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A REVIEW ON RECENT ADVANCES IN ENTERIC COATING AND ENTERIC POLYMERS

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ABSTRACT

Worldwide many researchers are seeking the knowledge or the advances of the enteric coating and the role of polymers. The present review focuses on the elevation of enteric coating and polymers. Enteric coated means a tablet or capsule or the other form of oral medication which is layered with a defensive coating. This coating is used to fortify the stomach from unwanted effects or detrimental effects of a medication. It is most frequently used in aspirin and other NSAIDs that are known to antagonize the stomach lining, but is also often used in medications or vitamins that need to dissolve in the small intestine and absorb properly. The main important role of enteric coating is to release the drugs after the stomach. The word enteric actually mean referring to the intestine. Most of the polymers are either man made or natural and they won't break down below levels of pH 5.5. From a pharmacological point of view the term enteric coating is not entirely scrupulous, because the gastric resistance can also be obtained by adding enteric polymeric systems. So in order to obtain a gastro resistant drug it should have enteric coating and suitable polymers for the dosage form. Different polymers were used in enteric coating like cellulose acetate phthalate, polyvinyl acetate phthalate, hydroxyl propyl methyl cellulose. The enteric coating was done on different type of dosage forms like tablets, capsules, pellets and granules. Recently there are so many advancements in the enteric coating.

KEYWORDS: Enteric coating, systemic absorption, enteric coating polymers, intestine.

INTRODUCTION

Coatings which are insoluble in the gastric juices of the stomach but dissolves in the alkaline environment of the intestine are known and are needed for a variety of medical reasons. Such coatings are variously referred to as enteric coatings[1]. An enteric coating is a protective layer that which controls the medication in the digestive system where it is absorbed. The word "Enteric" indicates small intestine; therefore enteric coating prevents the release of drug before it reaches the small intestine[2]. A tablet that has a special outer covering layer which was designed to dissolve in the small intestine and has an alkaline pH of about 7-9. So most of the currently used enteric coatings are weak acids which remain undissociated in the low pH environment but they readily get ionized when the pH rises to above 5.[3]

Enteric coating s are employed for a number of therapeutic and safety reasons. Some drugs are irritating when exposed to the gastric mucosa including aspirin, omeprazole and strong electrolytes such as ammonium chloride. Enteric coating is one method of reducing or eliminating irritation from such drugs.

EXAMPLE

Omeprazole is a drug which stops the stomach from producing acid, is itself broken down in acid and therefore the drug generally has an enteric coating around it either as a granule in the capsule or as a granule in the dispersible form.

Sulfasalazine is a drug which used for the treatment of arthritis and it was also used for the treatment of crohn's disease. Crohn's disease is a chronic disease that affects the intestines. When used for arthritis, it get absorbed more quickly because it was given without an enteric coating. Enteric coating has to be given to the medications which are used for the treatment of crohn's disease because it has to work in the intestines.

The low pH of the stomach destroys other drugs e. g. erythromycin and hence the enteric coating may be necessary to bring the drug to the more neutral intestinal contents. Another reason for enteric coating may be the desire to release the drug in the highest concentration possible within the intestine.[4-6]

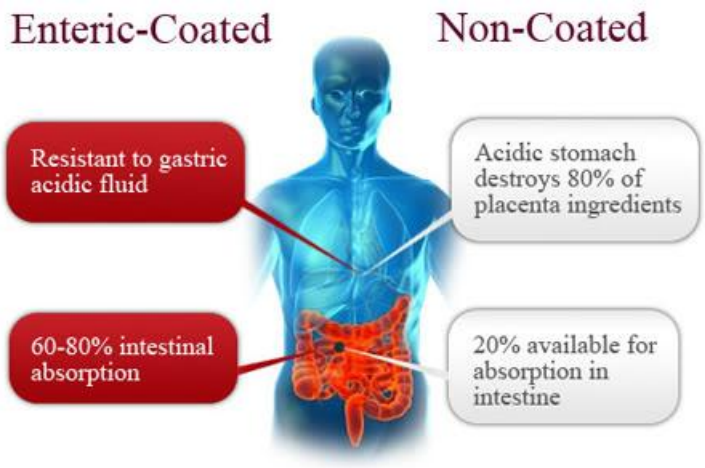

Figure 1:enteric and non- enteric.

