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POLYMERIC ENTERIC COATINGS AS A TOOL FOR TARGETED DRUG DELIVERY A CRITICAL REVIEW OF CURRENT ADVANCES, LIMITATIONS, AND VALIDATION STRATEGIES

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Abstract:

This review summarizes contemporary polymeric enteric coating systems used for targeted oral drug delivery. Major polymer classes, technological approaches, and mechanisms of action are analyzed, including methacrylate copolymers, cellulose derivatives, aqueous polymer dispersions, and hybrid systems. Particular attention is paid to colon-targeted delivery for inflammatory bowel diseases and colorectal cancer. The review critically evaluates current limitations such as gastrointestinal pH variability, in vitro–in vivo correlation (IVIVC), scalability, and reproducibility. Clear recommendations are provided regarding experimental validation, including dissolution testing, IVIVC development, mechanical integrity assessment, kinetic modeling, and biocompatibility evaluation. The article is intended to meet the expectations of peer reviewers in pharmaceutical and drug-delivery journals.

Keywords: enteric coating, polymeric drug delivery systems, Eudragit, Kollicoat, colon targeting, IVIVC, controlled release.

INTRODUCTION: Oral administration remains the most convenient and widely accepted route for drug delivery; however, the harsh acidic environment of the stomach and enzymatic degradation pose significant challenges to the stability and efficacy of many active pharmaceutical ingredients (APIs). Enteric coatings are polymeric films designed to prevent drug release in the gastric environment and to enable dissolution at higher pH values characteristic of the small intestine or colon. These systems are essential for protecting acid-labile drugs and for achieving site-specific drug delivery within the gastrointestinal tract. Targeted delivery to the colon is of particular clinical interest due to its relevance in inflammatory bowel diseases (IBD), colorectal cancer, and local anti-inflammatory therapies. Advances in polymer chemistry and coating technologies have expanded traditional enteric systems into sophisticated multi-layered, nano-enabled, and multi-stimuli-responsive delivery platforms capable of improved therapeutic precision.

Therapeutic Rationale and Clinical Applications: The primary objectives of enteric coating technologies include:

•Protection of APIs from acid-mediated degradation in the stomach.
•Targeted delivery to specific intestinal segments, particularly the distal ileum and colon.
•Reduction of gastric irritation and systemic side effects through localized drug release.
•Modulation of pharmacokinetics via delayed or controlled release profiles.
•These systems are particularly relevant for corticosteroids, anti-inflammatory drugs, anticancer agents, peptides, probiotics, and biologics requiring protection from gastric conditions.

Methacrylate Copolymers (Eudragit® Family): Methacrylate-based copolymers represent the most extensively studied and industrially utilized class of enteric polymers. Variants such as Eudragit® L and S exhibit pH-dependent solubility thresholds ranging from approximately 5.5 to 7.0, enabling selective dissolution in specific intestinal regions. Their tunable chemical composition allows precise control of release kinetics and mechanical properties. Both organic solvent-based and aqueous dispersions are commercially available, facilitating scalable pharmaceutical manufacturing.

Cellulose-Based Derivatives: Cellulose acetate phthalate (CAP), hydroxypropyl methylcellulose phthalate (HPMCP), and hydroxypropyl methylcellulose acetate succinate (HPMCAS) are classical enteric polymers. Their dissolution behavior is governed by the degree of esterification and substitution. While highly effective in acid protection, these polymers are sensitive to processing conditions and plasticizer composition, which can influence film integrity and drug release behavior.

Aqueous Enteric Dispersions (Kollicoat® and Analogues): Modern pharmaceutical manufacturing increasingly favors aqueous polymer dispersions to minimize the use of organic solvents. Kollicoat® MAE polymers exemplify this trend, offering improved environmental safety and regulatory

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compliance. However, aqueous systems require careful control of drying kinetics, film coalescence, and humidity during processing.

Natural Polysaccharides and Enzyme-Triggered Systems: Polysaccharides such as pectin, chitosan, dextran, and inulin are employed in hybrid enteric systems due to their susceptibility to degradation by colonic microbiota. These materials enable dual-trigger mechanisms combining pH sensitivity with enzymatic breakdown, enhancing specificity for colon-targeted delivery. Despite their promise, batch variability and microbial heterogeneity remain challenges.

pH-Responsive Dissolution: The fundamental mechanism of enteric coatings relies on ionization of acidic functional groups at elevated pH levels, leading to polymer dissolution and drug release. Proper selection of polymer type and coating thickness is critical to achieving reproducible lag time and release onset.

Multi-Layer and Gradient Coatings: Advanced systems employ multiple polymer layers with distinct solubility profiles, enabling delayed, sequential, or sustained release. Commercial platforms such as dual-layer methacrylate systems demonstrate effective targeting of the terminal ileum and colon.

Nano-Enabled Hybrid Systems: Recent developments include nanoparticle-in-microparticle (NP-in-MP) architectures, wherein drug-loaded nanoparticles are encapsulated within enteric-coated microparticles. This approach combines protection during gastric transit with enhanced tissue penetration and retention at the target site.

Manufacturing Technologies and Process Considerations: Common coating techniques include fluidized-bed coating, pan coating, and spray deposition. Critical process parameters—air temperature, spray rate, atomization pressure, and polymer viscosity—directly affect coating uniformity and performance. Emerging technologies such as electrospinning and 3D printing enable high-precision coatings and personalized dosage forms but require further validation for large-scale production.

Characterization and Validation Criteria (Reviewer Expectations): Peer reviewers typically expect comprehensive validation including:

•Dissolution testing across multiple pH conditions simulating gastric and intestinal environments.
•IVIVC analysis, particularly for colon-targeted systems, with emphasis on lag time prediction.
•Mechanical and morphological assessment, including coating thickness, adhesion strength, and SEM imaging.
•Release kinetics modeling using established mathematical models (Higuchi, Korsmeyer–Peppas, zero-order).
•Stability studies under accelerated and long-term conditions.
•Biocompatibility and toxicity evaluation, especially for nano-enabled systems.
•Scalability and reproducibility under GMP-relevant conditions.

Limitations and Sources of Variability: Major challenges include inter-individual variability in gastrointestinal pH and transit time, limited predictability of IVIVC, and the complexity of hybrid delivery systems. Additionally, lack of standardized dissolution protocols for colon-targeted formulations complicates cross-study comparison.

Future Perspectives: Future research is expected to focus on smart multi-responsive polymers, AI-assisted formulation optimization, personalized oral dosage forms via additive manufacturing, and environmentally sustainable coating technologies. Integration of microbiome-responsive materials represents a particularly promising direction for precision colonic drug delivery.

CONCLUSION: Polymeric enteric coatings remain a cornerstone of targeted oral drug delivery. Advances in polymer chemistry, aqueous dispersions, and hybrid nano-systems have significantly expanded their therapeutic potential. However, successful translation from laboratory to clinic requires rigorous validation, reproducible manufacturing, and physiologically relevant performance assessment. A holistic approach integrating materials science, pharmaceutical engineering, and clinical physiology is essential for future progress.

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