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A Review on Biodegradable Polymers for Enteric Coating Material

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ABSTRACT

Worldwide many researchers are exploring the potential use of biodegradable polymeric material as carriers for a wide range of therapeutic applications. In the past two decades, considerable progress has been made in the development of biodegradable polymeric materials, mainly in the biomedical and pharmaceutical industries due to their versatility, biocompatibility and biodegradability properties. The present review focuses on the use of biodegradable polymers for functional enteric coatings, which allow a dosage form to pass through the stomach without its internal contents being subjected to the harshly acidic and enzymatic conditions present there. The sustained release and slow dissolution in the GI tract of oral dosage tablets are controlled by using polymeric materials as a barrier to the dissolution process. If a tablet is described as having an 'enteric coating' (e/c), it means that there is a coating which is designed to hold the tablet together when in the stomach. The fact that, the stomach is acidic and the intestines, where food goes after the stomach is alkaline. The coating is designed to hold together in acidic conditions and break down in alkaline conditions and therefore the drug is released in the intestine.

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INTRODUCTION

The term "Biodegradable polymers" is quite fascinating in the pharmaceutical and medical device community. In fact, this class of polymers has been known for more than a 100 years in the chemical industry but unfortunately it has not received much attention because of their tendency to degrade under normal environmental conditions. Interestingly, it was later realized that this was an advantage for designing a biodegradable implant which would avoid the necessity of a second surgical procedure required to remove the remnants of a previous implant, as was the case for metallic implants. The first FDA approved biodegradable product, Dexon® was a suture introduced in 1970 by Davis and Geck.

Since then, there has been a revolution in the medical device industry which has introduced several orthopedic implants such as pins, screws, cranio-maxilla-facial plates and so on. After about two decades, in the 1990s, the pharmaceutical industry entered into this new era of biodegradable polymers introducing depot injections [1]. One of the most popular and commercially successful depot injection is Lupron®, manufactured by Takeda primarily used for the treatment of prostate cancer. Although there has been significant scientific, as well as, commercial progress in this area, the understanding of this technology remains limited to a few global companies. This is primary because of the complexities involved in the polymer chemistry, depot injection formulation technology, and high precision molding. There is tremendous scope for the adoption of these technologies by a greater number of pharmaceutical and medical device companies. This will help in extending the benefits of these novel technologies to larger patient population's worldwide, offering better patient compliance, especially in the case of chronic disease management. Through understanding polymer degradation in the presence of hydrolyzing agents available in the biological systems, various novel drug delivery systems for sustained and targeted release have been formulated as depot injections for weekly or monthly administration as implants, microspheres, microcapsules, nanoparticles, *in situ* gels etc. Properties such as flexibility, durability, and biocompatibility have made these polymers the preferred vehicles to administer safely *in vivo* for human use in the form of medical devices such dental and orthopedic implants, inserts, sutures, drug eluting stents, and contraceptive devices considering the sincere approach of environment protection.

Polymers are used extensively in the development and manufacture of Solid Dosage Forms (SDFs) and serve many purposes. For Immediate Release (IR) SDFs, they are used as binders in order to increase the density, flowability, and compatibility of bulky Active Pharmaceutical Ingredients (APIs), which would otherwise not process acceptably on high-speed tablet presses and encapsulation machines. Polymers are used for non-functional (aesthetic) coatings to impart colors and favorable mouth feels to tablets without relying on the time-intensive and highly skill-based process of sugar coating, which was the only alternative prior to the advent of polymer-based coatings. Polymer-based functional coatings, such as those used for moisture or oxygen barriers, can nevertheless be formulated as IR dosage forms, still allowing quick release and absorption of the API [2]. Cross-linked polymers that swell extensively in the presence of water and gastrointestinal fluids are used to promote disintegration of tablets and capsule plugs and are available in commercially available powder forms designed to be readily compatible with tableting and encapsulation formulas and processes.

