



## **Development of Floating Microspheres for Gastroretentive Delivery of an Anti-Diabetic Drug**

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Received: 19 December 2025

Revised: 29 December 2025

Accepted: 20 January 2026

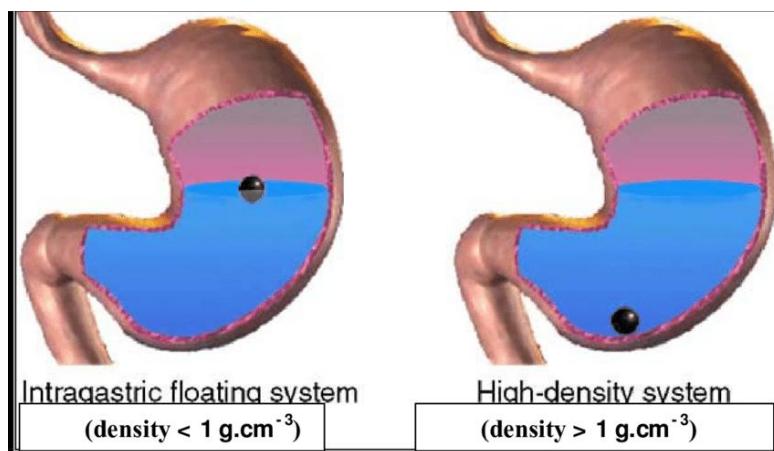
### **ABSTRACT**

Diabetes mellitus is a chronic metabolic disorder requiring long-term pharmacotherapy, where consistent drug absorption and sustained plasma drug levels are critical for effective glycaemic control. Conventional oral dosage forms often suffer from variable gastric emptying, short gastrointestinal residence time, and site-specific absorption limitations, leading to fluctuating bioavailability of anti-diabetic drugs. Gastroretentive drug delivery systems (GRDDS) have emerged as a promising strategy to overcome these challenges by prolonging gastric residence time and improving drug absorption in the upper gastrointestinal tract. Among various gastroretentive approaches, floating microspheres have gained significant attention due to their low density, multi-unit nature, controlled drug release characteristics, and improved patient compliance. This review comprehensively discusses the rationale, formulation principles, materials, preparation techniques, and evaluation parameters of floating microspheres designed for gastroretentive delivery of anti-diabetic drugs. The article further highlights the therapeutic advantages, mechanistic aspects of buoyancy, challenges in formulation development, and recent research advancements in this domain. By integrating formulation science with pathophysiological considerations of diabetes, this review provides a consolidated academic perspective on the role of floating microspheres as an advanced oral delivery platform for anti-diabetic therapy.

**Keywords:** Floating microspheres, gastroretentive drug delivery, anti-diabetic drugs, controlled release, gastric residence time, oral drug delivery.

### **I. INTRODUCTION**

Diabetes mellitus represents a major global health burden, characterized by persistent hyperglycaemia resulting from impaired insulin secretion, insulin action, or both. Oral anti-diabetic drugs remain the cornerstone of management for type 2 diabetes mellitus; however, their therapeutic success is often limited by poor oral bioavailability, short biological half-life, and inconsistent absorption profiles. Many anti-diabetic drugs exhibit preferential absorption in the stomach or proximal small intestine, making them ideal candidates for gastroretentive drug delivery systems.<sup>(1-2)</sup>



**Figure 1. Schematic representation of a floating microsphere-based gastroretentive drug delivery system.**



The diagram illustrates the low-density floating microspheres remaining buoyant over gastric fluid, enabling prolonged gastric residence and sustained release of anti-diabetic drugs in the upper gastrointestinal tract.

Traditional immediate-release oral formulations rapidly transit through the gastrointestinal tract, often before complete drug dissolution and absorption can occur. This leads to reduced therapeutic efficiency and increased dosing frequency, which may negatively affect patient adherence. Gastroretentive drug delivery systems are designed to remain in the stomach for an extended period, thereby enhancing drug availability at the absorption site and enabling sustained drug release. Floating microspheres, a novel class of gastroretentive systems, have emerged as a particularly attractive approach due to their ability to float on gastric fluids without affecting gastric emptying. Their particulate nature ensures uniform drug distribution, reduced risk of dose dumping, and improved safety profiles.<sup>3</sup>

