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# A REVIEW ON ENTERIC COATING TABLETS BY USING VARIOUS POLYMERS

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**ABSTRACT:**

Tablet dosage form is a common Pharmaceutical dosage form. Tablet coating advantages is masking taste, odour, and colour of the drug, Providing Physical, chemical Protection and bioavailability of active ingredient. In coating process polymer sprayed onto the free surface deposition of a thin, uniform film on the tablet. But that process required a skilled operation, various types of tablet coating include enteric coating, sugar coating and film coating. Development of film coated tablet has based on different types of polymer in various organic solvent system, aqueous system or hydro alcoholic system to prepare pharmaceutical solid dosage form. Film coating are dry blend of polymer, plasticizer and surfactants. A polymer used for film coating of tablets has great importance. This review focus on the basic concept tablet coating, coating techniques and various aspect on tablet coating.

**Keywords:** Aqueous Film coating, organic solvent film coating, Polymers

## INTRODUCTION:

The stability of the drug is unstable when exposed to the acidic pH conditions of the gastric milieu, to maintain the stability of the drugs enteric coating is performed. An enteric coating is a polymer barrier applied to oral medication that prevents its dissolution or disintegration in the gastric environment. This helps by either protecting drugs from the acidity of the stomach, the stomach from the detrimental effects of the drug or to release the drug after the stomach (usually in the upper tract of the intestine). The word “enteric” indicates small intestine[1]. Enteric coating is also an effective method to obtain drug targeting (such as gastro-resistant drugs). Other drugs such as some anthelmintics, antihypertensive, antipyretic may need to reach a high concentration in a specific part of the intestine. Enteric coating may also be used during studies as a research tool to determine

drug absorption. Enteric-coated medications pertain to the "delayed action" dosage form category. Tablets, mini-tablets, pellets and granules (usually filled into capsule shells) are the most common enteric-coated dosage forms. The enteric coatings prevent release of medication before it reaches the small intestine. The enteric coated polymers remain unionise at low pH, and therefore remain insoluble. But as the pH increases in the Gastro Intestinal Tract (GIT), the acidic functional groups are capable of ionisation and the polymer swells or becomes soluble in the intestinal fluid. Materials used for enteric coatings include Cellulose acetate phthalate (CAP), Cellulose acetate trimellitate (CAT), polyvinyl acetate phthalate (PVAP), and hydroxy propyl methyl cellulose phthalate (HPMCP), fatty acids, waxes, shellac, plastics and plant fibers[2].

**Advantages of Enteric Coating:**

- Resistance to the gastric fluids.
- Protect the drug from the stomach
- Protect the acid liable drugs from the gastric fluid e. g. enzymes and certain antibiotics.
- Coatings are necessary for tablets that have an unpleasant taste, and a smoother finish makes large tablets easier to swallow. [3]
- Forbid gastric distress or nausea due to irritation from a drug e.g., sodium salicylate[4].
- 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.
- Low therapeutic window.
- Formation of a continuous film.
- Nontoxicity.
- Low cost[5].

**Disadvantages:**

- Process is tedious.
- Time-consuming.
- Requires the expertise of highly skilled technician[6].

**Types of Coating:**

1. Sugar coating
2. Film coating
3. Enteric coating

**Sugar coating:**

Sugar coating is used in immediate release applications to mask an un-pleasant taste and odour of drugs or improve aesthetic qualities of the product. It may impact disintegration and dissolution of the drug. An enteric or sustained-release sugar-coated product, the formulation problem may become more complex to meet United State Pharmacopeia (USP) tablet disintegration and dissolution specifications.

Sugar coatings are essentially aqueous based, unless a seal coat (e.g., alcoholic confectioners glaze) is required to protect the core tablet from water used in the sugar-coating process. A sugar-coating process is lengthy and labour intensive, coating materials are inexpensive and readily available[7].

**Solvents used in sugar coating:**

Sugar-coating process consists of various steps, a variety of additives may be incorporated into each type of formulation to achieve a particular function. These include:

1. **Sucrose, other sugars, and sugar alcohols:**

The major ingredient used in sugar-coating process is sugar (primarily sucrose), although this may be substituted by other sugars and sugar alcohols (such as glucose, lactose, maltitol, mannitol, isomalt, sorbitol, xylitol, and sugar mixtures such as invert sugar and starch sugars) for low calorie diabetic products (typically in the candy industry) and for the fact that sucrose cause dental caries.

