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# EUDRAGIT LITERATURE: A REVOLUTIONARY OVERVIEW

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**ABSTRACT:**

This research used several grades of eudragit, such as eudragit E100, eudragit EPO, eudragit L 100-55, and eudragit L 100, to create diverse sorts of dosage forms, including ophthalmic aqueous solutions, transdermal spray nanoparticles, solid dispersions, and oral disintegrating tablets. This study provides a comprehensive analysis of several literature reviews and research papers that examine the different grades of eudragit in great depth. Eudragits are considered to be non-irritating and non-toxic substances.

**Keywords:** Eudragit, Dosage Forms, Eudragit E100, Eudragit L100, Nontoxic, Polymers

## INTRODUCTION:

Dr. Rohm invented the polymer family Eudragit® and the acrylic substance Plexiglas, which was released in 1933. ROHM have a profound understanding of acrylic acid and its many derivatives. The market was introduced to the first two polymers for enteric coatings, Eudragit L and Eudragit S, in 1954. They provided a superior synthetic polymer for film coating compared to substances like sugar or shellac. In the 1960s, the inclusion of Eudragit-based solutions for fast-disintegrating sustained-release coatings significantly broadened the range of possible uses. The introduction of Eudragit's aqueous polymer dispersion form in 1972 was a significant milestone, as it simplified, made safer, and increased the economic and adaptable nature of the coating process. The availability of various grades of Eudragit enables the exploration of multiple aspects of formulation development, including film-coating, granulation, direct compression, melt extrusion, immediate or sustained release, and the mastery of techniques for developing gastrointestinal-targeted, enteric coating, pulsatile release, and transdermal formulations. Due to its versatility as a drug delivery polymer, Eudragit was chosen for further testing.

Polymethacrylates are artificial polymers that may be either positively charged (cationic) or negatively charged (anionic). They are produced by combining dimethyl aminoethyl methacrylate, methacrylic acid, and methacrylic acid esters in various proportions. Various commercially available varieties may be obtained in the form of dry powders, aqueous dispersions, or organic solutions [1]. A often used organic phase consists of a combination of acetone and propan-2-ol in a ratio of 60:40. Polymethacrylates are mainly used as agents for coating films on dosage forms, such as tablets and capsules. Various polymer properties may be used to create films with varying degrees of solubility. The solubility characteristics of each category of Eudragit. Polymethacrylates are often used as agents for binding and diluting

tablets. In addition to the applications mentioned above, recent research has demonstrated that polymethacrylates have extensive uses in various formulations. These include taste masking, enhancing permeability through the skin, intestinal epithelium, and cornea, improving solubility, enhancing bioavailability, enteric coating, sustained release, radioprotection, pH dependent release, colon targeted therapy, and more. Therefore, polymethacrylates have a significant impact on the advancement of different kinds of dosage forms with a wide range of uses. Hence, the objective of this document is to gather and organise research publications and patents that explore different uses of Eudragit.

Polymethacrylate is a substance that goes by several names, including Acryl-EZE, Acryl-EZE MP, Eastacryl 30D, Eudragit, Kollicoat MAE 30 D, Kollicoat MAE 30 DP, and Polymeric Methacrylate. This paper examined the several types of Eudragit, a brand owned by GmbH & Co.K.G. Darmstadt, Germany, that was introduced to the market in the 1950s. The production of Eudragit included the polymerization of acrylic and methacrylic acids, or their esters. B. Butyl esters or dimethylaminoethyl esters. Figure 1 displays the chemical composition of Eudragit. Eudragit has been included into the United States Pharmacopoeia (USP), British Pharmacopoeia (BP), and European Pharmacopoeia (PhEur). The dry powder polymer form remains unchanged at temperatures lower than 30°C. The dry powder remains chemically unaltered for a minimum of 3 years when kept in a sealed container at temperatures below 30°C. The dispersion should be kept within the temperature range of 5 to 25°C and has a minimum stability period of 18 months.

