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COMPREHENSIVE RESEARCH ON BIODEGRADABLE FILMS AND COMPOSITE COATING

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Abstract

Biodegradable polymeric material is being investigated as a carrier for many therapeutic uses by scientists all over the world. Biodegradable polymeric materials have come a long way in the past two decades, particularly in the biomedical and pharmaceutical sectors due to their adaptability, biocompatibility, and biodegradability. This review focuses on the use of biodegradable polymers for functional enteric coatings, which protect the contents of a dosage form from the stomach's acidic and enzymatic environments. Polymeric polymers are used to manage the prolonged release and gradual dissolution in the GI tract of oral dose tablets. When a tablet is said to have a "enteric coating" (e/c), it signifies that it has been given a special coating to prevent it from breaking up in the stomach. The stomach is acidic, while the intestines, where food travels after being digested, are alkaline. The medicine is released in the colon because the coating is stable in acidic circumstances but dissolves in alkaline ones.

Keywords: Acidic media, alkaline medium, enteric coating, sustained release, biodegradable polymer.

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INTRODUCTION

To those working in the pharmaceutical and medical device industries, the phrase "Biodegradable polymers" is a term of great intrigue. Because of its fragility in everyday environments, this category of polymers has been known for almost a century in the chemical industry but has gotten little attention. It is interesting to note that this was later understood to be an advantage for constructing a biodegradable implant, which would eliminate the need for a second surgical surgery to remove the leftovers of a prior implant, as was the case with metallic implants. Davis and Geck introduced Dexon®, the first biodegradable product certified by the FDA, in 1970.

Orthopedic implants including pins, screws, cranio-maxillofacial plates, and so on have been introduced as a result of the subsequent revolution in the medical device business. About twenty years after the introduction of biodegradable polymers, depot injections were used in the pharmaceutical business [1]. Lupron®, made by Takeda, is a popular and commercially successful depot injection used primarily in the treatment of prostate cancer. Despite substantial scientific and economic advancements, only a select few worldwide corporations fully grasp the implications of this technology. This is mostly due to the difficulties inherent in high-precision molding, depot injection formulation technology, and polymer chemistry. The pharmaceutical and medical device industries have a lot of room to expand their use of these technologies. Improved patient compliance is especially important when dealing with chronic diseases, and this will help bring the advantages of these innovative technology to a wider range of patients around the world. Several novel drug delivery systems for sustained and targeted release, such as implants, microspheres, microcapsules, nanoparticles, in situ gels, etc., have been developed through an understanding of polymer degradation in the presence of hydrolyzing agents available in the biological systems. When a sincere approach to environmental protection is considered, the properties of these polymers—such as flexibility, durability, and biocompatibility—make them the preferred vehicles to administer safely in vivo for human use in the form of medical devices like dental and orthopedic implants, inserts, sutures, drug-eluting stents, and contraceptive devices. Polymers have several applications and are therefore often used in the creation of SDFs. Binders are employed to improve the density, flowability, and compatibility of large, bulky Active Pharmaceutical Ingredients (APIs) in Immediate Release (IR) SDFs that would otherwise not process acceptably on high-speed tablet presses and encapsulation machines. Non-functional (aesthetic) coatings made from polymers are used to color tablets and give them a pleasant tongue feel, eliminating the need for the labor-intensive and specialized technique of sugar coating. Functional coatings made of polymers, for example those utilized as moisture or oxygen barriers, can be designed as IR dosage forms that yet permit rapid API release and absorption [2]. Commercially available powder forms of cross-linked polymers used to promote disintegration of tablets and capsule plugs are designed to be readily compatible with tableting and encapsulation formulas and processes. These polymers swell significantly in the presence of water and gastrointestinal fluids.

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Polymers are used in functional enteric coatings, which protect the contents of a dosage form from the stomach's acidic and enzymatic environment, as part of Modified Release (MR) dosage forms [3, 4]. The acronym "DR" is sometimes used to describe this kind of formulation. Coatings and diffusional matrices for controlled release (CR) are made from other polymers [3, 4, and 5]. Many of today's APIs used in drug discovery are notoriously difficult to dissolve, however polymers can improve their solubility and bioavailability. Here, we'll provide you a rundown of the polymers utilized to improve the solubility and bioavailability of APIs that are difficult to dissolve or absorb [6, 7, 8] and in the more unusual and technically problematic dosage forms including MR (enteric and CR).

