INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

Review Article

A Review on Floating Drug Delivery

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ARTICLE INFO

Published: 01 Sept. 2025
Keywords:
Floating drug delivery systems, Gastro-retentive floating microspheres, Gastric retention
DOI:
10.5281/zenodo.17015729

ABSTRACT

In order to improve medicine efficacy, reduce side effects, and boost bioavailability, oral controlled release devices are made to release the medication in vivo with predictability. It is anticipated that floating drug delivery systems (FDDSs) will stay buoyant on the stomach contents for an extended period of time. Among the several buoyant preparations are laminated films, tablets, capsules, powders, granules, hollow microspheres, and pills. Because of their broad range of applications in delivering medications to the stomach, floating microspheres are particularly attracting interest. Hollow microspheres, often known as floating microspheres, are non-effervescent, gastro-retentive drug delivery devices. In the strictest definition, hollow microspheres are spherical, coreless, free-flowing powders made of proteins or artificial polymers that are ideally between one and a thousand micrometers in size. Low-density devices with enough buoyancy to float over stomach contents and stay in the stomach for an extended amount of time are known as gastro-retentive floating microspheres. Increased stomach retention and less variations in plasma drug concentration are the results of the drug's gradual release at the intended rate. By reducing the frequency of dosages, floating microspheres can increase patient compliance and improve the therapeutic efficacy of medications with short half-lives. improved absorption of medications that only dissolve in the stomach, and buoyancy lengthens the duration that food is retained in the stomach. The hollow inner core of floating microspheres is made using solvent diffusion and evaporation techniques.

INTRODUCTION

Gastroprotective Drug Delivery System:

GRDDSs (gastro retentive drug delivery systems) are a novel approach in this field. GRDDs are dosage forms that can be retained in the stomach and can improve the controlled delivery of drugs with an absorption window by continuously releasing the drug for a long time before it reaches its absorption site (Singh, 2000). Sometimes it is desirable to prolong the gastric retention of the

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

drugs in order to achieve therapeutic benefits of drugs that are absorbed from the proximal part of the GIT (gastro intestinal tract), those that are less soluble in or degraded by alkaline pH, or that encounter at the lower part of the GIT.

GRDDS are advantageous for these drugs by improving their-

- Bioavailability
- Therapeutics efficiency and Possible reduction of the dose.
- Maintenance of constant therapeutic levels over a prolonged period and thus reduction in fluctuation in the therapeutic levels.
- Reduce drug wastage Improves solubility of drugs that are less soluble at high pH environment (e.g. weakly basic drug like domperidone, papaverine) (Ali, 2005)

Stomach physiology:

Three regions make up the stomach's anatomy: the fundus, body, and antrum (pylorus). While the antrum is the primary location for mixing motions and serves as a pump for stomach emptying by pushing activities, the proximal portion, which is composed of fundus and body, serves as a reservoir for undigested materials (Chein, 1992). Both when fasting and when eating, the stomach empties. myloelectric cycle, also known as the migrating myoelectric cycle (MMC), which has four distinct phases. The pattern of contractions, commonly known as the digestive motility pattern, shifts from the fasted to the fed condition following the consumption of a mixed meal (Vedha, 2010).

1.Phase 1 (Basic phase) lasts 30 to 60 minutes and is characterized by sporadic contractions.

2. The preburst phase, or phase 2, lasts 20–40 minutes and is characterized by contractions and sporadic action potentials.

3. Phase 3 (Burst phase) lasts 10–20 minutes and is characterized by brief, strong contractions.

4. Phase 4 takes place between phases 2 and 1 of two consecutive cycles and lasts for 0–5 minutes.

Factors influencing the dose form's gastrointestinal retention time:

Density: The dosage form's density should be lower than the gastric contents' density (1.004g/ml)**.**

Size: A dosage form with a diameter greater than 7.5 mm has a longer stomach residence period than one with a diameter of 9.9 mm.

Shape of the dosage form: Compared to other devices of comparable size, the tetra hedron remained in the stomach for a longer amount of time. Compared to single unit dosage forms, multiple unit formulations allow for a greater margin of safety against dosage form failure, allow co-administration of units with different release profiles or containing incompatible substances, and exhibit a more predictable release profile with negligible performance impairment from unit failure.

Fed or unfed state: The gastric motility is typified by bursts of vigorous motar activity that happen every 1.5–2 hours during fasting. The MMC removes undigested material from the stomach, and if the formulation's timing aligns with that of the MMC, the unit's GRT can be quite brief. In the fast state, however, MMC is delayed and the GRT is prolonged.