For Modified Release (MR) dosage forms [3, 4], one use of polymers is for functional enteric coatings, which allow a dosage form to pass through the stomach without its internal contents being subjected to the harshly acidic and enzymatic conditions present there. This type of formulation is sometimes referred to as Delayed Release (DR). Other polymers are used for Controlled Release (CR) coatings or for CR diffusional matrices [3, 4, and 5]. Polymers can also be used to enhance the dissolution and bioavailability of the wide array of poorly soluble APIs that are the increasingly common products of current pharmaceutical discovery efforts. The following will present an overview of polymers used in the more exotic and technically challenging dosage forms involving MR (enteric and CR) as well as those used for enhancing the dissolution and bioavailability of poorly soluble APIs [6, 7 and 8].

Enteric coated tablets are solid unit dosage forms which are designed to bypass the stomach and release the drug in small intestine and are meant for oral administration. The word “enteric” indicates small intestine; therefore, enteric coatings prevent release of medication before it reaches the small intestine [9, 10, and 11]. Most enteric coatings work by presenting a coated surface that is stable at the highly acidic pH found in the stomach, but breaks down rapidly at a less acidic (relatively more basic) pH. Biodegradable polymers are frequently being used for enteric coating material and these have attracted the interest of many formulators due to their

advantages over the conventional drug delivery systems as they prolong the dosing intervals and also increase patient compliance [12, 13, and 14]. The study provides an overview of the recent advances that have taken place in this arena.

There are three reasons for putting such a coating on a tablet or capsule ingredient:

- 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 intestines.

The drugs which most commonly cause stomach ulcers like aspirin, diclofenac and naproxen are frequently available with enteric coatings. It can be seen that an enteric coating has advantages and therefore such tablets or the contents of enteric coated capsules should never be crushed before being taken [15].

Biodegradable polymer and coating

Generally, polymeric compounds are used as enteric coating materials that are specifically designed to degrade under controlled biological conditions. Many of the synthetic biodegradable polymers have a built-in self-destruct mechanism by which they undergo slow hydrolytic and microbial degradation, releasing the impregnated materials at controlled rates. [17] The search of a new polymeric drug carrier aims to improve the effectiveness of drug therapy.[18] The polymer coating specifically designed to degrade under controlled biological conditions and thus help release the drug in the targeted site.

Biodegradable polymers are a specific type of polymer that breaks down after its intended purpose to result in natural byproducts such as gases (CO_2, N_2), water, biomass, and inorganic salts.[8, 9] These polymers are found both naturally and synthetically made, and largely consist of ester, amide, and ether functional groups. Their properties and breakdown mechanism are determined by their exact structure. These polymers are often synthesized by condensation reactions, ring-opening polymerization, and metal catalysts.

Different types of tablets are manufactured in different ways. But, nowadays, modern contract manufacturing companies or encapsulation specialists have been making use of enteric coating materials due to various reasons. It is essential for tablets components to get released in the

intestinal region or when enters into the duodenum. Moreover, the method is essential to get used for drug which causes gastric irritation.

Enteric coating of tablets is an important process of ensuring quality and efficient ways of performing enteric coating on tablets. The process is important to ensure that the medicines that can easily react with the acid in the digestive system; especially the stomach, are coated with materials that react easily in alkaline environment and release only in the small intestine. [19, 20] The name enteric is derived from the small intestine; i.e., the enteric coating ensures that the medicine releases its compound in the small intestine area and not in the stomach that has acid content.

Coating of tablet

Tablet coating is moderation of tablet formulation. Coating may be defined as the process of compressing a granulating layer around the performed tablets. It is additional step for manufacturing of tablets. More recently coating has been used to control the site of drug release (enteric coating) and delay or prolong the release of drug from the dosage form. The nature of coating varies; it may be simple or complex. In its simplest form, it may merely consist of a thin film of varnish, applied to make the tablet dust free and reduce any better test. In most complex form, it may consist of inner and outer shell enclosing different types of drugs which may be incompatible or are required to be released at a specific time.[21]

Reasons for coating tablet

The reasons why tablets are coated varied. The major reasons or tablet coating can be summarized as follows:

- Protection of ingredient from the environment, particularly light and moisture.
- Coating provides an effective method of test masking tablets because of bitter test. Tablets those are also somewhat easier to swallow than uncoated tablets.
- Colored coatings also mask any batch wise differences in the appearance of raw materials and hence allay patient concern over tablets of differing appearance.
- Coating confers an added mechanical strength to the tablet core.

- Functional film coatings are used to important enteric or controlled release properties to the coated tablets.

