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Review Article

Review on Polymers Used for Film Coating

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ABSTRACT

Film coating is the process that involves the depositions of a thin, but uniform, film on to the surface of the substrate. Film coating systems are dry blend concentrates of polymers plasticizers, opacifiers, glidantsbinders, anti tacking agents, antifoaming agents, surfactants, fillers and extenders. Film coating systems are ready to use and are available in aqueous or organic systems. They can be reconstituted with organic solvent system, aqueous systems or hydro-alcoholic systems to prepare pharmaceutical solid oral dosage forms. A polymer used for film coating of tablets has great importance. These polymers are described in detail with their characteristics which are responsible for effective, enteric or sustained release action. Polymers are one of the important parts of this type of coating. There are various polymers from different chemical natures are used for film coating; e.g. vinyl polymers, cellulose ethers, polyesters, silicones, polysaccharides and so on. Each one of these polymers has different characteristics and that are useful for thin polymer coating, enteric coating, sustained release action. Among all these properties like solubility or insolubility in aqueous solvent, resistance to gastric fluid, mechanical properties, thermo mechanical properties are useful in preparing a effective form such as thin polymer coating, enteric coating, and so on.

Key-words: Polymers, Film Coating, Plasticizers

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1. INTRODUCTION

Film coating is the process whereby a tablet, capsule, or pellet is surrounded by a thin layer of polymeric material [1].This involves the deposition of thin polymeric film onto the dosage form[2].

This is the popular alternative to sugar coating. Film coating systems and pharmaceutical coatings films are extensively used by pharmaceutical companies for coating solid dosage form[3,4].

Film coating is a process of depositing a thin layer of material on to a substrate. The goal of film coating substrate is