IMPORTANT REASONS FOR ENTERIC COATING

- To protect the stomach from the drug
- To protect the drug from the stomach
- To release the drug after the stomach e .g. in the intestine
- To protect the acid liable drugs from the gastric fluid e. g. enzymes and certain antibiotics
- To forbid gastric distress or nausea due to irritation from a drug, e.g. sodium salicylate
- To deliver drugs intended for local action in the intestines, e. g. intestinal antiseptics could be delivered to their site of action in a concentrated form.
- Need for minimizing first pass metabolism.
- To extend a delayed release component for repeat- action tablets.[7, 4]

COMPOSITION OF ENTERIC COATING

An enteric coating composition including about 0.01% - 10% resin and about 0.01% - 10% polymer. The enteric coating composition may be applied to a substrate, such as pharmaceutical, neutraceutical, fruit, vegetable, agriculture or industrial product to form an enteric coating on the substrate.

A resin- e.g.- shellac, A polymer-e .g – alginate, A plasticizer- e. g.-tri ethyl citrate, A preservative- e. g.- sorbates, A detackifying agent- e. g.- monosterate, A lubricant- e. g.- palmitic acid, A colorant- e .g.- FD & C lake yellow no 5, A flavor- e. g.- blue berry, butterscotch, A sweetener- e. g.- sucrose, honey, A taste maskant- e. g.- carboxy methyl cellulose, An opacifier- e. g.- titanium dioxide, A buffering agent- e.g.- sodium citrate, An antioxidant- e. g.- tocopherol, A solvent- e. g.- ethanol, water and combinants therefore.[8]

ENTERIC COATING – IMPERATIVE

The tablet is swallowed and travels down the oesophagus to the stomach. In the stomach the tablet is churned and gyrated in highly acidic digestive secretions with pH (1-4) for 45 min to 2 hours. If anything left of tablet, it will be passed through the duodenum to the small intestine. Stomach acid breaks down tablets to prematurely release active ingredients i. e enzymes. The highly acidic environment of the stomach destroys the majority of the enzymes activities.[9]

The enteric coating was done on different types of dosage forms like tablets, capsules, pellets and granules these are most commonly used when compared to other dosage forms. The process of enteric coating on these different types of dosage forms is as follows:

ENTERIC COATING OF TABLETS

TABLET

A tablet can be defined as solid, flat or biconcave disc (also available in various shapes) prepared by compressing a drug or a mixture of drugs with or without suitable diluents. Tablets are the most popular dosage forms because of their ease of manufacturing, convenience in administration. They vary in shape differ greatly in size, weight depending on the amount of medicinal substances and the intended mode of administration. It is the most popular dosage form and 70% of the total medicines are dispensed in the form of tablets. One can administered 0.01mg of a drug dose to 1gm of a drug dose by oral route, formulating it as a tablet. About 90% of drugs are available in the form of tablets to produce a therapeutic effect when administered orally.[10-12]

TABLET COATING

The use of coating on drugs was probably an adaptation from early food preservation methods and French publication in the 1600s described coating as a means of masking the taste of medicines.[5, 4]

Tablet coating can be described as a process of applying an edible paint on the surface of a pharmaceutical dosage form to achieve specific benefits. The coating process in tableting which causes an increase in the cost of tablet production. When a coating solution is applied to a batch of tablets in a coating pan, the surface of the tablets gets covered with a tacky polymeric film. The coating technique involves parameters such as the spray pattern, drop

size, and nozzle spacing which must all be the precisely controlled in order to ensure uniform distribution of the coating material.[13]

