INTERNATIONAL JOURNAL OF CURRENT ADVANCED RESEARCH
ISSN: O: 2319-6475, ISSN: P: 2319-6505, Impact Factor: 6.614
Available Online at www.journalijcar.org
Volume 12; Issue 11; November 2023; Page No.2628-2633
DOI: http://dx.doi.org/10.24327/ijcar.2023.2633.1574

Review Article

FLOATING DRUG DELIVERY SYSTEMS: A REVIEW

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A R T I C L E I N F O

Article History:
Received 24th October, 2023
Received in revised form 3rd November 2023
Accepted 14th November, 2023
Published online 28th November, 2023

Key words:
Floating drug delivery systems, polymers, natural gums, gastric retention

A B S T R A C T

The most widely preferable method of drug delivery is through oral route of administration. Many different factors play crucial roles in the designing and the evolution of the oral drug delivery system, polymers have been one of the major components in formulation of dosage forms. A macromolecule called a polymer is a substance that is made up of many monomer units connected by bonds. For the drugs whose absorption occurs largely in the upper regions of the gastrointestinal tract, such as the stomach, duodenum, and jejunum, floating drug delivery systems represent a further benefit. The aim of this review on floating drug delivery systems was to focus on the different types of floating drug delivery systems, the theory and mechanism of flotation to accomplish gastric retention, and the polymers utilised in floating drug delivery systems.

INTRODUCTION

The most convenient and approving method of delivering drugs into the bloodstream is through oral administration. There has been a growing interest in the pharmaceutical industry regarding controlled release drug delivery via the oral route. This approach aims to enhance therapeutic benefits, including easy dosing, patient adherence, and flexibility in formulation. For drugs that are readily absorbed in the gastrointestinal tract (GIT) and have short half-lives, they are rapidly eliminated from the body's circulation, necessitating frequent dosing to achieve the desired therapeutic effect. To address this challenge, the development of oral sustained-controlled release formulations seeks to gradually release drugs into the GIT, maintaining effective drug concentrations in the bloodstream over an extended period of time. This method involves retaining the drug in the stomach region through oral administration, allowing controlled release and continuous supply to absorption sites in the GIT[1]. To create a targeted orally administered controlled release dosage form, it is desirable to extend the time the drug remains in the stomach, thereby increasing gastric residence time. Prolonged gastric retention offers several advantages, including improved bioavailability, prolonged drug release, reduced drug wastage, and enhanced solubility of drugs with low solubility in high pH environments. Moreover, an extended gastric retention time can also be beneficial for localized effects in the upper portion of the small intestine, such as treating conditions like peptic ulcers. Gastroretentive drug delivery is an approach that focus on prolonging gastric retention time, by allowing the site-specific drug release in the upper GIT for either local or systemic effects. This extended retention capability offers numerous benefits, including enhancing the activity duration of short half-life drugs[2,3].

Floating drug delivery systems

Floating drug delivery system which is also known as hydrodynamically balanced system (HBS). While this system remains afloat within the gastric contents, it facilitates the gradual release of the drug at the intended pace. Once the drug is released, the remaining system is excreted from the stomach. This sequence leads to an extended Gastric Residence Time (GRT) and improved management of variations in plasma drug levels. Floating drug delivery systems are particularly useful for drugs that exhibit low solubility or are less readily absorbed in the upper gastrointestinal tract[4,5]. By remaining buoyant, these systems prevent rapid gastric emptying and promote controlled drug release, thus improving the therapeutic effectiveness of the drug. These systems often rely on mechanisms such as incorporating gas-generating agents or using low-density materials that help maintain their buoyancy[6].

The concept of a floating drug delivery system is based on optimizing drug release and absorption, leading to improved patient compliance and therapeutic outcomes for specific medications[7].

Applications

The concept of a floating drug delivery system is based on optimizing drug release and absorption, leading to improved patient compliance. The concept of floating drug delivery has numerous applications, particularly for drugs with limited bioavailability due to their absorption primarily occurring in the upper gastrointestinal tract's confined region. This approach effectively keeps the drug dosage localised at the absorption site, leading to a notable improvement in bioavailability[8].

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Sustained Drug Delivery

HBS (Hydrodynamically Balanced Systems) exhibit the ability to remain within the stomach for extended durations, facilitating the gradual release of the drug over an extended time. This gives a solution to the problem of limited gastric residence time often encountered with oral controlled-release (CR) formulations. The elevated bulk density of these systems, designated as G1, enables them to float atop the gastric contents. These systems possess a larger physical size, effectively preventing their passage through the pyloric opening. Recently, sustained-release floating capsules containing nicardipine hydrochloride were developed and subjected to In vivo evaluation. A comparison was drawn between this formulation and commercially available MICARD capsules using rabbits as the experimental model. The resulting plasma concentration-time curves demonstrated a prolonged administration duration (16 hours) for the sustained-release floating capsules, in stark contrast to the conventional MICARD capsules (8 hours)[9].