1. To provide functional protective barrier to the outer surface of the substrate.
2. To provide a pleasing appearance.

1.1 Types of film coating[5]

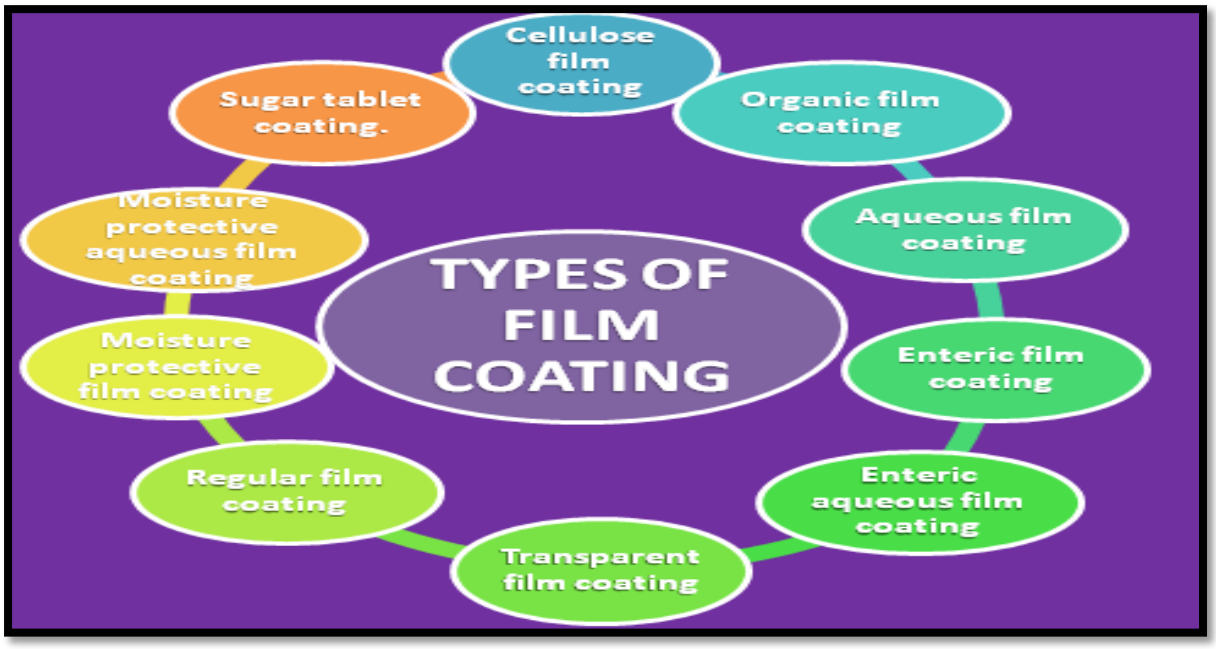


Fig. 1:Types of film coating

1.2 ADVANTAGES OF FILM COATING[6]

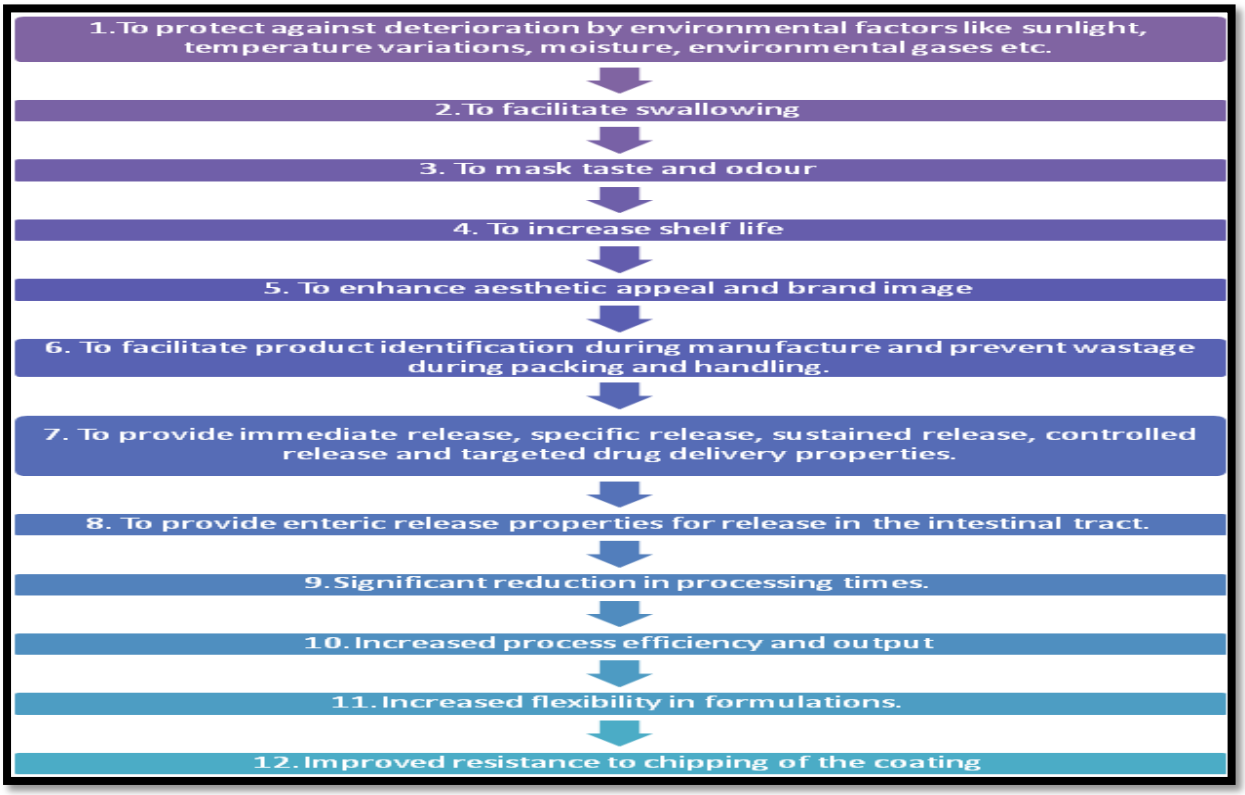


Fig.2: Advantages of film coating

1.3 DISADVANTAGES OF FILM COATING

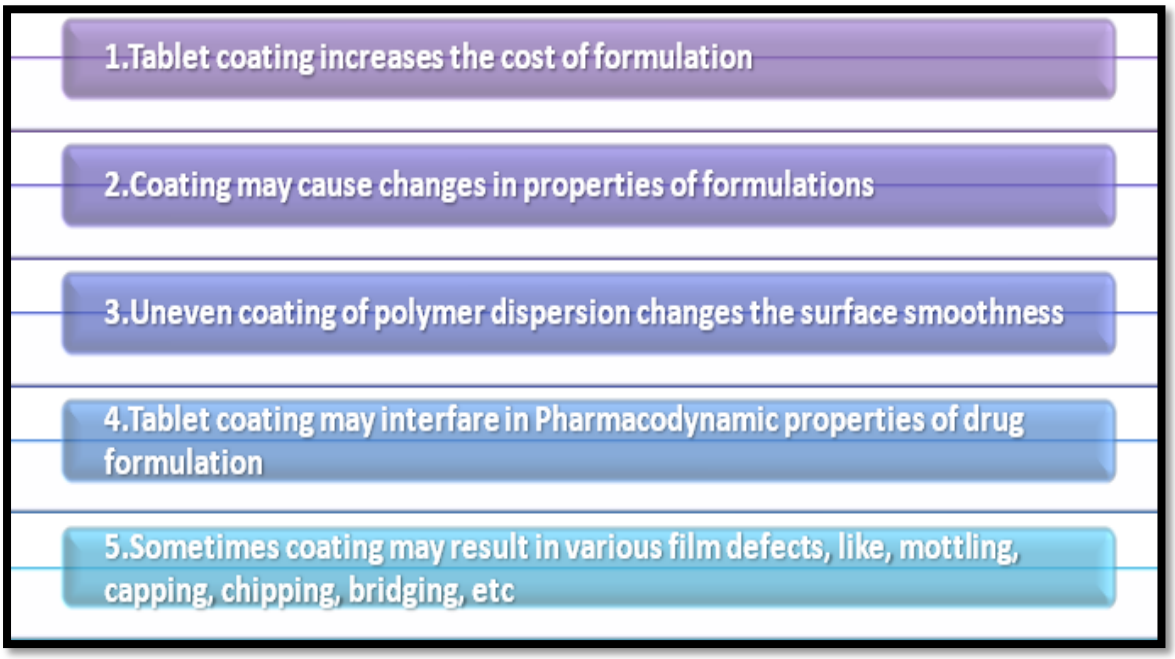


Fig. 3: Disadvantages of film coating

Film coating systems are dry blend concentrates of polymers, plasticizers, pigments, opacifiers, glidents, binders, antitacking agents, antifoaming agents, surfactants, fillers and extenders. Polymers constitute a

major component of the film coating systems and other systems are based on hydroxypropylmethylcellulose(HPMC),Polyvinyl alcohol (PVA), Sodium alginate(SA),cellulose acetate phthalate(CAP),Hydroxypropylmethylcellulosephthalate(HPMC-P), Methacrylic acid co-polymer. Likewise, pigments constitute a very critical component for visual distinction and other systems are based on lake colors, natural colors, aluminium lakes, FD&C Aluminium lakes and pharmaceutical grade titanium dioxide (Tio2).Film coating systems are ready to use and are available in aqueous or organic systems. They can be reconstituted with organic solvent systems, aqueous systems or hydro-alcoholic systems to prepare pharmaceutical solid dosage forms.MASK system can be used for taste masking of bitter active ingredients used in dry syrup and suspensions.[7,8,9]

2.1. COMPONENTS OF FILM COATING MATERIAL

Fig. 4: Components of Film Coating Material

2.1.1. POLYMERS:

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

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

systems is very critical for the success of aqueous coating formulation. By selecting the lower viscosity polymers, the solid content in the coating formulation can be increased which will result in lesser amount of water required which in turn can increase the coating speed. Various other polymers are also used in developing aqueous film coating formulations like sodium carboxymethylcellulose, polyvinylalcohol, polyvinyl pyrrolidone, sodium Alginate, Polyethylene Glycoletc either alone or in combinations.

