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REVIEW ARTICLE ON FORMULATION AND EVALUATION OF ENTERIC COATED TABLET

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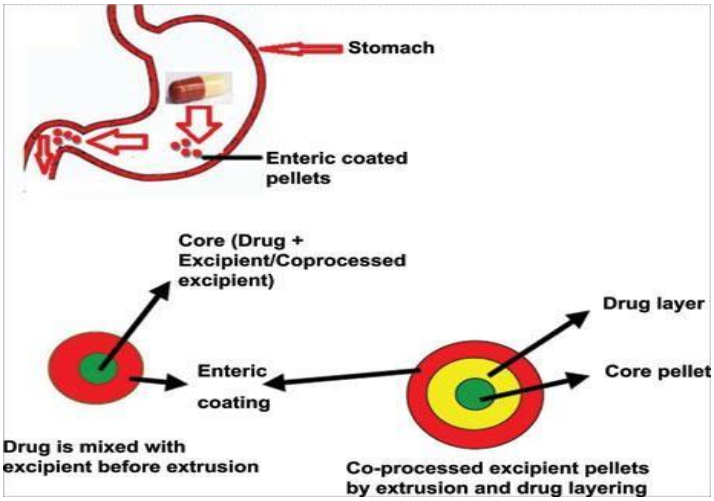
ABSTRACT

Enteric coated tablets are solid unit dosage forms intended for oral delivery; they are made to avoid the stomach and release the medication in the small intestine instead. Since the word "enteric" refers to the small intestine, enteric coatings stop medication from releasing before it gets there. The majority of enteric coatings function by providing a coated surface that is quickly broken down at a less acidic (slightly more basic) pH, but remains stable at the extremely acidic pH found in the stomach. Enteric coating materials consist of fatty acids, waxes, shellac, polymers, plant fibers, CAP, CAT, PVAP, and HPMCP. This study discusses enteric coating, including its optimal qualities, advantages, and disadvantages. It also discusses the different polymers utilized, their chemical structures, drug selection and mechanism criteria, and the production and assessment processes for enteric coated tablets. Due to their advantages over traditional drug delivery methods, which include longer dose intervals and higher patient compliance, these have recently piqued the interest of several formulators. An overview of the most recent developments in this field is given by the research.

Keywords: Enteric Coated Tablet, Coating Process, Methods Of Manufacturing Enteric Coated Tablet, Evaluation, Ideal Properties.

I. INTRODUCTION

A tablet is a solid pharmaceutical dosage form composed of an excipient mixture, usually in powder form, and an active substance that has been pressed or compacted into a stable form. The process of coating involves applying a coating substance to a dosage form's surface in order to provide it with particular advantages. An enteric coating is a barrier that facilitates the flow of oral medication into the intestine, where it is absorbed, while controlling its release in the stomach. Since the term "enteric" refers to the small intestine, enteric coatings prevent the medicine from releasing before it reaches there. At low pH, the enteric-coated polymers remain unionized and are therefore insoluble. However, as the pH rises in the gastrointestinal tract, the polymer swells or becomes soluble in the intestinal fluid because the acidic functional groups can ionize. Enteric coating materials include fatty acids, waxes, shellac, polymers, plant fibers, cellulose acetate phthalate (CAP), cellulose acetate trimellitate (CAT), poly(vinyl acetate phthalate) (PVAP), and hydroxypropyl methylcellulose phthalate (HPMCP). The ideal characteristics of enteric coating are resistance to stomach contents, permeability or susceptibility to intestinal fluid, compatibility with the majority of coating solution components and the drug substrate, continuous film formation, nontoxicity, affordability, and ease of application. Enteric coatings are made of a variety of polymers, including poly(vinyl acetate phthalate) (PVAP), cellulose acetate trimellitate (CAT), poly(methacrylic acid-co-methyl methacrylate), shellac (esters of aleuritic acid), and hydroxypropyl methylcellulose phthalate (HPMCP). Polymers were chosen based on the dissolving pH, which ranged from 4.5 to 7.0.