Site-Specific Drug Delivery

These systems offer significant benefits for the drugs, that are selectively taken in by the stomach or the upper segment of the small intestine. For instance, substances like riboflavin and furosemide fall into this category. Furosemide, mainly absorbed through the stomach and then the duodenum, saw an enhancement in bioavailability due to the creation of a cohesive, buoyant dosage form that extended its presence in the stomach.According to reports, a monolithic floating dosage form with a longer stomach residence duration was created, increasing the bioavailability[10,11].

Absorption enhancement

Drugs with limited bioavailability due to selective absorption within the upper gastrointestinal tract present an opportunity for development as floating drug delivery systems, aiming to optimize their absorption. Notably, a substantial enhancement in bioavailability of floating dosage forms (42.9%) was attainable, surpassing the bioavailability of commercially accessible LASIX tablets (33.4%) and enteric-coated LASIX-long product (29.5%)[12].

Classification of floating drug delivery system

1. Single Unit Floating Dosage Systems
a) Effervescent systems
b) Non-effervescent Systems
2. Multiple Unit Floating Dosage Systems
a) Non-effervescent Systems
b) Effervescent Systems
c) Raft Forming Systems
d) Hollow Microspheres
1. Single Unit Floating Dosage Systems
a) Effervescent systems:

These flotation systems use matrices composed of swellable polymers (such as HPMC), polysaccharides (such as chitosan), effervescent ingredients (such as sodium bicarbonate, citric acid, and tartaric acid), or contain substances that can be converted to gas by body heat. Liquid chamber. For the record, the recommended equilibrium ratio of citric acid to sodium bicarbonate for gas generation is 0.76:1. A typical method of preparing these systems is to embed bicarbonate-loaded resin beads coated with ethylcellulose. This insoluble but permeable coating allows water to permeate, causing the release of carbon dioxide, which subsequently floats the beads in the stomach. The most commonly used excipients in these systems include HPMC, polyacrylate polymers, polyvinyl acetate, Carbopol®, agar, sodium alginate, calcium chloride, polyethylene oxide, and polycarbonate[13].

Non - Effervescent systems:

This kind of system, upon ingestion, undergoes unrestrained expansion through absorption of gastric fluid to a degree that prevents their egress from the stomach. These systems can be labelled as "obstruction-type systems," given their tendency to remain lodged close to the pyloric sphincter. One of the best formulation approaches for such dosage forms which involves blending the drug with a gel that swells upon contact with gastric fluid. The air trapped by the swollen polymer imparts buoyancy to these forms. Illustrations of this type of FDDS (Floating Drug Delivery Systems) encompass colloidal gel barriers, micro-porous compartment systems, alginate beads, and hollow microspheres.

Another variation is the "Fluid-filled Floating Chamber," where a gas-filled flotation chamber is integrated into a micro-porous component housing a drug reservoir. Openings or apertures are positioned in the upper and lower walls, allowing gastrointestinal tract fluid to enter for drug dissolution[13,14].

Multiple Unit Floating Systems

The primary goal in developing multiple-unit dosage forms is to create a dependable formulation that retains all the advantages found in single-unit forms while effectively addressing the disadvantages inherent to single-unit formulations. To achieve this objective, numerous multiple-unit floatable dosage forms have been devised. Microspheres possess a notable loading capacity and have been crafted using various polymers like albumin, gelatin, starch, poly (methacrylate), polyacrylamide, and polyalkylcyanoacrylate. Additionally, spherical polymeric microsponges, colloquially known as "microballoons" have been synthesized. These microspheres exhibit a distinctive interior hollow structure and demonstrate excellent in vitro floatability.