2.1.2. PLASTICIZERS:

The next most important components of the coating formulation are plasticizers. A wide range of plasticizers are available to the formulator such as phthalate esters, phosphate esters, other esters like citrates, stearates, sebacate, oleate, adipate etc. oils, glycerol's,glycols etc. the important factors to be considered here are:

- Water solubility of plasticizers:Hydrophobic plasticizers will create problem in solution preparation and can affect the disintegration and dissolution profile of the finished product
- Water vapour transmission rate through the film: Higher concentrations of plasticizers in the film generally tend to increase the water vapour permeability.
- Concentrations in the coating formulations: Higher concentrations of plasticizers reduce the modulus of elasticity (a desired effect) and thus reduce the possibility of logo bridging but also reduce the tensile strength of the film (undesired effect).
- Film adhesion generally tends to increase with increase concentration of plasticizers.
- Higher concentration of plasticizers can lead to its bleeding (making the tablet surface feel oily) in most of the cases presence of plasticizers improves the gloss level in the finished product (depending on the quality and concentration of the plasticizer).
- Volatility of the plasticizers: Aqueous coating generally needs higher drying capacity during the coating cycle due to less volatility of water, if the plasticizers are more volatile. E.g. propylene glycol, much of the plasticizers may get lost during the coating process.

Therefore, one needs to strike a balance between the desired and undesired effects of the plasticizers and optimize its concentration in the coating formulations. Many a time's use of combination of plasticizers becomes necessary to achieve the most optimum results.