When taken orally, enteric-coated pills disperse their contents directly into the small intestine, skipping the stomach entirely. Since "enteric" refers to the small intestine, enteric coatings work to delay drug release until after the drug has reached that organ [9, 10, 11]. In order to protect the drug from being broken down too quickly in the stomach's less acidic (relatively more basic) environment, most enteric coatings present a coated surface that is stable at the stomach's high pH. As an alternative to traditional drug delivery systems, biodegradable polymers have caught the attention of several formulators due to their ability to promote patient compliance and lengthen the time between dosage [12, 13, 14]. The research summarizes the most current developments in this field.

Tablet and capsule ingredients can be coated for three different reasons:

- To prevent the medicine from causing harm to the stomach.
- To prevent stomach acid from damaging the medication.
- To allow for dosing to occur in the gastrointestinal tract rather than the stomach.

Aspirin, diclofenac, and naproxen, some of the most common ulcer-inducing medications, are often marketed with enteric coatings. The benefits of an enteric coating make it imperative that the tablets or capsule contents be consumed whole and uncrushed [15].

Polymer and coating that biodegrades

Materials for enteric coatings are typically polymeric polymers engineered for controlled biological degradation. In order to release the impregnated components at regulated rates, many of the synthetic biodegradable polymers feature an inbuilt self-destruct mechanism that involves slow hydrolytic and microbiological destruction. The quest for a novel polymeric drug carrier was initiated with the intention of enhancing the efficacy of medication therapy [17]. [18] The polymer coating is intended to break down in a precise set of biological conditions, allowing the medicine to be released at its intended spot.

After serving their original purpose, biodegradable polymers break down into natural byproducts such gases (CO2, N2), water, biomass, and inorganic salts. [8, 9] Functional groups such as ester, amide, and ether predominate in these polymers, which can be found in both natural and manufactured forms. Their precise structure determines their qualities and the mechanism by which they break down. Condensation processes, ring-opening polymerization, and metal catalysts are frequently used in the synthesis of these polymers.

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There is no single method for producing tablets. However, for a number of reasons, modern contract manufacturers and encapsulation experts have begun using enteric coating materials. The intestinal area or when enters the duodenum is crucial for the release of tablet components. The procedure is also mandatory for drugs that induce stomach upset.

Quality control measures for enteric coating of tablets are essential for guaranteeing effective and efficient enteric coating of tablets. Coating medications that are sensitive to stomach acid with substances that react readily in an alkaline environment allows them to be released exclusively in the small intestine, where they can have their intended effect. [19, 20] The term "enteric" refers to the small intestine because the enteric coating prevents the drug's active ingredient from being destroyed by the stomach's acid.

Tablet Encapsulation

Coating a tablet is like taking a moderate approach to making a tablet. To coat something means to squeeze a granulating coating tightly around the finished tablets. It's a necessary extra procedure in the production of tablets. Recently, coating has been employed to delay or prolong medication release from the dosage form as well as control the site of drug release (enteric coating). Coatings can be either simple or intricate in character. It could be as simple as coating the tablet in varnish to prevent dust and minimize the need for testing. To accommodate potentially incompatible or time-sensitive drug releases, its most sophisticated iteration may consist of an inner and outer shell. [21]

Tablet Coating: Why and How it Works

There was a wide range of motivations for coating tablets. In a nutshell, here are some of the main justifications for coating tablets:

- Keeping out environmental elements like light and moisture to preserve ingredients.
- The bitter taste of the test can be effectively concealed by coating the pills. These pills are also easier to swallow than their uncoated counterparts.
- Colored coatings hide batch-to-batch variations in raw material appearance and reassure patients that their pills all look the same.
- The mechanical integrity of the tablet itself is improved after being coated.
- Important enteric or controlled release features can be added to the coated tablets by the application of functional film coatings.

Coating Material Varieties

Tablets can be coated with a wide variety of materials. Possible four types here.

