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Eudragit as a novel polymer material for designing oral drug delivery systems with controlled release properties

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ABSTRACT: Nowadays, Cancer is the leading cause of death globally. As per the recent statistics by WHO, cancer incidence is increasing steadily worldwide, especially in developed countries. Despite the development of a variety of therapeutic approaches to prevent or manage this disease, there is also a need for additional effective solutions. Extended life span is directly correlated with a dramatic increase in deadly malignancies. Recently, pharmaceutical companies have invested significantly in researching and developing new cancer therapeutics. Even though progress has been made in this research, many obstacles exist that need to be overcome, especially in clinical trials, because the results are disappointing, preventing further development progress. To develop more effective treatment strategies, it is necessary to understand the pathophysiology of the disease properly. After overcoming so many obstacles, it is noteworthy that many significant advances have been made in cancer treatment due to the development of specialized medications, which seem to give better results than traditional therapies in recent years. This article aims to focus on the recent advancement in the developments of antineoplastic agents not only from a traditional point of view but also the recent therapeutics to combat this deadliest disease.

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INTRODUCTION:

Oral medication conveyance is a huge space for definition research due to the previously mentioned benefits for patients [1]. Significant pharmacological breakthroughs have been achieved to enhance medication regional targeting in the GI tract, but relatively few have made it to the clinical phase [2]. It is the most popular method among patients because of its benefits such as ease of use, non-invasiveness, and self-convenience. Drug distribution to specific upper or lower GI tract parts can also be improved using formulations [3]. The goal of

pharmacological therapy is to create a steady state at the blood or tissue level that is therapeutically beneficial while still being nontoxic during the release period of time. Typically, this is achieved by increasing medication availability. Though several innovative drug delivery methods are now accessible, scientists are continually developing new ways and polymeric materials for modifying and prolonging drug release [4]. A controlled drug delivery system is one that provides medications at a predefined pace, either locally or systemically, for a certain length of time. Various innovative strategies for modifying and prolonging medication release are employed in conjunction with new polymeric materials [5,6]. Polymers have become an integral part of drug delivery systems due to their improved pharmacokinetic properties. They have better circulation time than conventional small drug molecules and thus target tissue more specifically. Tremendous use of polymers has been witnessed in the area of polymer therapeutics and Nanomedicines [6].

Polymeric materials utilized in prolonged-release matrix systems may be divided into three types: (a) hydrophilic, (b) erodible, and (c) insoluble [7,8]. Polymers should be adjusted based on their physicochemical qualities related to release mechanisms in order to produce optimal release profiles. Polymers have turned into an indispensable piece of medication conveyance frameworks due to their improved pharmacokinetic properties. They have a longer circulation time than traditional tiny medication molecules, allowing them to target tissue more precisely. Polymers have been used extensively in the fields of polymer therapies and nanomedicine [9].

The objective is to perform a thorough review of Eudragit as a novel polymer material for designing oral drug delivery systems.

Poly (meth) acrylates Polymer:

Polymeric coatings have been applied to solid dosage forms to mask the harsh taste of the medicine, preserve sensitive drug components, control drug release, and/or give the dosage form an aesthetic character [10]. Eudragit is the brand name for a variety of polymethacrylates-based copolymers that are primarily sold by Evonik Industries in Germany. Rohm and Hass GmbH, Darmstadt, first introduced Eudragit in 1953 as an alkaline soluble medicinal coating substance resistant to stomach acid. These are synthetic polymers obtained by polymerization of acrylic acid (prop- 2-enoic acid; CH_2=CHCOOH) and methacrylic acids or their esters like butyl ester or dimethylaminoethyl ester and whose physicochemical properties are determined by their functional groups.

***Soluble Polymethacrylates*:**

They dissolve in gastric juices due to salt production. Polymers such as Eudragit L, S, FS, and E are examples [11]. These polymers with acidic or alkaline groups allow the active substance to be released in a pH-dependent manner [12]. Applications range from simple taste masking to controlled medication delivery in all parts of the gut [13].

***Insoluble Polymethacrylates*:**

These are insoluble in water but permeable to digestive juices [28]. Eudragit RL and RS polymers with alkaline groups and Eudragit NE polymers with neutral groups, for example, provide for regulated temporal release of the active component via pH-independent swelling [14,15].