Eudragite is often regarded as a chemical that is not harmful and does not cause irritation. The recommended daily human consumption is 2 milligrammes per kilogramme of body weight and is regarded to be safe. This information is included in the FDA Guide for Inactive Ingredients (Oral Capsules and Tablets). The guide covers medications authorised in the UK, except parenteral pharmaceuticals, and also contains the Canadian List of Acceptable Non-Drug Ingredients.

## LITERATURE REVIEW:

A comprehensive literature review is discussed in detail and examples of its applications are highlighted. "Research papers for each class are summarized." Some of these articles are critically discussed, especially with regard to Eudragit.

Eudragit L100 and 12.5:

Eudragit L 100 and 12.5 Eudragit L 100 and L 12.5 are anionic copolymers derived from methacrylic acid and methyl methacrylic acid. Both polymers possess comparable molecular weights of 125,000 g/mol, acid values of 315 mg KOH/g polymer, and glass transition temperatures above 150 °C. Both polymers are designed to release drugs specifically in the jejunum, and they breakdown at a pH of 6 and above. These coatings are used for their efficacy and stability, since they dissolve quickly in the upper intestine. They also facilitate the granulation of medicinal compounds into powder form, allowing for controlled release. Additionally, they provide site-specific drug administration in the gut. The only distinction between these two classes is in their physical form and odour. Eudragit L 100 is obtainable as a solid powder with a subtle characteristic scent, whilst Eudragit 12.5 is a colourless,

transparent to slightly cloudy liquid organic solution with the distinctive odour of isopropyl alcohol.

A recent analysis of Eudragit L 100 reveals its utilisation in several compositions, including microspheres, microsponges, nanoparticles, liposomes, lipotomes, and tablets, for a range of purposes such as enteric coating, sustained release, insulin permeability, and bioavailability. Lee et al. [2] incorporated insulin self-nanoemulsifying drug delivery system (SNEDS) inside enteric capsules made from Eudragit L100. An insulin release profile that is dependent on pH was discovered. Administration of SNEDDS in fasting rats significantly enhanced the relative bioavailability and glucose decrease by 2.7-fold and 3.4-fold, respectively. This research indicated an improved effectiveness of insulin and increased oral absorption. In their study, Sareen et al. (2014) [17] examined the ability of Eudragit L100 to carry drugs specifically to the colon. They achieved this by combining it with curcumin microsponges. Studies have shown that microsponges effectively inhibit the premature release of curcumin in the upper gastrointestinal tract and selectively release the medication in the colon at specified pH values. Eudragit L 100-containing microsponges show potential as an effective medication delivery mechanism for treating ulcerative colitis. Hosny et al. [18] devised a new method to address obstacles in the treatment of osteoporosis by creating enteric-coated alendronate sodium (ALS) nanoliposomes. Nanoliposomes coated with Eudragit L 100 were effectively engineered to withstand ALS release in acidic conditions and enhance bioavailability in rabbits. Wilson et al. [3] formulated and examined prolonged-release enteric-coated tablets containing pantoprazole. The pills were coated with enteric coating polymers, namely cellulose acetate phthalate and Eudragit L100, using the dip-coating method. The investigation determined that the tablets manufactured were capable of maintaining medication release in the gut. Pantoprazole enteric coated pills effectively reduce the occurrence of ulcers.

Eudragit S-100, 12,5 and FS30 D:

Eudragit S 100 and S 12.5 are anionic copolymers derived from methacrylic acid and methyl methacrylate. Eudragit S100 is a white solid substance in powder form, which has a little distinctive smell. Eudragit S12.5 is a transparent to slightly cloudy liquid that lacks colour and has the distinctive scent of isopropyl alcohol. Both types exhibit molecular weights, acid numbers, and glass transition temperatures of about 125,000 g/mol, 190 mg KOH/g polymer, and over 1500 °C, respectively. Eudragit S 100 is available in a powdered state. Eudragit S 12.5 is obtainable as a 12.5% organic solution. Both variants undergo dissolution at a pH of 7.0 and are especially used for medication delivery to the colon. Eudragit FS30D is a liquid that has a milky white appearance, a faint distinctive smell, and a low level of thickness. The substance is a water-based mixture containing an anionic copolymer composed of methyl acrylate, methyl methacrylate, and methacrylic acid. It exhibits insolubility in acidic solutions, but may dissolve via the production of salts when the pH exceeds 7.0. Furthermore, its ability to dissolve in alkaline conditions enables the precise administration of medications to the colon. The molecular weight of the substance is around 280,000 grammes per mole, its acid number is roughly 70 milligrammes of potassium hydroxide per gramme of polymer, and its glass transition temperature is approximately 480 degrees Celsius. Smooth film formation may be achieved with less plasticizer due to the low minimum film formation temperature. The product is present in the form of a water-based dispersion with a concentration of 30%.