- Polymers that can dissolve in water include gelatin, starch, carboxymethylcellulose, methylcellulose, hydroxyethyl cellulose, arabinogalactan, polyvinyl alcohol, and polyacrylic acid.
- Polymers that don't dissolve in water, like ethyl cellulose, polyethylene, polyamide, and polymethacrylate.
- The use of polymethacrylate and waxes.
- Some examples of waxes and lipids are paraffin carnauba wax, spermaceti bee's wax, stearic acid, stearyl alcohol, and glyceryl stearates.

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Tablet Coating Varieties

There are five main categories of tablet coatings.

1. Sweetening the deal
2. Coating films
3. Coating that is compressed using a press
4. Enteric coating.
5. Micron coating

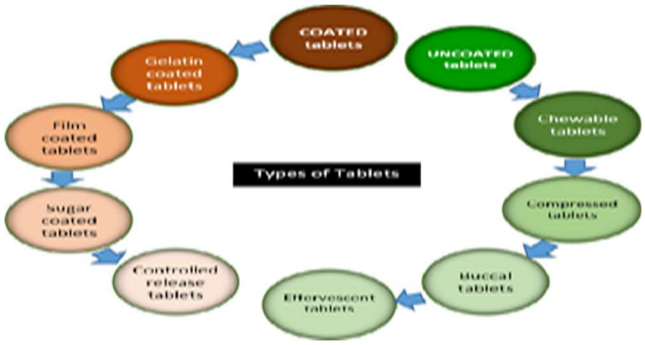

Fig. 1: Type of tablet coating

Enteric coating

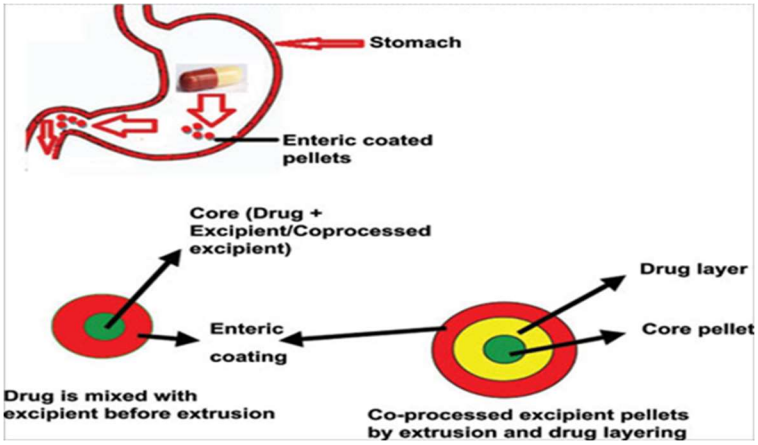

Fig. 2: Enteric coating of tablet

When a drug is taken orally, it is often protected by an enteric coating, which is a polymer covering. This is useful because it shields medicines from the acidic conditions of the stomach. [22, 23] The above-described coating solution may include, in addition to the enteric or non-enteric film formers, other components that help apply the coating material to the tablet or improve the coating's character. Surfactants, plasticizers, antifoaming agents, solubilizing agents, coloring agents, and so on are all examples of what may fall under this category. In most cases, this will equal to anywhere from 5% to 15% of enteric polymer depending on the total weight of the coating solution, with the optimal range lying somewhere between 9% and 12% (Fig. 2).

In order to protect their contents from the stomach's highly acidic pH, most enteric coatings

present a surface that rapidly degrades at a less acidic (relatively more basic) pH. For instance, they don't dissolve in the stomach's acidic contents (pH 3) but do in the small intestine's alkaline environment (pH 7-9). Fats, waxes, shellac, polymers, and even plant fibers are all employed as components of enteric coatings.

Aspirin and other drugs that can irritate the stomach can be coated with a chemical that allows them to breakdown only in the small intestine. Also, esomeprazole, omeprazole, pan, and all clustered azoles are activated by stomach acid. The addition of an enteric coating to the formulation helps prevent the medicine from being activated in the mouth and esophagus. However, this has been linked to a reduced degree of platelet inhibition. To prevent the tablet's core from disintegrating in the stomach's acid environment or to postpone breakdown until the upper intestine, enteric coating is applied [24]. Substances utilized for enteric coating are typically those-

- That are stable in the stomach's acidic environment.
- Which do not cause stomach distress.
- The function of which is found exclusively in the digestive tract.
- Which is absorbed in the digestive tract.
- Which necessitates delayed action.

