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Polymers Used In Enteric Coating: An Overview

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ABSTRACT: A specialised pharmaceutical technique called enteric coating ensures targeted release of medications in the intestines while shielding them from deterioration in the stomach's acidic environment. The main purpose of this coating is to improve patient compliance, medicine stability, and bioavailability on tablets and capsules. The mainstay of enteric coatings are polymeric substances with pH-dependent solubility, which enable them to dissolve in the intestines (pH >5.5) but stay intact in the stomach (pH 1-3). Polyacrylates (such as Eudragit® L and S grades), polyvinyl-based copolymers, and cellulose derivatives (such as hydroxypropyl methylcellulose phthalate and cellulose acetate phthalate) are often used polymers in enteric coating. These substances guarantee regulated medication release, enhance therapeutic effectiveness, and reduce gastrointestinal discomfort. Advances in polymer science continue to enhance enteric coatings by optimizing film formation, flexibility, and biodegradability. This review article highlights the enteric coating, procedure, mechanism and also the polymers used in the enteric coating.

Keywords: enteric coating, polymers, advantages, criteria.

I. INTRODUCTION:

A tablet is a solid pharmaceutical dosage form that is made up of a combination of excipients and active ingredients, usually in powder form, that are compressed or pressed into a stable shape. The practice of applying a coating substance to a dosage form's surface in order to provide it particular advantages is known as coating. An enteric coating is a barrier that facilitates the passage of oral medication into the intestine for absorption while regulating its release in the stomach. Enteric coatings stop the release of medication before it reaches the small intestine because the word "enteric" refers to the small intestine. At low pH, the enteric coated polymers continue to unionize and are hence insoluble. However, the polymer swells or becomes soluble in the intestinal fluid as the pH in the GIT rises because the acidic functional groups can ionize. Fatty acids, waxes, shellac, plastics, plant fibers, CAP, CAT, PVAP, and HPMCP are among the materials utilized for enteric coatings(1). Enteric coating has many desirable qualities, including resistance to stomach contents, susceptibility to or permeability to intestinal contents, compatibility with the majority of coating solution ingredients and the drug substrate, continuous film production, nontoxicity, affordability, and simplicity of use. Enteric coating uses a variety of polymers, including cellulose acetate phthalate (CAP), poly(methacrylic acid-co-methyl methacrylate), cellulose acetate trimellitate (CAT), poly(vinyl acetate phthalate) (PVAP), hydroxypropyl methylcellulose phthalate (HPMCP), and shellac (esters of aleurtic acid). Based on the dissolving pH, which ranges from 4.5 to 7.0, polymers were chosen(2).

Tablet coating: Coating is a procedure by which a basically dry, outer layer of coating material is put to the surface of a dosage form in order to bestow certain benefits that generally ranges from enabling product identification to changing medication release from the dosage form. It is frequently necessary to coat a good tablet after it has been made.(3). A variety of oral solid dosage forms, such as tablets, capsules, multiparticulates, and drug crystals, can be coated. A sticky polymeric film covers the tablet surfaces when a batch of tablets is coated with coating material in a coating pan. The applied coating transforms from a sticky liquid to a tacky semisolid and finally to a non-sticky dry surface layer before the tablet surface dries. The entire coating process is conducted in a series of mechanically operated acorn-shaped coating pans of galvanized iron stainless steel or copper. The smaller pans are used for experimental, developmental, and pilot plant operations, the large pans for industrial production(4).

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The main elements of tablet coating include:

- Tablet characteristics
- Coating process
- Coating equipment
- Coating process parameters
- Facility and auxiliary equipment
- Automation in coating processes (4).

Coating Process Design and Control: The majority of coating techniques include spraying the tablets with coating solution while they are being stirred in a pan, fluid bed, etc. A thin layer of the solution forms during spraying and sticks straight to each tablet. The coating can be created with a single application or by using several spraying cycles to build it up in layers(2). Rotating coating pans are frequently employed in the pharmaceutical business. First, the pan—which is usually angled from the horizontal—is filled with uncoated tablets. Next, the liquid coating solution is added to the pan as the tablets are falling. The liquid part of the coating solution is then evaporated by blowing air over the surface of the tumbling tablets. In contrast, a fluid bed coater works by moving air through a tablet bed quickly enough to hold and separate the tablets as separate entities. Following separation, the coating component is sprayed onto the tablets (3).