In the domain of carbon dioxide–generating multiple-unit oral formulations, recent patent literature outlines various devices that leverage carbon dioxide produced within the devices post-administration. These devices incorporate mechanisms that can elongate, unfold, or inflate due to the generated carbon dioxide. Importantly, these dosage forms are designed to prevent passage through the pyloric sphincter if their expanded state exceeds a diameter of approximately 12 to 18 mm[15].

a) Non - Effervescent system

The literature on non-foaming multi-unit systems is limited compared to foaming systems. Nonetheless, some researchers have discussed the potential of using chitosan as a polymer component to create such systems with indomethacin. One example is the fabrication of multi-unit hydrogel systems containing indomethacin by extrusion process. In this method, a mixture of drug, chitosan, and acetic acid is extruded through a needle, and the extrudate is cut and dried. Chitosan becomes hydrated and buoyant in an acidic environment, allowing controlled drug release by adjusting the ratio of drug to polymer[16].

b) Effervescent system

There are documented instances of sustained-release floating granules containing Tetracycline HCl. These granules are comprised of drug granulates divided into two stages, labelled as A and B. In stage A, the composition includes 60 parts of HPMC, 40 parts of polyacrylic acid, and 20 parts of the drug. On the other hand, stage B consists of 70 parts of sodium bicarbonate and 30 parts of tartaric acid. The blending process involves combining 60 parts by weight of stage A granules with 30 parts by weight of stage B granules, along with a lubricant. This mixture is then encapsulated[17].

c) Raft Forming Systems

Raft-forming systems have garnered significant attention as a means of delivering antacids and facilitating drug delivery for gastrointestinal infections and disorders. The fundamental process driving raft formation involves the creation of a cohesive and viscous gel upon interaction with gastric fluids. Within this process, each portion of the liquid undergoes swelling, resulting in the development of a continuous layer known as a "raft".

This raft, buoyed by the generation of CO_2, remains afloat and serves as a protective barrier. Its purpose is to effectively block the reflux of gastric contents, such as hydrochloric acid and enzymes, from entering the esophagus. Typically, these systems consist of a gel-forming agent combined with alkaline bicarbonates or carbonates. These components are responsible for the formation of the less dense structure, allowing the system to remain buoyant and float atop the gastric fluids[18].

d) Hollow Microspheres

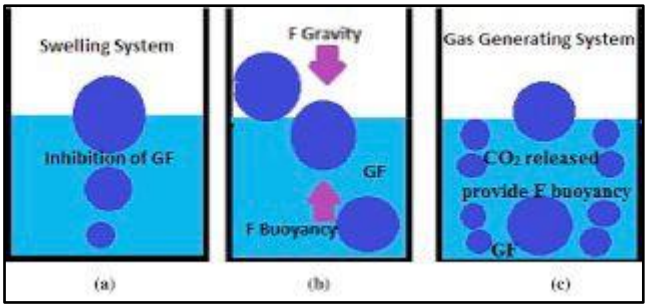
These are regarded as some of the most promising buoyant systems due to their combination of the distinct benefits seen in multiple unit systems and improved floating characteristics, facilitated by the central hollow space within each microsphere. The general methods employed for their creation encompass uncomplicated techniques such as the solvent evaporation method and the solvent diffusion and evaporation method.

The successful drug release and enhanced floating attributes primarily hinge on factors like the specific polymer utilized, the choice of plasticizer, and the solvents incorporated into the formulation. Polymers such as Polycarbonate, Eudragit®, and Cellulose acetate have been employed in the fabrication of these hollow microspheres, and the modulation of drug release can be achieved by careful optimization of the polymer-plasticizer ratio and the polymer quantity[19].

MECHANISM OF ACTION

As the system remains afloat within the gastric contents, the drug is gradually released at the intended rate from the system. As shown in figure 1, once the drug has been released, the remaining portion of the system is expelled from the stomach. Yet, beyond the necessity for a minimum amount of gastric content to ensure proper adherence to the buoyancy retention principle, it's also essential to maintain a minimum level of buoyant force to reliably keep the dosage form on the meal's surface.

For the assessment of floating force kinetics, a novel apparatus has been documented in the literature. This apparatus operates by continually measuring the force denoted as F over time, which is essential for maintaining submerged objects. This apparatus proves beneficial in the process of optimizing Floating Drug Delivery Systems (FDDS), specifically in terms of enhancing the stability and durability of the floating forces generated. This optimization is critical in mitigating the potential issues arising from unforeseen fluctuations in intragastric buoyancy capabilities[20,21].



$$F = F_{buoyancy} - F_{gravity} = (D_f - Ds)*g* v$$

Where, F = Total vertical force,
D_f = fluid density, Ds = object density, v = volume

Figure 1: Mechanism of floating drug delivery system

Polymers used in Floating Drug Delivery System

Polymers find application in floating systems with the aim of directing drug delivery to precise gastrointestinal regions, notably the stomach. This approach encompasses the utilization of both synthetic and naturally derived polymers within floating drug delivery systems. Among the natural polymers employed in such systems are Guar gum, Chitosan, xanthan gum, Gellan gum, and Sodium alginate. On the other hand, synthetic polymers like HPMC, Eudragit, and ethyl cellulose play a pivotal role in achieving buoyant drug delivery[22].