Types of coating material

Various types of coating materials are used for tablet coating. These may be of four types.

- Water-soluble polymer e.g. gelatin, starch, carboxymethylcellulose, methylcellulose, hydroxyethyl cellulose, arabinogalactan, polyvinyl alcohol and polyacrylic acid.
- Water-insoluble polymer e.g. ethyl cellulose, polyethylene, polyamide and polymethacrylate.
- Waxes and polymethacrylate.
- Waxes and lipid e.g. paraffin carnauba wax, spermaceti bee's wax, stearic acid, stearyl alcohol, glyceryl stearates.

Types of tablet coating

There are five types of tablet coating use as- (Fig-1)

i) Sugar coating

ii) Film coating

iii) Press coating (compressing coating)

iv) Enteric coating.

v) Micron coating.

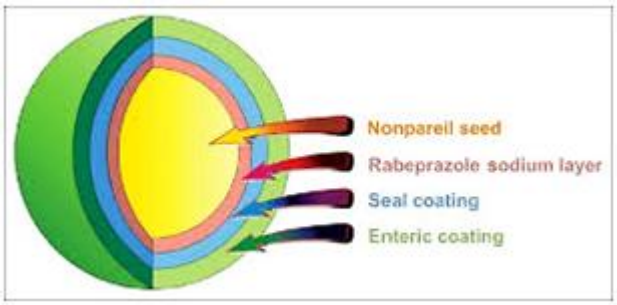

Fig. 1: Type of tablet coating

Enteric coating

An enteric coating is a polymer barrier applied on oral medication. This helps by protecting drugs from the pH (i.e. acidity) of the stomach.[22, 23] Aside from the enteric or non-enteric

film formers the above described coating solution may also contain other ingredients which may aid in the application of the coating material to the tablet or to improve the character of the coating. These may be such ingredients as surfactants, plasticizers, antifoaming agents, solubilizing agents and coloring agents. In general, this will amount to about 5% to about 15% by weight of enteric polymer based on the total weight of the coating solution with the preferred range being from about 9% to about 12% on the same weight basis (Fig-2).

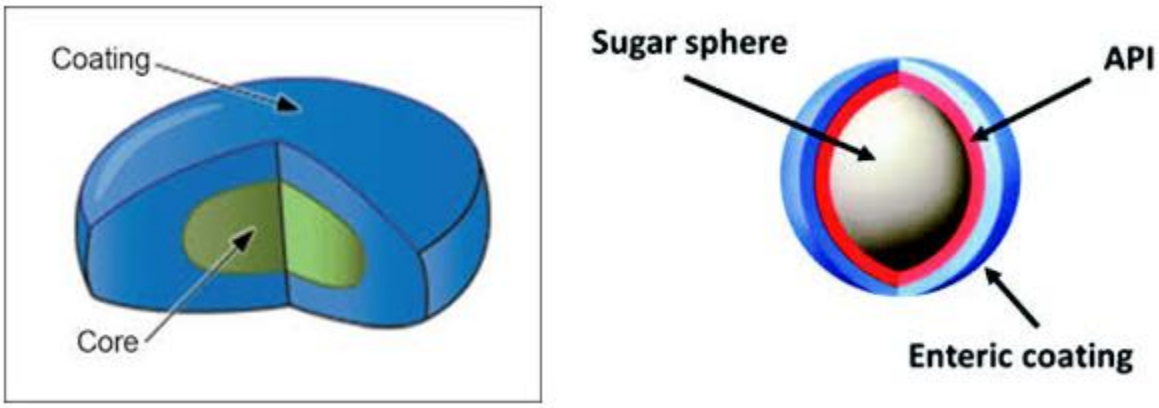

Fig. 2: Enteric coating of tablet

Most enteric coatings work by presenting a surface that is stable at the highly acidic pH found in the stomach, but breaks down rapidly at a less acidic (relatively more basic) pH. For example, they will not dissolve in the acidic juices of the stomach (pH ~3), but they will in the alkaline (pH 7-9) environment present in the small intestine. Materials used for enteric coatings include fatty acids, waxes, shellac, plastics, and plant fibers.