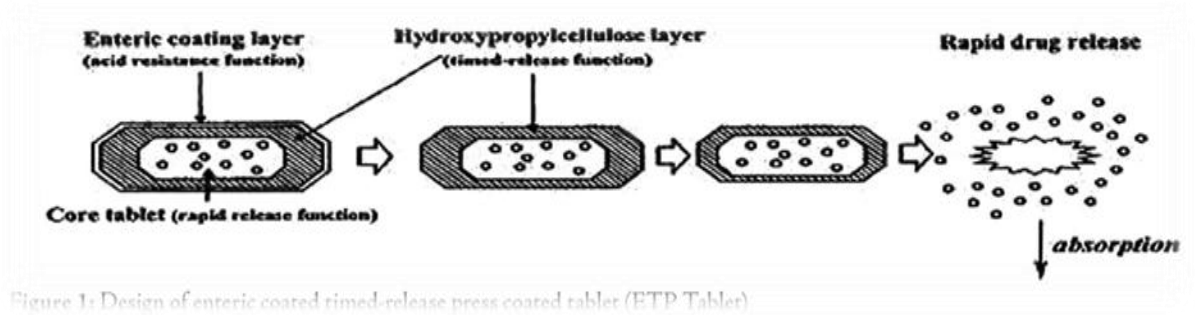

Figure 1: Design of enteric coated timed-release press coated tablet (ETP Tablet)

Figure 2: design of enteric coating.

ADVANTAGES

- Taste masking.
- Odor masking.
- Physical and chemical protection.
- Protects the drug in the stomach[14]
- To protect the drug from the gastric environment of the stomach with an acid resistant enteric coating.
- To incorporate another drug or formula adjuvant in the coating to avoid chemical incompatibilities or provide sequential drug release.
- To improve the pharmaceutical elegance by use of special colors and contrasting printing.[4]
- Low cost when compared to other dosage forms
- Lighter in weight
- Easy to swallow
- It can also facilitates printing on tablets.[15]

DISADVANTAGES

- Coating time is more
- High cost
- High bulk have led to the use of other coating materials.
- This process is tedious and time consuming
- It should be handled by highly skilled technician.[16]

COATING PROCESS

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 by a single application or may be built up in layers. Rotating pans are often used in the pharmaceutical industry. Uncoated tablets are placed in the pan, which is typically placed at an angle from the horizontal, and liquid coating solution is evaporated by passing air over the surfaces of the tablets. In contrast a fluid bed coater operates by passing air over the surfaces 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. The coating process is usually a batch driven task consisting of the phase like batch driven task containing of the phases like batch identification and recipe selection(film or sugar coating), loading/dispensing(accurate dosing of all required raw materials), drying, cooling and unloading.[17]

EQUIPMENT USED FOR TABLET COATING

A modern coating system combines several components

- A coating pan
- A spraying system
- An hair handling unit
- A dust collector.

NEW MATERIALS FOR TABLET COATING

- Zein
- Aqua zein®, which is an aqueous zein formulation containing no alcohol.
- Amylose starch and starch derivatives
- Dextrin's.[1]

TYPES OF TABLET COATING: There are five types of tablet coating

- Sugar coating
- Film coating
- Press coating
- Enteric coating
- Micron coating.[18]

RECENT TRENDS IN TABLET COATING TECHNIQUE

- Electrostatic dry coating
- Magnetically assisted impaction coating (MAIC)
- Aqueous film coating technology
- SUPERCELL coating technology.[19]

TABLET COATING DEFECTS

High quality tablets can be quickly and easily produced using a tablet coating machine and the correct excipients. Unfortunately several defects can arise with coatings. The following list provides helpful remedies for common issues that may be encountered.

I. BLISTERING

DEFINITION

It occurs when the flexibility and adhesive properties are compromised this leads to the separation of the film from the tablet surface.

CAUSE

- Blistering occurs because of entrapment of gases in film because of overheating during spraying.
- Maintaining high temperature during drying process.
- Effect of temperature on flexibility and adhesion of the film.

REMEDY

- Moderate temperature has to be maintained during coating process.
- Entrapment of gases should be avoided.
- Mild drying conditions.

II. CHIPPING

DEFINITION

It occurs when the edges of the tablet breaks, during subsequent handling and coating operations.

CAUSE

- Poor polymer
- Coating solution
- Decrease in rotation speed during coating process

- Sticking on punches
- More binding causes chipping
- Dry granules

REMEDY

- Choose a polymer with high molecular weight.
- Hardness of the film has to be increased by adjusting the amount of plasticizer.
- Die has to get polished to make it cylindrical.
- Punch edges has to get polished.