### **1.1. The Global Diabetes Crisis and Pharmacokinetic Challenges**

Diabetes mellitus is no longer merely a clinical diagnosis; it is a global socioeconomic burden characterized by chronic hyperglycemia. The pathophysiology involves a complex interplay between peripheral insulin resistance and pancreatic beta -cell exhaustion. While the pharmaceutical industry has produced potent molecules to manage blood glucose, the "delivery" of these molecules remains the Achilles' heel of diabetic therapy.<sup>4</sup>

Most oral antidiabetic agents (OADs), such as Metformin hydrochloride, exhibit a "narrow absorption window," primarily limited to the upper segment of the gastrointestinal tract (GIT). Conventional tablets often pass through this window too quickly, leading to incomplete absorption and the need for high-frequency dosing. This cyclical dosing not only increases the risk of systemic side effects but also leads to "pill fatigue," significantly reducing patient adherence in chronic care.<sup>5</sup>

## **2. The Rationale for Gastroretentive Drug Delivery Systems (GRDDS)**

To optimise the bioavailability of drugs that are locally active in the stomach or absorbed primarily in the proximal small intestine, the dosage form must be retained in the gastric environment for an extended period.<sup>6</sup>

### **2.1 Limitations of Conventional Oral Dosage Forms**

The transit of a dosage form is governed by the Migrating Myoelectric Complex (MMC). In the fasted state, the "housekeeper waves" of the MMC can expel a standard tablet from the stomach within 1.5 to 2 hours. For drugs like Metformin, which require slow, continuous absorption to avoid gastrointestinal distress, this rapid transit is counterproductive.<sup>7-8</sup>

### **2.2 The GRDDS Solution<sup>9</sup>**

Gastroretentive systems aim to extend the Gastric Retention Time (GRT). Strategies include:

- **Mucoadhesive systems:** Adhering to the gastric mucosa.
- **High-density systems:** Sinking to the bottom of the stomach.
- **Expandable systems:** Swelling to a size that prevents passage through the pylorus.
- **Floating systems:** Remaining buoyant on the gastric juice.

## **3. Floating Microspheres: The Multiparticulate Advantage<sup>10</sup>**

Among the various GRDDS, floating microspheres (often termed "hollow microspheres" or "microballoons") represent a pinnacle of engineering. Unlike single-unit floating tablets, microspheres are multiparticulate systems.

### **3.1 Mechanism of Buoyancy<sup>11</sup>**

Floating microspheres are spherical, empty-cored particles typically smaller than 200 micrometres. They possess a density lower than that of gastric fluid (1.004 g/cm<sup>3</sup>). Because they float, they remain sheltered from the pyloric emptying process, acting as a "reservoir" that slowly releases the drug into the gastric medium.



### **3.2 Advantages Over Single-Unit Systems<sup>12</sup>**

- 1. Reduced Risk of Dose Dumping:** If a single floating tablet fails, the entire dose is lost or absorbed prematurely. In a multiparticulate system, the failure of a few microspheres does not compromise the entire dose.<sup>13</sup>
- 2. Uniform Distribution:** Microspheres spread across the gastric contents, ensuring more consistent absorption and reducing localized mucosal irritation.<sup>14-15</sup>
- 3. Predictable Emptying:** Their small size allows for a more "statistical" and gradual emptying process compared to the "all-or-nothing" emptying of large tablets.

### **4. Formulation Components and Polymer Dynamics<sup>16</sup>**

The success of a floating microsphere is dictated by the choice of polymers and the manufacturing technique.

#### **4.1 Polymer Selection<sup>17</sup>**

Polymers must be biocompatible, provide a diffusion barrier, and maintain low density. Commonly used polymers include:

- Synthetic:** Ethylcellulose, Eudragit® (various grades), and Polycarbonate.
- Natural/Semi-synthetic:** Chitosan, Sodium Alginate, and Hydroxypropyl Methylcellulose (HPMC).

The ratio of hydrophilic to hydrophobic polymers determines the release kinetics. For instance, adding HPMC to an Ethylcellulose matrix can create pores, allowing for a controlled "wicking" effect that modulates drug release.