Enteric coatings can be made from a variety of commercially available materials, such as lipids and fatty acids, shellac and shellac derivatives, or cellulose acetate phthalates. Today, synthetic polymeric materials are being tested as a potential enteric coating. (Fig-3). The pH of a substance is crucial to the enteric coating ideas. Stomach acidity typically ranges from about 1.2 to 1.4, while intestinal acidity is closer to 7.0. The enteric coating on a pill or capsule will remain intact in the stomach's acidic environment, but it will begin to breakdown in the intestine's basic environment.

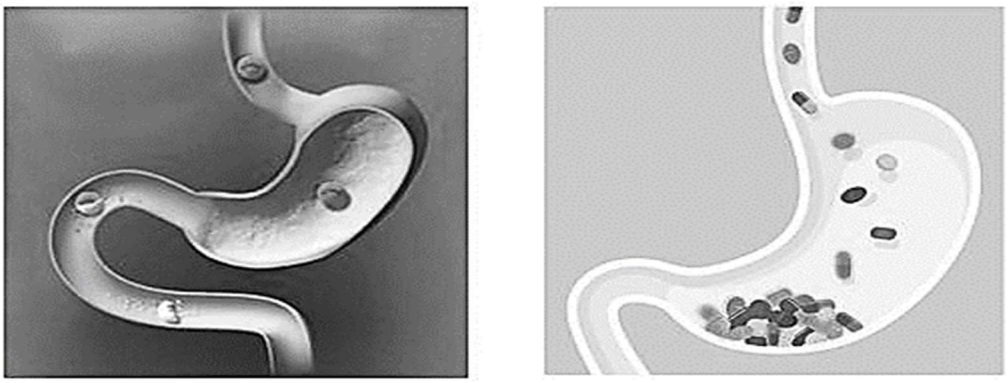

Fig. 3: Stomach and intestine

An enteric coating is a protective layer applied to orally administered drugs to direct their absorption into certain digestive tract regions. "Enteric" refers to the small intestine, hence enteric coatings work by blocking the absorption of drugs in the stomach and intestines [25]. Unionization of the enteric coated polymers persists even at low pH, making them intractable.

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However, at the higher pH found in the GIT, the polymer expands or becomes soluble in the intestinal fluid because the acidic functional groups are ionizable. Enteric coatings can be made from a variety of materials, including as polymers, plant fibers, fatty acids, waxes, shellac, CAP, CAT, PVAP, and HPMCP.

The following are the four most common justifications for using a coating on a tablet or capsule's active ingredient:

- Active pharmaceutical ingredients (APIs) like enzymes and some antibiotics need to be shielded from the stomach's acidic environment.
- Avoiding gastrointestinal side effects caused by drugs (like sodium salicylate) that irritate the stomach.
- To transport highly concentrated doses of medications to the digestive tract, where they can be absorbed most effectively.
- To furnish a timed-release ingredient for repeated use.
- Necessary for reducing the amount of time medicines spend in the liver.

The pH solubility profile of an enteric coated dosage form can be manipulated by adjusting both the polymer used and the thickness of the coated layer. Drugs including aspirin, diclofenac, and naproxen that commonly cause stomach ulcers are often available with enteric coatings [26]. Since omeprazole, a medicine used to prevent acid production in the stomach, is degraded by stomach acid, the granules used in capsules and the granules used in dispersible forms of the drug both include an enteric coating. Sulfasalazine is prescribed to patients suffering from Crohn's disease, an inflammatory bowel disorder, or rheumatoid arthritis [27]. It is typically administered with an enteric coating for Crohn's disease, where it must first be absorbed in the intestines before it may have any effect, but without an enteric coating for arthritis, where rapid absorption is more important.

To prevent inactivation by stomach acid and to maximize absorption in the small intestine, the antibiotic erythromycin base in ERY-TAB has been encapsulated in an enteric-coated tablet. Each white oval ERY-TAB (erythromycin delayed-release tablets) tablet contains either 250mg, 333mg, or 500mg of free base erythromycin, and can be used orally. Tablets with an enteric coating, such as aspirin, are also widely available. For instance, enteric-coated peppermint oil and Micropirin® 75mg EC pills. Such as Colpermin®.