III. CRACKING OR SPLITTING

DEFINITION

It occurs as a result of small fine cracks which were observed on the upper and lower center of tablets referred to as cracks i.e. cracking. Some splits are formed around the edges of the tablet referred to as splitting. It is observed because of rapid expansion of tablets, mainly when deep concave punches are used.

CAUSE

- Dry granules
- High molecular weight polymers
- Insufficient concentration of plasticizer or pigment
- Size of granules

REMEDY

- Granule size has to get reduced
- Adjust the concentration of plasticizer
- Low molecular weight polymers
- Tensile strength of the film has to get increased

IV. CAPPING AND LAMINATION

DEFINITION

It is defined as when the lower or upper portion of the tablet separates horizontally i.e. either partially or completely from the main body of a tablet and comes off as a cap, during ejection of the tablet press or during subsequent handling. Separation of the tablet into two or more

distinct layers is defined as lamination. It happens due to air entrapment during compression process or because of expansion of the tablet during ejection.

CAUSE

- Dry or low moisture content
- Improper drying of granules
- Excessive fines in granulation
- Deficient amount of binder
- Inadequate amount of lubricant
- Turret high speed
- Improper adjustment of lower punch

REMEDY

- Proper drying of granules
- Moisture content of granules has to get increased
- Excess of fine has to get reduced from granules
- Adjust sufficient or proper amount of binder
- Compress at room temperature
- Adjust sufficient or proper amount of lubricant
- Speed of turret has to get adjusted
- Acceptable adjustment of lower punch.

V. PICKING AND STICKING

DEFINITION

Picking is the term used to describe the surface material from a tablet is sticking to and being removed from the tablet surface by a punch. Sticking refers to tablet material adhering to the die wall or to the tablet press punches.

CAUSE

- Inadequate drying
- Over wetting due to low pan speed
- Serious sticking at ejection can cause chipping of tablet edges and can produce a rough edge
- Buildup of material on punch faces.

REMEDY

- Proper drying conditions has to be maintained
- Pan speed to avoid over wetting
- Plating of the punch faces with chromium is a method for producing smooth, non-adherent face
- In some cases colloidal silica added to the formula acts as a polishing agent and makes the punch faces smooth so that material does not cling to them.

VI. COLOR VARIATION

DEFINITION

It is defined as the variation of color of film.

CAUSE

- Improper coating
- Inadequate mixing during coating
- Poor spray pattern
- Alterations or changes in the spray zone or the size or shape of the spray zone
- Migration of dyes-plasticizers and other additives during drying.

REMEDY

- Adjust and ensure proper coating
- Mild drying conditions
- Pan speed to ensure proper mixing
- Adjust gun position to cover the tablet bed properly
- Adjust plasticizers type and concentration, reduce drying temperature.

VII. MOTTLING

DEFINITION

It is defined as unequal distribution of color on a tablet, with light or dark areas standing out in an otherwise uniform surface.

CAUSE

- Improper mixing of color binding solution
- A dye can cause mottling by migrating to the surface of a granulation during drying.
- When the drug substance is colored and excipients are white or colorless.

- Large particle size
- Dispersion of the dye.

REMEDY

- Proper mixing of colorant and adhesives
- Reduce drying temperature
- Change the solvent system
- Grind to a smaller particle size
- Use suitable colorants.

VIII. TWINING

DEFINITION

This is the term which was used for the tablets that stick together, and it's a common issue associated with capsule shaped tablets.

POSSIBLE REASONS

- High spray rate
- Low pan speed
- Less distance between spray guns and tablets bed
- Improper shape of tablets.

SOLUTIONS

- Minimize spray rate
- Increase pan speed
- Increase distance between spray guns and tablets bed
- Slight change in design of tooling.

IX. ORANGE PEEL

DEFINITION

It is defined as the where the surface of the film becomes rough and non-glossy appearance which was similar to that of orange.

CAUSES

- Uneven coating of the tablet
- Poor tablet composition
- High solution viscosity

- Improper spreading of coating solution

REMEDY

- Proper coating of the tablet
- Decrease the viscosity of the solution by using additional solvents
- Mild drying conditions.[16]

X. BRIDGING

DEFINITION

It occurs when the coating fills in the logo or the letters of the tablet.