Drugs that have an irritant effect on the stomach, such as aspirin, can be coated with a substance that will dissolve only in the small intestine. Likewise, certain groups of azoles (esomeprazole, omeprazole, pan and all grouped azoles) are acid-activated. For such types of drugs, enteric coating added to the formulation tends to avoid activation in the mouth and esophagus. However, it has been shown that this may lead to incomplete inhibition of platelets. Enteric coating is applied to the tablets to protect the tablet core from the disintegration in the acid environment of the stomach or to delay disintegration until they reach the upper intestine [24]. The substance, which is generally used for enteric coating, are those-

- Which are interred in the acidic medium of the stomach.

- Which do not produce irritation in the stomach.
- The action of which is required only in the intestines.
- Absorption of which takes place from the intestines.
- Delayed action of which is required.

The commercially used materials for enteric coating include fats and fatty acid, shellac and shellac derivative and the cellulose acetate phthalates. In the present day, synthesized polymeric materials are trying to use as an enteric coating material. (Fig-3). Actually, enteric coating concepts depend on the pH value. Normally pH of stomach is highly acidic, which is nearly 1.2 to 1.4 and pH of intestine is basic. Enteric coating material remains unchanged at the acidic medium that means in the stomach but start to dissolve at the basic medium that means in the intestine.

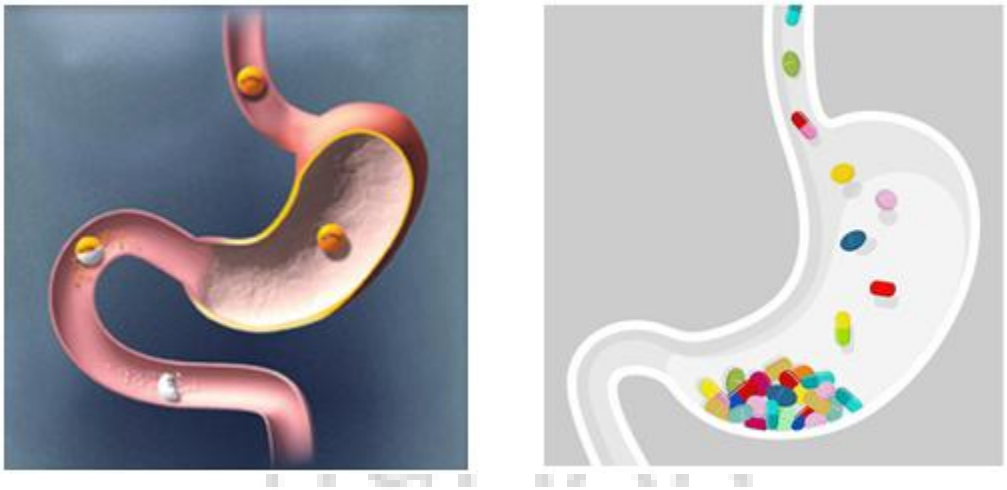

Fig. 3: Stomach and intestine

An enteric coating is a barrier that controls the location of oral medication in the digestive system where it is absorbed. The word "enteric" indicates small intestine; therefore, enteric coatings prevent the release of medication before it reaches the small intestine [25]. The enteric coated polymers remain unionization at low pH and therefore remain insoluble. But as the pH increases in the GIT, the acidic functional groups are capable of ionization, and the polymer swells or becomes soluble in the intestinal fluid. Materials used for enteric coatings include CAP, CAT, PVAP and HPMCP, fatty acids, waxes, shellac, plastics and plant fibers.

There are four reasons for putting such a coating on a tablet or capsule ingredient:

- Protection of active pharmaceutical ingredients, from the acidic environment of the stomach (e.g. enzymes and certain antibiotics).
- To prevent gastric distress or nausea from a drug due to irritation (e.g. sodium salicylate).
- For the delivery of drugs that are optimally absorbed in the small intestine to their primary absorption site in their most concentrated form.
- To provide a delayed-release component for repeat action.
- Required for minimizing first pass metabolism of drugs.

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. The most common drugs which cause stomach ulcers like aspirin, diclofenac and naproxen are frequently available with enteric coatings [26]. Omeprazole, which 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 capsules or as a granule in the dispersible form. Sulfasalazine is used either for the treatment of Crohn's disease which is inflammation of the intestines or for the treatment of arthritis [27]. When used for Crohn's disease where it is needed in the intestines to work, it is given with an enteric coating whereas for arthritis, it is very often given without an enteric coating so that it can be absorbed more quickly.