Enteric coating: An enteric coating is a barrier that regulates where oral medication is absorbed in the digestive tract. Enteric coatings stop the release of medication before it reaches the small intestine because the word "enteric" refers to the small intestine. At low pH, the enteric coated polymers continue to unionize and are hence insoluble. However, the polymer swells or becomes soluble in the intestinal fluid as the pH rises in the GIT because the acidic functional groups can ionize. CAP, CAT, PVAP, HPMCP, fatty acids, waxes, shellac, polymers, and plant fibers are among the materials used to make enteric coatings. Such a coating is applied to a tablet or capsule component for four reasons: Enzymes and several antibiotics are examples of active medicinal components that are shielded from the stomach's acidic environment. To avoid nausea or upset stomach caused by irritants (such sodium salicylate). For the transportation of medications in their most concentrated form to the main site of absorption, where they are best absorbed in the small intestine. To give repetitive action a delayed-release component. Essential for reducing medication metabolism in the first pass (5). To regulate the pH solubility profile of the enteric coated dosage form, the polymer selection and coating layer thickness are crucial. Enteric coatings are often available for the most common medications that cause stomach ulcers, such as aspirin, diclofenac, and naproxen. Since omeprazole, a medication that prevents the stomach from creating acid, is broken down in acid, it typically has an enteric coating surrounding it, either in the form of granules in capsules or in the form of granules in dispersible form. The medication sulfasalazine is used to treat arthritis or Crohn's disease, which is an intestinal inflammation conditions. While it is frequently used without an enteric coating for arthritis in order to facilitate faster absorption, it is administered with one for Crohn's disease, where it is required in the intestines to function. In order to prevent the inactivating effects of gastric acidity and to enable effective absorption of the antibiotic in the small intestine, ERY-TAB is an antibacterial medication that contains erythromycin base in a particularly enteric-coated tablet. Erythromycin delayed-release tablets, or ERY-TABs, come in three dosage strengths for oral administration. The free base in each white oval tablet is 250 mg, 333 mg, or 500 mg of erythromycin. Enteric-coated aspirin is another type of pill that is sold commercially. For example, enteric-coated peppermint oil with 75 mg EC tablets of Micropirin®. For instance, Colpermin®

The ideal properties of an enteric coating material:

- Resistance to stomach juices
- Permeable or susceptible to intestinal fluid
- The majority of coating solution components and the drug substrate are compatible, and a continuous film forms.
- Nontoxic, affordable, and simple to use
- The ability to print easily (6)

Coating Procedure (7)- (8):Within a perforated rotating drum, tablet coating is done in a controlled environment. After loading a batch of tablets into the coating pan, warm the tablets and give them time to flash out of the pan and collect dust. The tablet bed can be mixed thanks to air flow inside the drum and angled baffles installed within. Consequently, each tablet surface is exposed to an equal amount of deposited or sprayed coating when the tablets are raised and rotated from the sides into the center of the drum. Spraying can start as soon

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as the outlet air temperature reaches 42°C to 46°C, which is often within 15 minutes. A fine coating solution mist is produced by the spray guns, and it dries as soon as it comes into contact with the tablet. An inlet blower circulated warm air through the tablet bed to dry the liquid spray coating onto the tablets. In order to offer the operator with a totally isolated process atmosphere, the drum pressure is kept slightly negative in relation to the room while the air flow is controlled for temperature and volume to enable controlled drying and extraction rates. A thin layer forms on the tablet when the water evaporates, leaving the solids behind. The secret of tablet coating is to barely moisten the surface and then quickly dry it. Instead of using lengthy, slow shots, apply the coating in numerous short, quick exposures. Following the application of the base coating, you can progressively increase the pan speed and the rate of solution addition. Usually, it takes around 20 minutes before the spray rate and pan speed are noticeably increased. Very porous tablets might need a slower starting spray rate than the typical 100 milliliters per minute per gun. Keep an eye on the spraying process to observe whether the pattern changes. If it does, the gun tips probably have a solids buildup. This can only be fixed by cleaning the tips, which entails turning off the spray and the pan. A steady flow of hot air enters the drum and travels through the drum perforations into the tablet bed, causing the enteric coating solution to dry on the tablet surface. The film accumulates solids layer after layer over time. The pills need to cool after the solution has been applied and dried. The tablets must stay at a certain temperature, the solution must be administered steadily, and the motion of the tablets must be both active and calm for coatings to cling correctly. If any of these circumstances are disturbed, a faulty tablet will result.