#### **4.2 Preparation Techniques<sup>18</sup>**

- Emulsion Solvent Evaporation:** The most common method, involving an oil-in-water (o/w) or water-in-oil (w/o) emulsion where the polymer precipitates around the drug as the solvent evaporates.
- Ionotropic Gelation:** Often used for Alginate-based beads, utilizing cross-linking agents like Calcium Chloride.
- Spray Drying:** A rapid, scalable industrial method for creating uniform micro-spherical particles.

### **5. Application in Antidiabetic Therapy<sup>19-20</sup>**

**Table 1 Application in Antidiabetic Therapy**

| Drug          | Rationale for Floating Microspheres  |
|---------------|--|
| Metformin HCl | Large doses required; narrow absorption window in the upper GIT; high solubility but low permeability.           |
| Glipizide     | Short biological half-life (~2-4 hours); requires sustained plasma levels to manage post-prandial glucose.       |
| Pioglitazone  | Improved solubility in acidic pH; gastric retention enhances dissolution before entering the alkaline intestine. |

### **6. Evaluation Parameters for Floating Microspheres<sup>21-23</sup>**

To ensure pharmaceutical quality, several in vitro tests are critical:

- Floating Lag Time:** The time taken for the particles to reach the surface of the dissolution medium.
- Total Floating Time:** The duration the particles remain buoyant (ideally >12 hours).
- Entrapment Efficiency:** The percentage of the initial drug dose successfully incorporated into the microspheres.
- Micromeritic Properties:** Evaluation of flowability using the Hausner Ratio and Carr's Index, ensuring the powder can be filled into capsules efficiently.



## 7. Selection of Anti-Diabetic Drugs for Floating Microsphere Formulation<sup>24-25</sup>

The suitability of an anti-diabetic drug for incorporation into floating microspheres is governed by its physicochemical, pharmacokinetic, and pharmacodynamic characteristics. Drugs intended for gastroretentive delivery ideally possess a narrow absorption window, pH-dependent solubility, or limited stability in the distal intestinal environment. Many oral anti-diabetic agents fulfill these criteria, making them appropriate candidates for floating microsphere-based systems.

Biguanides such as metformin exhibit high solubility in acidic pH and are preferentially absorbed in the upper gastrointestinal tract. However, rapid gastric emptying often limits their residence time, resulting in reduced absorption and gastrointestinal side effects at higher doses. Sulfonylureas, including glipizide and gliclazide, possess short biological half-lives and require sustained plasma levels to prevent glycaemic fluctuations. Floating microspheres offer a platform to address these limitations by providing prolonged gastric retention and controlled drug release.<sup>26</sup>

Furthermore, drugs such as repaglinide and nateglinide, which display rapid absorption and elimination, benefit from sustained-release gastroretentive systems that reduce dosing frequency while maintaining therapeutic efficacy. Thus, careful drug selection plays a pivotal role in the successful design of floating microsphere formulations for anti-diabetic therapy.

## 8. Formulation Design Considerations<sup>27-30</sup>

### 8.1 Drug–Polymer Compatibility

Compatibility between the drug and polymer matrix is essential to ensure formulation stability and predictable release behavior. Drug–polymer interactions can influence entrapment efficiency, release kinetics, and long-term stability. Compatibility studies using techniques such as Fourier-transform infrared spectroscopy and differential scanning calorimetry are commonly employed to identify potential chemical or physical interactions.

### 8.2 Optimization of Buoyancy<sup>31</sup>

Buoyancy is a critical functional attribute of floating microspheres. It depends on the internal structure, polymer composition, and porosity of the microspheres. Hollow microspheres with entrapped air demonstrate superior floating capacity compared to solid particles. The viscosity of the polymer solution, solvent evaporation rate, and stirring speed during preparation significantly affect buoyancy characteristics.

### 8.3 Control of Drug Release Profile

Controlled drug release is achieved through careful selection of polymer type, polymer concentration, and microsphere size. Hydrophobic polymers tend to retard drug release, while hydrophilic polymers promote swelling and diffusion-controlled release. Blending polymers with complementary properties allows fine-tuning of release kinetics to achieve desired therapeutic outcomes.