Advantages of natural polymers surpass those of synthetic ones, including:

- Biodegradability
- Biocompatibility and lack of toxicity
- Affordability
- Eco-friendliness
- Accessibility within local areas.

Disadvantages of natural polymers[23]

- Susceptibility to microbial contamination
- Variability from one batch to another
- Lack of control over hydration rate
- Decreased viscosity during storage

Natural polymers

Plant-derived natural gums consist of hydrophilic carbohydrate polymers of significant molecular weight. Usually the yare insoluble in organic solvents such as hydrocarbons or ethers. This gum can be easily dissolved in water or exhibit the ability to absorb water, causing swelling or dispersion in coldwater, eventually forming a viscous solution or gel-like consistency.

Guar gum

Guar gum is a naturally occurring galactomannan polysaccharide. When mixed with cold water, it hydrates and swells, forming a thick colloidal dispersion or solution. This ability to form a gel can slow drug release, making it a

versatile option for slow-release drugs. In the pharmaceutical field, guar gum is used both as a disinter grant and as a polymer in buoyant drug delivery systems[24].

Benefits of incorporating guar gum in a floating drug delivery system include:

- The documented role of in influencing both the pattern and quantity of drug release through polymer swelling.
- Research has indicated that formulations containing guar gum exhibit a level of resistance to variations in stirring speed during in vitro drug dissolution testing, and any impact on the dissolution profile is notably minimal.

Xanthan gum

Xanthan gum is a high-molecular-weight extracellular polysaccharide synthesized through pure-culture aerobic fermentation of carbohydrates. It forms an elongated polysaccharide chain featuring numerous trisaccharide side chains. This gum showcases exceptional solubility and stability in both acidic and alkaline environments, as well as in the presence of salts, and it exhibits resistance to common enzymes.It finds application in altering the rate of drug release from formulations.

The benefits of Xanthan gum are as follows:

- It readily dissolves in water.
- Even at low concentrations, it exhibits high viscosity.
- It holds the potential for achieving drug release kinetics in a zero-order manner.

Certain tablets containing a combination of xanthan gum and citric acid demonstrate the unique property of buoyancy for periods exceeding 24 hours[25].

Chitosan

Chitosan is a natural polymer obtained through the deacetylation of chitin. Its biological properties are highly favourable, including non-toxicity, biodegradability, and biocompatibility. This bio adhesive polymer also possesses antibacterial qualities, rendering it suitable for targeted delivery applications. Chitosan is characterized by a high molecular weight and is a polycationic weak base with a pKa value of 6.2-7. When exposed to an acidic pH of 1.2 or neutral conditions, it undergoes a transformation into a buoyant state, facilitating controlled release[24,25].

By increasing the thickness of the chitosan film, the rate of release can be effectively reduced. The advantages of chitosan are as follows:

- It forms a film that mitigates the impact of gastrointestinal transit time.
- Hollow microcapsules have a tendency to remain afloat in gastric fluid for approximately 12 hours. The drug release rate follows zero-order kinetics.

Gellan gum

Gellan gum represents an anionic polysaccharide with a high molecular weight that has been deacetylated. This extracellular linear polysaccharide boasts remarkable attributes including exceptional flavour release, high gel strength, superb stability, and adaptability in processing, high clarity, effective film-forming capabilities, and the distinctive quality of forming thermally reversible gels. The production of gellan gum involves the fermentation of Spingomonas elodea[24].

The advantages attributed to gellan gum are as follows:

- It excels in flavour release, exhibits high gel strength, and maintains exceptional stability.
- It readily forms a gel when exposed to positively charged ions.

Sodium alginate

Sodium alginate primarily composed of sodium salt of alginic acid, which is mixture of poly-uronic acids which are made by using of residues from both d'mannuronic acid andL-guluronic acid[26].

Key Characteristics include

pH Balance: Acidity/alkalinity at pH 7.2 in a 1% w/v aqueous solution.

Solubility: It exhibits significant insolubility in ethanol (95%), ether, chloroform, and ethanol/water mixtures where the ethanol content exceeds 30%. Similar insolubility is observed in other organic solvents and aqueous acidic solutions with a pH below 3. Sodium alginate gradually dissolves in water, forming a viscous colloidal solution[27,28].