Polymers

The repeating units or monomers that make up polymers' chains give them extremely enormous molecular weights. Natural, semisynthetic, and synthetic polymers have all significantly improved health in the pharmaceutical and medical industries (9). The carboxylic acid groups in the polymers stay together in the stomach's low pH environment. As a result, the polymeric covering does not dissolve in the stomach juice. To enable the tablet core to dissolve in the small intestine, the polymeric coating breaks down or dissolves in the higher pH intestinal environment. The gut wall allows the active substances to enter the bloodstream after absorption. Since these polymers are soluble in organic solvents, they were initially used on tablets as solutions in different organic solvents. By neutralizing a significant amount of carboxyl groups, the enteric polymers are made water soluble or water dispersible by combining them with a water-soluble base. Cellulose acetate phthalates (C-A-P), cellulose acetate taramellites (C-A-T), hydroxypropyl methyl cellulose phthalates (HPMCP), hydroxypropyl methyl cellulose acetate succinate (HPMCAS), polyvinyl acetate phthalate (PVAP), and methacrylic acid are among the polymers that are effective as enteric coatings because they contain ionizable carboxylic groups(10). Some of the most widely used polymers in the pharmaceutical business are discussed here.

ACRYLATE POLYMERS: Eudragit L and Eudragit S are two types of enteric acrylic resins that are sold commercially. Both resins create films that can withstand stomach acid. Intestinal fluid can dissolve Eudragit L and Eudragit S at pH values of 6 and 7, respectively. Eudragit L can be purchased as an aqueous dispersion, solid, or organic solution. Eudragit S can be purchased as a solid or as an organic solution.

CELLULOSE ACETATE PHTHALATE (CAP): The industry has made extensive use of cellulose esters. The drawback of CAP is that it only dissolves at pH 6, which may cause delays in drug absorption. In contrast to other enteric polymers, it is also hygroscopic and comparatively permeable to moisture and gastric fluid. "Aquaretic" is a patented aqueous enteric coating created by FMC Corporation. A reconstituted colloidal dispersion of latex particles is known as an aquatic coating. It is made up of cellulose acetate phthalate solid or semisolid polymer spheres that range in size from 0.05 to 3 microns, with a typical particle size of 0.2 micron. Hydroxy propyl cellulose is the source of HPMCP-50, 55, and 55S, which are polymers that dissolve at a lower pH (5 to 5.5) than CAP or acrylic co-polymers. These polymers are extremely stable in contrast to CAP due to the lack of labile acetyl groups.

PVAP ORPOLYVINYL ACETATE PTHALATE: A partlyhydrolyzed polyvinyl acetate is esterified with phthlicanhydride to create polyvinyl acetate phthalate (PVAP). HP-55 and this

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polymer are comparable in stability and solubility that varies with pH. Enteric systems that are ready to use or disseminate are available (4).

HYDROXYPROPYL METHYL CELLULOSE : For pan spray coating and air suspension systems, this polymer is the preferred material. The polymer's solubility in gastrointestinal fluid and in organic and aqueous solvent systems, noninterference with tablet disintegration drug bioavailability, flexibility, chip resistance, and lack of taste or odor, stability in the presence of heat, light air, or appropriate moisture levels, and ease of incorporation of color and other additives into film are some of the factors contributing to its widespread use. The polymer has a propensity to fill or bridge the deobessed tablet surfaces when applied alone. To get rid of bridging or filling issues, hydroxypropyl methyl cellulose is combined with other polymers or plasticizers. Glossing solutions also make extensive use of this polymer**.**

ETHYLCELLULOSE: This substance cannot be utilized alone for tablet coating since it is totally insoluble in water and digestive juices. Usually, water-soluble chemicals like hydroxypropyl methylcellulose are added to it. In addition to being nontoxic, colorless, and tasteless, the polymer is soluble in a broad range of organic solvents and is generally stable in the environment.

HYDROXYPROPYL CELLULOSE: The hydroxypropylene molecule. It dissolves in a variety of polar organic solvents, gastrointestinal fluids, and water below 400C. This polymer may work well for a subcoat but not for a color or gloss coat because it dries sticky from a solution system. Flexible films are produced by the polymer. It is typically used in conjunction with other polymers rather than by itself(9).