2.1.3. ADDITIVES:

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

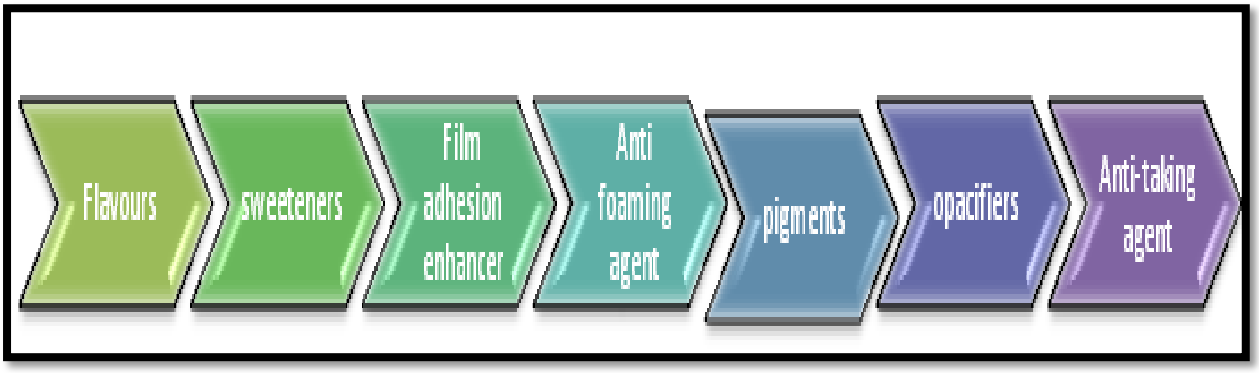


Fig. 5: Various other components of coating solution

The concentrations and the properties of each of these excipients can affect the quality of the resulting film, e.g.

1. The commonly used colourants in sugar coating are water soluble dyes. However, the overall colour effect of these dyes depend on the dye concentration at a particular point, thickness of film at that point and the residual moisture content in the film at that point. As these parameters can differ from tablet to tablet, the colour differences among various tablets within the same batch may become very visible.
2. The opacity of the film depends on the differences between the refractive index of the polymer and other components of the coating formulation. The lake colours used in film coating has refractive index similar to that of various polymers, thus the opacity of lake colours is very poor.
3. The most commonly used anti- tacking agent is talc, which if use in higher concentration tends to settle down from the coating suspension, thus affecting the composition of suspension during the coating process. Further, it is poor opacifier and tends to produce translucent films.
4. As the aqueous film coating need higher drying capacity, the volatile matter in the flavours used may get lost, changing the nature of the flavor. These volatile matters may also interact with other components of the coating formulations and can affect their properties. One, therefore, need to use specific flavours and incorporate them in the coating formulation in such a manner so that it does not affect the film quality. It, therefore, once again becomes a lot of balancing act while developing the optimized coating formulation[10,11,12].

2.2. SELECTION CRITERIA FOR POLYMERS USED IN FILM COATING[13].

2.2.1. SOLUBILITY:

For conventional film coating the polymer should have good solubility in aqueous fluids to facilitate the dissolution of active ingredients from the finished dosage form. However, where a modified release action is required then a polymer system of low water solubility or permeability will be chosen

2.2.2. VISCOSITY:

In general polymers should have a low viscosity for a given concentrations. This will permit the easy trouble free spraying of their solution in industrial film coating equipment.

2.2.3. PERMEABILITY:

Film coating can be used to optimize the shelf life of tablet preparation as some polymers are efficient barriers against the permeability of water vapor or other atmospheric gases. These properties vary widely between the individual polymers.

2.2.4. MECHANICAL PROPERTIES:A particular polymer chosen for a film coat formulation must be one week adequate strength to withstand the impact and abrasion encountered in normal handling [14,15]. Insufficient coating strength will be demonstrated by the development of cracks and other imperfections in the coating. It should be mentioned that the polymer chosen must also comply with relevant regulatory and pharmacopoeia requirements current in the intended marketing area.

2.3. CLASSIFICAITON OF POLYMER

Fig. 6: Classification of polymer

2.3.1 CLASSIFICATION BASED ON SOLUBILITY [16]

TABLE 1: CLASSIFICATION BASED ON SOLUBILITY

Sr.No.	Type of Polymer	Example of Polymer
1.	Water soluble polymers	Methylcellulose,Hydroxyethylcellulose, Hydroxypropymethylcelllulose
2.	Water insoluble polymers	Ethylcellulose

