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## Review Paper

# Probiotic Based Gastroretentive in Situ Gel Systems: A Review

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## ABSTRACT

Probiotics are beneficial live microorganisms that improve host health by maintaining intestinal microbial balance, enhancing immune responses, and preventing gastrointestinal infections. Despite their therapeutic importance, oral delivery of probiotics faces several limitations such as degradation in acidic gastric pH, low viability during storage, poor intestinal colonization, and insufficient residence time in the gastrointestinal tract. To overcome these limitations, gastroretentive drug delivery systems (GRDDS), particularly floating in situ gel systems, have emerged as promising approaches for probiotic delivery. In situ gel systems are liquid formulations that transform into gels upon exposure to physiological conditions such as pH changes, ionic interaction, or temperature variation. These systems prolong gastric retention time, protect probiotics from harsh gastric environments, and provide controlled and sustained release. This review comprehensively discusses the principles of gastroretentive systems, probiotic encapsulation, polymers used in in situ gels, formulation approaches, optimization methods, evaluation parameters, mechanisms of drug release, characterization techniques, recent advancements, and future perspectives.

## INTRODUCTION

The oral route remains the most widely used route of drug administration due to its convenience, patient compliance, cost-effectiveness, and ease of self-administration [19]. However, the major limitation of oral delivery is the rapid gastric emptying and unpredictable gastrointestinal

transit, which reduces drug absorption in the upper gastrointestinal tract [24].

Probiotics are defined as “live microorganisms which, when administered in adequate amounts, confer a health benefit on the host” [1]. Common probiotic strains include *Lactobacillus*, *Bifidobacterium*, *Saccharomyces boulardii*, and *Streptococcus thermophilus* [13]. These

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microorganisms play a significant role in restoring gut microbiota balance, suppressing pathogenic bacteria, improving lactose digestion, and modulating immune responses [2,12].

However, probiotic viability is highly sensitive to gastric acid, bile salts, oxygen exposure, heat, and moisture, leading to significant loss of cell viability before reaching the intestine [8,9,26]. Because of this, encapsulation-based and polymer-based delivery systems have been widely investigated to improve survival and therapeutic effectiveness [25].

Among these systems, gastroretentive floating systems and *in situ* gels have gained attention because they increase gastric residence time and protect probiotics from harsh gastric environments [5,30].

## II. Gastroretentive Drug Delivery Systems (GRDDS)

**2.1 Introduction:** Gastroretentive drug delivery systems are advanced oral formulations designed to remain in the stomach for extended periods, thereby enhancing drug absorption and bioavailability. GRDDS is a system capable of prolonging gastric residence time and improving localized drug delivery. These systems are especially beneficial for drugs and probiotics that are primarily absorbed in the upper gastrointestinal tract. Conventional dosage forms rapidly leave the stomach, reducing therapeutic effectiveness, whereas GRDDS prolong gastric retention and provide controlled release. Floating systems are among the most effective GRDDS because they remain buoyant on gastric fluid due to reduced density. Prolonged gastric retention improves probiotic colonization, protects microorganisms from rapid elimination, and enhances therapeutic action.[4,10]

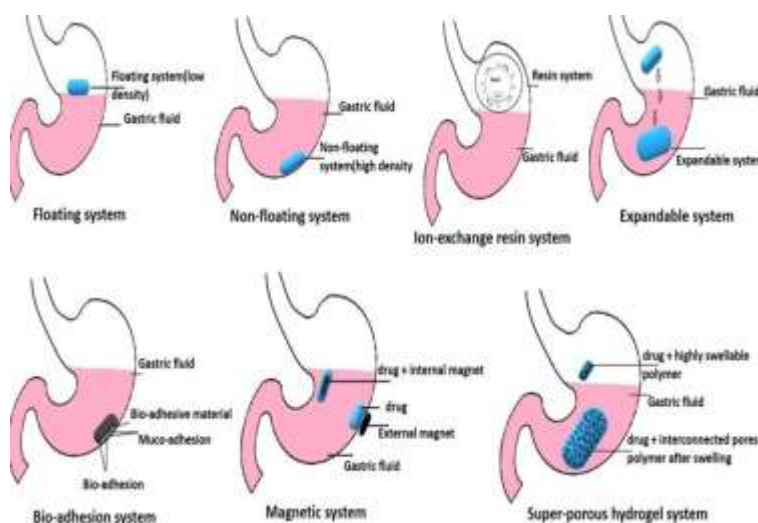


Figure 1: Schematic representation of various gastroretentive drug delivery systems

### 2.2 Rationale and Need

Conventional oral dosage forms are rapidly emptied from the stomach, resulting in reduced absorption and poor bioavailability [24]. This is especially critical for probiotics, which require sufficient time in the gastric region to survive and colonize the intestine [6].