Polymer enteric coatings with ideal characteristics

- Tolerance of stomach acid.
- Allows digestive fluid through it easily.
- The drug substrate and most components of the coating solution are compatible.
- A continuous film has been formed. Low cost, low toxicity, and simple application.
- Ability to print quickly and easily.

Enteric coating's benefits

- This method is implemented to keep the tablet's active ingredients intact while traveling through the stomach's acidic environment. [28]
- Protection of a low-pH-active ingredient from acid assaults.

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- To mitigate the stomach-irritating effects of medications such sodium salicylate.
- To improve distal absorption of a medicine that is taken by mouth and then absorbed in the stomach.
- To transport medications with a narrow therapeutic index to the intestinal tract.
- Optimal enteric coating material requirements
- The following characteristics make up a good enteric coating material:
- It ought to be resistant to stomach acid.
- Intestinal fluids should be able to penetrate or weaken it.
- Coating solution components and drugs should work fine with it.
- The ability to produce a continuous film is an important feature to have. It needs to be cheap and non-toxic.

Research on Dissolution

To determine how the polymer coating affects drug release, dissolution tests are conducted on both the core tablet and the coated tablet. Dissolution tests may be conducted using a USP Type-XXII dissolution apparatus (paddle stirrer), such as an Electro lab TDT-01 operating at 50 revolutions per minute. Both the stomach and the small intestine can be mimicked by using a solution with a pH of 1.2 and a buffer solution with a pH of 7.4. Dissolution trials begin with 1 L of simulated gastric fluid heated to (370.5) C and are repeated 2 hours later with fresh fluid. By one thousand milliliters of artificial intestinal fluid preheated to 37 0.5 degrees Celsius. Every 30 minutes during 2 hours, 5 ml of the simulated gastric fluid and every 15 minutes of the simulated intestinal fluid are removed and replaced with the same volume of fresh medium preheated to (370.5) C. A UV-VIS spectrophotometer (Model: U-1800) is used in conjunction with a calibration curve to determine the amount of medication dissolved at 274 nm. Coated tablets and one core tablet are used in the in-vitro release tests (Fig- 4, 5, and 6) [17, 18].

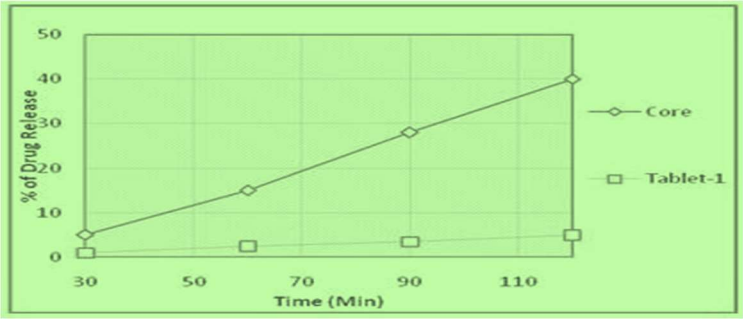

Fig. 4: Percentage of drug release from diclofenac sodium (DS) core and coated tablet in stimulated gastric fluid (pH = 1.2)

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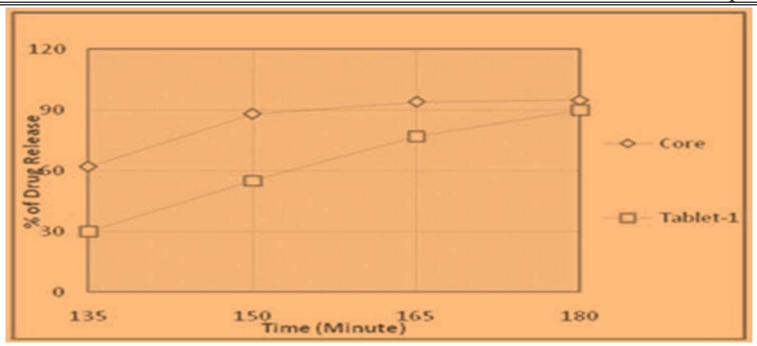

