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Review Article

Development and evaluation of Enteric-coated tablets: A review

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Abstract

Enteric-coated tablets represent an important category of modified oral drug delivery systems designed to prevent drug release in the acidic environment of the stomach and allow selective release in the intestine. This dosage form is particularly beneficial for drugs that are unstable in gastric conditions, cause gastric irritation, or require site-specific intestinal absorption. The development of enteric-coated tablets involves careful selection of core tablet composition, enteric polymers, coating techniques, and evaluation methods to ensure consistent performance and regulatory compliance. Various polymers, including cellulose-based derivatives and methacrylic acid copolymers, have been extensively studied for their pH-dependent solubility and film-forming properties. Evaluation of enteric-coated tablets includes tests for acid resistance, disintegration, dissolution, stability, and release kinetics. This review provides a comprehensive overview of the principles, formulation strategies, coating technologies, polymers used, and evaluation parameters involved in the development of enteric-coated tablets, highlighting their significance in improving therapeutic efficacy, gastric tolerability, and patient compliance.

Keywords: Enteric-coated tablets; pH-dependent polymers; delayed-release dosage forms; film coating; dissolution studies; oral drug delivery.

1. Introduction

Oral drug delivery remains the most preferred route of administration due to its convenience, safety, cost-effectiveness, and high patient acceptance. Among oral dosage forms, tablets are widely used because of their dose accuracy, stability, ease of manufacturing, and suitability for large-scale production [1]. However, conventional immediate-release tablets may not be ideal for drugs that are acid-labile, irritating to the gastric mucosa, or intended for intestinal-specific action. To overcome these limitations, modified oral drug delivery systems such as enteric-coated tablets have been developed [2].

Enteric-coated tablets are designed to withstand the acidic pH of the stomach and disintegrate only after reaching the higher pH of the intestine. This selective drug release is achieved through the application of pH-dependent polymeric coatings, which remain insoluble at low pH but dissolve or rupture at intestinal pH [3]. Such systems are particularly useful for protecting drugs from acid degradation, minimizing gastric irritation, and achieving site-specific delivery in the gastrointestinal tract [4].

The development of enteric-coated tablets requires a systematic approach that includes formulation of a suitable core tablet, selection of appropriate enteric polymers, optimization of coating parameters, and rigorous evaluation of performance characteristics [5]. Advances in polymer science and coating technology have led to the availability of a wide range of enteric polymers, such as cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, and methacrylic acid copolymers, each offering distinct dissolution thresholds and release profiles [6].

Evaluation of enteric-coated tablets is equally critical to ensure compliance with pharmacopoeial standards. Parameters such as acid resistance, disintegration time in intestinal pH, dissolution behavior, mechanical integrity, and stability play a crucial role in determining the quality and effectiveness of the final dosage form. Proper evaluation ensures that the tablet provides consistent gastric protection and predictable intestinal drug release [7].

This review aims to present a comprehensive overview of the development and evaluation of enteric-coated tablets, focusing on formulation principles, coating technologies, polymers employed, and evaluation strategies. By summarizing key findings from reported literature, this article highlights the importance of enteric-coated tablets in modern oral drug delivery and their role in improving therapeutic outcomes and patient compliance [8].

2. Rationale for enteric coating

Enteric coating is a specialized pharmaceutical technique employed to achieve delayed and site-specific drug release within the gastrointestinal tract. The primary objective of enteric coating is to prevent drug release in the acidic environment of the stomach and to ensure that the drug is released only after the dosage form reaches the intestine. The rationale for enteric coating arises from several physicochemical, physiological, and therapeutic considerations, which are discussed below [9].

2.1 Protection of Acid-Labile Drugs

Many drugs are chemically unstable in acidic conditions and undergo degradation in the gastric environment, leading to reduced therapeutic efficacy. Enteric coating provides a protective barrier that shields such drugs from gastric acid, ensuring that they remain intact until they reach the more favorable pH conditions of the intestine. This protection enhances drug stability and bioavailability [10].

