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## Process Parameters and Composition of Film coating: A Review

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### ABSTRACT

Tablet coating is perhaps one of the oldest pharmaceutical processes still in existence. The 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. Coating solution composition may affect the quality of final coated tablets. Some coating process parameters are affect the final quality of coated tablets so it is necessary to optimize the coating process parameters for particular equipment and particular film former. Optimization of composition of film coating solution is also required.

**Keywords:** Film coating, oral dosage form, Optimization, Coating Process parameters, Coating composition.

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## INTRODUCTION

All drugs have their own characteristic, like some drugs are bitter in taste or has an unpleasant odor, some are sensitive to light or oxides, some are hygroscopic in nature. Because of this reason tablet coating is the choice of option to solve such problems in conventional dosage form.<sup>1,2</sup>

In the past sugar coating was mostly borrowed from the confectionary industry. But now a days it is replaced with film coating, because the sugar coating process was a skilled manipulative process and could last for even five days. The operator must be highly skilled for such coating. Hence film coating is preferred over 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 solvent are used.) Some problems are associated with the non aqueous film coating like employee safety (it's dangerous, it smells, and it's not good to breathe.) atmosphere pollution etc. But key problem is with the approval of the regulatory authority. High quality aqueous film coating must be smooth, uniform and adhere satisfactorily to the tablet surface and ensure chemical stability of a drug.

### “ Why Tablet Coating is Required ? ”

A number of reasons can be suggested:

1. The core contains a material which has a bitter taste in the mouth or has an unpleasant odour.
2. Coating will protect the drug from the surroundings with a view to improve its stability.
3. Coating will increase the ease by which a tablet can be ingested by the patient.
4. Coating will develop the mechanical integrity, means coated products are more resistant to mishandling (abrasion, attrition etc.)
5. 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.
6. The active substance is coloured and migrates easily to stain hands and clothes.
7. The coated tablets is packed on high-speed packaging machine. Coating reduces friction and increases packaging rate.
8. Coating can modify the drug release profile, e.g., enteric coating, osmotic pump, pulsatile delivery.

### Definition :

A film coating is a thin polymer-based coat applied to a solid dosage form such as a tablet. The thickness of such a coating is usually between 20-100  $\mu\text{m}$ . Under close inspection the film

structure can be seen to be relatively non- homogenous and quite distinct in appearance, from a film forming, from casting a polymer solution on a flat surface.

Modern approach to coating tablets, capsules, or pellets by surrounding them with a thin layer of polymeric material.

### **ASPECTS OF TABLET COATING :<sup>3,4</sup>**

Aspects of tablet coating of a solid dosage form are often designed to perform a specific function. For example; protection against moisture, taste masking pH or time controlled release.

The aspects of coating pharmaceutical dosage form such as a tablet can be categorised into three main headings : Therapy, Technology, Marketing.

#### **i. Therapy**

- i) Avoid irritation of oesophagus and stomach
- ii) Avoid bad taste
- iii) Avoid inactivation of drug in the stomach
- iv) Improve drug effectiveness
- v) Prolong dosing interval
- vi) Improve dosing interval
- vii) Improve patient compliance

#### **ii. Technology**

- i) Reduce the influence of moisture
- ii) Avoid dust formation
- iii) Reduce influence of atmosphere
- iv) Improve drug stability
- v) Prolong shelf life

#### **iii. Marketing**

- i) Avoid bad taste
- ii) Improve product identity.
- iv) Improve appearance and acceptability.

#### **Advantages of tablet coating:-**

1. 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.

2. 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.

**Disadvantages of tablet coating:-**

- 1) Disadvantages of sugar coating such as relatively high cost, long coating time and high bulk have led to the use of other coating materials.
- 2) However the process of coating is tedious and time-consuming and it requires the expertise of highly skilled technician. r the process is tedious and time-consuming and it requires the expertise of highly skilled technician.

**FILM COATING:** <sup>5,6,7</sup>

Film coating and sugar coating shares the same equipments and process parameters. Two methods,

## 1) Pan-Pour method:

- Same as that of pan-pour sugar coating
- Method is relatively slow and relies heavily on skill and technique of operator
- Aqueous based film coating is not suitable due to localized over-wetting.