Mechanism of enteric coated time- release press coated (ETP) tablets:

A drug-containing core tablet (rapid release function), a press-coated swellable hydrophobic polymer layer (hydroxy propyl cellulose layer, or HPC), which has a time release function, and an enteric coating layer (acid resistance function) make up ETP tablets (11),(12). Because the outer enteric coating layer of the tablet is resistant to acid, the medicine is not released in the stomach. When the stomach empties, the enteric coating layer dissolves quickly, and the intestinal fluid starts to gradually erode the press coated polymer (HPC) layer. Since there is no drug release period (lag phase) following gastric emptying, the erosion process takes a long time, and rapid drug release happens when the erosion front reaches the core tablet. The duration of lag phase (drug release phase) is controlled either by the weigh or composition of the polymer (HPC) layer.

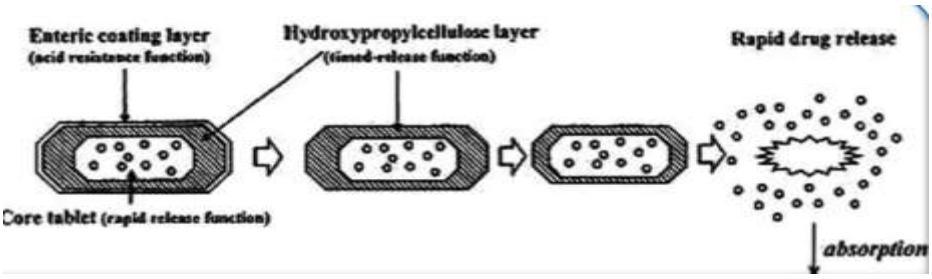

Figure 1: Design of enteric coated timed- released press coated tablet ((2)

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Method of manufacturing enteric coated tablets by spray coating technique (14):

- **Preparation of core tablets:**

The wet granulation process was used to create the granules. After passing the drug and other excipients through # 80, a sufficient amount of binding agent was gradually added to obtain dough mass. These granules were then passed through #20 and lubricated with magnesium stearate after the material was sieved through #8 and dried for approximately an hour at 45ºC. Using a shallow concave plain/plain punch, the mixed blend was compressed into tablets with a weight of 250 mg each, dimensions of 4.46 ± 0.21 mm, and a diameter of 7.9 mm on a single punch tablet compression machine.

- **Coating of core tablets: Preparation of enteric coating solution:**

50 milliliters of water were used to dissolve a weighed quantity of pectin, and 50 milliliters of isopropyl alcohol were used to dissolve ethyl cellulose. After thoroughly mixing the two solutions to create a homogenous mixture, PEG-6000 was added as a plasticizer.

- **Coating of core tablets:**

The typical coating pan technique is used to achieve enteric coating of the compressed tablets. Ten milliliters per minute were used to coat the tablets in a pan coater at 50 rpm and 50 degrees Celsius. The spraying procedure was used to coat, and it was then dried. Using a spray pistol, these solutions are administered to tablets at the proper pressure. A heat blower is used to dry the coated tablets, with a tray drier serving as a secondary drying method.

- **Coating methodology (15):**

One spray gun was used to coat tablets in a traditional coating pan. Previously, 95% alcohol was used to clean the coating pan. For coating, a batch size of 3.5 kilogram core tablets was chosen. The coating pan was filled with the core tablets. Tablet cores were preheated using an air compressor and drier to approximately 40°C. Throughout the coating operation, warm air—up to 50 to 55°C—was injected into the coating pan. Enteric coating solution was loaded into the spray gun, which was then set to run at the appropriate flow rate. The pan was started, and at an appropriate air pressure of 6–8 bar (87.0–116.0 psi), a seal coating dispersion was sprayed onto the falling cores. Tablets were blow dried in the coated pan for 20 to 25 minutes after the air heater was turned off. After being coated with enteric coating solution, the core tablets' weight increased by 10 ± 2%.

Additional considerations:

- The pan's air pressure should always be negative, meaning there should be more air exiting than in.
- Always wait at least 15 minutes for the exhaust temperature to stabilize after startup before adjusting fluid and/or air flows.
- For the first 1% weight growth, if any tackiness or sticking is observed, the spray rate of coating solution should be lowered by 15% to obtain the maximum enteric quality and adhesion between the core and enteric interface.
- Maintain a steady flow rate once the coating solution delivery process has started.
- During the coating process (Colorcon), keep the gun needles open.