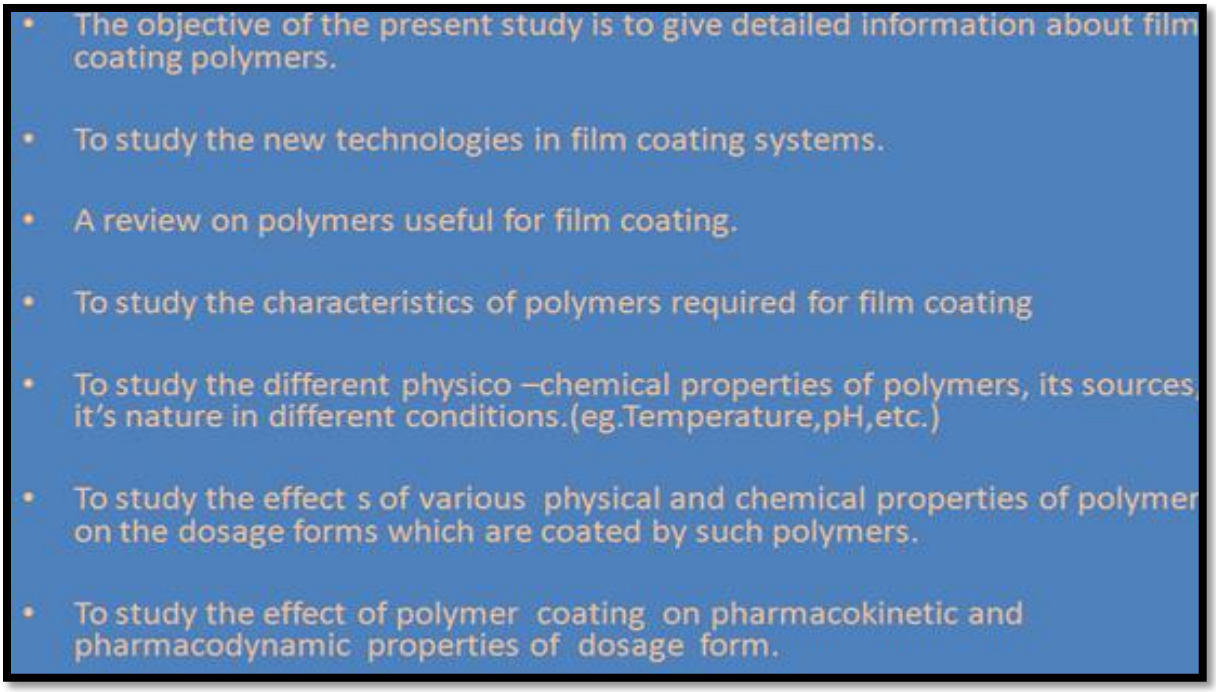
Polymers used as enteric coating materials that are soluble above certain ph, such as HPMC Phthalate, cellulose acetate phthalate, or those that dissolves following enzymatic degradation.

2.3.2 CLASSIFICATION BASED ON CHEMICAL NATURE

TABLE 2: CLASSIFICATION BASED ON CHEMICAL NATURE

Sr.No.	Type of Polymer	Example of Polymer
1.	Vinyl Polymers	Polymethacrylates,PolyvinylAlcohols,PolyvinylPyrrolidone (Povidone),Poly(Acrylic Acid) (Carbomer)
2.	Cellulose Ethers	Methycellulose,Ethycellulose,Hydroxy ethyl cellulose (HEC) Hydroxy propyl cellulose (HPC), Hydroxy propyl methyl cellulose (HPMC):Hydroxy ethyl methyl cellulose (HEMC), Sodium carboxy methyl cellulose
3.	Polyesters	Poly (lactic) and related copolymers, Poly (ε-caprolactone),polyglycolide
4.	Silicones	--
5.	Polysaccharides	Chitosan,Carragenan,Tragacanth,Acacia,Poly(allginic acid),xanthum gum
6.	Miscellaneous Polymers	Gelatin, polyanhydrides, polyethyleneglycols, poyethyene oxides

3. OBJECTIVE OF STUDY



4. SCOPE OF STUDY:

The scope of study of the polymers used in film coating is to find out the polymers that are more effective than available polymers the interesting part of study is that, We can introduced newer polymers.

The another scope that to find polymers which on coating on tablets do not show the changes in the properties of tablets like dissolution rate, disintegration, wait sustain release, action and pharmacokinetic and pharmacodynamic properties of drug formulation etc…

The polymers which on coating on tablets may be having properties like that:

- Low abration, smooth surface,good flow behavior .
- Masking of teste and smell
- Good protection against light, air and moisture.
- Impervious separatinglayes in the case of multilayer composition,
- Systematic release of active ingredients.
- Retardation,delayed dissolving.
- Low hygroscopicity, visual attractiveness(pharmaceutical drug safety).

5. COATING PROCESSES AND EQUIPMENT

In choosing a systems for film coating, the following points should be addressed:

- Adequate supply of process air for the volume of the pan.
- Ability to maintain temp. within a narrow range(typically 30 to 70°c).
- Ability to maintain dew point within a narrow range(typically10 to 20°c)
- Pan and spray systems designed to be easily cleaned/sanitized.
- Spray systems fluid path should have a minimum of dead spaces, since may coating formulation are dispersion or suspensions.
- Spray systems atomization and fan air are easily controlled, preferably from the exterior of the pan.
- Air flow bypasses capability (especially if the pan is used to be for sugar coating).
- Explosion prevention construction if flammable solvents are to be used
- Treatment of inlet and exhaust air as required by GMP and environmental regulations.