CAUSES

- Inadequate application of solution
- Excess amount of solid in solution
- High coating viscosity
- Improper atomization pressure
- High spray rate coupled with high drying capacity

REMEDY

- Increase the amount of plasticizer or change the plasticizer.[20-25]

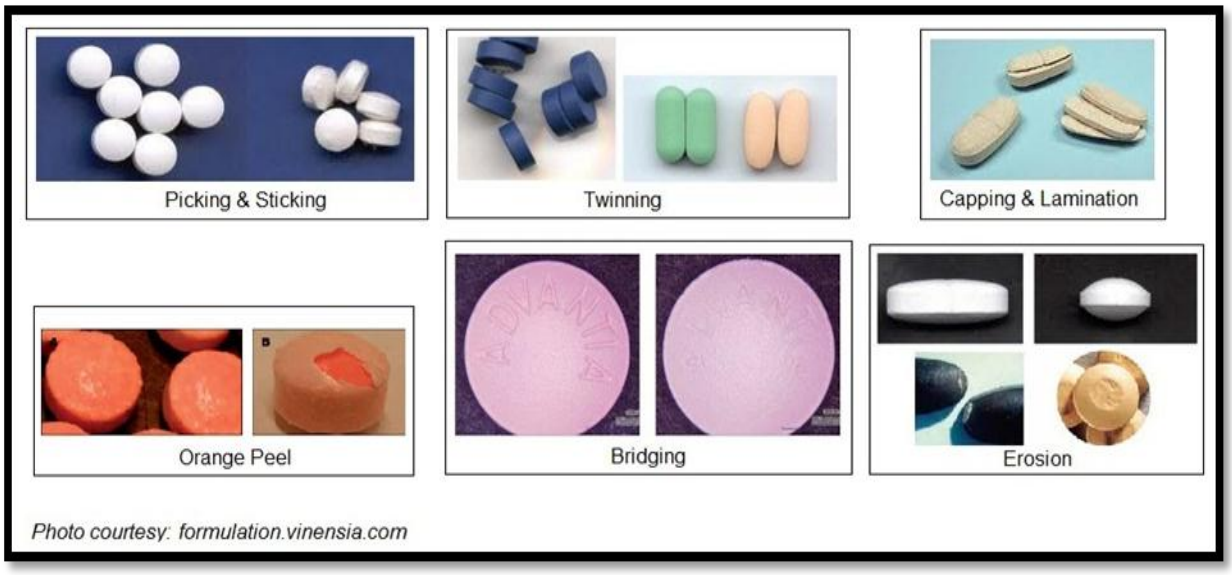

Figure 3: coating defects in tablet.

EVALUATION OF TABLETS

I. GENERAL APPEARANCE

The general appearance of a tablet include its shape, size, color, odor and its surface texture. The general characteristics or the appearance of the tablet should be monitored and controlled.

II. HARDNESS TEST

Tablets require a certain amount of strength or hardness in order to withstand stocks of handling during manufacturing, packaging and shipping. Sometimes it was termed as the tablet crushing strength. It was defined as the force which was required to break the tablet. The hardness of the tablet can be determined by Monsanto tester, Strong-cobb tester, the Pfizer tester, the Erweka tester and the Schleuniger tester.

III. FRIABILITY TEST

The friability of the tablets was measured by Roche friabilator. The preweighed tablets are taken and they are placed in the plastic chamber of the Roche friabilator. At the end the test tablets were dusted and reweighed and the loss of weight of tablet is the measure of friability and is expressed in % as

%Friability = Initial weight – Final weight/ Initial weight X 100

IV. UNIFORMITY OF WEIGHT

The test run by weighing 20 tablets individually and then the average weight of the tablets was determined. From this percentage deviation was calculated. It should be a satisfactory method for determining the drug content uniformity.

V. INVIVO DISINTEGRATION TEST

For most tablets the most important step toward solution is breakdown of the tablet into smaller particles or granules. The time required for complete disintegration is measured. The USP device to test disintegration uses 6 glass tubes that are 3 inches long, open at the top and held against a 10-mesh screen at the bottom end of the basket rack assembly.

VI. THICKNESS

Thickness of the tablet was measured by vernier calipers.