Gastroretentive systems overcome this limitation by increasing gastric residence time and providing sustained release of the active agent [23]. This leads to improved therapeutic efficacy, reduced dosing frequency, and better patient compliance [4,10].

### 2.3 Advantages and Limitations of GRDDS

| Advantages [7, 17]        | Limitations [5, 18]              |
|---------------------------|----------------------------------|
| Improved Bioavailability  | Dependence on Gastric Physiology |
| Sustained Drug Release    | Unsuitable for Certain Drugs     |
| Reduced Dosing Frequency  | Formulation Complexity           |
| Better Patient Compliance | Limited Drug Loading             |

### III. Probiotics

#### 3.1 Introduction

Probiotics are live non-pathogenic microorganisms that provide health benefits when administered in adequate amounts. Probiotics as beneficial microorganisms capable of improving host health. Common probiotic strains include *Lactobacillus*, *Bifidobacterium*, and *Saccharomyces* species, which help improve digestion, prevent gastrointestinal infections, reduce diarrhea, and enhance immunity [1,3]. They exert their effects through competitive inhibition of pathogenic microorganisms and modulation of host immune responses [2]. Probiotics produce antimicrobial compounds such as organic acids and bacteriocins that inhibit pathogenic bacteria. However, maintaining probiotic viability during manufacturing, storage, and gastrointestinal transit remains a major challenge because these microorganisms are highly sensitive to acidic pH, bile salts, moisture, and oxygen [6,13].

#### 3.2 Therapeutic Applications

Probiotics are widely used in the treatment of gastrointestinal disorders such as diarrhea, irritable bowel syndrome, inflammatory bowel disease, and lactose intolerance [2,13]. They also exhibit immunomodulatory properties and contribute to maintaining intestinal barrier integrity [12].

#### 3.3 Challenges in Oral Probiotic Delivery

Oral delivery of probiotics is difficult because living microorganisms are exposed to harsh physiological and environmental conditions before reaching the intestine. As observed that

gastric acid destroys bacterial cell walls and significantly decreases probiotic viability during gastrointestinal transit. Bile salts damage microbial membranes and interfere with probiotic survival. Oxygen exposure negatively affects anaerobic probiotic strains, while environmental conditions such as humidity and temperature reduce storage stability and shelf-life [6,8]. Probiotic stability during storage is strongly influenced by environmental factors including moisture content and temperature. In addition, rapid gastric emptying limits the contact time between probiotics and the gastrointestinal mucosa, resulting in reduced colonization efficiency and therapeutic effectiveness [9].

### IV. In Situ Gel Systems

#### 4.1 Introduction

*In situ* gel systems are liquid formulations that undergo gelation upon exposure to physiological conditions such as pH change, ionic interaction, or temperature variation [5,22]. These systems are easy to administer as liquids and form gels after reaching the stomach [21].

Floating *in situ* gels form a low-density gel matrix that remains buoyant in gastric fluid due to gas entrapment, allowing prolonged gastric retention and sustained drug release [17,30]. This property is particularly useful for probiotics, as it enhances survival and colonization potential [14].

#### 4.2 Mechanisms of Gelation

- **pH-Triggered Gelation:** pH-sensitive polymers undergo gelation in response to changes in environmental pH [5]. Carbopol-



based systems remain liquid under acidic conditions but undergo swelling and gel formation when pH increases because of ionization of carboxylic groups [20].

- **Ion-Activated Gelation:** Ion-activated gelation is one of the most commonly employed mechanisms in floating *in situ* gel formulations [21]. Sodium alginate forms crosslinked gel networks in the presence of calcium ions through interaction between calcium ions and guluronic acid residues [5].

This mechanism provides rapid gel formation and improved sustained release behavior.