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Tablet coating:-

The process of coating involves applying an exterior layer of coating material to a dosage form, which is essentially dry, with the goal of providing a range of benefits, from improving product identification to altering the release of medication from the dosage form. Making a decent tablet generally requires coating it. A variety of oral solid dosage forms, such as tablets, capsules, multiparticulates, and drug crystals, can be coated. Applying coating material to a batch of tablets in a coating pan results in a sticky polymeric film covering the tablet surfaces. The applied coating transforms from a sticky liquid to a tacky semisolid and then to a non-sticky dry surface before the tablet surface dries. Throughout the entire coating process, a sequence of mechanically driven, acorn-shaped coating pans composed of copper, stainless steel, or galvanized iron are employed. Larger pans are employed for industrial production, whereas smaller pans are utilized for pilot plant, experimental, and developmental operations.

Primary components involved in tablet coating:-

1. Tablet properties
2. Coating process
3. Coating equipments
4. Parameters of the coating process
5. Facility and ancillary equipments
6. Automation in coating processe

Coating Process Design C Control:-

In the majority of coating techniques, the coating solution is sprayed over the tablets while they are being stirred in a pan, fluid bed, etc. A thin coating forms as the solution is sprayed, adhering directly to each tablet. The coating can be created with a single application or by using several spraying cycles to build it up in layers. Rotating coating pans are a common tool in the pharmaceutical business. The liquid coating solution is added to the pan while the tablets are tumbling after the uncoated tablets have been added to it. The pan is typically tilted at an angle with respect to the horizontal.

Thereafter, the liquid component of the coating solution evaporates when air is forced across the surface of the falling tablets. A fluid bed coater, on the other hand, works by moving air through a bed of tablets quickly enough to support and divide the tablets into distinct pieces. The tablets are sprayed with the coating mixture once separation has occurred.

The coating process is usually a batch operating task consisting of the following phases:

- Identification of batch and Recipe selection (film or sugar coating)
- Loading/Dispensing (accurate dosing of all required raw materials)
- Warming
- Spraying (Both application and rolling are carried out simultaneously)
- Drying
- Cooling
- Unloading

Within a spinning drum with perforations, tablet coating is done in a regulated environment After the mixture has been placed into the coating pan, preheat the tablets and allow the dust and tablet flash time to depart the pan. Air flow inside the drum and slanted baffles put therein allow for tablet bed mixing. This causes the tablets to be raised and rotated from the sides into the drum's center, covering every tablet surface with an equal layer of coating that has been deposited or sprayed on. Spraying can start as soon as the outlet air temperature reaches 42°C to 46°C, which normally happens in 15 minutes. The coating solution sprayed on the tablet by the spray guns is a thin mist that quickly dries.

The liquid spray coating on the tablets was dried by heated air that was drawn through the tablet bed by an intake fan. In order to give the operator a totally isolated process atmosphere, the temperature and volume of the air flow are managed to produce controlled drying and extraction rates. At the same time, the drum pressure is kept slightly negative in relation to the room. The particles remain on the tablet in the form of a thin coating while the water evaporates. The secret to coating tablets is to wet the surface just a little bit and let it dry right away. Instead of applying the coating in lengthy, slow exposures, do so in numerous brief exposures. Following the application of the base coating, you can gradually raise

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the pan speed and the rate of solution addition. Usually, it takes 20 minutes or so to noticeably increase the spray rate and pan speed. Very porous tablets might need an initial spray rate lower than the standard 100 milliliters per minute per gun. Make careful to keep an eye on the spraying process to check whether the pattern changes. If it does, the gun tips probably have a solids buildup on them. Only clean the tips to remedy this, which entails turning off the spray and the pan. Because hot air is constantly entering the drum and entering the tablet bed through the perforations, the enteric coating solution dries on the tablet surface. The film gradually builds up layers upon layers of substances. The pills need to cool once the solution has been applied and dried. The tablets need to stay at a certain temperature, the solution needs to be applied consistently, and the tablets need to move in a calm but active manner in order for coatings to cling correctly. If any of these are compromised, a faulty tablet will result.

