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A Mini Review on Enteric Coated Tablet Dosage Form

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ABSTRACT

An enteric coating may be an obstruction connected to oral medicine that controls the area within the stomach-related framework where it is ingested. Enteric refers to the small intestine; therefore, the coating in the intestine prevents the release of the drug before it reaches the small intestine. Enteric polymers are insoluble in acidic media but soluble at higher pH (above 5.5). The coating solution concentration affects the coating film formation. The 3% coating solution (g/100ml) was selected as the coating solution. Various coating equipment are centrifugal granulators, fluidized bed, pellet coating machine, Vector Corporation, O'Hara technology, SUPERCELL™ pellet coating machine. The microencapsulation technique is also used to prepare a variety of unit dosage forms. In addition, there are different coating systems that cover the core material and deliver the drug into the gut. Coating is an art and must be done by someone with experience, otherwise, various problems can occur (doubles, peeling and shading, orange peels, etc.).

INTRODUCTION

The goal of drug delivery systems is to deliver therapeutic amounts of drugs to the appropriate sites in the body to rapidly achieve and maintain desired drug concentrations. Drugs are absorbed in specific areas of the gastrointestinal tract, primarily the upper intestinal tract. Currently, formulation methods are limited and no commercial products exist that allow sustained absorption (with a window of absorption in the gastrointestinal tract) of such drugs from oral formulations without compromising bioavailability. Improved enteric-coated formulations provide immediate release in the small intestine and sustained absorption of drugs with an absorption window while enhancing or preserving bioavailability of the formulation. 1

Enteric coated formulations are particularly useful for administration. Drugs that are not stable in gastric juices or that can cause irritation of the gastric mucosa and are absorbed in the duodenum or upper intestine. Once the acid-resistant coating dissolves in the intestine, it is important to release the drug immediately. 2

The effectiveness of enteric coatings arises from differences in the composition of the respective gastric and intestinal environments with respect to pH and enzymatic properties.

Although there have been repeated attempts to produce coating that are subject to intestinal enzyme breakdown, this approach is not popular, since enzymatic decomposition of the film is rather slow. Thus, most currently used enteric coatings are weak acids that remain undissociated in the low pH environment of the stomach but readily ionize when pH rises to about 5.3.

The in vitro disintegration of products coated with common enteric polymers (cellulose esters, polyvinyl derivatives, and polymethacrylates) occurs over a very short period of time, normally within 30 min in pH 6.8 phosphate buffer. However, this is not reflected in vivo; gamma scintigraphy studies have shown that it can take up to 2 h for such products to disintegrate in the human small intestine. Drug release will then occur in the distal small intestine and cause a delayed response to medication and potentially reduce the bioavailability of those drugs having an absorption window in the proximal small intestine. This in vivo/in vitro discrepancy is due in part to the inadequacy of the commonly used in vitro dissolution medium (compendial pH 6.8 phosphate buffer) to resemble the luminal

conditions of the upper small intestine in many respects such as pH, ionic composition, buffer capacity, viscosity and volume.4

Advantage of enteric-coated medicate conveyance framework -

1. Protects acid-labile drugs from gastric juices.

2. Prevents upset stomach and nausea caused by drug irritation.

3. For delivery of drugs that act locally in the intestine.

4. To deliver drugs in the form of the highest concentration to the primary site of absorption for optimal absorption in the small intestine.

5. Provides a sustained release component for repeated action. 5

6. Reduces healthcare costs by improving therapy, shortening treatment duration and reducing dosing frequency.

7. Maximize drug use and reduce total dosage.

8. Improves patient comfort and compliance by reducing dosing frequency.

Risks of Enteric-Coated Drug Delivery Systems -

1. Destitute In-vitro in-vivo relationship.

2. Reduced systemic availability compared with conventional immediate-release dosage forms:

3. this may be due to incomplete release, increased first-pass metabolism, increased instability, inadequate residence time for complete release, local absorption and pH-dependent solubility, and so on.

4. The potential for dose reduction is due to physiological changes or the food formulation or the patient chewing or crushing the oral formulation and thereby increasing the risk of toxicity.