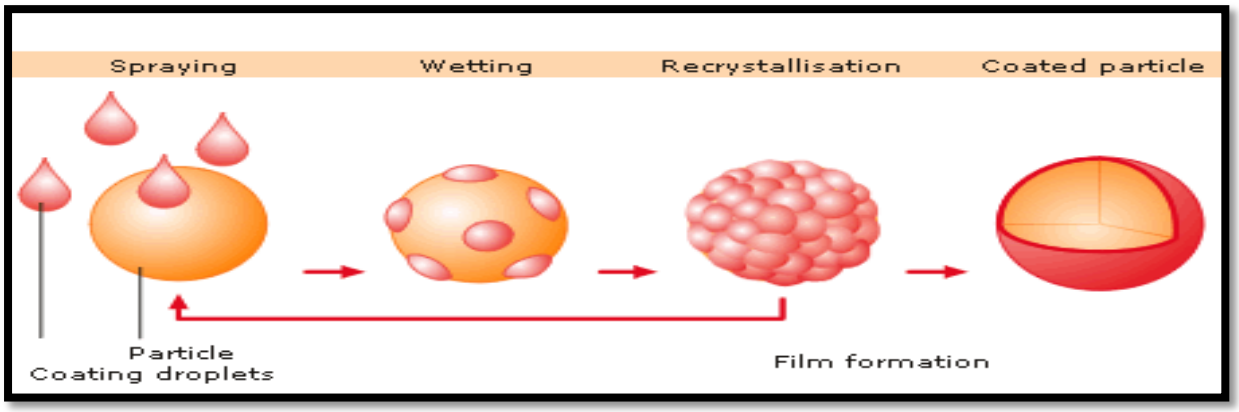
The pan should be equipped with appropriate sensors so that following conditions can be monitored/ controlled:

1. Pan rotation
2. Inlet air temperature
3. Inlet air dew point

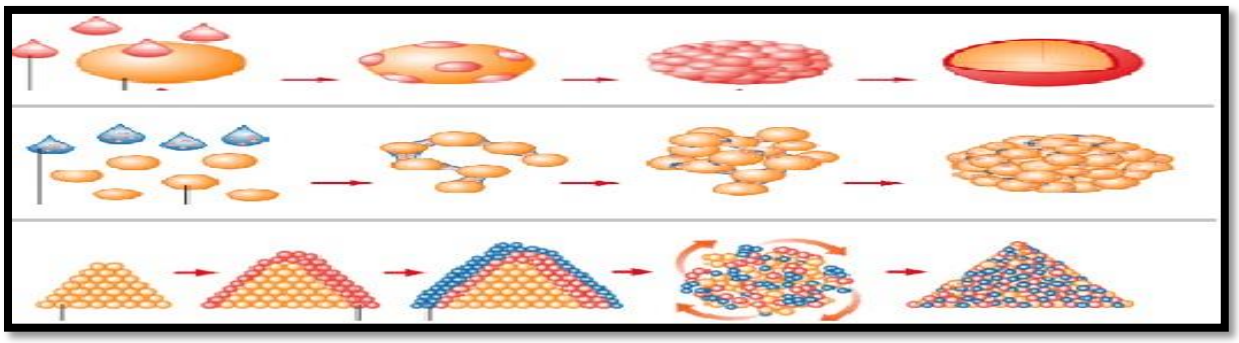
4. Inlet air flow rate
5. Spray systems atomization and fan air flow rate
6. Coating liquid spray rate
7. Exhaust air temperature
8. Product temperature. [17,18]

5.1 Process[19].

A very even application of the Coating material is an important feature of the coating process. Coating must be dense and without mechanical damage and cracks. Film coating is an effective process for the application of protective films for manipulating the product characteristics. Glatt offers various technical solution for coating different particles and tablets:



- Fluid Bed Coating (Top Spray Coating, Bottom Spray Coating, Rotor Coating).
- Drum Coating
- Spouted Bed Technology



In each case, the coating fluid is sprayed onto the solid material,[20] which is presented to it. The introduction of the process air evaporates the fluid and dries a film coating. Small droplets and a low viscosity ensure a uniform distribution.