ERY-TAB is an antibacterial product containing erythromycin base in an especially enteric-coated tablet to protect it from the inactivating effects of gastric acidity and to permit efficient absorption of the antibiotic in the small intestine. ERY-TAB (erythromycin delayed-release tablets) are available for oral administration in three dosage strengths, each white oval tablet containing 250mg, 333mg, or 500mg of erythromycin as the free base. Other commercially available tablets are enteric coated aspirin. E.g. Micropirin® 75mg EC tablets and enteric coated peppermint oil. E.g. Colpermin®.

Ideal properties of enteric coating polymer

- Resistance to gastric fluids.

- Susceptible permeable to intestinal fluid.
- Compatibility with most coating solution components and the drug substrate.
- Formation of continuous film. Nontoxic, cheap and ease of application.
- Ability to be readily printed.

Advantage of enteric coating

The technique is used to protect the tablet core from disintegration in the acid environment of the stomach for the following reasons: [28]

- Prevention of acid attacks an active constituent at low pH.
- To protect the stomach from the irritant effect of certain drugs e.g. Na-alicylates.
- To facilitate absorption of a drug preferentially absorbed distally to the stomach.
- To deliver drugs intended for local action in the intestine.

Criteria of an ideal enteric coating material

An ideal enteric coating material should have the following properties-

- It should have the resistant to gastric fluids.
- It should have susceptibility to or permeability to intestinal fluids.
- It should be compatible with most coating solution components and drug.
- It should have the property of formation of continuous film.

It should have no toxicity and low cost.

Dissolution studies

The dissolution studies for both the core tablet and the coated tablet are performed in order to evaluate the effect of the polymer on the release of the drug. A USP Type-XXII dissolution apparatus (paddle stirrer), Electro lab TDT-01 with a rotation speed of 50 rpm can be used for dissolution experiments. A pH=1.2 solution is used as the simulated gastric fluid and a pH=7.4 buffer solution is used as the intestinal fluid. One liter of simulated gastric fluid previously heated at (37±0.5)˚C is used initially for the dissolution studies which is replaced after 2 hours by 1000ml of simulated intestinal fluid heated previously at (37±0.5)˚C. Samples (5ml) are

withdrawn from the simulated gastric fluid at 30 minutes intervals for 2 hours and from intestinal fluid at 15 minutes intervals, which are immediately compensated with the same amount of fresh medium preheated at (37±0.5)˚C. The amount of drug dissolved is calculated at 274nm using a UV-VIS (Model: U-1800) spectrophotometer with the help of a calibration curve. The *in-vitro* release studies are performed on coated tablets and one core tablet (Fig- 4, 5 and 6) [17, 18].

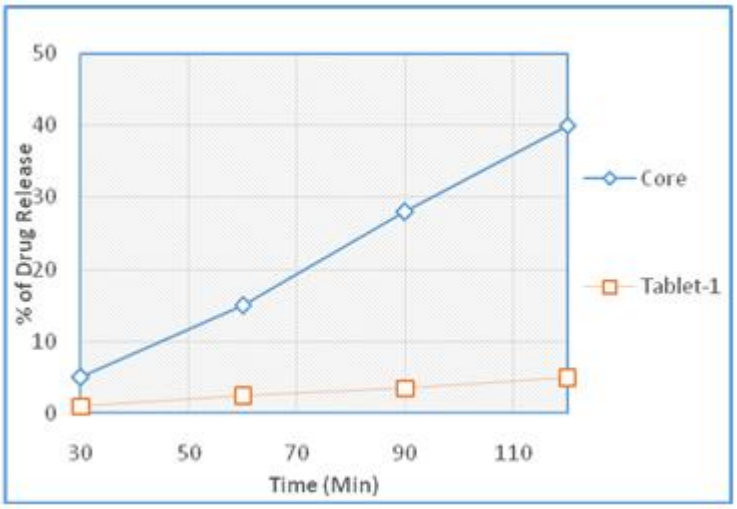

Fig. 4: Percentage of drug release from diclofenac sodium (DS) core and coated tablet in stimulated gastric fluid (pH = 1.2)