- **Temperature-Sensitive Gelation:** Thermosensitive polymers such as poloxamers remain liquid at room temperature and convert into gels at body temperature [22]. These systems are advantageous because they allow easy administration and rapid gel formation after oral intake [14].



Figure 2: Mechanism of in situ gelling system after oral administration

#### 4.3 Polymers Used in Floating In Situ Gel Systems

- **Sodium Alginate :** Sodium alginate is one of the most widely used polymers in floating *in situ* gel formulations because of its excellent biocompatibility, biodegradability, non-toxicity, and ion-sensitive gelation properties [5]. It is a naturally occurring polysaccharide obtained from brown seaweed and consists mainly of guluronic acid and mannuronic acid residues. In acidic gastric conditions, calcium ions interact with guluronic acid blocks of sodium alginate to form a stable three-dimensional gel network through ionic crosslinking [21]. Sodium alginate-based formulations are highly suitable for probiotic delivery because gelation occurs under mild conditions that do not significantly affect microbial viability. In addition, alginate gels provide sustained release characteristics and

improve gastric retention due to their floating capability. Alginate also acts as a protective barrier against acidic gastric conditions and improves probiotic survival during gastrointestinal transit [7].

- **Gellan Gum :** Gellan gum is an anionic polysaccharide produced by *Sphingomonas elodea* and is widely used in oral controlled-release formulations because of its excellent gel-forming ability [5]. It undergoes gelation in the presence of mono- or divalent cations such as calcium ions present in gastric fluid. Gellan gum-based formulations exhibit good viscosity, excellent floating capability, and prolonged gastric retention [30]. The polymer forms strong transparent gels capable of sustaining drug release over extended durations. Due to its low toxicity and high stability, gellan gum is considered highly

suitable for probiotic-based gastroretentive systems [5].

- **Chitosan** : Chitosan is a cationic biopolymer obtained by deacetylation of chitin and possesses excellent mucoadhesive and biodegradable properties [20]. It is widely used in gastroretentive formulations because it enhances adhesion to gastric mucosa and prolongs gastric residence time. Chitosan also improves probiotic encapsulation efficiency and protects microorganisms from acidic degradation [6]. Due to its positive charge, chitosan interacts with negatively charged mucosal surfaces, thereby enhancing retention and controlled release behavior. In addition, chitosan exhibits mild antimicrobial activity and biocompatibility, making it suitable for oral probiotic formulations [5].
- **Hydroxypropyl Methylcellulose (HPMC)** : Hydroxypropyl methylcellulose is a semi-synthetic hydrophilic polymer extensively used as a viscosity enhancer and release retardant in controlled-release formulations. HPMC increases gel viscosity and improves mechanical strength, thereby enhancing sustained release behavior [28]. The polymer also helps maintain gel integrity during prolonged gastric retention and reduces burst release of probiotics [5]. Different grades of HPMC are selected depending on the desired viscosity and release profile. Due to its non-toxic and inert nature, HPMC is widely employed in gastroretentive floating systems [11].
- **Carbopol** : Carbopol is a synthetic high molecular weight polymer widely used in pH-sensitive gel formulations [5]. It exhibits extensive swelling and viscosity enhancement after ionization of carboxylic groups at higher pH values [20]. Carbopol improves gel consistency, mucoadhesion, and sustained release characteristics [5]. In probiotic

formulations, carbopol-containing gels provide prolonged gastric retention and better microbial protection by forming highly viscous gel matrices [30].

#### 4.4 Floating Mechanism in *In Situ* Gel Systems

Floating behavior is essential for prolonged gastric retention [10]. Floating systems work on the principle of gas generation from sodium bicarbonate reacting with gastric acid to produce CO<sub>2</sub> [27]. The gas becomes entrapped in the gel matrix, reducing density and enabling buoyancy [10]. This floating behavior ensures prolonged gastric residence and improved drug absorption [17,18].

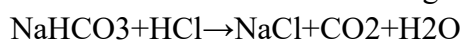
#### Mechanism

##### Step 1: Administration

The formulation is swallowed as a liquid.

##### Step 2: Carbon Dioxide Generation

Sodium bicarbonate reacts with gastric acid:



This generated carbon dioxide becomes entrapped within the gel matrix and decreases density, allowing the system to float [10].