6. SYNTHETIC POLYMERS FOR COATING PHARMACEUTICAL DOSAGE FORMS

Until the middle of this century, sugar was the preferred coating agent for pharmaceutical dosage forms, and sugar coating processes were developed and tested to perfection at a considerable expenditure of time and labor. On occasion the natural product shellac was used for insulating coatings and for protecting cores against gastric fluid, whereas zein always played a very subordinate role. Major progress was made with the introduction of semi synthetic cellulose derivatives such as methyl- and ethyl cellulose, the fully synthetic polymethacrylates with their specific solubility properties adapted to the pH condition of the digestive tract. In subsequent years, cellulose derivatives with carboxyl groups were further improved by changing the degree of etherification, and low-molecular-weight cellulose ethers were developed for water-soluble coatings. The range of gastro resistant methacrylic acid copolymers of graded, pH-dependant solubility in intestinal fluid was extended by taste-masking, gastro soluble poly amino alkyl methacrylates and permeable film formers for sustained-release coatings. Polymethacrylates for pharmaceutical purpose became known under the trademark EUDRAGIT®, some of their favorable properties deriving from the basic polymer polymethyl methacrylate.

Outstanding characteristics of PLEXIGLAS® are its crystal clarity in combination with high break resistance, light weight (density 1.1) and substantial hardness. The exceptional, decade-long stability of the material to air, light and water provides a good basis for the shelf life of coated pharmaceutical dosage forms. These favorable properties derive from the structure of the polymer skeleton, which is characterized by a continuous carbon chain acting as the backbone and methyl side groups which contribute a high degree of rigidity. It is these methyl side groups which make polymethacrylates so much harder than the soft and sticky polyacrylates. The ester groups in the side chains of polymethacrylates are extremely resistant to hydrolysis. Even in alkaline medium only individual, exposed terminal groups are prone to saponification. The degree of hydrolysis is thus scarcely measurable and acrylic polymers can, for this reason, also be used for protective coatings on alkaline masonry and cement or for stabilizing tone work. Very early on PLESIGLAS® was use for medical purpose. Ease of machining and thermoforming prompted its use for the manufacture of artificial joints and implants.

Compatibility with the skin and mucous membranes enable the development of artificial teeth, contact lenses intraocular lenses. In the course of time, the pure polymethacrylate was modified by copolymerization with acrylic esters and other monomers to suit special needs especially as far as hardness and porosity were concerned.

7. COATING AGENTS FOR PHARMACEUTICAL DOSAGE FORMS

Shellac and zein, although still use from time to time, are hardly able to meet present day requirements. Organic solvents should be reserved for special application only and chlorinated hydro carbons such as methylene chloride and chloroformare avoided although together since they impose a heavy load on the environment. Low molecular weight types of methylcellulose and hydroxypropyl methylcellulose can also be processed as aqueous solutions. Ethyl cellulose and cellulose acetate phthalate are available as aqueous dispersion, so called pseudo latexes.

They satisfied particularly stringent requirements in terms of purity. Further, quality characteristics are the high stability to environmental influences during storage and absolute skin friendliness that is indifference to bodily tissue fluids. The amount of acrylic polymer consumed with the active ingredients is very small, only a few milligrams in the case of coated tablets and approximately150mgper day with specific sustained release preparations. The average polymer quantity taken up by an adult is thus about to mg per kg of body weight. Since, they are high molecular weight substances which the body cannot absorbed, they are excreted unchanged with other indigestible food constituents within a short time in the past, acrylic, resins, were usually dissolved in alcohol acetone and then ladled or sprayed on the dosage forms.

8. CHANGES IN TECHNOLOGY CAUSED BY AQUEOUS DISPERSIONS

The development of purely water based EUDRAGIT® dispersion back in 1972 represented a measure improvement in processing conditions and opened up new applications.

This dispersion was obtained by emulsion polymerization. In the process, the polymer is precipitated from the monomers to needs, emulsified in water in the form of water insoluble, sub microscopic latex particles ranging from 0.01 to mm in diameter the resultant polymer dispersion have high solids contents of 30-40%, are very low in viscosity easy to process

During film formation, the latex particle first unit in a closed sphere packing and then coalescence as a result of the strong capillary forces generated by evaporating water. Above the so called minimum film forming temperature they then form a dense, coherent film. The minimum film temperature of EUDRAGIT® dispersion are near or below 25°c, so that perfect film formation is guaranteed under the usual processing conditions. The mechanism of film formation offers the unique opportunity to convert a water insoluble polymer to a water tight film. Once dry, the very first film layer to be spread on, although very thin, seals the active core against penetration of water throughout the coating process so that even comparatively water sensitive substrates can usually be film coated without an additional support.