Fig. 5: Percentage of drug release from diclofenac sodium (DS) core and coated tablet in intestinal fluid (pH =7.4)

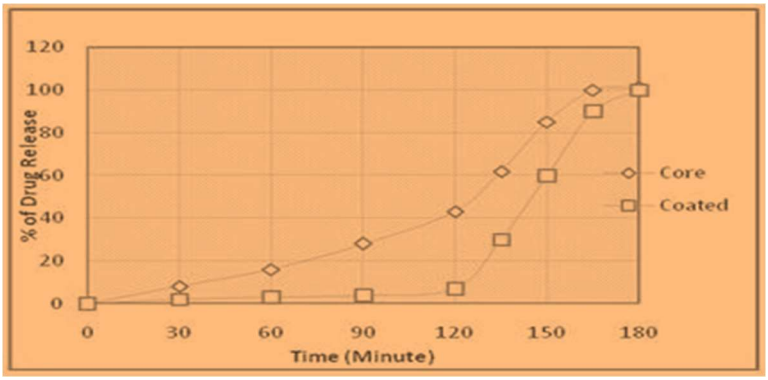

Fig. 6: Percentage of drug release from diclofenac sodium (DS) core and coated tablet (coated by biodegradable polymer) in stimulated gastric fluid (pH = 1.2) and in stimulated intestinal fluid (pH = 7.4)

Explaining a Process

The goal of enteric coating is to protect the formulations from stomach acid and delay medication release until the intestines or duodenum. Protecting the gastrointestinal mucosa from the unpleasant effects of the tablets' contents, such as aspirin, enteric coatings are designed to withstand the acidic stomach fluids and travel through the stomach without dissolving. The active chemicals, however, are able to be absorbed into the bloodstream once the coating dissolves in the neutral or alkaline environment of the colon. There are a few basic phases involved in the coating process of an enteric coated tablet:

Production of the Pill's Center

Coatings: Primers, Undercoats, and Topcoats

Coating, Enteric

Coloring Book

Shining Up

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Making the main tablet

Using a direct compression technique, the base tablets were made. Each ingredient was measured precisely before being processed and sieved over a No. 60 (250-micron) mesh screen to ensure a consistent particle size and distribution throughout the final product. After that, the components spent 30 minutes being mixed in a cube mixer. After being thoroughly mixed, the compound was compacted at a pressure of 4 to 6 kg/cm2 using a 10-station tablet punching machine and 6 mm round biconvex punches. Several versions of core pills were made, each with a different dissolving agent and enough of the active component to be comparable to 40mg. During preparation, all formulations were blended for the same amount of time and compacted under the same conditions [29].

Core tablet evaluation

We use a Vernier caliper to measure the thickness and diameter of the compressed tablets' cores, a Pfizer hardness tester (Sisco Ltd) to check their hardness, a Sartorius electronic balance to ensure each tablet has the same amount of weight, a Roche friabilator to check their friability, a disintegration test apparatus to measure how long it takes the tablets to break down, and a drug content analyzer to determine how much active ingredient is present. The enteric coating's optimal formulation is decided upon after the aforementioned assessments have been made.

Core tablet sealing coating

A seal coating composition including HPMC is applied as a subcoat to the optimum formulations. For 45 minutes, using a propeller mixer, disperse HPMC in a solvent mixture of isopropyl alcohol and dichloromethane (2:1). After going through a colloidal mill to lower the particle size if necessary, the dispersion is filtered via a 250 m sieve. The dispersion's total solids concentration is adjusted to 12% w/v.

Tablet core coating

To make coating solution, the biodegradable polymer is dissolved in an organic solvent that can evaporate quickly. In a tiny coating pan with constant hot air flow, the coating solution was sprayed over the tablets. After the solvent has evaporated and the tablets have dried, the coating pan is allowed to rotate.

"Undercoat" or "Precoat"

Premature drug release through the enteric coating film in acid media is a key problem in enteric coating formulations. If the coating substrates were first coated with a trace amount of a soluble substance before being subjected to enteric coating, this issue might be avoided. This thin film layer protects the medicine from being released too soon by blocking water from entering the cores.