##### Step 3: Gel Formation

Calcium ions initiate polymer crosslinking [5].

##### Step 4: Floating

Entrapped CO<sub>2</sub> decreases density, causing the gel to float [10].

#### 4.5 Formulation Components

Floating in situ gel formulations contain several important ingredients that work together to produce gelation, flotation, and sustained release. Sodium alginate acts as the primary gel-forming polymer, while calcium carbonate serves as a source of calcium ions required for crosslinking [5]. Sodium bicarbonate functions as the gas-generating agent responsible for floating behavior. Chitosan is used as a mucoadhesive polymer. HPMC is added to regulate viscosity and sustain



release, and probiotics serve as the active therapeutic component. Stabilizers and preservatives are important for maintaining probiotic viability during storage [9].

#### 4.6 Optimization of Formulation

Optimization is necessary to achieve ideal formulation characteristics such as appropriate viscosity, gel strength, floating lag time, and sustained release behavior. Polymer concentration strongly influences gel viscosity and mechanical stability [4]. Calcium ion concentration affects gel formation and crosslinking efficiency, while gas-generating agents determine buoyancy and floating duration [5]. Statistical optimization techniques such as factorial design, Box–Behnken design, and response surface methodology are commonly used to evaluate interactions between formulation variables and determine optimal compositions [4,23].

#### V. Evaluation Parameters

- **Physical Appearance:** The formulation should be clear, homogeneous, and free from particulate matter [5].
- **pH Measurement:** The pH should be suitable for oral administration and probiotic stability [9].
- **Viscosity Study:** Viscosity affects pourability and gelation efficiency [5]. Instrument : Brookfield viscometer.
- **Floating Lag Time:** Time required for the formulation to float after contact with gastric fluid [10]. Ideal floating lag time: Less than 1 minute.
- **Total Floating Duration:** Time during which the gel remains buoyant [10]. ideal duration: More than 12 hours.
- **Gel Strength:** Measures mechanical integrity of the formed gel [5]. Strong gels: Resist gastric motility , Provide sustained release

- **Drug Content Uniformity:** Ensures equal distribution of probiotics [9].
- **In Vitro Drug Release:** Determines release pattern over time [5]. Common dissolution medium: Simulated gastric fluid (0.1 N HCl)

#### VI. Drug Release Kinetics

Drug release kinetics play an important role in understanding how probiotics are released from gastroretentive *in situ* gel systems over time [5]. These models help in determining whether the release is diffusion-controlled, erosion-controlled, or follows mixed mechanisms, which is essential for optimizing sustained release behavior [28].

##### 6.1 Zero Order Kinetics

In zero-order kinetics, drug release occurs at a constant rate independent of concentration. This is ideal for maintaining uniform probiotic delivery over extended gastric residence time [28].

$$Q_t = Q_0 + K_0 t$$

where:

- $Q_t$  = amount of drug released at time  $t$
- $Q_0$  = initial amount of drug
- $K_0$  = zero-order release constant
- $t$  = time

Zero-order kinetics are generally observed in systems with strong matrix control or reservoir-type formulations that maintain a constant release rate.

##### 6.2 First Order Kinetics

In first-order kinetics, the release rate depends on the concentration of the drug remaining in the system. As concentration decreases, release rate slows down [5].

$$\log C = \log C_0 - kt/2.303$$

where:

- $C$  = concentration of drug remaining at time  $t$
- $C_0$  = initial concentration of drug
- $k$  = first-order rate constant
- $t$  = time



This model is commonly observed in water-soluble drug formulations and porous matrix systems.

### 6.3 Higuchi Model

$$Q = K_H \sqrt{t}$$

This model explains drug release by diffusion from a matrix system [5].

- $Q$  = amount of drug released
- $K_H$  = Higuchi constant
- $t$  = time

### 6.2 Korsmeyer-Peppas Model

$$M_t/M_\infty = Kt^n$$

This model is used to identify the mechanism of drug release such as: diffusion, erosion, swelling [5].

Where:

- $M_t/M_\infty$  = fraction of drug released at time  $t$
- $k$  = release constant
- $n$  = release exponent indicating release mechanism

## VII. Characterization Techniques

Characterization studies are essential for evaluating physicochemical properties, compatibility, morphology, thermal stability, and release behavior of probiotic-loaded *in situ* gel systems [5]. These studies help ensure formulation quality, stability, and reproducibility.

