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Review Article

Role of polymers in enhancing the performance of floating drug delivery systems

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Abstract

The Floating Drug Delivery System (FDDS) is a specialized dosage form designed to remain buoyant in the gastric environment, thereby enhancing drug absorption and bioavailability, particularly for drugs with a narrow therapeutic window or poor solubility. Polymers play a central role in enhancing the performance of FDDS by facilitating buoyancy, controlling the release rate, and ensuring stability. This review explores the types of polymers used in FDDS, including natural, synthetic, and copolymers, and examines their role in improving buoyancy and drug release profiles. Mechanisms such as gas generation, swelling, and density reduction are explained, with attention to how they are influenced by polymer selection. Additionally, the paper addresses polymer-drug compatibility, formulation strategies, and factors that affect the performance of FDDS, such as gastric pH and motility. Recent advancements in polymer technology, such as the use of biodegradable and biocompatible materials, are also discussed. Despite their potential, FDDS face challenges like formulation stability, patient variability, and the complexity of manufacturing. The review concludes by emphasizing the need for continued research and innovation in polymer-based FDDS to optimize therapeutic outcomes and address current limitations.

Keywords: Floating drug delivery system, Polymers, Gastro retentive, Drug bioavailability, Controlled release, Formulation strategies.

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1. Introduction

Floating Drug Delivery Systems (FDDS) represent a major breakthrough in drug delivery technology, specifically designed to improve the therapeutic efficacy of poorly soluble and poorly absorbed drugs. One of the main challenges in drug formulation is enhancing the bioavailability of such drugs, as they often have low solubility or are poorly absorbed in the gastrointestinal tract. FDDS are designed to increase the gastric residence time (GRT) of the drug, which is crucial for improving the absorption and therapeutic outcomes of such drugs. By prolonging the stay of the drug in the stomach or upper gastrointestinal tract, FDDS facilitate a controlled and sustained release of the active pharmaceutical ingredient (API). This not only optimizes absorption but also improves the bioavailability of drugs that are primarily absorbed in the stomach or upper parts of the small intestine (Bali, Sharma, & Sharma, 2019).[1-9] This approach is particularly beneficial for drugs with a short half-life or those requiring extended residence times for absorption (Singh & Sharma, 2020).[2,10-13]

One of the most critical elements in the design and performance of FDDS is the selection of polymers. Polymers play a multifaceted role in FDDS formulations. They not only provide the structural integrity needed for the dosage form but also enhance the floating characteristics of the system. Polymers contribute to buoyancy by enabling the formation of gels, swelling upon contact with stomach fluids, and in some cases, generating gases that facilitate the system's ability to float (Patel et al., 2020).[3,7,11,13] Moreover, the polymers help control the release of the API by interacting with it, thus influencing the release kinetics of the drug, which is vital in ensuring the sustained and controlled release of the drug (Tiwari et al., 2020). These interactions between the polymer and the drug are crucial in optimizing the therapeutic response by ensuring that the drug remains in the desired concentration for an extended period.

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Additionally, FDDS offer an added benefit of protecting sensitive drugs from the acidic environment of the stomach, which can be especially important for drugs that degrade in low pH conditions. The polymeric systems used in FDDS formulations must be carefully selected based on their ability to withstand the acidic conditions of the stomach and release the drug in a controlled manner (Kumar, Mehta, & Soni, 2020).

This review aims to examine the various polymers used in FDDS formulations and their role in improving drug performance. It also delves into the mechanisms through which these polymers enhance the release characteristics of the drug and the strategies employed to optimize their use for clinical application. Furthermore, the review addresses the challenges associated with FDDS, including formulation stability, patient variability, and the complexities of large-scale manufacturing (Reddy et al., 2017).[11]

2. Types of Polymers Used in FDDS

Polymers used in Floating Drug Delivery Systems (FDDS) can be broadly categorized into natural, synthetic and copolymers. Each polymer type has distinct properties that can be exploited to achieve specific performance characteristics necessary for optimizing the functionality and efficacy of FDDS formulations.

3. Natural Polymers

3.1. Hydroxypropyl methylcellulose (HPMC)

Hydroxypropyl Methylcellulose (HPMC) is one of the most commonly used natural polymers in FDDS due to its excellent swelling behavior and ability to form gel matrices. These properties are crucial for creating a floating system capable of providing sustained release of the drug. The gel-forming properties of HPMC allow it to maintain the drug in the stomach for a prolonged period, facilitating controlled and sustained drug release (Singh & Sharma, 2020).