2.2 Reduction of Gastric Irritation and Adverse Effects

Certain drugs are known to cause gastric irritation, ulceration, or discomfort when released in the stomach. Enteric coating delays drug release, thereby minimizing direct contact of the drug with the gastric mucosa. This approach is particularly beneficial for drugs that are irritating in nature or require prolonged therapy, as it improves patient tolerability and compliance [11].

2.3 Targeted Intestinal Drug Release

Enteric coating enables site-specific drug **delivery** by releasing the drug in the intestine, where absorption may be more efficient or where local therapeutic action is required. Targeted intestinal release is advantageous for drugs intended to act locally in the intestine or those with pH-dependent absorption characteristics [12].

2.4 Improvement in Therapeutic Efficacy

By ensuring that drug release occurs at the appropriate site and time, enteric coating helps maintain optimal drug concentrations at the absorption site, leading to improved therapeutic outcomes. Delayed release can also reduce fluctuations in plasma drug levels, contributing to more predictable pharmacokinetic profiles [13].

2.5 Protection of Gastric Mucosa from Drug-Induced Damage

Some drugs can damage the gastric lining upon prolonged exposure. Enteric coating acts as a protective strategy for the gastric mucosa, reducing the risk of ulceration and inflammation. This is particularly relevant for drugs requiring chronic administration [14].

2.6 Enhancement of Patient Compliance

By reducing gastric side effects and improving tolerability, enteric-coated tablets enhance patient acceptance and adherence to therapy. Improved compliance is especially important in long-term treatment regimens [15].

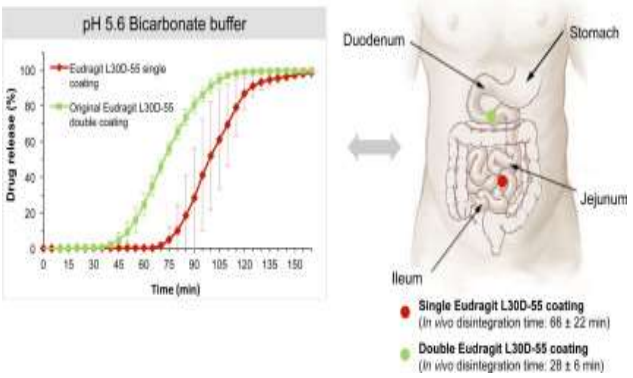
2.7 Compatibility with Modern Polymer Technologies

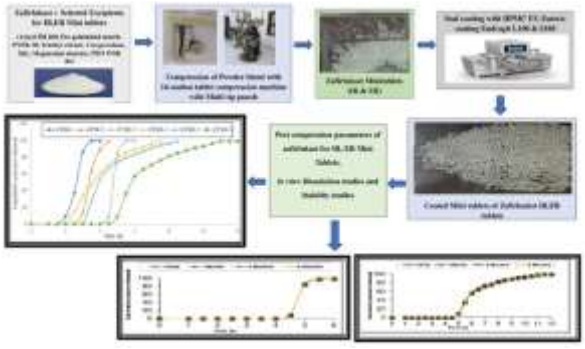
Advancements in pH-dependent polymer science and coating technologies have made enteric coating more reliable and reproducible. Modern enteric polymers provide precise dissolution thresholds and uniform film formation, enabling consistent performance and regulatory compliance [16].

The rationale for enteric coating lies in its ability to protect drugs and the gastric environment, enable targeted intestinal release, improve therapeutic efficacy, and enhance patient compliance. As a result, enteric-coated tablets play a vital role in modern oral drug delivery systems and continue to be widely employed for drugs with specific gastrointestinal delivery requirements [17].

3. Polymers Used in Enteric-Coated Tablets

Enteric coating performance is primarily governed by the type of polymer used, as these polymers determine the pH threshold for dissolution, film integrity in gastric conditions, and drug release behavior in the intestine. Enteric polymers are generally weak acids that remain unionized and insoluble in acidic pH but ionize and dissolve at higher intestinal pH values. Based on their origin and chemical nature, enteric polymers can be broadly classified into natural, semi-synthetic (cellulose-based), and synthetic polymers [18].