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Substrate coatings

Hypromellose hydroxypropyl methylcellulose

The Substance Known as PVP

Hydroxpropyl methyl cellulose

• Polyethylene glycol (3350), (4500), and (8000)

To Name a Few: • Methylcellulose

Ethylcellulose pseudo-ester

For example: • Amylopectin

Sub coating helps when a medication is very water-soluble in a formulation. This is the most common location for unintended medication release. The release of acidic medicines in basic conditions may be improved by sub coating as well. The result is an acidic microenvironment right where the intestinal lining meets the inside. In basic media, drug release is slowed because the drug migrates through the interface. [30, 31]. It is important to consider both the prevention of premature drug release in acidic media and the achievement of rapid drug release in basic media in light of the constraints imposed by regulatory regulations. In order to work around the latter limitation, a novel concept of organic acid addition in coating substrates or sub coating layer is launched to increase the basic microenvironment (pH 5-6) at the interface of the enteric film and the cores, which might speed up the polymer dissolution.

The roughness of the coated substrate is decreased by the sub coating layer, and the enteric film's adherence to the substrate is enhanced. Because of the strong film formation this creates, less enteric coating polymer may be needed to get the same level of protection. The concentration of the non-enteric film-forming polymer in the solutions that will be utilized to manufacture the overcoat and undercoat layers of the present tablets may also vary. Preferred concentration is between about 5% and about 6% of said non-enteric film former on the same weight basis [32]. The former typically accounts for between about 2% and about 8% by weight of said non-enteric film forming polymer based on the total weight of the coating solution.

Coat of Many Colors

The same film coating solution used for sub-coating is then used to apply a film coating consisting of about 3% solids to the tablet surface. In this stage, the coating solution can be dyed. The coating applied in this stage prevents tablets from sticking together during high-temperature stress testing [33]. It also allows for more variety in the product's color preparation.

Polishing

Polishing the color-coated tablets from the previous stage involves carefully rotating the coating pan while sprinkling the tablet bed's surface with 0.01% powdered polishing wax [34]. To coat the

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tablets, they are rolled in a pan until they become slippery. The unused wax is subsequently burned off by the exhaust system. The total film coating solids on these completed enteric films coated tablets come to about 12.5%.

The lowest temperature at which a film can form.

Water emulsion polymer has the issue of Minimum Film-Formation Temperature (MFT) built into it. The MFT is the substrate temperature at which a continuous, robust layer of the finish can be formed. In actual operations, the product temperature is typically between 30 and 40 degrees Celsius for aqueous dispersion-based enteric coating techniques. Due to the hydrophilicity of enteric coating polymers, the effect of product temperature becomes problematic. In damp weather, they often become sticky. When the temperature is too low, coated particles tend to clump together. When making pellets, the issue becomes critical since the coating conditions must be altered quickly to prevent the formation of sticky pellets, which can destroy the entire batch. The sprayed liquid droplets become more viscous and scarcely spread on the surface of the coating substrates if the product temperature is set too high, which accelerates the solvent/aqueous evaporation [35]. This causes what is known as "orange peel appearance," a form of coating breakdown. The coating layer becomes uneven as a result. The trapped air behind the coating may expand in volume more quickly if the surrounding temperature is high. Some plasticizers, including triethyl citrate, are evaporated more quickly by high temperature and long processing times, altering the enteric film characteristic.

Dispersal of Coating Films

The evenness of a coating can be traced back to how the sprayed liquid is dispersed throughout the coating substrates. This is related to how the machinery was constructed. For instance, in pan coating systems, the pan speed greatly affects the uniformity with which the film is dispersed across the mass. Polymer dosage for maximum enteric protection depends on the variation in the tablets' motion [36, 37]. coated uniformity in Wurster-type fluid bed systems is proportional to the number of coated substrates that move through the spray zone. The width of the space between the Wurster partition and the air distribution plate plays a role, as do the air volume and spray morphology at the entrance [38]. The coating substrates tend to not be equally covered when the inlet air volume is low and the partition level is low.