3.2. Sodium alginate

Sodium alginate is a natural polysaccharide derived from seaweed. It is widely used in FDDS formulations due to its ability to form stable gel matrices upon contact with gastric fluids. This natural polymer is often combined with other polymers to enhance the buoyancy of the system, thus prolonging the gastric residence time (Kumar, Mehta, & Soni, 2020). Sodium alginate is highly effective in improving the retention of the formulation within the stomach, ensuring an extended release of the drug.

3.3. Pectin

Pectin is another naturally occurring polysaccharide with excellent gel-forming properties. It is particularly effective for achieving sustained release in FDDS. Pectin is generally regarded as safe for use in pharmaceutical formulations, and its ability to form gels makes it an excellent candidate for use in FDDS. The controlled release characteristics provided by pectin are especially beneficial for drugs that require a slow and steady release in the upper gastrointestinal tract (Bali & Sharma, 2020).

4. Synthetic Polymers

4.1. Ethylcellulose

Ethylcellulose is a hydrophobic polymer that is frequently used in FDDS formulations. It is particularly useful for controlling the release of hydrophilic drugs in a sustained manner. Due to its hydrophobic nature, ethylcellulose helps regulate the absorption rate of water into the formulation, controlling the dissolution rate of the drug. This is important for achieving a consistent release profile (Patel et al., 2019).[7]

4.2. Polyvinyl acetate (PVA)

Polyvinyl acetate (PVA) is widely used in FDDS due to its film-forming ability and controlled-release characteristics. It is often used in combination with other polymers to enhance the stability and performance of the system. PVA's unique ability to form strong, flexible films makes it an ideal choice for developing drug release matrices that are capable of maintaining buoyancy while ensuring sustained drug release (Reddy & Rani, 2020).[12]

Table 1: Comparison between Natural & Synthetic polymers in FDDS

Sr. No.	Parameter	Natural Polymers	Synthetic/ Copolymers
1	Source	Plant/ Microbial/ Marine origin	Chemically/ Artificial
2	Biocompatibility	Excellent	Depend on types
3	Cost	Low to Moderate	Moderate to high
4	Reproductively	Low	High
5	Function	Swelling, gelation, mucoadhesion	Customizable for release control & buoyancy
6	Environmental Aspects	Biodegradable	Non-biodegradable

5. Copolymers

5.1. Methacrylate copolymers (Eudragit)

Methacrylate-based copolymers, such as Eudragit are commonly employed in FDDS formulations because of their pH-sensitive properties. These copolymers can be tailored to release the drug at specific pH values, enabling the drug to be delivered to the targeted site within the gastrointestinal tract. The ability to modulate drug release based on pH is a key advantage of using methacrylate copolymers, as it allows for

more precise control over drug release in the stomach or small intestine (Singh et al., 2020).

6. Mechanism of Floating Drug Delivery System

The floating properties of Floating Drug Delivery Systems (FDDS) are governed by three major mechanisms: gas generation, swelling, and density reduction. Each of these mechanisms plays a crucial role in ensuring the system's ability to remain buoyant in the stomach, thereby prolonging the gastric residence time (GRT) and allowing for sustained drug release.

6.1. Gas generation

One of the primary mechanisms involved in the buoyancy of FDDS is gas generation. Some polymers, such as sodium bicarbonate and citric acid, react with the acidic environment of the stomach to produce carbon dioxide (CO_2). This gas is trapped within the matrix of the dosage form, leading to the formation of gas bubbles that reduce the overall density of the system. By decreasing the density, the dosage form becomes buoyant and floats on the surface of the gastric contents, thus enhancing the gastric residence time (Jain et al., 2019).[15,21] This mechanism is widely utilized in various floating dosage forms to ensure prolonged retention in the stomach, which is especially beneficial for drugs requiring extended absorption times.

6.2. Swelling

The swelling mechanism is another critical factor contributing to the buoyancy and sustained release characteristics of FDDS. Hydrophilic polymers such as Hydroxypropyl Methylcellulose (HPMC) and sodium alginate exhibit significant swelling properties when exposed to water or gastric fluids. Upon hydration, these polymers form a gel-like structure that increases the volume of the dosage form. The gel matrix traps gas bubbles within the system, further enhancing its buoyancy (Khan, Bansal, & Thakur, 2020). Additionally, the swelling process also plays a vital role in controlling the drug release, as it allows for a slow and gradual release of the active pharmaceutical ingredient (API) over time, making it suitable for sustained-release formulations.