**Table 2 Comparative Performance of Floating Microspheres vs Conventional Formulations in Diabetes**

| Evaluation Parameter   | Conventional Formulation | Floating Microspheres    |
|------------------------|--------------------------|--------------------------|
| Gastric retention time | Short (1–2 hours)        | Prolonged (>8–12 hours)  |
| Drug release pattern   | Immediate or variable    | Sustained and controlled |
| Plasma concentration   | Fluctuating              | Stable                   |
| Dosing frequency       | Multiple doses per day   | Reduced                  |
| Patient compliance     | Moderate                 | Improved                 |

## 9. In Vitro Evaluation Strategies: Beyond Conventional Testing<sup>32-35</sup>

### 9.1 Advanced Buoyancy Assessment

Traditional buoyancy tests involve observing floating behaviour in simulated gastric fluid; however, advanced studies incorporate dynamic dissolution systems that better mimic physiological gastric conditions. These systems allow evaluation of floating behaviour under variable agitation and fluid volumes.



## **9.2 In Vitro-In Vivo Correlation (IVIVC)**

Establishing IVIVC is essential for predicting clinical performance based on in vitro data. Floating microspheres demonstrate improved IVIVC due to their prolonged gastric residence and consistent release patterns. Mathematical modelling and pharmacokinetic simulations are increasingly employed to establish robust correlations.

## **10. Clinical Relevance in Diabetes Management**

The chronic nature of diabetes necessitates long-term pharmacotherapy with minimal adverse effects and high patient adherence. Floating microsphere-based formulations address these requirements by reducing dosing frequency, minimizing plasma level fluctuations, and enhancing therapeutic consistency. Improved glycaemic control achieved through sustained drug delivery may also contribute to reduced long-term complications associated with diabetes.

## **11. Comparative Analysis with Other Gastroretentive Systems<sup>36</sup>**

Floating microspheres must be evaluated in the context of alternative gastroretentive approaches, including floating tablets, expandable systems, mucoadhesive formulations, and high-density systems. While single-unit floating tablets may suffer from unpredictable gastric retention and dose dumping, floating microspheres offer greater reliability due to their multiparticulate nature.

Expandable systems rely on size enlargement, which may raise safety concerns, whereas mucoadhesive systems depend on mucus turnover and hydration state. Floating microspheres overcome these limitations by combining buoyancy with controlled release and uniform gastric distribution.

## **12. Emerging Innovations and Smart Gastroretentive Systems<sup>37</sup>**

Recent advancements in material science have introduced smart polymers capable of responding to physiological stimuli such as pH, temperature, or enzymatic activity. Integration of such polymers into floating microspheres enables adaptive drug release tailored to individual patient conditions.

Nanostructured floating microspheres and hybrid systems combining gastroretentive and targeted delivery mechanisms represent emerging research frontiers. These innovations hold promise for further improving therapeutic outcomes in diabetes management.

## **13. Disease-Specific Rationale for Gastroretentive Delivery in Diabetes<sup>38</sup>**

### **2.1 Pathophysiological Considerations**

In diabetes mellitus, maintaining stable blood glucose levels is essential to prevent acute and chronic complications. Frequent fluctuations in plasma drug concentration can result in inadequate glycaemic control or increased risk of hypoglycaemia. Many anti-diabetic drugs exhibit narrow therapeutic windows, making controlled delivery particularly important.

### **2.2 Absorption Characteristics of Anti-Diabetic Drugs**

A significant proportion of oral anti-diabetic drugs demonstrate preferential absorption in the stomach or proximal small intestine. Research studies consistently report reduced absorption when these drugs pass rapidly into distal intestinal segments. Floating microspheres prolong gastric residence time, thereby improving drug exposure at optimal absorption sites.

**Table 3. Summary of Disease-Oriented Outcomes Reported in Recent Research on Floating Microspheres**

| Anti-Diabetic Drug Studied | Formulation Approach            | Key Therapeutic Outcome                             | Disease-Oriented Relevance            |
|----------------------------|---------------------------------|---|---------------------------------------|
| Metformin                  | Floating polymeric microspheres | Prolonged drug release and improved bioavailability | Reduced gastrointestinal side effects |
| Glipizide                  | Hollow floating microspheres    | Sustained hypoglycaemic effect                      | Prevention of sudden glucose drop     |
| Gliclazide                 | Polymer-blended microspheres    | Extended plasma drug concentration                  | Improved glycaemic stability          |
| Repaglinide                | Gastroretentive microspheres    | Delayed peak plasma levels                          | Reduced dosing frequency              |

**14. Survey of Novel Research Outcomes in Anti-Diabetic Floating Microspheres<sup>39</sup>****14.1 Formulation Trends Reported in Recent Studies**

Recent studies demonstrate a strong preference for polymer-based floating microspheres using hydrophobic and hydrophilic polymer combinations. Research outcomes consistently indicate that polymer blending enhances both buoyancy and release modulation. Investigators report high drug entrapment efficiencies and sustained floating durations exceeding 12 hours in simulated gastric conditions.