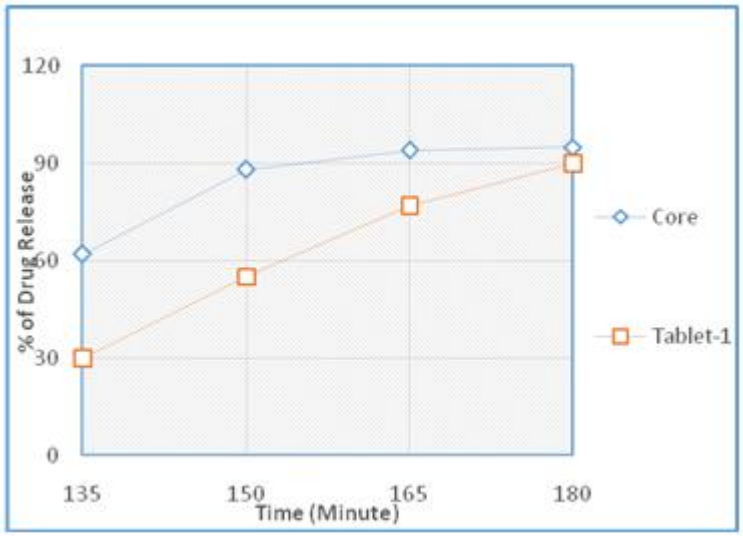

Fig. 5: Percentage of drug release from diclofenac sodium (DS) core and coated tablet in intestinal fluid (pH = 7.4)

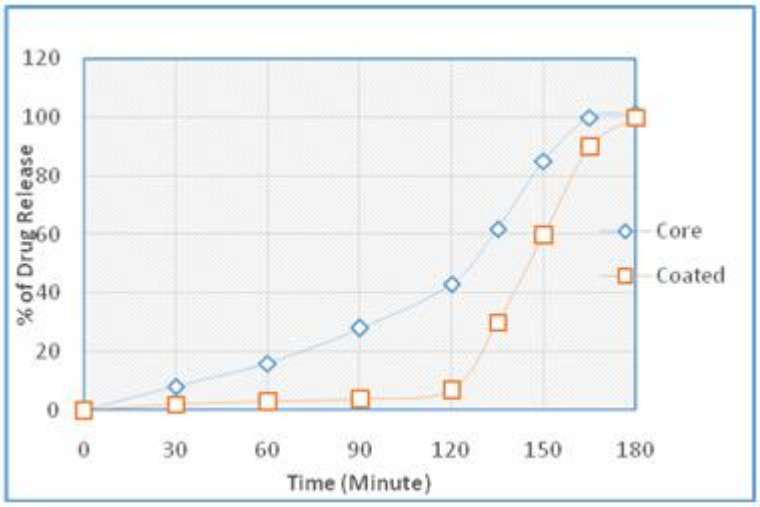

Fig. 6: Percentage of drug release from diclofenac sodium (DS) core and coated tablet (coated by biodegradable polymer) in stimulated gastric fluid (pH = 1.2) and in stimulated intestinal fluid (pH = 7.4)

The following curves should be obtained for an ideal coating of polymeric materials.

Process description

Enteric coating is aimed to prevent the formulations from gastric fluid in the stomach and release the drug component in the intestinal region or once it has passed into the duodenum. Enteric coated tablets resist the action of the acidic stomach fluids and pass through it before the coating can dissolve thus protecting the gastric mucosa from the irritating effects of the ingredients in the tablets e.g. aspirin. However, this coating dissolves in the neutral or alkaline milieu of the intestine and the active ingredients become available for absorption into the blood stream. Basically, coating process of enteric coated tablet consists of several steps:

- Manufacturing of tablet core
- Pre-coating/ Sub coating/Undercoat
- Enteric Coating
- Color Coat
- Polishing

Preparation of core tablet

The core tablets were prepared by direct compression method. All the ingredients were accurately weighed, milled and passed through sieve no. 60 (250 microns) to get uniformly distributed and uniform sized particles. The ingredients were then blended in a cube mixer for 30 minutes. The homogeneously blended mixture was then compressed on a 10 station tablet punching machine using 6 mm round biconvex punches at a pressure of 4 to 6 kg/cm^2. Different formulations of core tablets were produced with drug equivalent to 40mg of active ingredients and various disintegrating agents. All the formulations were prepared with similar blending time and compaction conditions [29].