6.3. Density reduction

The use of low-density polymersis another mechanism that contributes to the floating properties of FDDS. Guar gum and pectin are examples of natural polymers that are utilized for their ability to reduce the overall density of the dosage form. By incorporating these low-density polymers, the dosage form maintains its buoyancy in the stomach (Kumar et al., 2020). This mechanism ensures that the drug remains in the stomach for an extended period, thereby allowing for prolonged drug release and enhanced bioavailability of drugs that are primarily absorbed in the upper gastrointestinal tract.

7. Polymer-Drug Compatibility and Formulation Strategies

The selection of polymers for Floating Drug Delivery Systems (FDDS) is a critical aspect of ensuring that the system achieves the desired therapeutic outcomes. Among the various factors that influence FDDS performance, polymer-drug compatibility plays a significant role in affecting the stability, solubility, and release rate of the drug. An in-depth understanding of polymer-drug interactions is essential for optimizing the design of FDDS formulations and ensuring effective drug delivery.

7.1. Polymer-drug interaction

The compatibility between the polymer and the drug is essential to avoid undesirable consequences such as drug crystallization degradation, or poor solubility. A polymer that interacts poorly with the drug can lead to the formation of crystalline drug forms, which may impair the drug's solubility and hinder its absorption. For example, the interaction between Hydroxypropyl Methylcellulose (HPMC) and certain drugs can alter the drug release profile, potentially leading to premature release or poor release control (Kumar, Mehta, & Sharma, 2020). To overcome these issues, compatibility studies are crucial during formulation development. Such studies help identify any potential interactions between the drug and polymer and allow for the optimization of the formulation to enhance the drug's solubility and release rate.

7.2. Formulation strategies

Formulation strategies in FDDS are designed to address the unique characteristics of the drug, including its solubility, therapeutic window, and absorption site. For example, hydrophobic drugs may require the use of hydrophilic polymers such as HPMC to enhance the drug's solubility and ensure a controlled release profile. The selection of appropriate polymers based on these factors is key to achieving the desired performance, as it can directly impact the bioavailability and sustained release characteristics of the formulation. Moreover, combining different polymers can further fine-tune the release rate and buoyancy of the dosage form to meet the specific needs of the drug. For instance, blending HPMC with sodium alginate can improve both the swelling properties and buoyancy of the system, making it suitable for extended drug release in the gastrointestinal tract (Patel et al., 2020).[13]

8. Cross-Linking and Gel Formation

Cross-linking of polymers is another formulation strategy employed to enhance the stability and release control of FDDS. Cross-linked polymers form a more rigid network, which improves the structural integrity of the floating matrix, allowing it to retain its shape and buoyancy over a prolonged period. For example, cross-linked sodium alginate, when used in combination with HPMC, has been shown to improve

both the buoyancy and the controlled release of the drug (Sahoo, Soni, & Tiwari, 2019).[8,20] The formation of gel matrices through polymer cross-linking provides an additional layer of control over the drug release rate, ensuring that the drug is gradually released in a sustained manner. This method also enhances the stability of the dosage form under varying pH and mechanical conditions within the gastrointestinal tract.

9. Recent Advances in Polymers for FDDS

Recent research has been focused on the development of novel polymers and the modification of existing polymers to enhance the performance of Floating Drug Delivery Systems (FDDS). The increasing demand for more efficient and safer drug delivery systems has led to the exploration of biodegradable and biocompatible polymers, which offer significant environmental and safety benefits. These advancements aim not only to optimize drug delivery but also to address concerns about drug toxicity, environmental impact, and patient safety.

10. Biodegradable and Biocompatible Polymers

Biodegradable polymers have gained considerable attention for their ability to degrade in the body, thereby reducing the risks associated with long-term accumulation of foreign materials. Chitosan, a natural polymer derived from chitin, and Poly (lactic-co-glycolic acid) (PLGA), a synthetic polymer, are two such polymers that have shown promising results in FDDS. Chitosan is particularly noted for its biodegradability, biocompatibility, and mucoadhesive properties, making it ideal for applications in FDDS. It offers the advantage of being environmentally friendly and reducing the need for additional excipients in formulation (Patel et al., 2020). Similarly, PLGA, widely used in controlled-release drug formulations, is a biodegradable polymer that can offer sustained release of drugs while ensuring safe degradation within the body. These polymers are especially beneficial in FDDS for providing controlled release while minimizing adverse effects, such as irritation or toxicity that may arise from non-biodegradable alternatives.