3.1 Natural Polymers

Natural polymers such as shellac and zein were among the earliest materials used for enteric coating. These polymers provide acid resistance but suffer from batch-to-batch variability, poor reproducibility, and stability issues, which limit their use in modern pharmaceutical formulations. Consequently, their application has largely declined in favor of more predictable synthetic alternatives [19].

3.2 Semi-Synthetic (Cellulose-Based) Polymers

Cellulose derivatives are widely used due to their good film-forming properties, regulatory acceptance, and reliable enteric performance. Common examples include cellulose acetate phthalate (CAP)**,** hydroxypropyl methylcellulose phthalate (HPMCP)**, and** hydroxypropyl methylcellulose acetate succinate (HPMCAS)**.** These polymers dissolve at different intestinal pH ranges depending on their degree of substitution, allowing some control over the site of drug release [20].

3.3 Synthetic Polymers

Synthetic polymers, particularly **methacrylic acid copolymers**, are extensively used in modern enteric coating applications. These polymers are available in different grades with well-defined pH dissolution thresholds, offering precise control over drug release location. They provide excellent film flexibility, uniform coating, and reproducible dissolution behavior, making them highly suitable for industrial-scale manufacturing [21].

3.4 Comparison of Enteric Polymers

Table 3.1: Comparative Evaluation of Commonly Used Enteric Polymers

Polymer	Polymer type	pH of dissolution	Key advantages	Limitations
Shellac	Natural	≥ 7.0	Good acid resistance	Variable quality, aging effects
Zein	Natural	≥ 6.5	Biocompatible	Poor reproducibility
Cellulose acetate phthalate (CAP)	Semi-synthetic	≥ 6.0	Widely used, good film strength	Brittle films, solvent-based
HPMCP	Semi-synthetic	5.0–6.0	Early intestinal release	Moisture sensitivity
HPMCAS	Semi-synthetic	5.5–6.8	Adjustable release, good stability	Higher cost
Methacrylic acid copolymer (Type L)	Synthetic	≥ 6.0	Rapid intestinal release, flexible films	Costlier than cellulose polymers
Methacrylic acid copolymer (Type S)	Synthetic	≥ 7.0	Distal intestinal release	Slower onset of release

3.5 Significance of Polymer Selection

The selection of an appropriate enteric polymer is critical for achieving the **desired release profile**.

- **Lower pH-threshold polymers** (e.g., HPMCP, methacrylic acid Type L) are suitable for **early intestinal release**.
- **Higher pH-threshold polymers** (e.g., methacrylic acid Type S) are preferred for **distal intestinal or colonic targeting**.

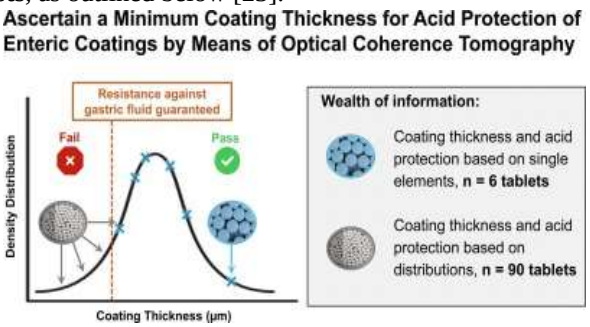
In addition to polymer type, **coating thickness, plasticizer content, and processing conditions** also influence enteric performance and must be optimized during formulation development.

Enteric polymers play a pivotal role in the **design and performance of enteric-coated tablets**. Among available options, **cellulose-based and methacrylic acid copolymers** are most widely used due to their **predictable pH-dependent solubility and regulatory acceptance**. Comparative evaluation of these polymers enables rational selection of an appropriate coating system to achieve **effective gastric protection and targeted intestinal drug release** [22].