Enteric Coating Necessary:-

1. **After taking a typical supplement:**

After being swallowed, the tablet passes down the throat and into the stomach. For 45 minutes to two hours, the pill gets churned and agitated in the stomach's extremely acidic digestive secretions (pH 1-4). Any remaining tablet material will be transported to the small intestine via the duodenum.

2. **Fate of Uncoated Tablets:**

Tablets are broken down by stomach acid, causing the active components (enzyme) to release prematurely.The majority of the enzyme's activities are destroyed by the stomach's extremely acidic environment. Poor-quality tablets that include fillers and binder may slip through the stomach and intestines without being absorbed.

Primary Component Involved In Enteric Coated Tablets Formulation:-

- Manufacture of Tablet core:
- Coating Composition:

a) Polymers
b) Plasticizer
c) Solvent
d) Colorant

- Coating process

Coating equipment:-

A modern tablet coating system combines several components:

- A coating pan
- A spraying system
- An air handling unit
- A dust collector

Composition of Enteric Coating

Between 0.01% and 10% polymer and between 0.01% and 10% resin are found in tablets with an enteric coating. To create an enteric coating on the substrate, the enteric coating composition can be pharmaceutical, neutraceutical, fruit, vegetable, agricultural, or industrial products.

Additives	Polymers
Resin	Shellac
Polymer	Alginate
Plastisizer	Triethyl citrate
Preservative	Sorbates
Detackifying agent	Monosterate
Lubricant	Palmitic acid
Colorant	FD CC lake yellow

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Ideal properties of enteric coating material:-

1. Resistance to gastric fluids
2. Susceptible/permeable to intestinal fluid
3. Compatibility with most coating solution components and the drug substrate
4. Formation of continuous film
5. Nontoxic, cheap and ease of application
6. Ability to be readily printed

Advantages of tablet coating:-

- Tablet coatings must adhere to the intricate shapes of embossed characters or logos on tablets, avoid causing the tablets to clump together during the coating process, and be sturdy and stable enough to withstand handling.
- Coatings can also be used to print on tablets if needed. Tablet coatings are required to provide a smoother finish, make big pills simpler to swallow, and cover up an unpleasant flavor.

Disadvantages of tablet coating:-

- Other coating materials are being used as a result of sugar coating's drawbacks, which include its comparatively expensive cost, lengthy coating time, and large bulk.
- However, coating is a laborious and time-consuming operation that calls for the knowledge of a highly qualified professional.

Enteric coating:-

An enteric coating is a type of barrier that regulates where oral medication is absorbed in the digestive system. Since the word "enteric" refers to the small intestine, enteric coatings stop medication from releasing before it gets there. At low pH, the enteric coated polymers continue to unionize and are hence insoluble. However, as the pH rises in the gastrointestinal tract, the polymer swells or becomes soluble in the intestinal fluid because the acidic functional groups can ionize. Enteric coating materials consist of fatty acids, waxes, shellac, polymers, plant fibers, CAP, CAT, PVAP, and HPMCP.

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

- Defense of active medicinal components (such as enzymes and some antibiotics) against the stomach's acidic environment.
- To prevent gastric distress or nausea from a drug due to irritation (e.g. sodium salicylate).
- For the transportation of medications to their major absorption site in the small intestine where they are best absorbed.
- To provide a component for a postponed release in exchange for additional actions.
- Necessary to reduce a drug's first pass metabolism.

Controlling the pH solubility profile of the enteric coated dosage form is largely dependent on the polymer selection and coating layer thickness.