CLASSIFICATION OF EUDRAGIT:

Eudragit is classified into four groups that are Eudragit E (soluble below pH 5.5) is used for taste masking; Eudragit L and S (soluble above pH 6 and 7, respectively) are used for colon targeting/enteric coating; Eudragit RL and RS (pH-independent solubility) are used for sustained release drug delivery; Eudragit NE and NM (swellable and permeable) are used for sustained release drug delivery [16]. It is widely used as a vehicle for producing solid dispersions and amorphous systems such as microspheres, microparticles, and nanoparticles in order to increase the solubility of low-solubility drugs [17].

Pharmaceutical Properties of Eudragit:

EUDRAGIT® is the brand name for poly (meth) acrylates in the business. These polymers allow the active ingredient in your solid dose form to work while traveling through the body. The ability to combine multiple polymers allows you to establish the required drug release profile by releasing the medication at the right place, at the right time, and, if necessary, over a specified time period. Other critical features include resistance to external stimuli (moisture) and taste/odor masking to improve patient compliance [25]. The product line offers complete flexibility for specified medication release profiles by providing the greatest performance for enteric, protective, and sustained-release features. EUDRAGIT® polymers are copolymers produced from acrylic and methacrylic acid esters, with functional groups determining their physicochemical properties (R).

Table 1. Classification of Polymethacrylates Polymers.

Common Name	Description	Application	References
Eudragit E 12.5	Cationic, Yellow in color	Film coating	[18]
Eudragit E 100	Cationic, Yellow in color	Film coating	[18]
Eudragit E PO	-	Film coating	
Eudragit L 12.5 P	Anionic, White free flowing powders	Enteric coating	[19]
Eudragit L 12.5	Anionic, White free flowing powders	Enteric coating	[19]
Eudragit L 100	Anionic, White free flowing powders	Enteric coating	[19]
Eudragit L 100-55	Anionic, White free flowing Powders	Enteric coating	[19]
Eudragit L 30 D-55	Anionic, White free flowing Powders	Enteric coating	[19]
Eudragit S 12.5 P	Anionic, White free flowing powders	Enteric coating	[20]
Eudragit S 12.5	Anionic, White free flowing powders	Enteric coating	[20]
Eudragit S 100	Anionic, White free flowing powders	Enteric coating	[20]
Eudragit FS 30D	Anionic, Milky white, Low viscosity	Enteric coating	[20]
Eudragit RL 100	Cationic, non- biodegradable	Sustained release	[21]
Eudragit RL 30D	Cationic, non- biodegradable	Sustained release	[21]
Eudragit RS 12.5	Cationic, non-biodegradable	Sustained release	[21]
Eudragit RS 100	Cationic, non- biodegradable	Sustained release	[21]
Eudragit RS PO	Cationic, non- biodegradable	Sustained release	[21]
Eudragit RS 30 D	Cationic, non- biodegradable	Sustained release	[21]
Eudragit NE 30 D	Cationic, Yellow in color	Sustained release, tablet matrix	[22]
Eastacryl	Cationic	Sustained release, tablet matrix	[22]
Eastacryl 30 D	Cationic	Sustained release, tablet matrix	[22]
Kollicoat MAE 30 D	Anionic, Milky white, Low viscosity	Enteric coating	[23]
Kollicoat MAE 30 DP	-	Enteric coating	[23]
Acryl-EZE	-	Enteric coating	[24]
Acryl-EZE MP	-	Enteric coating	[24]

Table 2. Tabulation for solubility of various grades of Eudragit.

Grades of Eudragit	Recommended Solvents	Solubility	References
Eudragit E12,5; Eudragit E100; Eudragit EPO	Acetone, alcohol	Soluble in gastric fluid to pH 5	[27]
Eudragit L 30 D-5, Eastacryl 30D, Kollicoat 30D, Kollicoat 30DP, Acryl EZE Acryl EZE MP	Water	Soluble in intestinal fluid from pH 5.5	[28]
Eudragit S 12.5P, Eudragit S 12.5, Eudragit S 100	Acetone, alcohol	Soluble in intestinal fluid from pH 7	[29]
Eudragit L-12.5P, Eudragit L-12.5, Eudragit L 100	Acetone, alcohol	Soluble in intestinal fluid from pH 6	[29]
Eudragit RL12.5, Eudragit RL100, Eudragit RD 100, Eudragit RL PO	Acetone, alcohol	High permeability	[30]
Eudragit RS 12.5, Eudragit RS 100, Eudragit RS PO	Acetone, alcohol	Low permeability	[30]
Eudragit NE 30D, Eudragit NE 40D	Water	Swellable, permeable	[31]

EUDRAGIT® polymers are available in a variety of physical forms (aqueous dispersion, organic solution granules, and powders). EUDRAGIT® L, S, FS, and E polymers with acidic or alkaline groups allow for pH-dependent active component release [26].