Dynamic Viscosity: A variety of commercially available sodium alginate grades yield aqueous solutions with varying viscosities. A typical 1% w/v aqueous solution at 20.8°C can possess a viscosity of 20–400 mPa·s (20–400 cP). The viscosity may fluctuate based on factors like concentration, pH, temperature, or the presence of metal ions. Notably, viscosity diminishes beyond pH 10.

Advantages of Floating drug delivery systems

1. Prolonged Gastric Residence Time: FDDS are designed to float on the gastric fluid, enabling prolonged retention in the stomach. This extended residence time can be particularly beneficial for drugs that require sustained release or targeted delivery to the stomach.
2. Enhanced Bioavailability: FDDS can improve the bioavailability of certain drugs by keeping them in the stomach for a longer duration. This can be crucial for drugs with poor solubility or those that undergo significant first-pass metabolism.
3. Reduced Variability: By controlling the gastric emptying rate and drug release kinetics, FDDS can lead to reduced variability in drug absorption, resulting in more predictable and consistent therapeutic outcomes[29,30].
4. Improved Patient Compliance: FDDS can often reduce dosing frequency due to their sustained release properties, leading to improved patient adherence to medication regimens.
5. Reduced Side Effects: Controlled and sustained drug release offered by FDDS can potentially lead to reduced peak drug concentrations, minimizing adverse effects associated with high drug concentrations.
6. Localized Drug Delivery: FDDS can be designed to release drugs in specific regions of the stomach, allowing targeted delivery to sites of action or absorption.

7. Minimized Drug Waste: The prolonged gastric retention provided by FDDS can help minimize drug wastage, as the drug has more time to be absorbed before passing through the digestive system.
8. Improved Therapeutic Efficacy: For drugs with narrow absorption windows, FDDS can increase the likelihood of drug absorption within the optimal absorption window, leading to improved therapeutic efficacy.
9. Flexibility in Formulation: FDDS can be designed as multi particulate systems (e.g., microspheres or pellets) or monolithic systems (e.g., tablets or capsules), offering formulation flexibility to suit specific drug characteristics and release profiles.
10. Enhanced Drug Stability: FDDS can protect certain drugs from degradation in the harsh acidic environment of the stomach, thereby improving drug stability[31,32].

Disadvantages of Floating drug delivery systems

1. Variability in Gastric Emptying: Gastric emptying rates can vary between individuals and situations, leading to inconsistent and unpredictable drug release profiles from FDDS. This can affect the efficacy and reliability of drug delivery.
2. Positional Dependence: FDDS rely on buoyancy to float on the gastric fluid. However, changes in body position (e.g., lying down or standing up) can affect the positioning of the FDDS in the stomach, potentially altering drug release characteristics.
3. Gastric Irritation: The presence of FDDS in the stomach might cause irritation or discomfort, leading to gastrointestinal issues for some patients.
4. Drug Release Variability: Formulating FDDS to provide consistent drug release rates can be challenging, as factors like particle size, shape, and coating may affect the floating behaviour and drug release kinetics.
5. Limited Formulation Flexibility: Certain drugs or formulations might not be suitable for FDDS due to their physical and chemical properties. This limits the scope of drugs that can be effectively delivered using this approach.
6. Risk of Overdose: If FDDS remain in the stomach for an extended period and release the drug too slowly, there is a risk of accumulating high drug concentrations, potentially leading to overdose.
7. Gastrointestinal Effects: The extended retention of FDDS in the stomach might disrupt normal gastric functions, leading to conditions like bloating, nausea, or vomiting.
8. Patient Compliance and Acceptance: While FDDS can reduce dosing frequency, some patients might find it challenging to tolerate the sensation of the floating dosage form in their stomach, affecting compliance and overall treatment satisfaction[31,32,33].

CONCLUSION

Floating drug delivery systems (FDDS) offer the added benefit of drugs that are absorbed primarily in the upper GI tract, including the stomach, duodenum, and jejunum. Polymers can be used to facilitate the controlled release of drugs from dosage forms. These polymers serve a variety of functions in formulations, including as gelling agents, emulsifiers, viscosity enhancers and speed inhibitors. Therefore, understanding polymer properties is very important in the field of drug delivery. However, great efforts are still needed to overcome various physiological and pharmaceutical barriers and develop more effective dosage forms. Future research efforts in FDDS should prioritize exploring methods to precisely modulate the rate of drug delivery in the gastrointestinal tract. This pursuit is critical to optimizing the pharmacokinetic and toxicological profiles of drugs.

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How to cite this article:

Tadikonda Rama Rao., Gardas Shreya and Thadanki Madhurilatha., 2023 Floating Drug Delivery Systems: A Review. *International Journal of Current Advanced Research.*12 (11), pp.2628-2633.

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