Enteric coated versions of the most often prescribed medications that cause stomach ulcers, such as aspirin, diclofenac, and naproxen, are widely accessible. Since omeprazole, a medication that prevents the stomach from creating acid, is broken down by acid, it usually has an enteric coating around it, either in the form of granules in capsules or in a form that is dispersible. Sulfasalazine is used for the treatment of arthritis as well as Crohn's disease, an inflammatory bowel condition. In the case of Crohn's disease, when the medication must be absorbed through the intestines, it is administered with an enteric coating; however, in the case of arthritis, it is frequently administered without an enteric coating to facilitate faster absorption.

Erythromycin base is an antibacterial medication found in the enteric-coated tablet ERY- TAB. This coating protects the tablet from the inactivating effects of stomach acidity and facilitates effective absorption of the antibiotic in the small intestine. Three dose levels of erythromycin delayed-release tablets, or ERY-TABs, are available for oral administration. Erythromycin 500 mg, 333 mg, or 250 mg is the free base found in each white oval tablet. Enteric coated aspirin is another type of pill that is sold commercially. Take Micropirin® 75 mg EC pills with enteric coating and peppermint oil, for instance.

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Polymers used for enteric coating:-

Table no:-1 Different polymer used for enteric coating

Polymers	Dissolution PH
Shellac (esters of aleurtic acid)	7.0
Cellulose acetate phthalate (CAP)	6.7
Poly(methacrylic acid-co-methyl methacrylate)	5.5-7.0
Cellulose acetate trimellitate (CAT)	5.0
Poly(vinyl acetate phthalate) (PVAP)	5.0
Hydroxypropyl methylcellulose phthalate (HPMCP)	4.5-5.5

New materials used for tablet coating:-

- Zein
- Aqua-Zein®, which is an aqueous zein formulation containing no alcohol.
- Amylose starch and starch derivatives
- Dextrins

Criteria for selection of drugs for Enteric coated tablet:-

Table no:-2 Different criteria used for the selection of drugs in CDDS

Criteria	Pharmacological class	Non-peptide drugs	Peptide drugs
Drugs used for local effects in colon against GIT diseases	Anti-inflammatory drugs	Oxyprenolol, Metoprolol, Nifedipine	Amylin, Antisense oligonucleotide
Drugs poorly absorbed from upper GIT	Antihypertensive and antianginal drugs	Ibuprofen, Isosorbides, Theophylline	Cyclosporine, Desmopressin
Drugs for colon cancer	Antineoplastic drugs	Pseudoephedrine	Epoetin, Glucagon
Drugs that degrade in stomach and small intestine	Peptides and proteins	Bromophenaramine, 5-Flourouracil, Doxorubicin	Gonadoreline, Insulin, Interferons
Drugs that undergo extensive first pass metabolism	Nitroglycerin and corticosteroids	Bleomycin, Nicotine	Protirelin, sermorelin, Saloatonin
Drugs for targeting	Antiarthritic and antiasthamatic drugs	Prednisolone, hydrocortisone, 5- Amino salicylic acid	Somatropin, Urotoilitin

Limitations:-

The existence of a broad variety of pH values and distinct enzymes in the GI tract that the medications must interact with before reaching the intended spot casts doubt on the dependability and effectiveness of the administration.