Evaluation of core tablet

The core tablets after compression are evaluated for thickness and tablet diameter using a Vernier caliper, hardness by the use of Pfizer hardness tester (Sisco Ltd), uniformity in weight of tablets via an electronic balance (Sartorius), friability with (Roche friabilator, EI), disintegration time by means of disintegration test apparatus (EI) and drug content. Based on the above evaluations, optimized formulation is selected for the enteric coating.

Seal coating of core tablet

The optimized formulations are sub-coated with a seal coating composition incorporated with HPMC. The seal coat is prepared by dispersing HPMC in solvent mixture of isopropyl alcohol and dichloromethane (2:1) with continuous stirring using a propeller mixer for 45 min. The dispersion is size reduced, if necessary through colloidal mill then filtered by passing through 250 μm sieve. The total solid content of the dispersion is made to 12% w/v.

Coating of core tablet

The biodegradable polymer is dissolved in volatile organic solvent to prepare coating solution. The coating solution was sprayed over the tablets in a small coating pan with continuous hot air flow. The coating pan is allowed to rotate until the solvent evaporated and tablets dried.

Sub-coating (pre-coating)

The major concern in enteric coating formulations is a risk of premature drug release through the enteric coating film in acid media. This problem could be solved by an application of a sub coating layer where the coating substrates are subject to coating with a small amount of a soluble material prior to enteric coating. This thin film layer impedes water penetration through the cores and thus prevents the premature drug release.

Sub-coating materials

- Hydroxypropyl methylcellulose
- Polyvinyl pyrrolidone
- Hydroxypropyl cellulose
- Polyethylene glycol 3350, 4500, 8000
- Methylcellulose
- Pseudo ethylcellulose
- Amylopectin

Sub coating is supportive in formulations which contain highly water-soluble drugs. This is where premature drug release mostly occurred. On the contrary, sub coating could also enhance the release of acidic drugs in basic media. This causes a problem of acidic microenvironment at the interface between the core and the enteric film. The migration of diffused drug through the interface results in the delay of drug release in basic media [30, 31]. Due to the restriction in the regulatory requirements, not only the prevention of premature drug release in acidic media should be taken into account, but also the accomplishment of rapid drug release in basic media. To cope with the latter constraint, a new concept of organic acids addition in coating substrates or sub coating layer is initiated in order to promote the basic microenvironment (pH 5-6) at the interface between the enteric film and the cores which could accelerate the polymer dissolution.

The sub coating layer reduces surface roughness of the coating substrate and improves adhesion of the enteric film on the substrate surface. This generates a robust film formation where a lower amount of enteric coating polymer may be required for enteric protection. The solutions which

will be used to prepare the overcoat or undercoat layers of the present tablets may also vary as to concentration of the non-enteric film forming polymer. Usually, the latter will constitute from about 2% to about 8% by weight of said non-enteric film forming polymer based on the total weight of the coating solution with the preferred concentration being from about 5% to about 6% of said non-enteric film former on the same weight basis [32].

Color coat

Approximately 3% film coating solids are applied to the tablet surface using the same film coating solution as described in sub-coating and applied in a similar manner. The coating solution in this step could be colored. Application coating in this step prevents tablets from sticking to each other when stress tested at high temperature [33]. It also gives flexibility when preparing this product in different colors.

Polishing

The color coated tablets from the previous step are polished in the coating pan with exhaust turned off by sprinkling 0.01% powdered polishing wax onto the surface of the tablet bed while rotating slowly [34]. The tablets are rolled in the coating pan until they start to slide. The exhaust is then turned on to remove the excess wax. These finished enteric film coated tablets have approximately 12.5% total film coating solids applied.