Methods of curing and storing

Curing processes at increased temperatures and high relative humidities are necessary to produce the polymer coalescence in some enteric coating polymers, such as HPMCAS. Film instability is a problem with CAP and CAT coatings during storage, especially at elevated temperatures [39]. This occurs because ester groups are hydrolyzed, resulting in insoluble cellulose acetate. Hydrophilic plasticizers added to finished objects coated with aqueous dispersion systems cause the coating to become sintered during storage [40].

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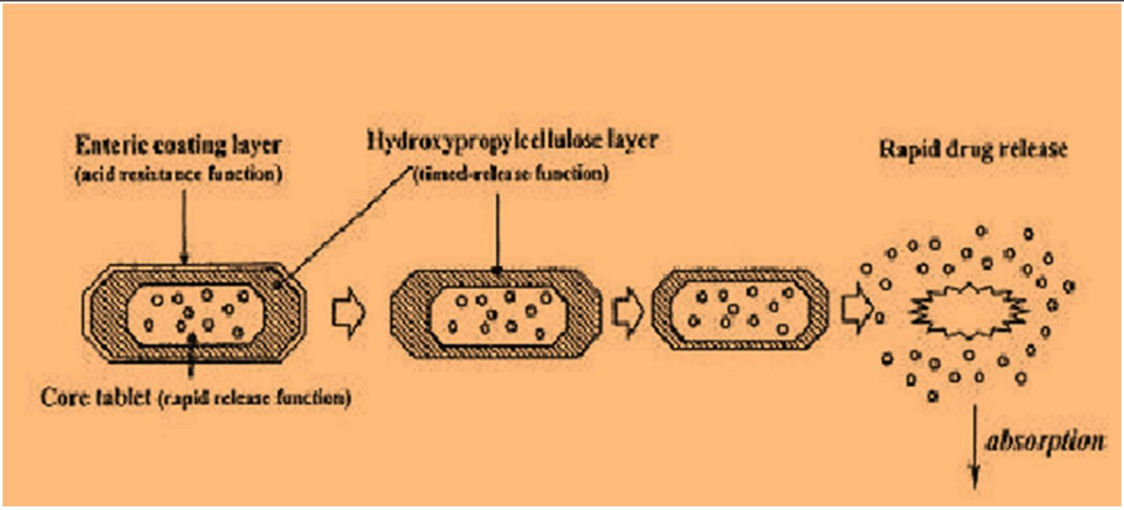

Fig. 7: Enteric coated polymer layer

In addition, the enteric-coated solid dosage forms can be further refined by polishing or overcoating with sugar or other substances using any technique now in use (Fig-7). [41, 42]. Before the solid dosage forms are treated with the enteric coating in accordance with this invention, undercoating with conventional coating materials is an option. The following examples are meant to show how this invention can be used and should not be taken as restricting the scope of the invention. All of the fractions and percentages shown here are weight-based.

Conclusion

Pharmaceutical formulations, such as drug delivery systems, implant materials, and stents, make substantial use of biodegradable polymers. Coating of pharmaceutical dosage forms has undergone significant innovation in recent decades to guarantee and improve product quality. There have been major advancements in the areas of particle transportation, heat and energy transmission, film distribution, drying efficiency, and continuous processing. Huge advances will be needed in tablet coating in the near future. Based on the information presented above, it is clear that enteric-coated tablets are created so that the drug is not exposed to the harsh conditions of the stomach and is instead delivered to its intended location in the intestines. Streptococcal pharyngitis (strep throat) and pyoderma (spray-on dermatitis) can be treated with enteric-coated tablets, as can Streptococcus pneumoniae (pneumonia), Mycoplasma pneumonia (pneumonia), and Legionella pneumophila (Legionnaires' disease) pneumonia. The pH solubility profile of an enteric coated dosage form can be manipulated by adjusting both the polymer used and the thickness of the coated layer.

In general, drugs with a low oral bioavailability (50%), a short biological half-life (3 hours), and appropriate protein binding are the ones most often chosen for formulation into enteric coated dosage forms. This dosage form is preferred since it is easy to make, cheap, and doesn't need expensive machinery. This is why this dose form has become so popular recently.

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The chemistry of polymer synthesis, factors impacting biodegradation, and strategies for producing biodegradable polymer-based formulations are also highlighted in the present review.

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