Sucrose in the sugar coating process ranges from 50-60%, since syrups with a sugar content of less than 65% are stable at room temperature ($24^0$C) without crystallization occurring(8).

2. **Binders:**

Binders increase the strength and elasticity of the coating by forming bonds and thus a coherent matrix. Examples of binders used in sugar coating include polyvinyl acetate (PVA)(10-30%), polyvinyl pyrrolidone (PVP)(0.5-5%w/w), carboxymethyl starch, dextrin(low molecular weight carbohydrates), acacia gum (30%), gelatin (40%), agar-agar (0.22-0.5%), sodium alginate (upto7%) and starches(upto3%w/w).

3. **Colorants:**

Colourants add color to the coatings and cover imperfections which may appear in the tablet core. Examples include lakes (aluminum lakes), and pigments (titanium dioxide or other inorganic coloring agents).

4. **Flavoring agents:**

Flavors improve and enhance the acceptability and palatability of the dosage form in order to maximize patient compliance. E.g., cinnamon, fruit flavors, etc (9).

**Film Coating:**

A film coating is a thin polymer-based coat that is typically sprayed on to solid pharmaceutical dosage form, such as a tablet, capsule, pellet or granule. Film coating can impact both its appearance and its pharmacokinetics making it an essential process in making the final product(10).

Coating is process in which dry the outer layer of coating material is applied to the surface of the tablets to gain the specific benefits on dosage form identification to modifying drug release from the dosage form after

making a good tablet. Coating is applied to a wide range of oral solid dosage forms like tablets, capsule, and drug crystals.

As per the researchers, the sugar-coating process is very time consuming so this technique has been replaced by film coating technology, the process solvent spraying onto a tablet bed to form a uniform thin film on the tablet surface. film coating performs by two types of techniques non aqueous (generally organic solvent used) and aqueous film coating (water solvent used), different types of polymers are used in film coated tablets- cellulose ethers, polymers, silicones, polysaccharides, vinyl polymer etc[(11)].

**Non-aqueous (organic solvent) film coating:**

The most common technique for coating solid dosage form in the liquid coating, mixture of polymer, pigments and excipients is dissolved in an organic solution, and then sprayed onto the dosage form in a pan coater and dry to providing heat, until a coating film is formed. Organic solvent based coating provides a useful polymer. Most of the polymer are soluble in the wide range of organic solvents[(12)].

**Aqueous film coating**:

Aqueous based coating has highly used compare to organic based coating. Disadvantages of organic solvent need to shift on water based solvent. Its coating process more economical and need to less upgrade coating facility[(13)].

**Coating composition:**

Materials used in film coating are:

- Film formers
- Solvents
- Plasticizers[(14)]

**Film formers:**

Ideal requirement of film coating material:

- Solubility in solvent of choice for coating preparation
- Solubility requirement for the intended use e.g., free water-solubility, slow water solubility and pH-dependent solubility[(15)].
- Capacity to produce an elegant looking product.
- High stability against heat, light, moisture, air and the substrate being coated.
- Nontoxic with no pharmacological activity.
- High resistance to cracking[(16)].

**Solvents:**

Solvent is used to dissolve or disperse the polymer and other additives and convey them to substrate surface.

- It dissolve/disperse polymer system.

- Easily disperse other additives into solvent system
- It should be colourless, tasteless. Odourless, inexpensive. Inert, nontoxic and non-flammable
- Rapid drying rate.
- No environmental pollution[17].

**Plasticizers:**

These are generally added to film coating formulations to modify the physical properties of the polymer to make it more usable. One important property is their ability to decrease film brittleness[18].

Examples of plasticizers are:

- Polyols-polyethylene glycol-400.
- Organic esters-diethyl phthalate.
- Oils/glycerides-fractionated coconut oil.

In general, only water-miscible plasticizer can be used for aqueous-based spray systems[19].

**Enteric coating:**

Enteric coating is a polymer applied to oral medication. It serves as a barrier to prevent the gastric acids in the stomach from dissolving or degrading drugs after swallow them. This helps by either protecting drugs from the acidity of the stomach, the stomach from the release of the drug after the stomach (usually in the upper tract of the stomach)[20].