Minimum film forming temperature (MFFT)

Minimum Film-Formation Temperature (MFT) is an inherent problem to water emulsion polymer. MFT is the minimum temperature of the substrate at which the finish will form a strong continuous film. For enteric coating processes based on aqueous dispersion systems, product temperature is usually set to a range of 30-40°C, in practical operations. The effect of product temperature becomes troublesome in enteric coating due to the hydrophilicity of enteric coating polymers. They tend to become sticky under humid conditions. The agglomeration of coated particles most likely occurs when the temperature is set too low. This problem becomes crucial in the case of pellet formulations as the growth of sticky pellets takes place in a very short time which could ruin the whole batch if the coating conditions cannot be adjusted in time. If the product temperature is set too high, this accelerates the solvent/

aqueous evaporation, generating more viscous sprayed liquid droplets which barely spread on the surface of the coating substrates [35]. This leads to one kind of coating failure which is called 'orange peel appearance'. It results in an inconsistency of the coating layer. High temperature condition could accelerate the volume expansion of the air trapped under the coating layer. High temperature and longtime processing also accelerate the evaporation of some plasticizers, for example, triethyl citrate, thus changing the enteric film property.

Coating film distribution

Coating uniformity is attributed to the distribution of sprayed liquid on the surface of the coating substrates. This correlates with the design of the equipment used. For example, in pan coating systems, pan speed has a significant influence on the quality of the film distribution through the mass variance of the moving tablets which determines the optimal amount of polymer for the enteric protection [36, 37]. In Wurster-type fluid bed systems, the coating uniformity depends on the mass of coating substrates passing through the spray zone. It is influenced by inlet air volume, spray shape, flow pattern of the substrates and the gap between the Wurster partition and the air distributing plate [38]. The condition of low inlet air volume and low level of the partition tends to generate a dead zone, where the coating substrates cannot be uniformly coated.

Curing process and storage condition

Some types of enteric coating polymers, such as HPMCAS, require a special curing process at an elevated temperature and high relative humidity to induce the polymer coalescence. CAP and CAT coatings present instability of the film upon storage especially at high temperatures [39]. This is due to the hydrolysis of ester groups followed by the formation of insoluble cellulose acetate. Final products coated with aqueous dispersion systems tend to be sintered upon storage, if hydrophilic plasticizers are incorporated [40].

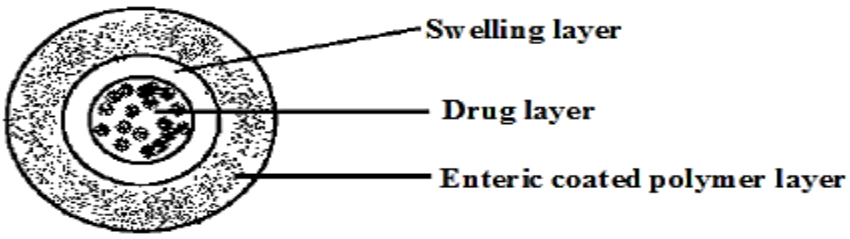

Fig. 7: Enteric coated polymer layer

It should be added that the enteric-coated solid dosage forms are optionally overcoated with sugar or other materials or polished according to any known methods (Fig-7) [41, 42]. It is also optional that the solid dosage forms are subjected to undercoating with conventional coating materials before they are treated with the enteric coating in accordance with the method of this invention. The following examples are illustrative of the method of this invention and are not to be construed as limiting. In the examples, parts and percentages are all based on weight. [43]

CONCLUSION

Biodegradable polymers are used extensively in pharmaceutical formulations, from drug delivery to implants and stents. In recent decades, coating of pharmaceutical dosage forms has been subject of remarkable developmental efforts aiming to ensure and enhance end product quality. Improvements regarding particle movement, heat and energy transfer, film distribution, drying efficiency and continuous processing have contributed to significantly develop this technology. In future, there are enormous developments has to be done in the area of tablet coating. 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. Enteric coated tablets could be used to treat *Streptococcal* infections of the throat (strep throat) and the skin and can also be used in treating lung infections (pneumonias) caused by *Streptococcal pneumoniae, Mycoplasma pneumonia* and *Legionella pneumophila* (Legionnaires disease). 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.

Drugs which are having low oral bioavailability (<50%), short biological half-life (about 3 hrs.) and an adequate protein binding that are preferred while formulating enteric coated dosage form. 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. The present review also emphasizes areas such as the chemistry of polymer synthesis, factors affecting the biodegradation, methods for the production of biodegradable polymer based formulations.

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