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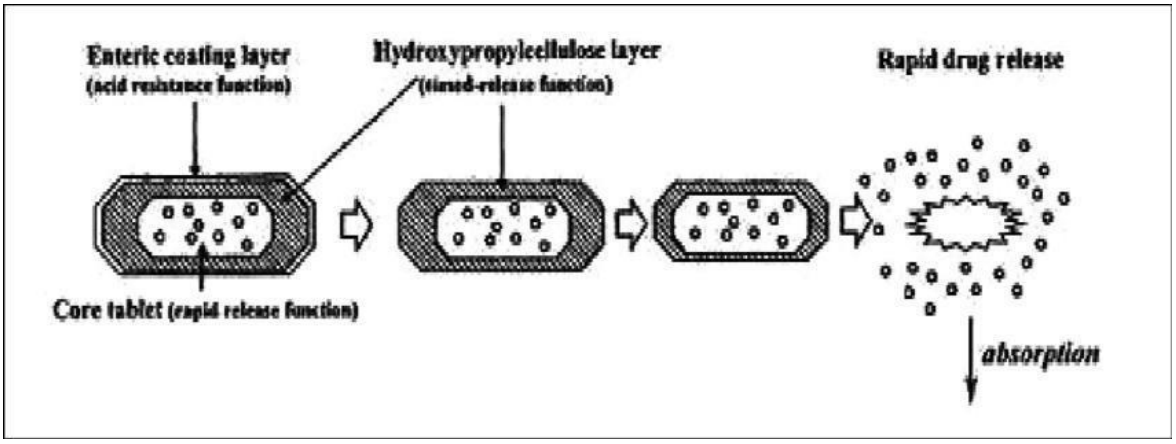
Mechanism of Enteric Coated Tablets:-

The three layers that make up ETP tablets include an enteric coating layer (which has an acid resistance function), a press-coated swellable hydrophobic polymer layer (also known as the Hydroxy Propyl Citric Layer, or HPC), and a drug-containing core tablet (which has a quick release function).

Because the outer layer of the enteric coating is resistant to acid, the tablet does not release the medication into the stomach. Following gastric emptying, the intestinal fluid starts to gradually erode the press-coated polymer (HPC) layer as the enteric coating layer rapidly dissolves. Since there is no drug release period (lag phase) following stomach emptying, rapid drug release happens when the erosion front reaches the core tablet. This is because the erosion process is time-consuming. The weight or makeup of the polymer (HPC) layer determines how long the lag phase (drug release interval) lasts.



Method Of Manufacturing Enteric Coated Tablet by Spray Coating Technique

Preparation of core tablet:-

Wet granulation was the procedure used to make the granules. The medication and additional excipients were filtered through #80, and then gently added enough binding agent to create dough mass. After passing through #8 sieve and drying at 45ºC for approximately one hour, the bulk was passed through #20 sieve and magnesium stearate was used as lubricant. The mixture was compressed using a shallow concave plain/plain punch into tablets with a diameter of 7.9 mm and a weight of 250 mg each, using a single punch tablet compression machine.

Coating of core tablet:- Preparation of Enteric coating solution:-

50 ml of water was used to dissolve a weighed quantity of pectin, and 50 ml of isopropyl alcohol was 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 tablet:-

The typical coating pan technique is used to achieve enteric coating of the compressed tablets. The tablets were taken and coated in a pan coater operating at 50 rpm, 50 oC, and 10 milliliters per minute of flow rate. Spraying was used to apply the coating, which was then cured. With a spray pistol and the proper pressure, these solutions are administered to the tablets. The coated pills are dried in a tray drier after being first dried with a heat blower.

Coating Methodology:-

One spray gun was used to coat tablets in a traditional coating pan. 95% alcohol was used to clean the coating pan before. For coating, a batch size of 3.5 kilogram core tablets was chosen. The core tablets were put into the coating pan. Tablet cores were preheated using an air compressor and drier to roughly 40°C. Throughout the whole coating process, warm air—up to 50–55°C—was injected into the coating pan.

Enteric coating solution was put into the spray gun, which was then turned on at the right flow rate.

When the pan reached the proper air pressure (87.0-116.0 psi), 6–8 bar, seal coating dispersion was sprayed onto the falling cores. The tablets were blow dried in the coating pan for twenty to twenty-five minutes after the air heater was turned off. After being coated with enteric coating solution, the weight of the core tablets

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increased by 10 ± 2%.

Preformulation Studies:-

Measurement of angle of repose:-

The angle of repose was computed using the funnel method. Angle of repose has a link with interparticle cohesiveness, making it an indirect way to measure powder flow ability. When the angle of inclination is high enough to counteract frictional forces, a static heap will begin to slide and come to a stop when the forces are balanced by gravity. The angle of repose, formed by the heap's sides and the horizontal, is known.[17] Using a funnel that may be lifted vertically to the maximum cone height (h), powder is poured into the center of the dish.

