizing involves the chemical modification of a basic polymer to alter the physical properties of the polymer. Changes in the degree of substitution, the type of substitution, and the polymer chain length influence the physical characteristic of the polymeric film. Generally, the formulator must work with the polymers that are available, and the film properties are altered by the addition of external plasticizers. The selection of the proper plasticizers is very necessary because it affect the final coating of the any pharmaceutical dosage forms.

- The external plasticizer can be another polymer, a non-volatile liquid, or even the aqueous solvent. The plasticizer alters the polymer-polymer interactions to improve the flexibility of the film by relieving molecular rigidity. As a general rule, the film will become more flexible and more resistant to mechanical stress when a plasticizer is added to a coating composition. There is an optimal concentration of plasticizer to use for any film composition.[15,16]

The water-insoluble polymer suspension formulation requires high concentrations of water-insoluble plasticizers. The plasticizers facilitate the transformation of the discrete polymer particles on the sprayed surface into a continuous film when heat is applied. Several of the insoluble plasticizers may be incorporated in combination with one or more water-soluble plasticizers for the water-soluble polymer compositions. Some of these ingredients are hygroscopic and retain water in the films. Water itself can be an effective plasticizer, but the concentration will vary depending on the environmental temperature and relative humidity. Similarly, the properties of the film will be affected by the changing storage conditions.

Typical Plasticizers are listed:

1) Castor oil, USP
2) Propylene glycol, USP
3) Glycerine, USP
4) Polyethylene glycols, NF, low molecular weight of the 200 and 400 series
5) Surfactants

Colorants

Coating solution formulations may contain a wide variety of components in addition to the film former, solvents, and plasticizer. Colorants may be soluble in the solvent system or suspended as insoluble powders. They are used to provide distinctive colour and elegance to

a dosage form. To achieve proper distribution of suspended colorants in the coating solutions requires the use of fine powdered colorants (<10 microns). Repetitive production of coloured coating solutions from different lots of the same colorant can be particularly difficult if colorant lots have different dye content, crystal form of dye, or particle size distribution. In general, the suspended colorants must be milled in the coating solvent or solution to attain a uniform dispersion of the colorants. Colour variation in a product can be readily detected by the pharmacist and patient; therefore, the colours must be reproducible and stable.[15]

The most common colorants in use are:

1. FD&C dyes
2. FD&C lakes
3. Iron oxide
4. Titanium dioxide

Opaquant-extenders

These are very fine inorganic powders used in the coating solution formulations to provide more pastel colours and increase film coverage. These opaquants can provide a white coating or mask the colour of tablet core. Colorants are much more expensive than these inorganic materials, and effectively less colorant is required when Opaquant are used. The most commonly used material for this purpose is titanium dioxide.[15]

Some other materials are

1. Silicates (talc, aluminium silicate).
2. Carbonates (magnesium carbonates).
3. Sulphates (calcium sulphate).
4. Oxides (magnesium oxide).
5. Hydroxides (aluminium hydroxide).

Supplemental coating ingredients

Frequently adding other ingredients to a coating composition is necessary to stabilize or improve the product. The ingredients used in a film are generally tasteless, and flavours or sweeteners are added to enhance the esthetic properties of the product or to mask objectionable trace odours or tastes. Surfactants were previously identified as possible plasticizer; they also serve to solubilize minor ingredients, to reduce the surface tension of the coating composition, and to facilitate faster dissolution of the film. The stability of some colouring system can be significantly improved by the addition of antioxidants such as

ascorbic acid or alpha to copherol. Cellulosic coating solution can be particularly prone to microbial growth. Prolonged storage of aqueous-based coating preparations should be avoided, or antimicrobials should be incorporated in the formula. Antimicrobials that are routinely used in pharmaceuticals should be considered, including the parabens, ascorbic, and benzoates.

Typical aqueous-based coating composition includes

Table 2: Simple aqueous-based coating composition.