5. Recalls are difficult due to toxicity, toxicity or hypersensitivity reactions.

6. High formulation cost.6

Enteric Polymer

These materials are connected either broken up in a natural dissolvable or as an watery scattering. Customarily, it has been the hone to limit enteric polymers dissolving at pH 7 and over for colon focusing on. Determination of enteric polymer dissolving at pH ≥ 7 and Optimization of coat thickness is basic to guarantee medicate discharge within the whole gastrointestinal tract. The list of enteric polymeric materials commercially accessible is given in Tables 1-3. Alterations to the thickness of the enteric polymer coat will offer assistance to amplify the choice to those dissolving at pH less than 7. Work of imaging strategies, particularly scintigraphy of the definition within the gastrointestinal tract, has been found to be a valuable apparatus in optimizing coat thickness.

Phthalate-Based Enteric Polymers-

Initial Formulation code	Material Name	Polymer Concentration And Formulation Code		
		8%	10%	12%
E1	Aquateric (Cellulose Acetate Phthalate) FMC	E1i	E1j	E1k
E2	EmCoat 120 N (Shellac) Emerson	E2i	E2j	E2k
E3	Acryl EZE White (Methacrylic Acid Co Polymer) Colorcon	E3i	E3j	E3k
E4	Sureteric (Polyvinylacetate Phthalate) Colorcon	E4i	E4j	E4k
E5	HP-55 (Hypromellose Phthalate) Seppic	E5i	E5j	E5k

COATING SOLUTION

The producer is whether to utilize a fluid coating or a natural coating framework. Both have focal points and drawbacks. Though natural coating gives more prominent security against dampness take-up amid the coating preparation (critical for moisture-sensitive fixings) and is less demanding to apply because of the quick vanishing of solvents, the issues related to natural control of natural solvents going within the air, the got to perform dissolvable buildup tests, and they have to be have explosion-proof offices regularly yields to these preferences of fluid coating frameworks. In later a long time, numerous advancements within the detailing of watery coatings made them a nearly generally acknowledged mode of application.9

The choice of diverse sorts of arrangement utilized in the enteric coating is based on the polymer solvency in dissolvable. 6-8 % increment in the weight of the tablets is required to

urge craved corrosive safe and impermeability. The dissolvable utilized in coating are acetone, decontaminated water, liquor, methylene chloride10 Chloroform, Methylene ethyl ketone and porogen was utilized as the coating arrangement. The concentration of coating arrangement was over 4%, the thickness of the coating arrangement would be as well extraordinary to wrap up the coating handle. When the concentration of the coating arrangement is lower than 2%, the coating membrane would be troublesome to make. The coating arrangement must be defined to have a sprayable arrangement viscosity. Generally this implies a consistency of the coating arrangement within the extent of 150-400 mPa•s, in spite of the fact that higher viscosities may be conceivable beneath certain gear conditions. Definitions may contain discretionary surfactants, plasticizers, or shades. It ought to be famous, in any case, that these extra excipients can influence the thickness of the coating arrangement. However the major calculation controlling the detailing is the thickness of the polymer review being utilized and the concentration of polymer within the solution.12

COATING EQUIPMENT:

A cutting-edge tablet coating framework combines a few components: a coating skillet, a splashing framework, an air handling unit, a clean collector, and the controls. The coating dish is really a punctured drum that turns inside a cabinet. The cabinet empowers you to control wind current, temperature, weight, and the coating application. The splashing framework comprises of a few splash weapons mounted on a complex, a arrangement pump, a supply tank and blender, and an discuss supply. The pump conveys the coating arrangement to the weapons, where it combines with atomizing to form a fine fog that’s coordinated at the bed of tablets within the coating skillet. The discuss taking care of unit warms and channels the discuss utilized to dry the coating on the tablets. Depending on your circumstances, it may incorporate a humidifier or dehumidifier. The tidy collector extricates the disc from the coating container and keeps a marginally negative weight inside the cabinet. The controls enable you to coordinate the operation of all the components to realize the specified comes about. Once you stack a clump of tablets into the coating container, you wish to preheat the tablets and permit time for tidy and tablet streak to exit the container. Once the temperature of the outlet comes to 42° to 46°C, more often than not within 15 minutes, showering can start. The splash weapons make a fine fog of coating arrangement that dries fairly after it contacts the tablet. As the water vanishes, it clears out the solids behind to create a lean film on the tablet. The key to tablet coating is to urge the surface marginally damp and promptly

dry. Your objective is to apply the coating in numerous brief, quick exposures, not in long, moderate exposures.13

Ordinary coating dishes are subglobular, pear-formed, or indeed hexagonal with a single front opening through which materials and handling discuss enter and take off. Their hub is regularly slanted at roughly 450 to the level plane and they are turned between 25 to 40 rpm, the exact speed depending, most frequently, on the item included. One adjustment of the ordinary container has been the substitution of a cylindrical shape, rotted evenly with the region of the dividers punctured by little gaps or slots. Within the Accela-Cota and Hi-Coater, the stream of discussion through the tablet bed and out through the punctured divider of the container. In the Driacoater discuss stream from the punctured container divider through the tablet and in to the central locale. The Glatt-Coater grants either a co- or countercurrent discuss stream to suit specific items.