### 7.1 FTIR Spectroscopy

FTIR is used to identify functional groups and detect possible interactions between probiotics and polymers [5]. It ensures chemical compatibility of formulation components.

### 7.2 DSC (Differential Scanning Calorimetry)

DSC evaluates thermal behavior and compatibility between drug and excipients [5]. It helps confirm stability of probiotics during formulation processing [14].

### 7.3 SEM Analysis

SEM is used to study surface morphology and internal structure of gel systems [6]. It helps visualize probiotic entrapment within polymer networks.

### 7.4 XRD Analysis

XRD is used to determine crystalline or amorphous nature of components. Reduced crystallinity often improves drug release and stability [5].

### 7.5 Rheological Studies

Rheology evaluates viscosity and flow behavior of formulations [5]. It is critical for determining pourability before administration and gel strength after administration.

## VIII. Stability Studies

Stability studies are essential for determining the shelf life and viability of probiotic formulations [9]. Since probiotics are highly sensitive organisms, their survival depends on temperature, humidity, oxygen exposure, and formulation matrix protection [26].

Key parameters include:

- Viable cell count
- Gel integrity
- pH stability
- Storage temperature effect

Encapsulation and polymer protection significantly improve stability compared to free probiotic cells [25].

### Stability Testing Conditions

Stability studies are generally performed according to ICH guidelines under accelerated and long-term storage conditions [9]. Formulations are stored at controlled temperature and humidity conditions, and samples are analyzed at regular intervals.

## IX. Recent Advances



Nanoencapsulation improves probiotic protection against acidic gastric conditions and enhances targeted delivery [6]. Nanoparticles provide large surface area, improved encapsulation efficiency, and sustained release behavior.

Polymeric nanoparticles and lipid-based carriers are increasingly investigated for oral probiotic delivery [14].

### 9.1 Smart Hydrogels

Smart hydrogels are stimuli-responsive systems capable of responding to pH, temperature, or ionic changes [5]. These systems release probiotics selectively under specific physiological conditions and improve targeted delivery.

### 9.2 Synbiotic Systems

Synbiotic systems combine probiotics with prebiotics to improve microbial survival and colonization [2]. Prebiotics act as nutritional substrates that promote probiotic growth within the intestine.

### 9.3 3D Printing Technology

Three-dimensional printing technology enables fabrication of personalized gastroretentive dosage forms with precise geometry and controlled release characteristics [14]. This technology offers significant potential for individualized probiotic therapy.

## FUTURE PERSPECTIVES

Future research in probiotic gastroretentive systems is mainly focused on improving microbial stability, targeted delivery, and patient-specific therapy [14]. Artificial intelligence and machine learning approaches are increasingly being explored for formulation optimization and prediction of release behavior. Development of advanced biopolymers with improved mucoadhesion and stimuli-responsive properties may further enhance gastric retention and

probiotic survival [5]. Personalized microbiome therapy is another emerging area in which probiotic formulations may be designed according to individual microbial profiles [15]. Clinical translation and commercialization of probiotic gastroretentive systems require large-scale manufacturing methods capable of maintaining probiotic viability and formulation reproducibility [9]. Future advancements in polymer science, nanotechnology, and biotechnology are expected to improve therapeutic effectiveness and commercial feasibility of these systems [14].

## CONCLUSION

Probiotic-based floating *in situ* gel systems represent a highly effective gastroretentive drug delivery strategy for overcoming limitations associated with oral probiotic administration [4]. These systems improve gastric residence time, protect probiotics from acidic degradation, enhance viability, and provide sustained release behavior [5,10]. Polymers such as sodium alginate, gellan gum, and chitosan play a central role in gel formation, floating ability, and microbial protection [21]. Floating mechanisms based on carbon dioxide entrapment ensure prolonged gastric retention and improved therapeutic efficiency [27]. Recent advancements in nanotechnology, smart hydrogels, synbiotic systems, and 3D printing have significantly improved formulation potential [6,14]. Despite challenges in stability and scale-up, these systems show strong promise for future clinical probiotic therapy [25]

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