Sr.No	Ingredients	Quantity
1	Hydroxypropyl methylcellulose 2910,15 cps	6%
2	Propylene glycol	1.2%
3	Colorant/ Opaquant	0.5%
4	Water q.s	100%

Coating process

In most cases, the coating process is the last critical step in the tablet production cycle. Tablet coating is the application of a coating composition to a moving bed of tablets with the concurrent use of heated air to facilitate evaporation of the solvent. The distribution of the coating is accomplished by the movement of the tablets either perpendicular (coating pan) or vertical (air suspension coater) to the application of the coating composition. The successful application of the coating solution formula to a tablet provides the visual characteristics for the products; thus, the quality of product may be judged on this final production step. The coating process can be divided in to two types; i.e. sugar coating and film coating. The type of process chosen depends on the of coating that is to be applied, the durability (toughness) of the tablet core, and the economics of the process. Because of the ever-increasing cost of energy and labour, the cost of organic solvents, and the associated environmental constraints, the economics of the process is receiving greater emphasis.[18]

Introduction to the coating room

Aqueous film coating requires equipment with high airflow and excellent control over the coating process. Aqueous film coating needs tighter control of the coating process than organic solvent-based coating systems. The tablets are normally designed to disintegrate in water, so the rate of application of the coating composition is critical; too slow or too rapid application of the coating will cause the tablet to undergo excessive erosion and breakage. View of a typical coating operation.[19]

(A) What the operator sees

1. Coating Pan
2. Suspension vessel
3. Pumping System
4. Spraying System

(B) What the operator doesn't sees

1. Inlet side of the pan
2. Inlet air turbine
3. Inlet air filtration with paper & HEPA filters
4. Air treatment packages:
5. Air heating system
6. Steam, high-pressure hot water, electricity (not recommended)
7. Humidification and dehumidification systems
8. Outlet side of the pan:
9. Solvent recovery system (refrigeration, torch)
10. Bag house (or scrubber)
11. Outlet air turbine

Coating Equipment's

Most coating processes use one of three general types of equipment

1. The standard coating pan.
2. The perforated coating pan.
3. The fluidized bed (air suspension) coater.

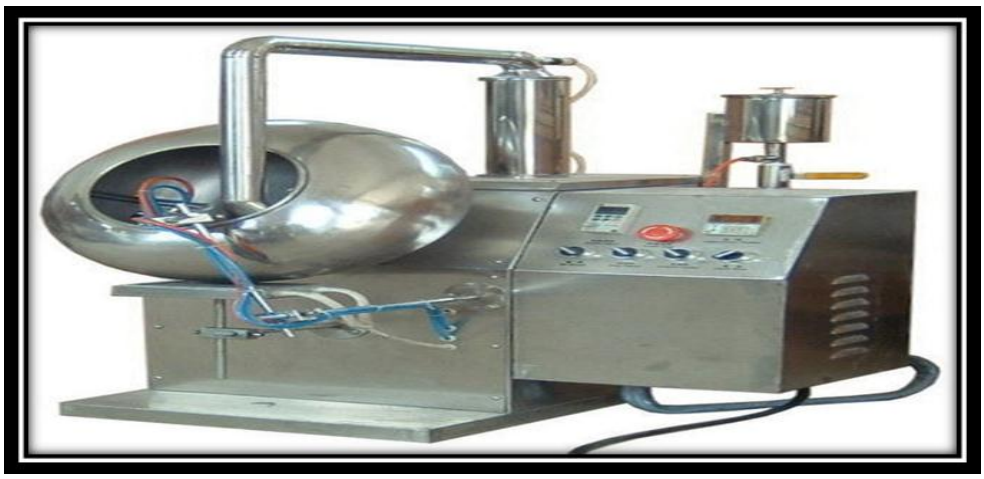


Fig. 3: Standard coating pan.

Fig. 4: Entire operation of perforated coating pan.

Fig. 5: The fluidized bed (air suspension) coater.

The following coating pans can provide adequate airflow and control to be used for aqueous coating: -Two Basic Types of Perforated Coating Pans: Pliva Pharmaceuticals (Poland): The side vented and front-vented coating pan are as follows in which side vented is completely perforate and remaining is partially perforate.[20]

1. **Accela cota:** This is an angular pan operating on a horizontal axis. Drying air is directed into the pan, through the tablet bed, and exhausted out the perforations in the periphery of the pan.
2. **Hi-Coater:** This is similar to Accela Cota, but only a portion of the pan periphery has perforations. Like the Accela Cota, continuous venting of the exhaust air from the pan is still attained The Hi-coater in which Air in let, air outlet, sprayer and pan with perforated ribs.
3. **Driacoater:** This introduces drying air through hollow, perforated ribs located on the inside periphery of the pan. As the pan rotates, the ribs pass under the tablet bed, and drying air can fluidize the tablets. The exhaust air passes out the back of the pan.