The film coating preparation can be carried in routine skillet, in spite of the fact that operation factors such as speed of container revolution, point of dish hub, and temperature and mugginess control may be more critical.14

DELAYED-RELEASE (ENTERIC) COATINGS

Enteric coatings are basically utilized for the taking after purposes:

❑ Maintains stability of unstable API when exposed to acidic conditions of the gastric environment. These APIs include erythromycin, pancreatin, and the class of proton pump inhibitors, such as omeprazole.

❑ Minimizes side effects (eg, nausea, stomach irritation, and bleeding) that can occur with certain APIs, such as aspirin and certain nonsteroidal inflammatory compounds.

❑ Provide an opportunity for an “overnight dosing” strategy, the purpose of which is to allow the dosage form to be used at bedtime, to achieve effective blood levels of API just prior to awakening.

Facilitating the administration of drugs in the colon. The function of the enteric coating is highly dependent on changes in the pH of the environment to which the enteric coating product is exposed. That means this function can be greatly influenced by many factors, such as:

❑ the nature of the API contained in the dosage form; this is especially true when that API has a distinct effect on pH;

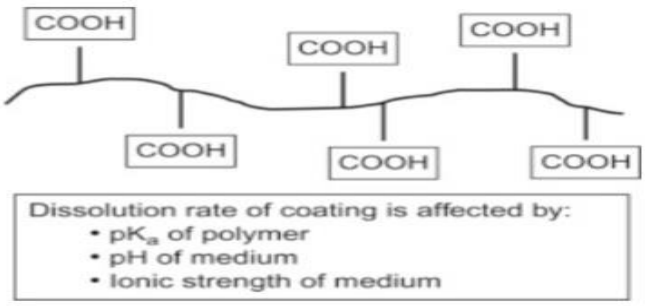
❑ amount of coating applied; insufficient coating can lead to ineffective gastric resistance, while excessive coating can severely delay drug release as the dosage form passes through the small intestine;

❑ the presence of defects in the coating (for example, cracks, "pitting", etc.) can also lead to a decrease in gastric resistance;

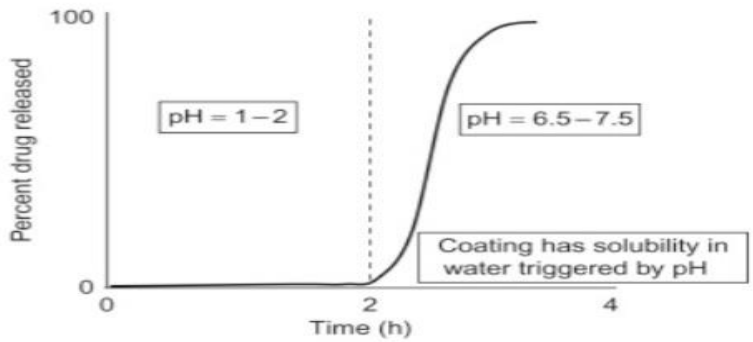
❑ chemical properties of the polymer used (especially the solubility pH and dissolution rate at a given pH);

❑ influence of the in vitro test conditions used (such as the pH and ionic strength of the test medium, as well as the agitation rate used in the test).

Enteric membrane polymers are actually polyacids (see Figure 1.1) and are usually only soluble in water with a pH above 5.0 to 6.0. These polymers were chosen for their capacity to:



1.1 Structure of enteric-coating polymers.



1.2 Typical drug release profile from products coated with enteric coatings.

A list of commonly utilized enteric-coating polymers is given in Table 2.1 and they form the basis for enteric-coated formulations used in organic solvent-based formulations or in formulations covered containing water. Analysis of coating systems specifically designed for water-based coating applications is shown in Table 2.2.