## 2) Pan-Spray method:

- Use of automated spraying system

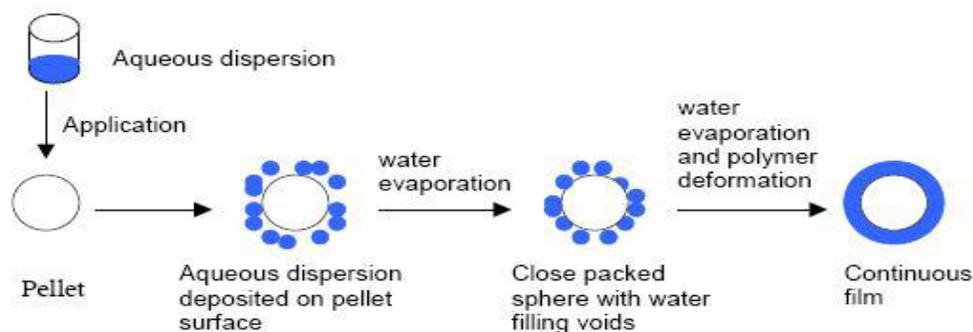
**Types of Film Coating**

- Immediate release
- Modified release

**Mechanisms of Film Formation** <sup>8,9,10</sup>

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 complete evaporation of the residual water, the individual polymer chains align themselves to form a cohesive film. 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. Film formation from dispersion occurs when polymeric particles coalesce to form a continuous film (Figure.1), making it a more complex mechanism compared to film formation from solution.



**Figure 1: Film formation from aqueous polymer dispersion**

The coalescence of aqueous polymer dispersion deposited on the surface of the tablet into a 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 particles come into contact with each other, they must deform and fuse in order to coalesce into a film. 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. 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 of coatings.

**FILM COATING FORMULATION CONTAINS FOLLOWING COMPONENTS:-<sup>11,12,13</sup>**

- I. Polymer,**
- II. Plasticizer,**

**III. Solvent / Vehicle,****IV. Colourants,****V. Miscellaneous coating solution components.**

Ideal requirements of film coating materials are summarized below :

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

**POLYMERS:-<sup>14,15,16</sup>**

Table No:1 Amongst the vast majority of the polymers used in film coating are cellulose derivatives and copolymers.

<b>Immediate release coating polymers</b>	<b>Modified release coating polymers</b>	
<p><b>1.Cellulose derivatives:</b> The mostly widely used of cellulosic polymers is <b>HPMC (WHY?)</b></p> <ul style="list-style-type: none"> <li>- <b>It is readily soluble in aqueous media</b></li> <li>- Forms film with good mechanical properties ( strength, flexibility and adhesion to the tablet core)</li> <li>- <b>Easy application of the coat</b></li> </ul> <p>Other examples are MC &amp;</p>	<p><b>Extended release</b></p> <p>They are dissolved in Organic solvent or dispersed in aqueous medium (why for enteric coating?)</p> <p><b>Cellulosic derivatives:</b> Highly substituted cellulosic ether, thus rendering the polymer water-insoluble. E.g. Ethyl cellulose</p>	<p><b>Enteric coating</b></p> <p><b>1.Methacrylic acid copolymers:</b> The presence of carboxylic acid groups renders this class to be insoluble in water at low PH (stomach) but gradually becomes soluble as the PH rises. E.g. Ethyl cellulose towards neutrality (upperpart of the small intestine).</p> <p><b>2. Phthalate esters:</b> e.g. cellulose</p>

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**HPC 2. Vinyl derivatives:**

acetate phthalate

PVP, it has a limited use in film coating because of its inherent tackiness. A copolymer of PVP and vinyl acetate forms better films.

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**Non-enteric polymers**

Hypromellose, Hydroxyethyl cellulose, Hydroxyethylmethyl cellulose Carboxymethylcellulose sodium, Hydroxypropyl cellulose, Polyethylene glycol, Ethylcellulose.

**Enteric polymers**

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:

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

Several kinds of enteric layer systems are now available -

One layer system - The coating formulation is applied in one homogeneous layer, which can be white-opaque or coloured. Benefit is only one application needed.

Two layer system - To prepare enteric tablets of high quality and pleasing appearance the enteric formulation is applied first, followed by coloured film. Both layers can be of enteric polymer or only the basic layer contains enteric polymer while top layer is fast disintegrating & water-soluble polymer.