The fluidized bed (air suspension) coater: the working principle of fluidized bed or air suspension system is basically similar to that of the other spraying systems. This process will continue until you achieve the right coating on your tablets.

- It has a vertical cylinder
- A column of drying air flows upwards suspending all the tablets. This causes the tablets to move upwards, outwards and then downwards, a process we refer to as fluidization.

Process parameters

Many quality aspects of the final coated product are greatly influenced by the combined effect of process parameter values used in aqueous film coating. Coating process parameter affects the spreading, penetration and drying (i.e. evaporation of water) of the coating liquid on the tablet surface and subsequently, the surface roughness and the residual moisture of the coated tablets. There are number of the process parameters which taken in to consideration for getting success in the final coated formulations during the aqueous film coating process.[22,23]

Some of the important process parameters in the coating process are as follows

1. **Air flow rate**

Although process air is an essential element in the manufacture of pharmaceutics, earlier studies of pan coater have not put much emphasis on the effects of airflow rate on the coating process. The flow rate of perforated pan coater, the airflow is reported to affect the drying efficiency of the coating unit and, the quality of the coated tablets. An increase of the inlet airflow rate causes a linear increase in the tablet bed temperature, increasing the evaporative capacity of the coating unit and eliminating over wetting problems of tablets. However, it

does not find the inlet airflow to affect the content uniformity of the coating composition or coating efficiency. So the air flow rate is very important which affect the coating because there are two inlet and out let air therefore it is necessary to maintain the proper flow of the both inlet and outlet air throughout the coating process.[24]

2. Absolute humidity of inlet air

The Absolute humidity of the coating process air is effect on the properties of the film coated tablet. It is obvious that the humidity of the coating process air is an important factor affecting the penetration and evaporation of water on the tablet surface. The water removal efficiency of the coating process is linearly correlated with the residual moisture content, tensile strength and porosity of the coated core tablet.[25]

3. Spraying air pressure

The spraying air pressure disperses the coating liquid into droplets and affects the droplet size distribution and the droplet spreading and penetration on the tablet surface. For the formation of an adequate and adhesive film coat, the atomized droplets have to spread completely over the surface of the tablet and only limitedly penetrate into the tablet core. Increasing the spraying air pressure to form smaller droplets and to increase the droplet velocity and momentum increases the extent of droplet spreading and therefore the rate of droplet drying and could thus reduce the degree of solution penetration into the substrate.

In general, increasing the spraying air pressure decreases the surface roughness of coated tablets and produces denser and thinner film. If spraying air pressure is excessive, the spray loss is great; the formed droplets are very.

4. Flow rate of coating solution

During a successful aqueous film coating process, the flow rate of the coating liquid is equal to the rate of water evaporation from the coated tablet's surface. Increasing the flow rate allows a greater number of droplets to be sprayed onto the tablet bed per time unit and increases the droplet size. The flow rate is an important parameter since it impacts the moisture contents of the formed coating and, subsequently, the quality and uniformity of the film. A low coating liquid flow rate causes incomplete coalescence of polymer due to insufficient wetting, which could result in brittle film. A high coating liquid flow rate may result in over wetting of the tablet surface and subsequent problems such as picking and sticking.

5. Pan air temperature

It is an important that the Pan Air temperature is monitored, because the spray tablet core interface is where problems manifest during aqueous film coating. The spray rate of coating solution, inlet airflow rate and inlet air temperature have significant effect on tablet bed surface temperature, whereas spraying air pressure and pan speed do not. During the coating process, the initiation of the spraying causes a rapid drop in the pan air temperature until equilibrium is attained. The pan air temperature affects the drying efficiency (i.e. water evaporation) of the coating pan and the uniformity of coating.

6. Rotating speed of the pan

It is well recognized that increasing the rotating speed of the pan improves the mixing of tablets. The pan speed affects the time the tablet spend on the spraying zone and the homogeneous distribution the coating solution on the surface of each tablet throughout the batch. Increasing the pan speed decreases the thickness variation and improves the uniformity of coatings. Too rapid a rotating speed of the pan will cause the tablet to undergo excessive attrition and breakage.