Here is a recent study article on Eudragit S 100. It is used in the production of transdermal patches, nanoparticles, microparticles, microballoons, solid dispersions, and spherical crystals. It is used for a range of purposes including targeted drug administration to the colon, prolonged release of medication, enhanced absorption into the body, and better particle size characteristics. Madan et al. [4] assessed the ability of Eudragit S100 to release medication over a prolonged period of time. They achieved this by creating transdermal patches containing donepezil, utilising different polymers, plasticizers, and penetration enhancers. Eudragit S100, Eudragit E100, and HHPMC were used as matrix formers throughout the production of the patches. The researchers determined that transdermal patches had the capacity to extend the duration of donepezil release and enhance its absorption. Hence, Eudragit S 100 may be used to extend the duration of donepezil release in transdermal patches. Lee et al. [2] examined if it is possible to release medications specifically in the colon by using an enteric coating made of Eudragit S 100 for model pharmaceuticals. The process of achieving the enteric coating included the application of Eudragit S 100 onto microencapsulated 5-fluorouracil and leucovorin that were loaded with folic acid-chitosan nanoparticles. When the pH value approached the dissolving threshold of Eudragit S-100, a continuous and gradual release of the medicine was consistently observed. Eudragit S100 is used for targeted medication delivery to the colon in chemotherapy. Nandi et al. [5] developed and analysed a multiparticulate system of indomethacin that releases the drug gradually over time. The microspheres were produced utilising an innovative pseudoemulsion solvent diffusion method, using a blend of ethylcellulose (EC) and Eudragit RS 100/Eudragit S100. Increasing the quantity of Eudragit polymer led to a substantial reduction in medication release ($p<0.05$). Therefore, this strategy proposed that the use of EC and Eudragit S100 microspheres might facilitate the optimal delivery of indomethacin to the colon. No scholarly articles about Eudragit S 12.5 were found in PubMed indexed journals. Nevertheless, there is a scarcity of published articles about the use of Eudragit FS 30 D in several forms of medication, including multiparticulates, tablets, and capsules, specifically for the purpose of enteric coating. Drue et al. [6] manufactured many tablets by compressing enteric coated pellets. The ideal coating was obtained by blending two acrylic polymers: the comparatively fragile Eudragit® L30 D-55 and the more pliable Eudragit® FS 30 D. The final formulation discharged 9% of the medication in an acidic environment. The biconvex form of the tablets and the protective coating composed of Kollidon VA 64 were crucial factors in developing an enteric-resistant coating, in addition to the coating itself. [7] devised an alternate technique for applying enteric coating to HPMC capsules that eliminates the need for a sealing process prior to coating. The outcome consists of enteric-coated capsules that are prepared for immediate use. These capsules are suitable for various settings such as retail shops, hospital pharmacies, and R&D departments in the pharmaceutical sector. Additionally, they may be used in the manufacturing of enteric-coated biomaterials that are sensitive to heat and moisture. The amount of thymidine released in 0.1 N HCl after 2 hours from capsules coated with Eudragit L30D-55, Eudragit FS 30 D, Aqoat AS-HF, and Sureteric was 0.6 +/- 0.03, 0.6 +/- 0.3, 1.2 +/- 0.2, and 7.3 +/- 1.9%, respectively. This new approach proved replicable and offered a means to circumvent the laborious and expensive sealing stage necessary in conventional coating procedures.