4. Evaluation Parameters

Evaluation of enteric-coated tablets is essential to ensure that the dosage form provides **effective gastric resistance, reproducible intestinal drug release, mechanical integrity, and stability** in accordance with pharmacopoeial and regulatory requirements. The quality and performance of enteric-coated tablets are assessed

using a combination of **physical, chemical, and functional tests**, as outlined below [23].



4.1 Physical Evaluation Parameters

4.1.1 Appearance and Coating Uniformity

Enteric-coated tablets are visually examined for:

- Color uniformity
- Surface smoothness
- Absence of defects such as cracks, peeling, blistering, or mottling

A uniform, defect-free coating indicates proper formulation and optimized coating conditions [24].

4.1.2 Weight Variation

Weight variation is evaluated to ensure **uniform coating thickness and dose consistency**. Excessive variation may indicate non-uniform coating or poor process control [25].

4.1.3 Hardness and Friability

- **Hardness** ensures sufficient mechanical strength to withstand handling and packaging.
- **Friability** assesses resistance to abrasion and shock; values below **1%** are generally acceptable.

Adequate hardness and low friability are crucial to maintain **coating integrity** during storage and transport.

4.2 Acid Resistance Test

The acid resistance test is the most critical evaluation for enteric-coated tablets.

- **Medium:** 0.1 N HCl (pH ≈ 1.2)
- **Duration:** 2 hours
- **Requirement:** No disintegration, cracking, or drug release

This test confirms the ability of the enteric coating to **protect the tablet core from gastric conditions**.

4.3 Disintegration Test

Disintegration is evaluated using a **two-stage method**:

1. **Acid stage:**
    - Medium: 0.1 N HCl
    - Tablets should remain intact
2. **Buffer stage:**
    - Medium: Phosphate buffer pH 6.8
    - Tablets should disintegrate within the specified pharmacopoeial time

This test ensures **pH-dependent behavior** of the enteric polymer.

4.4 In-Vitro Dissolution Studies

Dissolution testing is performed to evaluate **drug release behavior**.

- **Apparatus:** USP Type I or II
- **Conditions:** 37 ± 0.5 °C
- **Two-stage dissolution:**
    - Acid stage (0.1 N HCl)
    - Buffer stage (pH 6.8)

No drug release should occur during the acid stage, followed by **rapid and reproducible release in intestinal pH**.

4.5 Drug Content Uniformity

Drug content is determined to ensure that each tablet contains the intended amount of active ingredient. Acceptable limits typically range between **90–110%** of the labeled claim [26].

4.6 Release Kinetics and Mechanism

Dissolution data are analyzed using kinetic models such as:

- Zero-order
- First-order
- Higuchi model
- Korsmeyer–Peppas model

This analysis helps in understanding the **mechanism of drug release** once the enteric coat dissolves.

4.7 Stability Studies

Stability testing is conducted as per **ICH guidelines** to evaluate the effect of temperature and humidity on:

- Physical appearance
- Drug content
- Acid resistance
- Dissolution behavior

Stability studies ensure **shelf-life prediction and formulation robustness**.

4.8 Regulatory and Pharmacopoeial Compliance

Enteric-coated tablets must comply with standards specified in:

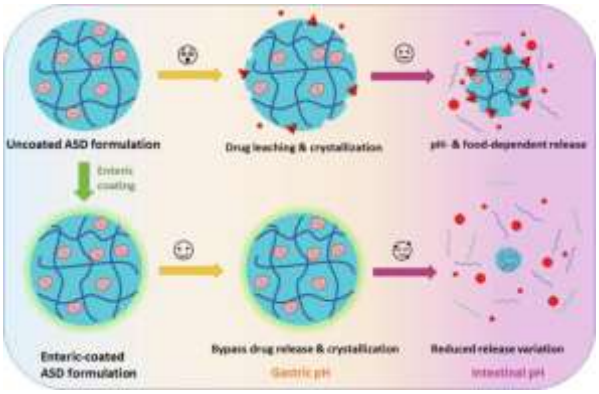
- **Indian Pharmacopoeia (IP)**
- **United States Pharmacopeia (USP)**
- **ICH guidelines**