7. Inlet and outlet temperatures

- An alert organization keys on an outlet air temperature target and let the inlet vary within a range.
- Outlet air target is usually between 45and 55 0C.
- Important Distinction!
- Inlet air temperature is a set point, whereas outlet air temperature is a function.

1. Inlet air CFM + Inlet air Temp + Spray Rate+ Atomizing air = Outlet Temp.
2. Inlet temp is a set point, outlet temp is a function
3. Monitoring outlet air temperature helps us determine if any of the other factors have
4. Changed or shifted.

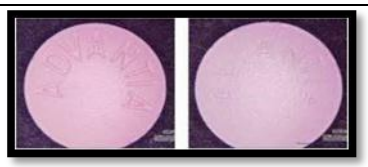
Coating defects

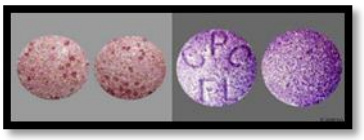
Variations in formulation and processing conditions may result in unacceptable quality defects in the film coating. The source of these defects and some of their probable causes are described in the following sections.

Aqueous Film Coating Defects

There are numbers of the limitations in aqueous film coating process if wrong selection of the coating composition and process parameters are selected so before process of the coating is going on the possible quality defects should be minimized by proper selection.

The following are the list of the aqueous film coating defects

Sr.no	Defect		Causes	Remedies
1	Orange peel effect: Surface defect resulting in the film being rough and nonglossy. Appearance is similar to that of an orange.		1). Not enough vehicles. 2). High atomizing air. 3). High CFM/inlet temp.	1). Thinning the solution with additional solvent. 2). Moving the nozzle closer to the tablet bed
2	Picking: isolated areas of film are pulled away from the surface when the tablet sticks together and then apart.		1). Spray rate too high. 2).Guns too close together. 3).Insufficient atomizing air.	1).Reduce the liquid application rate. 2).Increase in the drying air temperature and air volume.
3	Colour variation: involves variation in colour of the film.		1).Processing conditions. 2).Improper mixing, uneven spray pattern.	1).Reformulation with different plasticizers and additives
4	Bridging of logo: The letters and numbers fill in with dried suspension.		1).Inadequate atomizing air. 2).Poor tooling design	1).Plasticizer or opaquants reduces the film strengt
5	Cracking: the film either cracks		1).Internal stress in the film exceeds	1).Tensile strength of the film can be

	across the crown of the tablet		tensile strength of the film	increased by Using higher molecular weight polymers
6	Mottling: uneven distribution of the colour on the surface of the tablet, with dark and light patches.		1).Due to different colouration of the excipient or the degradation product of the tablet is coloured.	1).Coating solution prepare properly in sufficient quantity

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 and to understand coating defects like, sticking, picking, mottling, and so on. It was also conclude that this study helps in selection of polymer for film coating, so that these polymers can be used for controlled drug delivery systems, enteric coating and other such type of coatings.

REFERENCES

1. http://www.pformulate.com/pformcoating.htm.
2. Lachman/Lieberman's, The theory and practice of Industrial Pharmacy., 2013; 4: 497-498.
3. Leon Lachman- pharmaceutical dosage forms: Tablet, 3.
4. Lachman L, Lieberman HA and Joseph LK. The Theory and Practice of Industrial Pharmacy. Varghese Publishing House; Mumbai., 1989; 3: 297-321.
5. Lachman L, Liberman H, and Kanig J. The Theory and Practice of Industrial Pharmacy., 1992; 3: 293-345, 346-373.
6. Aulton M. Pharmaceutics: The Science of Dosage Form Design. International Student Edition, 304-321, 347-668.
7. Obara S and Mc Ginity JW. Influence of processing variables on the properties of Free films prepared from aqueous polymeric dispersions by a spray technique. Int. J. Pharm., 1995; 126: 1-10.