Using the provided formula, one can determine the angle of repose. $\alpha = \tan^{-1}$

(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 in order to determine the apparent real density (ρb). Using this procedure, the bulk volume (Vb) of the blend was found. Then, using the formulas below, the true density was found.

$\rho b = M/Vb$

This was done thrice, from that average true density and standard deviation was calculated.

Tap density:-

After a predetermined amount of time, the measured cylinder with a known mass (M) of mix was tapped to determine the minimum volume (Vt) that the cylinder contained. The following formulas were used to compute the tapped density.

Tap density = M/Vt

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

Porosity:-

The ratio of the volume of the voids to the bulk volume of the package defines the porosity of the powder and the voids.

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

Carr's Index:-

The following formula was used to calculate the bulk drug's percentage compressibility based on the tapped density and apparent bulk density.

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

Hausner's Ratio:-

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

II. EVALUATION OF CORE AND COATED TABLET

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

- **Hardness:-**

A Monsanto tablet hardness tester was used to determine the tablet crushing strength. It was noted that when a tablet was positioned between the anvils and the crushing strength, the tablet broke.

- **Friability Tablet strength:-**

was examined using a Roche friabilator. After precisely weighing twenty pills, the friabilator was turned on for 100 revolutions in four minutes. After the tablets were dedusted, a new weight measurement was made to determine the percentage of weight reduction. Tablets that lost less than 1% of their weight were deemed compliant.

- **Weight variation:-**

An electronic balance was utilized to determine the average weight after twenty tablets were randomly

selected to account for weight fluctuation. Each tablet was weighed separately and then compared to the average weight.

- **Disintegration time:-**

The disintegration equipment USP was used to measure the disintegration time in 0.1N HCl for two hours and phosphate buffer pH 6.8 for one hour while keeping the temperature constant at 37±2°C.

- **Thickness:**

Vernier calipers were used to measure the tablet's thickness.

- **Drug content studies:-**

After ten pills were weighed and ground into a powder, five milligrams of the medication were taken, 50 milliliters of 95% ethanol was added, and the mixture was agitated for half an hour. To make 100ml, enough ethanol (95%) was added. A suitable volume of the liquid supernatant—equivalent to 0.5 mg of drug—was pipetted out and diluted with 50 milliliters of 95% ethanol after it was centrifuged. A The drug content was determined using a UV/visible single beam spectrophotometer at 236 nm.

- **In vitro drug release studies:- In gastric C intestinal PH:-**

Enteric-coated tablet in vitro drug release was investigated utilizing a USP XXIV six station dissolution rate test device with paddle stirrer. The dissolving rate was examined for two hours at a pace of 50 ml per minute in 900 ml of 0.1 N HCl (pH 1.2) at 37±1ºC.rpm, and then for an additional four hours in phosphate buffer (pH 7.4).

Every hour, 5 ml samples were taken out, filtered through 0.45 µm, and then replaced with 5 ml of brand-new dissolving media. The samples were diluted appropriately if needed, and the cumulative percentage of drug release was computed after spectrophotometric estimation at 236 nm using a UV/visible single beam spectrophotometer.

III. CONCLUSION

In summary, enteric-coated pills are designed to prevent first-pass metabolism, minimize gastric discomfort and breakdown, and ensure that the medication reaches the intended intestines. Enteric coated tablets have the potential to cure lung infections (pneumonias) caused by Streptococcal pneumoniae, Mycoplasma pneumoniae, and Legionella pneumophila (Legionnaires disease), as well as 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 essential.

When creating an enteric coated dosage form, medications with a low oral bioavailability (<50%), a short biological half-life (about 3 hours), and sufficient protein binding are sought. This dose form is recommended since it is inexpensive, highly handy, 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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