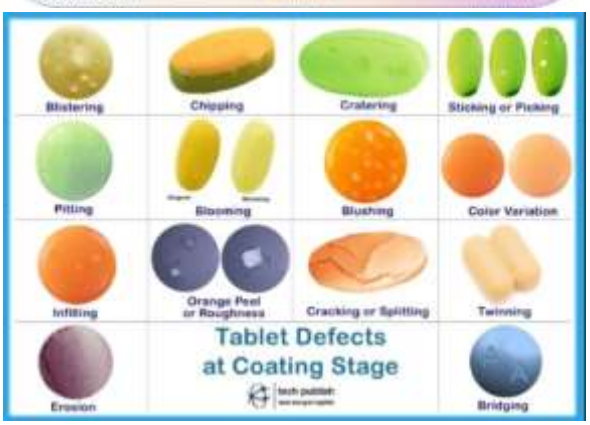
Compliance ensures **quality, safety, and therapeutic efficacy** of the dosage form.

Evaluation parameters play a vital role in determining the **quality and performance of enteric-coated tablets**. Comprehensive assessment of physical properties, acid resistance, disintegration, dissolution, drug content, and stability ensure that the formulation provides **consistent gastric protection and targeted intestinal drug release**, making enteric-coated tablets a reliable and effective oral dosage form [27].

5. Challenges in Enteric-Coated Tablet Development

Despite the widespread use of enteric-coated tablets, their development presents several **formulation, processing, and regulatory challenges**. These challenges arise from the complex interplay between **drug properties, polymer behavior, coating technology, and gastrointestinal physiology**. Understanding and addressing these issues is essential to achieve a robust and reproducible enteric-coated dosage form [28].





5.1 Selection of Suitable Enteric Polymer

One of the primary challenges is the **selection of an appropriate enteric polymer** with the desired pH-dependent solubility.

- Polymers differ in their **pH dissolution threshold**, which directly affects the site and onset of drug release.
- Inappropriate polymer selection may lead to **premature drug release in the stomach or delayed release in the intestine**, compromising therapeutic efficacy.

Balancing polymer type, grade, and concentration is therefore critical.

5.2 Optimization of Coating Thickness and Uniformity

Achieving **uniform coating thickness** is technically demanding:

- **Insufficient coating thickness** may result in failure of acid resistance.
- **Excessive coating thickness** can delay disintegration and drug release in intestinal pH.

Maintaining uniformity across large batches requires precise control of **spray rate, pan speed, atomization pressure, and drying conditions**.

5.3 Core Tablet Properties

The performance of enteric-coated tablets is strongly influenced by the **quality of the core tablet**:

- Inadequate hardness may lead to **tablet breakage during coating**.
- Excessively hard tablets may show **delayed disintegration** even after the enteric coat dissolves.
- Poor flow or content non-uniformity in core tablets can result in **batch-to-batch variability**.

Thus, designing a robust core tablet capable of withstanding the coating process is a major challenge.

5.4 Moisture and Solvent Sensitivity

Many enteric polymers, particularly in **aqueous coating systems**, are sensitive to moisture:

- Prolonged exposure to water during coating can cause **drug migration, degradation, or core swelling**.
- Solvent-based coatings, although effective, raise concerns related to **toxicity, environmental safety, and residual solvents**.

Selecting a suitable coating system while protecting moisture-sensitive drugs remains a significant formulation hurdle.

5.5 Coating Defects and Process-Related Issues

Enteric coating processes are prone to defects such as:

- Cracking
- Peeling
- Blistering
- Orange peel effect
- Twinning

These defects may compromise **acid resistance and aesthetic quality** of the tablets. Process optimization and skilled operation are essential to minimize such issues [29]

5.6 Variability in Gastrointestinal pH and Transit Time

Physiological factors such as inter-individual variability in gastric pH, intestinal pH, and gastric emptying time can affect the in-vivo performance of enteric-coated tablets. Variations in food intake, disease conditions, and age further complicate predictable drug release, posing challenges in achieving consistent **in-vitro–in-vivo correlation (IVIVC)** [30].