9. APPLIATIONSOF POLYMERS FOR THE FORMULATIONS OF CONVENTIONAL DOSAGE FORMS

1. SOLID DOSAGE FORMS

- Tablets
- Capsules
- Film coating of solid dosage forms

2. DISPERSE SYSTEMS

3. GELS

10. APPLICATIONS OF POLYMERS FOR CONTROLLED DRUG DELIVERY[21,22,23].

1. Drug diffusion through the matrix of the dosage form.

2. Drug dissolution within aqueous fluid of the gastrointestinal tract.

3. Drug diffusion through the aqueous fluid of the gastrointestinal tract to the surrounding tissue, e.g., and the villi of small intestine.

4. Absorption of the drug across the wall of the gastrointestinal tract.

5. Entry into the systemic circulation and deposition at the required site of action

11. THIN FILM DRUG DELIVERY[24,25].

Thin film drug delivery, also referred to as orally dissolving thin film, has emerged as an advanced alternative to the traditional tablets, capsules and liquids often associated with prescription and OTC medication. Similar in size, shape and thickness to a postage stamp, thin film strips are typically designed for oral administration with the person placing the strip on under the tongue are along the inside of the cheek. As the thin film dissolve, the technology enables the drug to be delivered to blood stream eitherintragastrically, buccally or sublingually.

The first commercial non drug products to use thin film for cosmetic purposes was the Listerine. Pocket packs breathe strip. Since then, thin film products for other breath fresheners, as well as a number of cold, cough, flu and anti snoring medication, have entered the marketplace. There are currently several projects in development that will deliver prescription drugs utilizing the thin film dosage form.

11.1. ADVANTAGES OF THIN FILM DRUG DELIVERY

The design of thin film, often referred to as pharmafilm, as an oral drug delivery technology offers several advantages over other modes of drug delivery, such as ingestible tablets, chewable tablets, orally dissolving tablets, soft gels, liquids or inhalants:

- The sublingual and buccal delivery of a drug via thin film has the potential to improve the onset of action, lower the dosing, and enhance the efficacy and safety profile of the medicament.

- All tablet dosage forms, soft gel and liquid formulations primarily enter the blood stream via the gastrointestinal tract, which subjects the drug to degradation from stomach acid, bile, digestive enzymes and other first pass effects. As a result, such formulations often require higher doses and generally have a delayed onset of action.
- Conversely, buccal and sublingual thin film drug delivery can avoid these issues and yield quicker onsets of action at lower doses.
- Thin film is more stable, durable and quicker dissolving than other conventional dosage forms.
- Thin films enables improved dosing accuracy relative to liquid formulations since every strip is manufactured to contain a precise amount of the drug.
- Thin film not only ensures more accurate administration of drugs but also can improve compliance due to the intuitive nature of the dosage form and its inherent ease of administration. These properties are especially beneficial for pediatric, geriatric and neurodegenerative disease patients where proper and complete dosing can be difficult.
- Thin films ability to dissolve rapidly without the need for water provides an alternative to patients with swallowing disorders and to patients suffering from nausea, such as those patients receiving chemotherapy.
- Thin film drug delivery has the potential to allow the development of sensitive drug targets that may otherwise not be possible in tablet or liquid formulations.
- From a commercial perspective thin film drug delivery technology offers an opportunity to extend revenue lifecycles for pharmaceuticals companies whose drug patent is expiring and will soon be vulnerable to generic competition.

11.2. KEYS TO THIN FILM DRUG DEVELOPMENT

11.2.1. TASTE MASKING

An important aspect of thin film drug delivery technology is the masking of the often bitter and poor taste of drug formulations. One method of taste-masking is encapsulation, the coatings of drug particles with a polymeric covering sufficient to mask the taste of the drug particle while maintaining the ability to release the drug for absorption.Encapsulation is an efficient method for combining a high ratio of drug-to-non-drug elements in the taste-masked particle. Another method is the use of an ion exchange resin to bind the drug, forming a resinate that is less bitter than the drug alone.

11.2.2. DRUG CONTENT UNIFORMITY

It is a requirement for all dosage forms, particularly those containing low dose highly potent drugs. To uniquely meet this requirement, thin film formulations contain uniform dispersions of drug throughthe whole manufacturing process.

11.2.3. AVOIDING DRUG DEGRADATION

Sensitive drugs may degrade over time in an aqueous environment. Thin film formulations must ensure that the integrity of the drug remains constant over time. To overcome these challenges, developers of thin film have created highly specialized unique and often proprietary processes to deliver drugs on thin film.

12. CONCLUSION AND SUMMARY

From the present study it was concluded that the study of polymer is very important to prevent various 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. This study is important for the establishing a effective polymer dispersion for film coating of solid dosage forms.Thin film drug delivery can be achieved by using suitable polymer compositions.

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