Polymer	Comments
Cellulose acetate phthalate	Hydrolysis potential—high[a]
Cellulose acetate trimellitate	Hydrolysis potential—medium[a]
Polyvinyl acetate phthalate	Hydrolysis potential—low[a]
Hydroxypropylmethylcellulose phthalate	Hydrolysis potential—medium[a]
Hydroxypropylmethylcellulose acetate succinate	Hydrolysis potential—low[a]
Poly (MA-EA) 1:1	–
Poly (MA-MMA) 1:1	Relatively high dissolution pH
Poly (MA-MMA) 1:2	Relatively high dissolution pH

2.1 Examples of Common Polymers Used in Enteric Coating Formulations

Product	Form	Polymer
Eudragit L30D[a]	Latex dispersion	Poly (MA-EA)
Eudragit L100-55[a]	Spray-dried latex	Poly (MA-EA)
HP-F	Micronized dry powder	HPMCP
Sureteric	Formulated, dry powder system	PVAP
Acryl-Eze	Formulated, dry powder system	Poly (MA-EA)
Aquarius Control ENA	Formulated, dry powder system	Poly (MA-EA)
Aquateric	Spray-dried pseudo latex	CAP
Aquacoat ECD	Pseudo latex dispersion	CAP
Aquasolve	Micronized, dry powder	HPMCAS
CAP	Dry powder	CAP
CAT	Dry powder	CAT

2.2 Examples of Aqueous Enteric Coating Systems

While enteric coated products are usually available in tablet form, there has recently been a preference for enteric coated products due to their more consistent gastrointestinal transit properties. Enteric capsules (especially monolithic capsules, containing garlic or fish oil for nutritional applications) have also become quite popular.

Polymers utilized for enteric coating:

❖ **Polyvinyl acetic acid derivation phthalate (PVAP):**

Polyvinyl acetic acid derivation phthalate may be a free-flowing white to off-white powder with a slight scent of acidic corrosive. The onset of watery disintegration of PVAP starts at a pH of approximately 5.0 permitting for enteric discharge as well as potential for focused on sedate discharge to the proximal little digestive system.

❖ **Hydroxypropyl methylcellulose phthalate (HPMCP):**

HPMCP may be a white to marginally off-white, free-flowing drop or granular powder with a somewhat acidic odor and a scarcely recognizable taste. It may be a subordinate of Hydroxypropyl methylcellulose.

❖ **Cellulose acetic acid derivation phthalate (CAT):**

Cellulose acetic acid derivation phthalate, moreover known as cellacefate is the most seasoned and most broadly utilized engineered enteric coating polymer. CAP is synthesized by responding to a molecule acetic acid derivation ester of cellulose with phthalic anhydride within the nearness of the tertiary natural base such as pyridine, or a solid corrosive such as sulfuric corrosive.

TABLET COATING:

The coating is prepare by which an basically dry, external layer of coating fabric is connected to the surface of a measurement shape in arrange to bestow particular benefits that broadly range from encouraging item distinguishing proof to adjusting medicate discharges from the measurement frame after making a great table, one must frequently coat it.

Coating may be connected to numerous run or verbal strong measurement shape, when coating composition is connected to a clump of tablets in a coating container, the tablet surface gets to be secured shabby polymeric film. Sometime recently the tablet surface dries the connected coating changes from a sticky fluid to a tasteless semi-solid and inevitably to a non-sticky surface dish. The enteric coating prepare is conducted in a arrangement of mechanically worked oak seed-formed coating container of galvanized press stainless steel or copper. The littler container are utilized for exploratory, formative and pilot plant operations, the bigger dish is for mechanical generation.

COATED PILLS:

The defensive coating put around pills is imperative within the treatment of ailment as the chemical included within the pills. Pills contain a fulfill assortment of reason, depending on the sort of medicine they are improving. In a few circumstances, the coating is utilized to amplify the valuable life of the drugs by securing it from presentation to temperature, damp or light. The coating moreover keeps the pills from being split or broken amid taking care of. A few defensive coatings cover the taste of chemicals, making the pills simple to swallow. In other case coating acts as a defensive boundary.

CAPSULE COATING:

Enteric coated measurement shapes, such as coated tablets, sugar-coated tablets, delicate and difficult gelatin capsules, granules or pellets have their put in therapeutic weapons store (1a, 2). An examination of 181 ready-to-use enteric-coated medicaments uncovered that this test contain approximately 59% sugar-coated tablets (106 arrangements), around 27% film-coated tablets (49 arrangements) and approximately 49% of delicate and difficult gelatin capsules (25 arrangements). In any case, this gather explored the arrangements on German showcase.