Eudragit E100, E12.5 and EPO:

The series consists of many varieties, including Eudragit E100, EPO, and E12.5. All three are positively charged copolymers composed of dimethylaminoethyl methacrylate, butyl methacrylate, and methyl methacrylate. They are chemically referred to as poly(butyl methacrylate-co-(2-dimethylaminoethyl) methacrylate-co-methyl methacrylate). Their molecular weight is around 47,000 g/mol, and their alkali value is 180 mg KOH/g polymer. The Eudragit E series is distinguished by its ability to dissolve in the stomach at a pH of up to 5.0, its strong adherence, and its little increase in polymer weight. These substances are often used for the purpose of film coating, concealing odours and tastes, as well as providing protection against moisture and light. They exhibit variations in their physical characteristics. Eudragit S100 is present in granular form. The granules are composed of colourless to yellow particles that emit a distinct amine-like scent. Eudragit E 12.5 is obtainable as an organic solution. The substance is a transparent to slightly cloudy, thin consistency, light yellow liquid with a distinct smell of a solvent. Eudragit EPO is available as a powder with a distinct amine-like scent.

A recent literature analysis of Eudragit E 100 reveals its extensive use in various pharmaceutical applications such as nanoparticles, microparticles, transdermal sprays, ocular drops, and floating drug delivery systems. Quinteros et al. [8] introduced a new eye drop solution that relies on the ionic complexation of Eudragit E 100 and flurbiprofen. The dispersion of the drug-Eudragit complex in a 0.9% w/v sodium chloride (NaCl) solution resulted in enhanced release of flurbiprofen by ion exchange, regulated release without causing irritation, and improved penetration into the cornea. Paradkar et al. [9] developed clotrimazole transdermal sprays by combining various proportions of ethanol and acetone, as well as different types of Eudragit and ethylcellulose. The following factors were assessed: drying time, viscosity, appearance, adhesion, water washability, and skin integrity. The intended specifications were met by using Eudragit E100 in combination with a blend of ethanol and acetone at a ratio of 80:20. The optimised formulation demonstrated enhanced drug permeability across rat skin and better antifungal effectiveness, as shown by a broader zone of inhibition. Dominguez et al. [10] used Eudragit® E 100 as the polymer and created suspensions of triclosan nanoparticles using the solvent-shift emulsification-diffusion technique. Triclosan was evenly distributed at a molecular level inside the nanoparticle batches that also contained triclosan. The nanoparticles exhibited greater permeability in comparison to both solutions and creams. Patil et al. [11] examined the efficacy of Eudragit E 100 as a taste-masking ingredient in orally disintegrating tablets that contained tramadol hydrochloride. The findings indicated that it effectively concealed the unpleasant taste.

No scientific literature on Eudragit 12.5 was identified in any journal indexed by PubMed. An extensive analysis of the applications of Eudragit EPO shown its suitability for many formulations, including solid dispersions, orally disintegrating tablets, nanoparticles, nanosuspensions, and as an effective moisture barrier for stabilising liposomes and solid dosage forms. Cantor et al. [12] investigated the ability of Eudragit EPO to conceal the taste of clindamycin hydrochloride by creating orally disintegrating tablets. The study showed that

the use of Eudragit EPO solution as a coating for clindamycin hydrochloride, followed by compression into tablets, enhanced clindamycin adherence in paediatric and geriatric patients. Salmani et al. [13] examined the potential for enhancing the solubility and bioavailability of orally disintegrating tablets made from a solid dispersion of atorvastatin with Eudragit EPO. The use of solid dispersion greatly enhanced the solubility of atorvastatin. In vivo tests demonstrated a 434% increase in bioavailability compared to conventional atorvastatin tablets. The researchers examined the capacity of Eudragit EPO nanoparticles to enhance the therapeutic efficacy of meloxicam and compared it to a traditional meloxicam solution. "Nanoparticles containing Meloxicam were prepared using the nanoprecipitation method using Eudragit EPO as the carrier." The optimised nanoparticles were shown to have decreased ulcerogenicity and enhanced anti-inflammatory properties. Hasanovic et al. [15] enhanced the physicochemical characteristics of liposomes by including cationic polymers, namely H. Chitosan and Eudragit EPO. The liposomes were prepared using high-pressure homogenization with 1,2-Dipalmitoyl-sn-glycero-3-phosphocholine (DPPC) as the main component. The stability of the polymer liposomes was confirmed by the measurements of zeta potential and average particle size. The polymer liposomes maintained a consistent particle size and zeta potential in the presence of medicines such as acyclovir and minoxidil. In addition, the application of chitosan or Eudragit EPO to the liposomes enhanced the permeation of both medicines through the skin. The enhanced dermal diffusion is believed to be attributed to the interaction between the negatively charged surface of the skin and the positively charged liposomes.