**Polymers used in different active pharmaceuticals as enteric coating:**

| Sl.No | Coating polymer | Name of the drug | Inference |
|---|---|---|---|
| 1. | Hydroxy propyl methyl cellulose(HPMC),Eudragit L100 on carboxylated agarose hydrogel. | Tartrazine | Release rate: Controlled release Disintegration time: Up to 3hrs[21]. |
| 2. | Cellulose acetate phthalate. | Sodium valproate | Disintegration time: HCl for 2 hrs[22]. |
| 3. | Tamarind seed gum, fenugreek seed gum, hydroxy propyl methyl cellulose(HPMC). | Propranolol hydrochloride | Sustained release for HPMC is up to 14hrs[23]. |

| | | | |
|---|---|---|---|
| 4. | HPMCP 50 and Eudragit L100. | Ilaprazole | Drug release for 1hr[24]. |
| 5. | Hydroxypropyl cellulose, polyvinyl pyrrolidone(PVP). | Rosiglitazone sodium | Rosiglitazone sodium was released from enteric coated tablet formulation within 2 hrs of agitation.[25] |
| 6. | Cellulose acetate phthalate, Eudragit L -100 and drug coat L-100. | Pantoprazole | 7.02±0.21 min[26]. |

**Challenges of enteric coating tablets:**

**Blistering:**

Blistering is a coating defect in which the film becomes detached from the substrate and forming a blister[27].

**Remedy to avoid Blistering**:

- Use mild drying conditions is the $134^0$F to $136^0$F.

**Blooming/dull film:**

It is also a coating defect in which the coating of the tablet becomes dull immediately or after prolonged storage at high temperature[28].

**Remedies to avoid Blooming**:

- Use lower concentration (55 to 125) of plasticizer.
- Use high molecular (50000 to 100000) weight of plasticizer.

**Cratering:**

It is a defect in the films coating results in volcanic like craters appears on the tablet which

may results in the exposure of the tablet surface[29].

**Remedies to avoid Cratering:**

- Decrease the spray rate (0.5 to 3mm) and use optimum drying conditions.
- Decrease spray application rate.
- Increase viscosity of coating solution

**Cracking:**

It is a defect in which the tablet film has cracks across the crown of the tablet or splits around the edges.

**Remedies to avoid Cracking:**

- Adjusting the type and concentration of plasticizer.
- Use low molecular weight polymeric blends and polymers.
- Avoid mineral type excipient.
- Avoid over heating the tablet core.

**Chipping:**

It is a common tablet coating defect in which the film becomes chipped and dented usually at the edges of the tablet[30].

**Picking:**

Picking is a coating defect in which the tablets film gets momentarily stick to the pan, after that they pass through the spray zone, then the sticked area gets detached from the tablet surface[31].

**Capping:**

Capping is the term used, when the upper or lower segment of the tablet separates horizontally, either partially or completely from the main body of a tablet and comes off as a cap, during ejection from the tablet press, or during subsequent handling. Capping is usually due to the air–entrapment in a compact during compression, and subsequent expansion of tablet on ejection of a tablet from a die.

**Lamination:**

Lamination is the separation of a tablet into two or more distinct horizontal layers. Lamination is due to air entrapment during compression and subsequent release on ejection. The condition is exaggerated by higher speed of turret[32].

**Remedies to avoid Lamination:**

- Spray the lubricant into the punch and die cavity immediately before die filling directly go to the surfaces of the tooling.
- Adjust the lubricant levels.
- Add hygroscopic substance e.g., sorbitol, methyl cellulose, or PEG 4000.

**Mottling:**

Mottling is the term used to describe an unequal distribution of colour on a tablet, with light or dark spots standing out in an otherwise uniform surface. One cause of mottling may be a coloured drug, whose colour differs from the colour of excipients used for granulation of a tablet(33).

**Conclusion:**

From the above research, we can conclude that tablets were made enteric-coated formulation for avoiding the first pass metabolism, gastric irritation and degradation of the drug to target intestines and protects the drug which is unstable in gastric fluids. Enteric coated tablets were evaluated for hardness, weight variation, thickness, friability, appearance, dissolution test and disintegration test. This dosage form is preferred as it is very convenient and easy to formulate, cost-effective and does not require high cost equipments. For that reason, this dosage form has been gaining so much attention nowadays.

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