Ideal properties of enteric coating material are summarized as below

- i) Resistance to gastric fluids.
- ii) Susceptible/permeable to intestinal fluid.
- iii) Compatibility with most coating solution components and the drug substrate.
- iv) Formation of continuous film.
- v) Nontoxic, cheap and ease of application.
- vi) Ability to be readily printed.

Some examples of enteric coating polymers

Hypromellose phthalate, Polyvinyl acetate phthalate, Cellulose acetate phthalate, Polymethacrylates, Shellac.

**1. Hydroxypropyl methylcellulose (HPMC) :**

Substituent groups: -CH<sub>3</sub>, -CH<sub>2</sub>-CH(OH)-CH<sub>3</sub>

It is available in different viscosity grades. It is a polymer of choice for air suspension and pan spray coating systems because of solubility characteristics 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 odour, color and other additives can be easily incorporated.

Disadvantage includes:

when it is used alone, the polymer has tendency to bridge or fill the debussed tablet surfaces. So mixture of HPMC and other polymers/plasticizers is used.

**2. MHEC (Methyl Hydroxy Ethyl Cellulose) :**

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

**3. EthylCellulose (EC) :**

Substituent groups: -CH<sub>2</sub>-CH<sub>3</sub> 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 pseudo latex systems contain high solids, low viscosity compositions that have coating properties quite different from regular ethyl cellulose solution.

**4. Hydroxy Propyl Cellulose (HPC) :**

Substituent groups: -CH<sub>2</sub>-CH(OH)-CH<sub>3</sub>

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.

**5. 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.

#### **6. Sodium carboxy methylcellulose :**

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.

#### **7. 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.

#### **8. Cellulose acetate phthalate (CAP) :**

Substituent groups: -CO-CH<sub>3</sub>, -CO-C<sub>6</sub>H<sub>4</sub>-COOH

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.

#### **9. Shellac:**

This is a purified resinous secretion of insect *Lacifer lacca*. Various grades of dewaxed material can be produced by removing some or all of the approximately 5% of wax in the final shellac.

Shellac is insoluble in water but shows solubility in aqueous alkalis; it is moderately soluble in warm ether.

Variety of application, which are included

- A seal coat for tablet cores prior to sugar coating.
- An enteric coating materials
- A modified release coating

## II. PLASTICIZERS :

As solvent is removed, most polymeric materials tend to pack together in 3-D honey comb arrangement. “Internal” or “External” plasticizing technique is used to modify quality of film. 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.

### PLASTISIZERS ARE CLASSIFY IN THREE GROUPS -

- 1) Polyols
- 2) Organic esters
- 3) Oils/glycerides

#### 1) Polyols :

Polyethylene glycol 400,  
glycerol,  
propylene glycol.

#### 2) Organic esters :

phthalate esters,  
dibutyl sebacete,  
citrate esters.

#### 3) Oils/glycerides :

castor oil,  
acetylated,  
monoglycerides,  
fractionated coconut oil.

## III) SOLVENTS :

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

Ideal requirement are summarized below :

- i) Should be either dissolve/disperse polymer system

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

Mostly solvents are used either alone or in combination with water, ethanol, methanol, isopropanol, chloroform, acetone, methylene chloride, etc.

#### **The major classes of solvents being used are**

Water, Alcohols, Ketones, Esters, Chlorinated hydrocarbons. Because of environmental and economic considerations, water is the solvent of choice; however organic coating is totally can not be a voided.

#### **IV. COLOURANTS :**

Colourants can be used in solution form or in suspension form. To achieve proper distribution of suspended colourants in the coating solution requires the use of the powdered colourants (<10 microns). Most common colourants in use are certified FD & C or D & C colourants. These are synthetic dyes or lakes. Lakes are choice for sugar or film coating as they give reproducible results.

Concentration of colourants 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 otherhand, 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 intestinal track.

Water insoluble pigments are more favourable than water soluble colours for the following reasons :

- Better chemically stability in light
- Optimised impermeability to water vapour
- Better opacity
- Better covering ability.

#### **Colourants classified as-**

A) Organic dyes,

B) Inorganic colours,

C) Natural colours.