COATING SOLUTION:

The producer is whether to utilize a watery coating or a natural coating framework. Both have focal points and drawbacks. While natural coating gives more noteworthy security against dampness take-up amid the coating handle (vital for moisture-sensitive fixings) and are less demanding to apply because of the quick dissipation of solvents, the issues related to the natural control of natural solvents going within the environment, the ought to perform dissolvable buildup tests, and the have to be have explosion-proof offices regularly yields to these focal points of fluid coating frameworks. In later a time, numerous improvements within the detailing of watery coatings made them a nearly generally acknowledged mode of application.9

The dissolvable utilized in the coating are acetone, filtered water, liquor, and methylene chloride10 Chloroform, Methylene ethyl ketone and porogen was utilized as the coating arrangement. The concentration of the coating arrangement was over 4%, the thickness of the coating arrangement would be as well incredible to wrap up the coating prepare. The coating arrangement must be defined to have a sprayable arrangement thickness. By and large this implies a viscosity of the coating arrangement within the extent of 150-400 mPas, in spite of

the fact that higher viscosities may be conceivable beneath certain hardware conditions. Formulations may contain discretionary surfactants, plasticizers, or shades. It ought to be famous, in any case, that these extra excipients can influence the viscosity of the coating arrangement.

COATING EQUIPMENT:

A modern tablet coating line combines several components such as coating pans, spray systems, air handling units, dust collectors and controllers. The coating pan is actually a perforated drum that rotates within a housing. Cabinets allow you to control airflow, air temperature, air pressure, and coating application. The spray system consists of multiple spray guns mounted on a manifold, a solution pump, a storage tank and mixer, and an air supply. Once a batch of tablets is placed in the pan, the tablets should be preheated and given time for any dust or tablet particles to come out of the pan. Once the exhaust temperature reaches 42-46°C, you can usually start spraying within 15 minutes. The spray gun produces a fine mist of coating solution that dries quickly on contact with the tablets. As the water evaporates, the solid remains and forms a thin film on the tablet. The key to tablet coating is to keep the surface slightly damp and dry quickly.

Conventional coating pans are quasi-spherical, pear-shaped or even hexagonal with a single front opening for material to pass through. Process air enters and exits. Its axis is usually tilted about 45 degrees to the horizontal and it rotates at 25-40 rpm, the exact speed depending largely on the product in question. A modification of the usual pot was to replace the horizontally rotten cylinder with small holes or slits in the wall section. In the Accela-Cota and Hi-Coater, the airflow passes through the tablet bed and out through the perforated walls of the pan. In a doria coater, air flows from a perforated bath wall through the tablets to the central area. Depending on the product, the gratt coater can have co-current or counter-current air flow.

RECENT TREND OF ENTERIC-COATED TABLETS:-

In recent years, the pharmaceutical industry has witnessed a notable trend in the field of enteric-coated tablets. An important trend is the continued improvement of tablet formulations to optimize drug delivery. Pharmaceutical companies are increasingly striving for accurate release profiles, ensuring drugs are delivered to the correct locations in the gastrointestinal tract for maximum effectiveness. In addition, patient-centered designs have

become prominent. This includes efforts to make enteric-coated tablets more user-friendly, with improvements to improve ease of swallowing, reduced pill size and improved taste masking to improve patient compliance. Environmental concerns also influence the trend, leading to research into biodegradable enteric coatings. These eco-friendly coatings are designed to degrade more easily in the environment, addressing the sustainability issues associated with pharmaceutical waste.

In addition, the application of enteric coatings has expanded to include more drugs. In addition to drugs that treat gastrointestinal diseases, enteric coatings are also applied to drugs that can irritate the stomach, helping to improve patient comfort and absorption.

Researchers are exploring advanced drug delivery systems beyond traditional tablets, including enteric-coated capsules and multi-particle systems, to provide better control of drug release. Quality assurance remains paramount, with constant attention paid to ensuring that the enteric-coated tablet manufacturing process meets stringent regulatory standards, ensuring a reliable supply of drugs and consistency for the patient. Together these recent trends demonstrate the changing landscape of enteric-coated tablets in the pharmaceutical industry.

CONCLUSION:-

From the above assessment, we can conclude that the tablets are encapsulated in the intestine to avoid first-pass metabolism, gastric irritation and breakdown, and also direct the drug to the target intestine. Enteric-coated tablets can be used to treat strep throat and skin infections, as well as to treat lung infections (pneumonia) caused by strep throat. Polymer selection and coating thickness are important in controlling the pH solubility of enteric coated dosage forms. It is very convenient and easy to build, cost-effective and does not require expensive equipment. It is for this reason that this dosage form is receiving so much attention today.

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