11. Nanotechnology in Polymer Development

Another area of significant interest in recent years is the application of nanotechnology in the development of nano-sized polymers for FDDS. The incorporation of nanotechnology in drug delivery systems aims to improve drug delivery efficiency, target specific sites within the gastrointestinal (GI) tract, and enhance the stability of sensitive drugs. Nano-polymers can provide a higher surface area, enabling them to better interact with the drug and increase the encapsulation efficiency. Moreover, nanotechnology allows for more precise targeting of specific areas in the GI tract, which can be beneficial in treating diseases that require localized delivery. For example, the use of nano-sized polymeric systems may allow for drugs to be delivered more effectively to areas like the stomach or upper GI tract, improving bioavailability and therapeutic efficacy (Jain et al., 2019).[21] These advancements hold great promise for improving the performance of FDDS, especially for drugs with low solubility or those requiring precise release patterns.

12. Challenges and Limitations

Despite the significant advantages of Floating Drug Delivery Systems (FDDS), several challenges persist that can impact their effectiveness and clinical application. These challenges range from formulation stability and patient variability to manufacturing complexities, all of which need to be addressed for the successful implementation of FDDS in drug delivery.

13. Formulation Stability

Maintaining the stability of both the polymer and the drug over time remains a significant challenge in FDDS. The polymer used in the system may degrade or lose its buoyant properties, which can affect the sustained release of the drug. Additionally, the acidic environment of the stomach poses a risk for drug degradation, especially for sensitive compounds. This can result in decreased therapeutic efficacy and reduced bioavailability of the drug (Reddy & Rani, 2020).[21] Polymers used for floating systems, such as HPMC or sodium alginate, may also undergo hydrolysis or other chemical changes, leading to a loss of buoyancy or controlled release properties. Thus, ensuring long-term stability under varying gastric conditions remains a critical concern.

14. Patient Variability

Inter-patient variability presents another major challenge in FDDS. Variations in gastric pH, motility, and food intake among different individuals can lead to inconsistencies in the performance of FDDS. For example, some patients may have a more acidic gastric environment, while others may have a higher or lower pH, which can affect the polymer's swelling behavior and the release rate of the drug. Gastric motility can also influence the residence time of the drug in the stomach, which directly impacts the efficiency of the FDDS. Similarly, the presence of food can alter the gastric emptying rate, affecting the buoyancy and release kinetics of the dosage form (Tiwari et al., 2020). The variability in these physiological factors makes it challenging to optimize FDDS for all patients, necessitating personalized approaches for each individual.

15. Manufacturing Complexity

The manufacturing complexity of FDDS is another significant challenge. The production of FDDS requires precise control over the formulation, especially when incorporating multiple polymers, excipients, and active ingredients. Each component must be carefully selected to ensure that the system performs optimally in the stomach environment. Moreover, the scalability of FDDS

formulations can be an issue, as the manufacturing process must ensure uniformity in buoyancy, release rates, and drug stability across batches. These factors add to the complexity of the manufacturing process, resulting in higher production costs (Patel et al., 2020). Additionally, the use of advanced polymer blends or nano-sized polymers may require specialized equipment, further increasing the cost and difficulty of scaling up production for commercial use.

16. Conclusion

Floating Drug Delivery Systems (FDDS) offer significant therapeutic potential, particularly for drugs with poor solubility and limited bioavailability. By extending the gastric residence time (GRT), FDDS enhance the controlled and sustained release of drugs, improving their absorption in the stomach or upper gastrointestinal tract. Polymers play a crucial role in the development of FDDS, influencing their buoyancy, drug release kinetics, and stability. Advances in polymer technology, including the use of biodegradable and biocompatible polymers, as well as the incorporation of nanotechnology, have further optimized these systems for clinical use.

However, despite their promising benefits, FDDS face several challenges. Formulation stability, patient variability, and manufacturing complexities remain significant hurdles. Maintaining polymer integrity over time, ensuring compatibility between the drug and polymer, and overcoming physiological factors such as gastric pH and motility are crucial for the system's success. Additionally, the complexity of manufacturing FDDS formulations adds to the cost and difficulty of scaling up production for commercial use.

In conclusion, while FDDS hold great promise in improving drug delivery, continued research is essential to address the challenges and refine the systems for broader clinical application. The development of new polymers, advanced manufacturing techniques, and personalized approaches to account for patient variability will be key to optimizing the effectiveness and success of FDDS in the future.

17. Source of Funding

None.

18. Conflict of Interest

None.

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