**14.2 Drug Release and Glycaemic Control Outcomes**

Disease-oriented studies emphasize sustained drug release profiles that correlate with prolonged hypoglycaemic activity. Experimental findings frequently report gradual reduction in blood glucose levels without sharp declines, suggesting reduced risk of hypoglycaemia. These outcomes align with clinical objectives in diabetes management, where stable glycaemic control is prioritized over rapid glucose lowering.

**15. Comparative Disease-Oriented Analysis with Conventional Dosage Forms<sup>40</sup>**

Comparative studies consistently report superior therapeutic outcomes for floating microspheres over immediate-release formulations in diabetic models. Improved glycaemic stability, reduced dosing frequency, and enhanced patient compliance are recurrent findings across research reports.

These outcomes reinforce the relevance of floating microspheres as a disease-oriented delivery platform rather than a purely technological innovation.

**16. Translational Significance and Clinical Relevance<sup>41-42</sup>**

Disease-specific research increasingly focuses on translational applicability rather than formulation novelty alone. Floating microspheres demonstrate strong potential for clinical translation due to their reproducible performance, patient-friendly dosing, and alignment with therapeutic goals of diabetes management.

The ability to reduce dosing frequency while maintaining efficacy directly addresses one of the major challenges in chronic diabetic therapy—medication adherence.

**Table 4. Disease-Oriented Rationale for Floating Microspheres in Anti-Diabetic Therapy<sup>43</sup>**

| Diabetes-Related Challenge     | Limitation of Conventional Oral Dosage Forms  | Advantage Offered by Floating Microspheres        |
|--------------------------------|---|---|
| Short gastric residence time   | Rapid gastric emptying reduces absorption     | Prolonged gastric retention enhances absorption   |
| Fluctuating plasma drug levels | Peaks and troughs cause glycaemic instability | Sustained release ensures stable drug levels      |
| Narrow absorption window       | Drug reaches distal intestine prematurely     | Drug retained at optimal absorption site          |
| Frequent dosing requirement    | Poor patient adherence                        | Reduced dosing frequency                          |
| Risk of hypoglycaemia          | Sudden drug release                           | Controlled release minimizes glucose fluctuations |

**17. Future Research Directions Based on Disease Needs<sup>44-45</sup>**

Emerging research trends suggest integration of smart polymers, predictive pharmacokinetic modelling, and patient-specific dosing strategies. Disease-oriented formulation design is expected to play a key role in the next generation of gastroretentive systems for diabetes.

The transition of floating microspheres from laboratory-scale research to clinical application hinges on addressing the variability of gastric pH. The "fed vs. fasted" state significantly impacts buoyancy. Future research is pivoting toward "smart" polymers that respond to physiological triggers or combining buoyancy with mucoadhesion (dual-mechanism systems) to ensure retention regardless of the stomach's volume.



In conclusion, floating microspheres offer a sophisticated solution to the pharmacokinetic "cliff" faced by many antidiabetic drugs. By extending gastric residence and providing a sustained release profile, these systems hold the potential to transform diabetes management from a burden of frequent dosing to a streamlined, effective, and patient-centric therapeutic regimen.

## 18. Conclusion<sup>46-49,24</sup>

A disease-oriented survey of contemporary research clearly demonstrates that floating microsphere-based gastroretentive systems offer significant therapeutic advantages for the oral delivery of anti-diabetic drugs. By addressing key challenges associated with diabetes mellitus—such as variable absorption, short drug half-life, and glycaemic fluctuations—these systems represent a rational and clinically relevant advancement in drug delivery science.

The convergence of formulation innovation and disease-specific therapeutic goals positions floating microspheres as a promising platform for improving long-term diabetes management. Continued research with a translational and patient-centric focus is likely to further enhance their clinical impact.

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How to cite this article:

Aditya Kumar Tripathi et al. Ijppr.Human, 2026; Vol. 32 (2): 59-67.

Conflict of Interest Statement: All authors have nothing else to disclose.

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