Eudragit L30, D55 and L100-55:

Eudragit L 30 D 55 is a water-based solution of an anionic polymer that has methacrylic acid as its functional group. The substance is a colourless, thin liquid with a faint distinctive smell. Eudragit L 100-55 is an anionic copolymer derived from methacrylic acid and ethyl acrylate, and it is available as a 30% aqueous dispersion. "The substance is a white powder that has a faint distinctive scent." Both variants of Eudragit possess a molecular weight of 320,000 g/mol, an acid number of 315 mg KOH/g polymer, and a glass transition temperature of 1100 °C. Both polymers possess a specific region intended for drug release in the duodenum and undergo dissolution at a pH level of 5.5. Both polymers are used for efficient and stable coatings that quickly dissolve in the upper intestine, provide regulated release, and enable targeted administration of drugs to the intestines.

A recent literature review on the applications of the polymer Eudragit L 30 D 55 indicates that it is commonly utilised in the production of microspheres, microparticles, film-coated tablets, pellets, transdermal films, enteric coatings, and other forms. These applications serve various purposes, including symptom alleviation, enhanced drug absorption, controlled release in the intestines, and sustained drug release. Nair et al. [16] assessed the efficacy of four distinct polymers, namely Eudragit L-30 D-55, hydroxypropyl methylcellulose phthalate, cellulose acetate phthalate, and acrylic EZE®, in the formulation of enteric coated tablets containing esomeprazole magnesium trihydrate. Tablets that had a 5% increase in weight did not pass the disintegration test when exposed to a media containing 0.1 N HCl. The disintegration test revealed that 8% w/w of the enteric coating successfully passed. Eudragit L 30 D 55 and

Acrylic EZE, which are methacrylic polymers, exhibited superior dissolving rates compared to cellulose polymers. Naseem et al. [24] developed a transdermal film containing tenoxicam and Eudragit L 30D55, together with permeability enhancers such as polyethylene glycol (PEG) and propylene glycol (PG). The interaction between tenoxicam and Eudragit L30D-55 resulted in a drag effect, causing a delay in the release of tenoxicam. Bendas et al. [17] conducted a study where they tried using extrusion-spheronization to create pellets of ranitidine HCl. These pellets were then coated with a leaky enteric coating using a spray method. The pellets were prepared by combining Eudragit L 30 D-55 with PEG8000, surfactants, and soluble lactose, namely either Span 60 (hydrophobic) or Tween 80 (hydrophilic). In the event of a breach in the enteric-coated pellets, a certain quantity of the medication will be discharged into the stomach juice.