**A) Organic dyes :** Sunset yellow,  
Tartrazine,  
Erythrosine.

**B) Inorganic colours :** Iron oxide,  
Titanium dioxide,  
Talc.

**C) Natural colours :** Anthrocyanins,  
Ribofloavine,  
Carmine.

### **MISCELLANEOUS COATING SOLUTION COMPONENTS:**

To provide a dosage form with a single characteristic, special materials may be incorporated into a solution.

**Flavours and sweeteners** are added to mask unpleasant odours or to develop the desired taste. For example, aspartame, various fruit spirits (organic solvent), water soluble pineapple flavour (aqueous solvent) etc.

**Surfactants** are supplementary to solubilize immiscible or insoluble ingredients in the coating. For example, Spans, Tweens etc.

**Antioxidants** are incorporated to stabilize a dye system to oxidation and color change. For example oximes, phenols etc.

**Antimicrobials** are added to put off microbial growth in the coating composition.

Some aqueous cellulosic coating solutions are mainly prone to microbial growth, and long-lasting storage of the coating composition should be avoided. For example alkylisothiazoloinone, carbamates, benzothiazoles etc.

### **PROCESS PARAMETER :**

#### **Spray rate :-<sup>17</sup>**

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. A low coating liquid spray rate causes incomplete coalescence of polymer due to insufficient wetting, which could effect in brittle films. A high coating liquid spray rate may result in over wetting of the tablet surface and subsequent problems such as picking and sticking. 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.

### **Atomizing Air Pressure :<sup>18</sup>**

In general, increasing the spraying air pressure decreases the surface roughness of coated tablets and produces denser and thinner films. 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. If spraying air pressure is inadequate, the film thickness and thickness variation are greater possibly due to change in the film density and smaller 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 Pressure :<sup>19</sup>**

The inlet air temperature affects the drying efficiency (i.e. water evaporation) of the coating pan and the uniformity of coatings. 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. Too much air temperature increases the premature drying of the spray during application and, subsequently, decreases the coating efficiency. 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.

### **Rotating Speed of Pan :<sup>20,21,22</sup>**

It is well documented that increasing the rotating speed of the pan improves the mixing of tablets. 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. Too much rotating speed of the pan will cause the tablet to undergo unnecessary attrition and breakage

### **Defects In Tablet Coating:-<sup>23</sup>**

Here is a list of common defects associated with coated tablets .

**Picking and sticking.:** This is when the coating removes a piece of the tablet from the core. It iting the tablets, by under-drying, or by poor tablet quality.

**Bridging.:** This occurs when the coating fills in the lettering or logo on the tablet and is typically caused by improper application of the solution, poor design of the tablet embossing, high coating

viscosity, high percentage of solids in the solution, or improper atomization pressure..

**Capping:** This is when the tablet separates in laminar fashion. The problem stems from improper tablet compression, but it may not reveal itself until you start coating. How you operate the coating system, however, can exacerbate the problem. Be careful not to over-dry the tablets in the preheating stage. That can make the tablets brittle and promote capping.

**Erosion:** This can be the result of soft tablets, an over-wetted tablet surface, inadequate drying, or lack of tablet surface strength.

**Twinning:** This is the term for two tablets that stick together, and it's a common problem with capsule shaped tablets. Assuming you don't wish to change the tablet shape, you can solve this problem by balancing the pan speed and spray rate. Try reducing the spray rate or increasing the pan speed. In some cases, it is necessary to modify the design .

**Peeling and frosting:** This is a defect where the coating peels away from the tablet surface in a sheet. Peeling indicates that the coating solution did not lock into the tablet surface. This could be due to a defect in the coating solution, over-wetting, or high moisture content.

**Mottled color:** This can happen when the coating solution is improperly prepared, the actual spray rate differs from the target rate, the tablet cores are cold, or the drying rate is out of spec.

**Orange peel:** This refers to a coating texture that resembles the surface of an orange. It is usually the result of high atomization pressure in combination with spray rates that are too high.

#### CONCLUSION:-

Tablet coating has been subject of remarkable developmental efforts aiming to ensure and enhance end product quality of tablet dosage form. Film coating is now a days very important in the field of pharmacy particularly in formulation development. Process parameters and coating composition play an important in coating of tablets. Use of different polymers during film coating is very interesting and important for improving quality of coating, So for getting good final quality of coated tablet it would be necessary to optimize the parameters. In future there is enormous developments has to be done in the area of tablet film coating

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