5.7 Stability Issues

Enteric polymers may undergo **chemical or physical changes during storage**, leading to:

- Altered dissolution behavior
- Loss of acid resistance

- Changes in film flexibility

Ensuring long-term stability under different climatic conditions is a key challenge, particularly for formulations intended for tropical regions [31].

5.8 Regulatory and Quality Control Challenges

Enteric-coated tablets must comply with **stringent pharmacopoeial and regulatory requirements**, including:

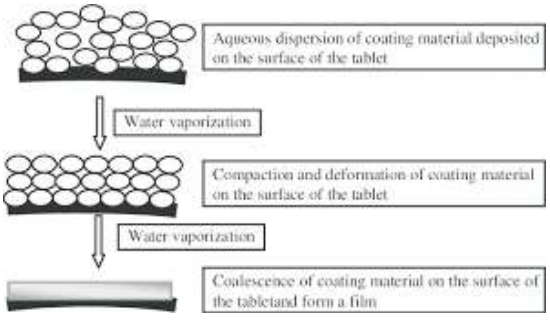
- Acid resistance testing
- Two-stage disintegration and dissolution testing
- Stability testing as per ICH guidelines

Meeting these requirements consistently during scale-up and commercialization adds to development complexity.

The development of enteric-coated tablets is a **multifactorial and technically demanding process**. Challenges related to polymer selection, coating uniformity, core tablet design, moisture sensitivity, coating defects, physiological variability, stability, and regulatory compliance must be carefully addressed. Overcoming these challenges through rational formulation design, advanced coating technologies, and thorough evaluation strategies is essential for the successful development of effective and reliable enteric-coated tablet dosage forms [32].

6. Recent Advances in Enteric Coating Technology

Recent progress in polymer science, process engineering, and analytical evaluation has significantly improved the **reliability, safety, reproducibility, and performance** of enteric-coated tablets. Modern enteric coating technologies now enable **precise control of coating quality and site-specific drug release**, while meeting stringent regulatory expectations. Key advances are summarized below [33].



6.1 Advanced pH-Responsive and Tailored Polymer Systems

Modern enteric coatings increasingly use **engineered polymer grades** that provide:

- More precise **pH-triggered dissolution**
- Improved **film flexibility** and reduced cracking
- Better **adhesion** to different tablet cores

Examples include optimized grades of **HPMCAS/HPMCP** and **methacrylic acid copolymers (Type L, S and mixed blends)**. Polymer blending is also used to fine-tune:

- **lag time**
- **release site** (proximal vs distal intestine)
- **release rate** after coat dissolution

6.2 Shift Toward Aqueous Enteric Coating Systems

A major trend is the replacement of organic solvents with **aqueous polymer dispersions**, due to:

- Better environmental safety
- Reduced operator exposure
- Lower residual solvent risk

Advancements in aqueous systems include:

- Improved latex dispersions for smoother films
- Faster drying through optimized process conditions
- Use of **anti-tacking agents** and improved plasticizers to minimize sticking and defects [34]

6.3 Improved Plasticizers, Stabilizers, and Additives

Modern formulations incorporate optimized excipients to enhance film properties:

- **Plasticizers (e.g., triethyl citrate, PEG grades)** improve flexibility and reduce brittleness
- **Anti-tacking agents** reduce sticking, twinning, and picking
- **Pigments/opacifiers** improve appearance and photostability
- **Pore formers** can be used to modulate the onset and rate of intestinal release

These advances have reduced coating defects and improved batch reproducibility.

6.4 High-Efficiency Coating Equipment and Process Automation

Modern coating equipment provides:

- Enhanced spray uniformity and mixing
- Precise control of **inlet/outlet temperature, spray rate, atomization, and airflow**
- Improved scalability from lab to commercial batches

Technologies such as:

- **Perforated pan coaters**
- **fluid bed coaters (Wurster process)** have improved coating efficiency, reduced processing time, and minimized variability.