Moreover, a recent extensive investigation on the polymer Eudragit L100-55 indicates its potential for utilisation in many formulations, including pH-responsive medication release, taste masking, intestinal drug release, radiation protection, and more. Rotiker et al. [18] created a ketoprofen dosage form using extrusion and spheronization procedures. The idea is founded on the principle of pH-responsive double-pulse release. The pellets were coated with Eudragit S100, a pH-sensitive material, in order to achieve drug release at a particular spot and with a delayed timing. After a delay of 2 and 5 hours, a dual-pulse release was seen. The first administration of the first dosage occurred over a period of 2 hours, starting at a pH level of 1.2 and then transitioning to a pH level of 6.8. The second dosage of pellets was administered at pH levels of 1.2, 6.8, and subsequently at pH 7.5 for the duration of the trial. The researchers determined that a multiparticulate formulation of ketoprofen helped alleviate circadian symptoms of rheumatoid arthritis that occur between late-night and early-morning hours. Maniruzzaman et al. [19] created extrudates of the cationic model medicine propranolol HCl by employing extrusion and spheronization procedures with anionic polymers Eudragit L100 and Eudragit L100-55. The determination of taste masking was conducted using an electronic tongue. The use of FT-IR spectroscopy and NMR research allowed for the identification of intermolecular interactions as a mechanism for effectively disguising taste. Aguilar et al. [28] used an electrospinning technique to produce nanofibers utilising polyurethane and Eudragit® L100-55. The composite mats exhibited satisfactory mechanical capabilities and cellular biocompatibility in laboratory conditions, indicating that the material has the potential to be used as a protective layer for drug-eluting stents. "DeBarros et al. [29] created a formulation of laminated polymer film for delivering live vaccinations and probiotic microorganisms to the intestines." Polymer laminates based on Eudragit L 100-55 effectively shielded dried probiotic or live bacterial vaccine cells from simulated gastric fluid (SGF) for a duration of 2 hours. Subsequently, all live cells were discharged into simulated intestinal fluid within 60 minutes after transfer.

Eudragit NE30D, NE40D and NM30D:

Eudragit NE 30D, NE 40D, and NM 30D are water-based solutions containing neutral copolymers derived from ethyl acrylate and methyl methacrylate. These liquids are milky white, have a small distinctive odour, and have low viscosity. The minimum temperature required for film formation is 50 °C for all three. NE 30D and 40D both have a molecular

weight of around 750,000 g/mol, whereas NM 30D has a molecular weight of 600,000 g/mol. NE 30 D and 40D exhibit a glass transition temperature (Tg) of around 80 °C, whereas NM 30 D exhibits a Tg of around 11 °C. Eudragit NE 30D, NE 40D, and NM 30D are offered as aqueous dispersions with concentrations of 30%, 40%, and 30%, respectively. All of them are very adaptable and do not need the use of plasticizers. They are used in the development of controlled release products that are unaffected by the pH of the gastrointestinal tract.

Eudragit NE 30D is extensively used in modified release formulations across a range of dosage forms, including multiparticulates, microparticles, pellets, and films, as shown in Table 6. [52] devised a multiparticulate floating drug delivery system including zolpidem tartrate to prolong the duration of stay in the stomach and enhance the absorption of the medicine. The system included a membrane consisting of an effervescent layer (sodium bicarbonate) and a polymer layer (Eudragit NE 30D). The drug release in a laboratory setting was influenced by the amount of coating on the polymeric membrane (Eudragit(®) NE 30D), which had a crucial impact on the release of the medication. Kumaria et al. [20] created and assessed a loratidine buccal film for the treatment of allergic rhinitis. Loratidine buccal adhesive films were formulated by combining hydroxypropylmethylcellulose (HPMC)-E5, K100, and Eudragit® NE 30D as a retardant. The films were fabricated using a solvent casting technique. The addition of higher amounts of Eudragit® NE 30 D in the films resulted in reduced hydration, erosion, and drug release, while simultaneously prolonging the mucoadhesion duration.

Eudragit NE 40 D has been extensively studied in the literature for its use in the pharmaceutical field. It has been shown to be effective in many uses such as an adhesive film for oral administration and a non-occlusive skin treatment system for modifying drug release and improving bioavailability. Kumulia et al. [21] fabricated oral adhesive films containing prednisolone utilising hydroxypropyl methylcellulose (K100), Carbopol 940, and/or Eudragit® NE 40–D by a solvent casting technique. Administering prednisolone by the buccal route was determined to be a feasible choice. Minghetti et al. [22] created a cohesive structure by combining Plastoid E 35 L, a hydrophilic sticky polymer, with Eudragit NE 40 D, a hydrophobic polymer that can control the release of drugs. Continuous medication delivery maintained for a minimum of 24 hours by the system. No scientific material on formulations using Eudragit NM 30D could be located in PubMed indexed journals.

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