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COATING METHODOLOGIES USED FOR EUDRAGIT:

Eudragit polymers are widely used as coating materials to achieve either drug-release behavior modification or taste masking. Polymeric films are typically applied to solid dosage forms using the spray atomization technique for coating. Polymethacrylate polymers have traditionally been dissolved in organic solvents such as isopropanol and acetone. Organic coating dispersions are typically turbid, which disrupts the coating process. To improve the appearance of the organic coating dispersion, a small amount of water should be added [32]. Furthermore, ready-to-use aqueous dispersions of many Eudragit grades are available commercially. Prior to the coating process, the solid core materials are frequently preheated in the coating equipment. Anti-adherent compounds are commonly included in coating formulations to reduce stickiness and agglomeration of coated substrates, and talc is one of the most common anti-adherents. Talc may cause an increase in drug dissolution, presumably by forming cracks in the coating [33]. While organic solvent film-coating technology suffers from toxicological, environmental, cost, and safety-related disadvantages [34], the aqueous-based coating technology is associated with the limitations of slow drying rate of coating, high energy input, possibility of microbial contamination, and stability issues with water-sensitive drugs [35]. Various dry coating techniques for pharmaceutical products have recently received a lot of attention as an alternative to liquid-based coating, and these techniques have also been used for coating with Eudragit polymers.

Compression coating:

To achieve constant rate-regulated release, a seal coat of Eudragit RS PO and S 100 was applied to the tablets. The polymer coating was discovered to be porous, allowing diffusion medium to enter the core tablets, and NMR analysis revealed water diffusion into compression-coated tablets [36].

Modified fluidized bed Wurster process:

To achieve sustained and delayed release, pellets are coated with various formulations of Eudragit RS, ethyl cellulose, and shellac. The process, on the other hand, is based on the use of a small amount of liquid plasticizer in a polymer solution to facilitate film formation [37].

Dry powder coating:

Eudragit polymers, such as Eudragit E PO [38], Eudragit RS/RL [39], and Eudragit L 100-55, are used to coat tablets. Some polymers with higher glass transition temperatures (Tg), such as Eudragit RS, Eudragit L, and Eudragit L100-55, were pre-plasticized with liquid plasticizer prior to coating using hot-melt extrusion in order to lower Tg and generate binding force at certain operating temperatures. A partially melted polymer that generates binding force between particles and tablet surface improves powder adhesion to the tablet [40].

Electrostatic spray powder coating:

Eudragit polymers, specifically Eudragit RS and Eudragit E, are used. Wet granulation was used to create the coating powder, which was then dried in a fluid bed and micronized in a fluid energy mill. Using specialized equipment, both sides of the tablets were coated separately [41]. Curing with infrared radiation completed the polymer particle fusion process. The aforementioned process was later shown to have difficulties coating tablets with well-defined edges [42].

A modified coating process based on the creation of an electrical field by an electrostatic charging gun and a

grounded substrate to aid in the deposition of charged powder particles has also been reported for coating tablets with Eudragit RS and RL. However, in order to achieve optimal coating, these solvent-free coating processes must be modified [43].

SAFETY PROFILE OF EUDRAGIT:

Eudragits are classified as non-biodegradable polymers due to their stability in the presence of digestive enzymes and bodily fluids. Eudragit E, a basic methacrylate polymer, has been demonstrated to be non-toxic and its properties moderated greatly by its lack of absorption as a result of the large effective molecular weight [44]. It has been proposed that Eudragit E is GRAS (Generally Regarded As Safe) on the basis of scientific procedures, as discussed at 21 CFR, Section 170.30, with regard to its use as direct and indirect food ingredients [44]. Similarly, the median lethal dose (LD50) of anionic methacrylate copolymer (Eudragit FS 30 D) in male and female Sprague- Dawley rats of CD(SD)BR strain was found to be in excess of 2,000 mg/kg body weight [45]. No-Observed-Adverse- Effect-Level (NOAEL) was found to be 400 mg/kg body weight/day in a short-term toxicity study conducted for 28 days on male and female Beagle dogs [46], while the same has been reported as 1,500 mg/kg body weight/day in sub-chronic oral toxicity study conducted for 26 weeks on male and female Sprague-Dawley rats [47]. The *in vitro* cell mutation assay has demonstrated non-mutagenicity of the polymer [48]. In the USA, various grades of Eudragit are approved and listed in the US FDA's "Inactive Ingredients for Approved Drug Products" list with the maximum potency of these grades specified with respect to the particular use [49,50].