6.5 Process Analytical Technology (PAT) and Quality-by-Design (QbD)

A highly significant advancement is the application of **PAT and QbD** concepts in coating operations:

- Inline monitoring of coating thickness and uniformity using **NIR spectroscopy**
- Real-time assessment of moisture content and drying end point
- Statistical process control to maintain critical quality attributes (CQAs)

PAT tools reduce batch failures and support regulatory expectations for consistent quality.

6.6 Functional Multilayer and Hybrid Coating Systems

Recent formulation strategies include **multi-layer coatings** to achieve enhanced performance:

- **Seal coat + enteric coat** to prevent drug migration and core degradation
- **Subcoat (barrier layer)** to improve adhesion for difficult APIs
- **Enteric + sustained release layers** for complex delivery goals (chronotherapy, dual release)

Hybrid coating systems improve stability and allow more customized release profiles.

6.7 Enteric-Coated Multiparticulate Systems (MUPS and Pellets)

Enteric technology has expanded beyond single tablets to:

- **Enteric-coated pellets in capsules**
- **MUPS (Multiple-Unit Pellet System) tablets**

Advantages:

- Reduced risk of dose dumping
- Better distribution in the GI tract
- More consistent release and reduced variability between patients

6.8 Better In-Vitro Tools for Biorelevant Evaluation

Dissolution testing now increasingly uses:

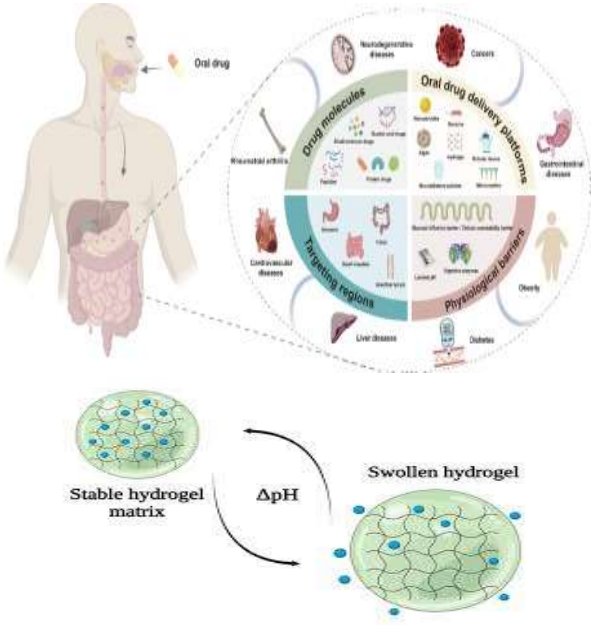
- **two-stage dissolution protocols**
- **biorelevant media** simulating fed/fasted states
- improved modeling approaches (f_2, DE%, kinetic fitting)

These tools strengthen prediction of in-vivo performance and support development of IVIVC.

Recent advances in enteric coating technology—particularly **aqueous polymer dispersions, tailored polymer blends, automated coating systems, PAT/QbD implementation, multilayer strategies, and multiparticulate enteric systems**—have significantly enhanced the performance and reproducibility of enteric-coated dosage forms. These developments support the design of **robust, stable, and patient-friendly enteric-coated tablets** with controlled, site-specific intestinal drug delivery [35].

7. Future Perspectives

The field of enteric coating technology continues to evolve in response to increasing demands for **precision drug delivery, patient-centric formulations, regulatory robustness, and sustainable manufacturing practices** [36]. Future developments are expected to focus on improving **predictability of in-vivo performance, formulation flexibility, and industrial scalability**, while addressing existing limitations of conventional enteric-coated systems [37].



7.1 Development of Smart and Stimuli-Responsive Polymers

Future research is likely to emphasize **next-generation enteric polymers** that respond not only to pH but also to other physiological stimuli such as:

- Enzymes
- Redox environment
- Microbiota-specific triggers

Such **smart polymers** could enable more precise site-specific delivery within different regions of the intestine or colon, enhancing therapeutic outcomes for targeted therapies [38].