Table no 1: Parameters of coating process(13)

Factor	Condition
Equipment	Erweka Coating Pan
Substrate	50 mg Erythromycinstearate tablets
Pan Charge	3.5 Kg
Dispersion solid content	15.0% (w/w)
Pan speed	14 rpm
Inlet Temperature	52- 58˚C
Exhaust air temperature	40-42˚C
Bed Temperature	35-40˚C
Spray rate	50 g/min
Distance between spray gun and tablet bed	15 cm
Coating time	160 min

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Table 2: Parameters of coating formulation(13)

Parameter	Coating
Theoretical weight gain (mg)	10 ± 2%
Polyethylene glycol (PEG6000)	1.4% (w/w)
Deionized water	72.5% (w/w)

Evaluation of granules: (14)

- **Measurement of angle of repose:**

The funnel method was used to calculate the angle of repose. Static angle of repose is the term used to describe the angle of repose determined using this method. Because of their connection to interparticle cohesiveness, angle of repose is an indirect way to measure powder flow ability. When the angle of inclination is sufficiently large to overcome frictional forces, a static heap will slide; when the forces are balanced by gravity, the heap will stop. The angle of repose is the angle formed by the heap's sides with the horizontal(15) A funnel that can be lifted vertically is used to pour powder into the center of the dish until the maximum cone height (h) is reached. The angle of repose can be calculated by the given formule.

$\alpha = \tan^{-1}$ (h/r), where h is height of pile and r is radius of pile.

This was done thrice, from that average angle of repose and standard deviation was calculated.

- **Pore/ Bulk density**

The pre-weighed (M) blend was poured into a graduated cylinder to determine the apparent real density (ρb). This approach was used to determine the blend's bulk volume (Vb). The true density was then ascertained using the formulas listed below.

$\rho b = M/Vb$

After completing this three times, the average real density and standard deviation were determined.

- **Tap density**

The minimal volume (Vt) occupied in the measured cylinder, which contained a known mass (M) of mix, was measured after it was tapped for a certain amount of time. The following formulas were used to determine the tapped density.

Tap density= M/Vt

After completing this three times, the average tap density and standard deviation were determined.

- **Porosity**(16)

The porosity of voids and of the powder id defined as the ratio of void volume to the bulk volume of the packaging.

$E = (Vb - Vp)/Vb = 1 - (Vp/Vb)$

- **Carr's Index**

Based on the apparent bulk density and the tapped density, the percentage compressibility of the drug was determined by using the following formula:

%Compressibility = tapped density - bulk density/tapped density X100

- **Hausner's Ratio**

The ratio of tapped density to bulk density of the powders is called Hausner's ratio.

Evaluation of core and coated tablets:

The hardness, friability, weight fluctuation, disintegration time, thickness, drug content, and in vitro release tests of the coated and core tablets were assessed.

- **Hardness:** A Monsanto tablet hardness tester was used to measure the crushing strength of the tablets. A tablet was positioned between the anvils, and the crushing force that broke the tablet was noted (17).
- **Friability:** Roche Friabilator was used to measure tablet strength. After being precisely weighed, twenty pills were put in the friabilator and spun for 100 revolutions in four minutes. After the tablets were dedusted, they were weighed again to determine the % weight reduction. Tablets were deemed compliant if they lost less than 1% of their weight.
- **Weight Variation:**Twenty tablets were chosen at random for the weight variation, and an electronic balance was used to calculate the average weight. Each tablet's weight was measured separately and compared to the average(18).
- **Time of disintegration:** The disintegration equipment USP was used to measure the disintegration time in 0.1N HCl for two hours and in phosphate buffer pH 6.8 for one hour while keeping the temperature at 37 ± 2°C(17).
- **Thickness:** Vernier calipers were used to measure the tablet's thickness(18)
- **Drug content studies:** After weighing and powdering ten pills separately,50 milliliters of 95% ethanol were added, along with an amount equal to five milligrams of the medication, and the mixture was agitated for

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half an hour. To make 100 ml, enough ethanol (95%) was added. After centrifugation, a pipette was used to remove an appropriate volume of the supernatant liquid (0.5 mg of medication) and dilute it with 50 ml of 95% ethanol. Filtration was performed on the solution (through 0.45 µm). At 236 nm, the drug content was determined using a UV/visible single beam spectrophotometer(18).