DOSAGE FORMS USING EUDRAGIT:

It is feasible to create modulated drug release by using Eudragits as release-manipulating excipients, either by polymeric coating on the drug reservoir core or through the use of a polymeric matrix including the drug itself, as indicated in Table 3.

ROLE OF EUDRAGIT IN ORAL DRUG DELIVERY SYSTEM:

Controlling the pace of dissolution and the location of medication release in the GI tract for subsequent absorption. It is feasible to enhance targeting to 3 separate sections of the GI tract by employing modified formulations (stomach, small intestine, and colon) [69].

Drugs are often targeted to the small intestine using gastroretentive dosage forms, pH-dependent dosage forms, or mucoadhesive dosage forms [70].

pH-responsive coatings or matrices are especially useful for drugs that are susceptible to degradation by gastric enzymes or the acidity of the gastric fluid, as well as drugs that can cause irritation to the gastric mucosa and release the drug in the distal part of the small intestine or the colon [71].

pH-dependent polymer coatings, either alone or in combination, have been employed for colonic targeting, including certain methacrylic resins (commercially available as Eudragit® [72].

Eudragit products are pH-dependent methacrylic acid polymers containing carboxyl groups. The number of esterified carboxyl groups affects the pH level at which dissolution takes place. Eudragit S coatings protect well against drug liberation in the upper parts of the gastrointestinal tract and have been used in preparing colon-specific formulations [73].

To maximize patient compliance, the active component must be resistant to moisture and light. By disguising tastes and smells, Eudragit E polymers aid in sealing sensitive activities and promote patient compliance. Even tiny coatings of Eudragit produce the intended effect, making it a very cost-effective application. Pharma Polymers provides cationic Eudragit E grades in a variety of sizes for protective coatings [74].

CONCLUSION:

The current study demonstrates that Eudragit belongs to a class of synthetic polymethacrylate copolymers that are utilized as functional excipients in a variety of medicinal dosage forms. Eudragit polymers can be used to provide time-controlled drug release formulations, enteric formulations for GI targeting, and protective formulations for moisture protection and odor/taste masking. The numerous uses of eudragit polymers in NDDS have made important contributions to the field. Because of the safety associated with the use of Eudragits, they are appealing candidates for improving existing dosage forms and creating new ones. It has been concluded that eudragit polymers can be effectively used in the future as a unique and versatile chemical tool for the manufacture of pharmacological formulations. This review is helpful in the selection of polymers for site-specific delivery.

Table 3. Reported literature on Eudragit Grades.

Sl. No.	Drug	Dosage form	Method of Preparation	Reference
EUDRAGIT RS 30D				
1	Meloxicam	Pellets	Extrusion-spheronization	[51]
2	Aspirin	Granules	Hot-melt granulation	[52]
3	Metformin	Microcapsules	Microencapsulation	[53]
EUDRAGIT RSPO				
1	Itraconazole	Microsponges	Quasi-emulsion solvent diffusion	[54]
2	Propranolol hydrochloride	Liqui-tablet	Liqui-mass technology	[55]
3	Metformin	Microcapsules	Solvent evaporation method	[56]
EUDRAGIT RS100				
1	Acebrophylline	Microspheres	Ionic gelation	[57]
2	Repaglinide	Tablets	Wet granulation	[58]
3	Omeprazole	Nanoparticles	Nanoprecipitation	[59]
EUDRAGIT RL 30D				
1	Fluorouracil	Microsponges	Quasi-emulsion solvent diffusion	[60]
2	Ropinirole hydrochloride	microspheres	non-aqueous solvent evaporation technique	[61]
3	Captopril	Pellets	Extrusion and Spheronization	[62]
EUDRAGIT RLPO				
1	Benznidazole	Nanoparticles	Spray-drying	[63]
2	Acetaminophen	Pellet	Hot melt extrusion	[64]
3	Glimepiride	Microparticles	emulsion solvent evaporation	[65]
EUDRAGIT RL100				
1	Moxifloxacin hydrochloride	Nanoparticles	Spray-drying	[66]
2	Paliperidone	Tablets	Compression-coated	[67]
3	Paclitaxel	Nanoparticles	Nanoprecipitation	[68]

The contributions given by researchers on Eudragit® polymer applications showed their future potential and significance.

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