7.2 Integration of Quality-by-Design (QbD) and Digital Manufacturing

The adoption of **QbD principles** will continue to expand, with greater reliance on:

- Identification of critical material attributes (CMAs)
- Control of critical process parameters (CPPs)
- Use of **design space** for regulatory flexibility

Additionally, **digital manufacturing tools**, including process modeling, real-time analytics, and artificial intelligence–based optimization, are expected to improve coating efficiency and batch-to-batch consistency [39].

7.3 Expansion of Enteric-Coated Multiparticulate Systems

Future enteric delivery systems are expected to increasingly utilize:

- **Enteric-coated pellets**
- **MUPS (Multiple-Unit Pellet Systems)**
- **Hybrid tablet–pellet dosage forms**

These systems offer advantages such as reduced inter-patient variability, improved GI distribution, and minimized risk of dose dumping, making them particularly suitable for **high-potency and narrow therapeutic index drugs** [40].

7.4 Improved In-Vitro–In-Vivo Correlation (IVIVC)

Advancements in **biorelevant dissolution testing, physiologically based pharmacokinetic (PBPK) modeling**, and simulation tools are expected to strengthen IVIVC for enteric-coated dosage forms [1]. This will:

- Reduce dependence on extensive in-vivo studies
- Accelerate product development timelines
- Enhance regulatory acceptance

7.5 Personalized and Patient-Centric Enteric Formulations

With the rise of **personalized medicine**, future enteric-coated products may be tailored based on:

- Patient age and physiology
- Disease state
- Feeding conditions

Customized enteric coatings with adjustable dissolution thresholds could improve therapeutic efficacy and patient adherence, especially in chronic therapies.

7.6 Sustainable and Green Coating Technologies

Environmental considerations will drive further innovation in:

- **Solvent-free and low-energy coating processes**
- Biodegradable and bio-based polymers
- Reduction of coating waste and energy consumption

Green enteric coating technologies will align pharmaceutical manufacturing with global sustainability goals.

Future perspectives in enteric coating technology highlight a transition toward **smarter polymers, digital and QbD-driven manufacturing, multiparticulate systems, improved IVIVC, personalized therapy, and sustainable practices**. These advancements are expected to significantly enhance the **efficacy, safety, and reliability** of enteric-coated tablets, reinforcing their importance in next-generation oral drug delivery systems.

8. Conclusion

Enteric-coated tablets represent a well-established and highly effective approach within oral drug delivery systems for achieving **gastric protection and site-specific intestinal drug release**. The application of pH-dependent polymeric coatings enables drugs that are acid-labile, gastric-irritant, or intended for intestinal action to be delivered more safely and effectively. This review has comprehensively discussed the **rationale, polymer selection, coating methods, evaluation parameters, challenges, recent technological advances, and future perspectives** associated with the development of enteric-coated tablets.

Advances in **enteric polymer chemistry**, particularly cellulose-based derivatives and methacrylic acid copolymers, have significantly improved the predictability and reproducibility of enteric-coated dosage forms. The evolution from solvent-based to **aqueous coating systems**, coupled with improvements in plasticizers, additives, and coating equipment, has enhanced product safety, environmental sustainability, and manufacturing efficiency. Furthermore, the integration of Quality-by-Design (QbD) and Process Analytical Technology (PAT) has strengthened process control, reduced variability, and facilitated regulatory compliance.

Despite these advances, the development of enteric-coated tablets continues to face challenges related to **polymer selection, coating uniformity, core tablet design, physiological variability, and long-term stability**. However, emerging trends such as **smart pH-responsive polymers, multiparticulate enteric systems, biorelevant dissolution testing, and digital manufacturing tools** offer promising solutions to overcome these limitations.

In conclusion, enteric-coated tablets remain a **critical and versatile dosage form** in modern pharmaceutical therapy. Continued innovation in materials, processing technologies, and evaluation methodologies is expected to further enhance their performance and clinical relevance. With ongoing research and technological integration, enteric coating technology is poised to play an increasingly important role in the development of **patient-centric, effective, and sustainable oral drug delivery systems**.

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