VII. INVITRO DISSOLUTION STUDIES

Dissolution test was performed by using USP type II apparatus with 50rpm. Temperature should be maintained at **37_+0.5c.** A single tablet was placed in the dissolution medium contained in a 100ml flask. The samples are collected at regular intervals for analysis of the drug from tablet.[26-32]

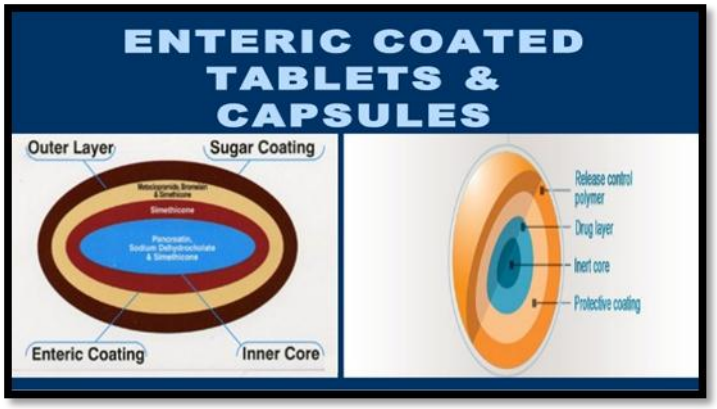

Figure 4: enteric coated tablets and capsules.

ENTERIC COATING OF CAPSULES

Many medicaments of oral administration are put into capsules, usually of gelatin; this conceals the taste of the drug, and enhances the ease of administration. Gelatin 1 capsules usually break up upon reaching the gastric contents, causing the drugs to lose their therapeutic activity. In order to permit the capsule to reach the upper intestines, so called enteric coatings are employed as protective coverings for the capsule.[33]

Enteric coated soft gelatin capsules are desirable for the administration of liquid medications which are unpleasant to the patient, or for the drugs which are unstable in the acidic environment of the stomach or for the drugs which cause some effects like nausea or gastric distress. In addition, enteric coatings are useful for producing a delayed action of a drug or to deliver medication to the intestinal tract when this is the intended site of action.[34]

Enteric coated capsules are capsules which are coated with an acid resistant material as a protective layer which doesn't allow the breakdown of the drug in the acidic environment of the stomach. They get activate only in the alkaline environment of the small intestine having a pH of 5.5. It's important to note that the enteric coated capsules are acid resistant by design.

BENEFITS OF ENTERIC COATED CAPSULES

Enteric coated capsules do not dissolve in the mouth and therefore are perfect for formulations that need not to be activated by acid exposure. The coating prevents the capsule from dissolving while in the mouth and oesophagus areas.

Many drugs can cause irritation to the stomach if released there; with enteric coated capsules, the formulation will pass through the stomach lining.

The enteric coating also prevents any enzyme present in the capsule from dissolving in the acid environment of the stomach area.

This enteric coated capsule typically taken an hour or two to dissolve, making it ideal for time sensitive medications.[35]

IDEAL PROPERTIES

An ideal enteric coating material should have the following characteristics

- Resistance to gastric fluids
- Ready susceptibility to or permeability to intestinal fluids
- Compatibility with most coating solution components and the drug substrates
- Stability alone and in coating solutions. The films should not change on aging
- Formation of a continuous film
- Non toxicity, cheap and ease of application
- Low cost
- Ease of application without specialized equipment
- Ability to be readily printed or to allow film to be applied to deobessed tablets.[4]

POLYMERS

Polymers have a very large molecular weights made up of repeating units or monomers throughout their chains. In the medical and the pharmaceutical fields, natural, semisynthetic, and synthetic polymers have made significant contributions to the improvement of health.[04]

In the low pH stomach environment, the carboxylic acid groups in the polymers remain unionized. Therefore the polymeric coating remains insoluble in the gastric fluid. The polymeric coating disintegrates or dissolves in the higher pH intestinal environment to allow dissolution of the tablet core in the small intestine. The active ingredients are absorbed through the intestinal wall for delivery to the blood stream.

Originally these polymers were applied to tablets as solutions in various organic solvents since the polymers are soluble in organic solvents. The enteric polymers are water solubilized with a water soluble base through neutralization of sufficient number of carboxyl groups so that the polymer becomes water soluble or water dispersible.