8. Harris MR and Ghebre-Sellassie I. Aqueous polymeric coating for modified.
9. Release oral dosage forms. In Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms. Marcel Dekker Inc., New York, 1997; 2: 81-100.
10. Ruotsalainen M. Studies on aqueous film coating of tablets in side vented perforated pan coater. Academic Dissertation, Helsinki, 2003.
11. Obara, S. and Mcginity, J.W. Influence of processing variables on the properties of free films prepared from aqueous polymeric dispersions by a spray technique. Int. J. Pharm., 1995; 126: 1-10.
12. Aulton, M.E. and Twitchell, A.M., Film coat quality. In Pharmaceutical coating technology, (Cole, CG. Ed.) Taylor & Francis, UK, 1995; 363-408.
13. Dobler F and Holl Y. Mechanism of particle deformation during latex film formation. In Film Formation in Waterb orne Coatings, Provder T, Winnik MA and Urb an, MW. eds., ASC Symposium Series Washington., 1996; 648: 22-43.
14. Dansereau, R., Brock, M. and Furey-redman N., Solubilisation of drug and excipient into a HPMC-based film coating as a function for the coating parameters in a 24" Accela-Cota. Drug Dev. Ind. Pharm., 1993; 19: 793-808.
15. Krogars, K., Antikainen, O., Heinamaki, J., Laitinen, N. and Yliruusi, J., Tablet film coating with amylose-rich maize starch. Eur. J. Pharm. Sci., 2002; 17: 23-30.
16. Lachman/Lieberman's. The Theory and Practice of Industrial Pharmacy., 2013; 4: 500–506.
17. Encyclopaedia of pharmaceutical technology, Volume-1, Edited by- James Swarbrick & James C. Boylan., 337-349.53
18. Porter, S. C. and Felton, L. A. Techniques to assess film coatings and evaluate film-coated products. Drug Development and Industrial Pharmacym, 2010; 36: 128–42.
19. Lachman/Lieberman's. The Theory and Practice of Industrial Pharmacy., 2013; 4: 506.
20. Dr. P.D. Bharadia*, Dr. Vikram M. Pandya, A Review on Aqueous Film Coating Technology, Indian Journal of Pharmacy and Pharmacology September, 2014; 1(1): 78-80.
21. Fred A. Rowley Director, Corporate Manufacturing Technical Support Watson Labs. Inc. The International Society of Pharmaceutical Engineers, Los Angeles Chapter, 2005; 12.
22. https://www.saintytec.com/types-of-tablet-coating-machine/
23. Obara, S. and Mcginity, J.W. Influence of processing variables on the properties of free films prepared from aqueous polymeric dispersions by a spray technique. Int. J. Pharm., 1995; 126: 1-10.

24. Twitchell, A.M., Hogan, J.E. and Aulton, M.E., The behaviour of film coating droplets on the impingement onto uncoated and coated tablet. J. Pharm. Sci., 1995; 5: 190-195.
25. Cole GC May G Neale PJ Olver MC and Ridgway K. The design and performance of an instrumentation system for aqueous film coating in an industrial tablet coating machine. Drug Dev. Ind. Pharm., 1983; 9: 909-944.
26. Poukavoos, N. and Peck, G.E., Evaluation of moisture sorption by tablet cores containing superdisintegrants during the aqueous film coating process. Pharm. Res., 1993; 10: 1212-1218.
27. Shah A. Coating Tablet Defects: The Cause and The Remedies, 2011. http://vikramthermo.blogspot.in/2011/06/picking-and sticking.html
28. Picta R. Problems Associated with Tablet Manufacturing, 2011. http://www.pharmainfo.net/rajapicta1023/blog/problems-associated-tablet-manufacturing.
29. Shah A. Coating Tablet Defects: The Cause and the Remedies. Coating Polymers, 2011. http://vikramthermo.blogspot.in/2011/06/picking-andsticking.html?goback=.gde_329 2037_member_56911500.
30. Shah A. Coating Tablet Defects: The Cause and The Remedies. Coating Polymers, 2011. http://vikramthermo.blogspot.in/2011/06/picking-andsticking.html?goback=.gde_329 2037_member_56911500.
31. Gupta Ankit *, Bilandi Ajay, Kataria Mahesh Kumar, Khatri Neetu, Tablet Coating Techniques: Concepts And Recent Trends, International Research Journal Of Pharmacy., 2012; 3(9): 57.
32. Himaja V, Sai Koushik O*, Karthikeyan R and Srinivasa Babu P, Research Article A Comprehensive Review on Tablet Coating, Austin Pharmacol Pharm., 2016; 1(1): 4.