- **In vitro drug release studies:**The pH of the stomach and intestines. The USP XXIV six station dissolution rate test apparatus with paddle stirrer was used to conduct an in vitro drug release investigation of enteric coated tablets. For the first two hours, the dissolution rate was measured in 900 ml of 0.1 N HCl (pH 1.2) kept at 37±1ºC with a speed of 50 rpm. For the next four hours, the phosphate buffer (pH 7.4) was used. Every hour, 5 ml of samples were taken out, filtered through 0.45 µm, and then replaced with 5 ml of brand-new dissolving media. Using a UV/visible single beam spectrophotometer, the samples were spectrophotometrically assessed at 236 nm, diluted appropriately if needed, and the cumulative % drug release was computed(18)

Advantages of enteric coating:

- ✓ Keep the medication away from the stomach.
- ✓ Preserve medications that are susceptible to acid reflux from the stomach fluid, such as enzymes and some antibiotics.
- ✓ Large pills are simpler to swallow when they have a smoother finish, and coatings are required for tablets with an unpleasant taste(19).
- ✓ Prohibit nausea or gastrointestinal distress brought on by a medication's irritant, such as sodium salicylate(20).
- ✓ Deliver medications meant to function locally in the bowels; for example, intestinal antiseptics could be supplied in a concentrated form to their site of action(21)

Disadvantages of enteric coating:

- ✓ Need a highly qualified technician's expertise(22).
- ✓ This procedure takes a lot of time and is laborious(23).

Applications:

- **Reduced GI Toxicity**

An enteric-coated version of the sodium salt of MPA was created in order to get around the Gl side effects. (EC-MPS. Myfortic or EC mycophenolate sodium). A delayed-release tablet coated in hypromellose phthalate is the commercial product. Patients' pharmacokinetic investigations verified the delayed release, and MPA's peak plasma concentration occurred 1.5–2.75 hours after oral MPS dose, which was later than MMF's (T 0.5–1b). EC-MPS was able to reliably reach an AUC >30 ug h/mL at regular dosages, which is thought to be the threshold required for effectiveness. For active moiety mycophenolate, comparable doses of MMF and EC-MPS were found to have comparable efficacy and adverse effects. 720 mg of MPS is equal to 1000 mg of MMF. Given that pharmacokinetic analysis demonstrated that EC-MPS was not linked to an increase in adverse events and that it achieved statistically higher plasma concentrations at equimolar doses, it is possible that EC-MPS will be more tolerable than systemic exposure, allowing more patients to receive therapeutic concentrations. Due to numerous confounding factors, including the stress of surgery, data collection methods, concurrent drugs, and the high occurrence of Gl events even in the absence of MPA treatment, it is challenging to assess Gl adverse events after transplantation. According to one study, patients who were moved from MMF to EC-MPS experienced less severe Gl episodes. Similar results following the switch from MMF to MPS were reported in other studies. MMF 42.1% and MPS 26.9% dosage reductions in cardiac transplantation differed significantly ($p<0.05$). There have been conflicting accounts on liver transplants. These writers came to the conclusion that converting MMF to MPS is advantageous.

- **Targeting to specific regions of the GI Tract**

Targeting the small intestine's release of active ingredients can provide therapeutic advantages for certain medications. When a medication is intended to be released in the small intestine rather than the stomach or cecum, cysteamine has been shown to provide the most exposure. However, the perceived delayed in vivo breakdown of dose forms once the enteric cover disintegrates may make site-specific administration to the proximal small intestine challenging. Effervescent formulations with an enteric coat were proposed as early as the 1970s to achieve quick breakdown in the proximal small intestine. The proximal small intestine is the primary location of

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absorption for many medications, including erythromycin and indomethacin. To guarantee that the dosage form is transferred intact from the stomach and then promptly made available for absorption, these medications must be carefully formulated as enteric products. Enteric coat compositions with diameters no larger than5 mm are one method that has been suggested in these situations for good reproducibility and low intersubject variability.

II. CONCLUSION:

Based on the review above, we may infer that enteric coating is used to route the medicine to the target intestines while avoiding first pass metabolism, gastric discomfort, and degradation. In addition to treating lung infections (pneumonias) brought on by Streptococcal pneumoniae, Mycoplasma pneumoniae, and Legionella pneumophila (Legionnaires disease), enteric coated pills may also be used to treat streptococcal infections of the skin and throat (strep throat). To regulate the pH solubility profile of the enteric coated dosage form, the polymer selection and coating layer thickness are crucial. When creating enteric coated dosage forms, drugs with a short biological half-life (about three hours), low oral bioavailability (<50%), and sufficient protein binding are preferred. This dose form is favored since it is inexpensive, simple to prepare, and doesn't require expensive equipment. This dosage type has been receiving a lot of attention lately as a result.

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