The polymers which are useful as enteric coating includes ionizable carboxylic groups and includes cellulose acetate phthalates(C-A-P), cellulose acetate trimellitates(C-A-T), hydroxypropyl methyl cellulose phthalates(HPMCP), hydroxypropyl methyl cellulose acetate succinate(HPMCAS), polyvinyl acetate phthalate(PVAP), and methaacrylic acid.[36]

The following discussion describes some of the most commonly used polymers by pharmaceutical industry.

ACRYLATE POLYMERS

Two forms of commercially available enteric acrylic resins are Eudragit L and Eudragit S both resins produces film that are resistant to gastric fluid. Eudragit L and Eudragit S are soluble in intestinal fluid at pH 6 to 7 respectively. Eudragit L are available as an organic solution, solid, or aqueous dispersion. Eudragit S are available as an organic solution and solid.

CELLULOSE ACETATE PHTHALATE (CAP)

Cellulose esters has been widely used in the industry. CAP has the disadvantage of dissolving only above the pH 6, and possibly delaying the absorption of drugs. It is also hygroscopic and relatively permeable to moisture and gastric fluid, in comparison with other enteric polymers. FMC Corporation has developed a patented aqueous enteric coating called "Aquateric". Aquateric coating is a reconstituted colloidal dispersion of latex particles. It is composed of solid or semisolid polymer spheres of cellulose acetate phthalate ranging in size from 0.05 to 3 microns with an average particle size of 0.2 micron.HPMCP-50, 55,55S these are derived from Hydroxy propyl cellulose, these polymers dissolves at low pH (5 to 5.5) than CAP or acrylic co-polymers. These polymers are quite stable compared with CAP because of their absence of labile acetyl groups.

POLYVINYL ACETATE PHTHALATE (PVAP)

Polyvinyl acetate phthalate (PVAP) is manufactured by the esterification of a partially hydrolyzed polyvinyl acetate with phthlicanhydride. This polymers is similar to HP-55 in

stability and pH-dependent solubility. It is supply as ready-to-use or ready-to-disperse enteric systems.[4]

HYDROXYPROPYL METHYL CELLULOSE

This polymer is a material of choice for air suspension and pan spray coating systems. The reason for its wide spread includes

- Solubility characteristics of the polymer in gastrointestinal fluid and in organic and aqueous solvent systems
- Noninterference with tablet with tablet disintegration drug bioavailability
- Flexibility, chip resistance, and absence of taste or odor
- Stability in presence of heat light air or reasonable levels of moisture
- Ability to incorporate color and other additives into film without difficulty
- When used alone the polymer has the tendency to bridge or fill the deobessed tablet surfaces. A mixture of hydroxypropyl methyl cellulose with other polymers or plasticizers is used to eliminate bridging or filling problems. This polymer is also used considerably in glossing solutions.

ETHYLCELLULOSE

This material is completely insoluble in water and gastrointestinal fluids and thus cannot be used alone for tablet coating. It is usually combined with water soluble additives, e. g. hydroxypropyl methylcellulose. The polymer is soluble in a wide variety of organic solvents and is nontoxic, colorless, tasteless, and quite stable to most environmental conditions.

HYDROXYPROPYLCELLULOSE

It is soluble in water below 400C, gastrointestinal fluids and many polar organic solvents. This polymer is tacky as it dries from a solution system and may be desirable for a subcoat, but not for a color or gloss coat. The polymer yields flexible films. It is usually not used alone, but it is used in combination with other polymers.[4]

CONCLUSION

From the above review, we can conclude that tablets are made enteric-coated for avoiding the first pass metabolism, gastric irritation and degradation and to direct the drug to the target intestines. In recent decades coating of pharmaceutical dosage forms has been subject of remarkable developmental efforts aiming to ensure and enhance the quality of dosage form. The choice of the polymer and the thickness of the coated layer are critical to control the pH

solubility profile of the enteric coated dosage form. An ideal polymer should be selected depending upon the type of the dosage form. Enteric coating provide a delayed- release component for repeat action tablets. This dosage form is preferred as it is very convenient and easy to formulate, provides delayed release of dosage forms. For that reason this dosage form has been gaining so much attention nowadays. In future there are enormous developments has to be done in the enteric coating.

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