The nature of the meal: feeding indigestible polymers or fatty acids can alter the stomach's

motility pattern to a fed state, which slows down the rate at which the stomach empties and extends the release of drugs.

Caloric content: A high-protein and high-fat meal can boost GRT by 4–10.

Feed frequency: Because MMC occurs infrequently, the GRT may increase over 400 minutes when consecutive meals are compared to a single meal.

Gender: Regardless of height, weight, or body surface, the mean ambulatory GRT for males (3.4 hours) is lower than that of their age and race-matched female counterparts (4.6 hours).

Age: Individuals over 70 have a noticeably longer GRT.

GRT can be prolonged by concurrent pharmacological administration of opiates like codeine and anticholinergic drugs like atropine and propantheline (Robinson) .

Gastro-retentive medication delivery systems' benefits:

1. When using this gastroretentive drug delivery method instead of a non-gastreptive one, the bioavailability of therapeutic drugs can be greatly increased, particularly for those that are processed in the upper gastrointestinal tract. A number of distinct elements pertaining to drug absorption and transit in the gastrointestinal tract (GIT) work together to affect the extent of drug absorption**.**
2. Sustained release may lead to a flip-flop pharmacokinetics for medications with a short half-life and can allow for less frequent dosage with better patient compliance.
3. Additionally, they have an advantage over their traditional system in that it can be used to overcome the challenges of both the gastric emptying time (GET) and the gastric retention time (GRT). Since these devices have a lower bulk density than the stomach fluids, they should stay buoyant on the gastric fluid without changing the intrinsic rate of absorption.
4. Using dose forms that provide local therapy in the stomach and small intestine, gastroretentive drug delivery can result in a prolonged and sustained release of medications. Therefore, they are helpful in treating conditions pertaining to the small intestine and stomach.
5. The gradual, regulated administration of medication.

   A gastroretentive dose form minimizes or completely eliminates systemic medication exposure by providing adequate local action at the sick location. This site-specific medication distribution lessens unwanted side effects.
6. Drug concentration and impact fluctuations are reduced by gastroretentive dose formulations. As a result, negative consequences linked to peak concentrations that are concentration dependent can be shown. This characteristic is especially crucial for medications with a limited therapeutic index.
7. The gradual, regulated administration of medication

   A gastroretentive dose form minimizes or completely eliminates systemic medication exposure by providing adequate local action at the sick location. This site-specific medication distribution lessens unwanted side effects.
8. Drug concentration and impact fluctuations are reduced by gastroretentive dose formulations. As a result, negative consequences linked to peak concentrations that are concentration dependent can be shown. This characteristic is especially crucial for medications with a limited therapeutic index (Amit, 2010).

Floating Drug Delivery System:

Low-density systems with enough buoyancy to float above the contents of the stomach and stay there for an extended amount of time are known as floating systems. The drug is released gradually at the appropriate pace while the system floats over the contents of the stomach, increasing the gastro retention period and decreasing fluctuations in the plasma drug concentration (Chawla, 2003).

Floating Drug Delivery System Types: There are two types of FDDS:

1. Effervescent systems
2. Non-effervescent systems

1. Effervescent systems:

Gas-generating Systems: By using effervescent interactions between carbonate/bicarbonate salts and citric/tartaric acid, these buoyant delivery systems release CO2, which becomes trapped in the systems' gellified hydrocolloid layer, lowering its specific gravity and causing it to float over chime (Vyas, 2002). Swellable polymers like methocel, polysaccharides like chitosan, effervescent substances like sodium bicarbonate, citric and tartaric acids, or chambers filled with a liquid that gasifies at body temperature can all be used to create these buoyant devices. According to reports, the ideal stoichiometric ratio for gas formation is 0.76:1 for sodium bicarbonate and citric acid. These systems are typically prepared using resin beads coated with ethyl cellulose and loaded with bicarbonate. Water can pass through the covering because it is permeable despite being insoluble. As a result, the beads float in the stomach due to the release of carbon dioxide. Floating minicapsules with a core of sodium bicarbonate, lactose and polyvinyl pyrrolidone coated with hydroxypropyl methylcellulose (HPMC), a mixture of sodium alginate and sodium bicarbonate, highly swellable hydrocolloids and light mineral oils, floating systems based on ion exchange resin technology, etc. are additional methods and materials that have been reported.

Volatile liquid containing systems: An inflatable chamber that holds a liquid, such as ether or cyclopentane, that gasifies at body temperature to induce the chamber to inflate in the stomach can be used to maintain the GRT of a drug delivery system. In order to allow for the spontaneous ejection of the inflatable systems from the stomach, the device may also include a bioerodible plug composed of PVA, Polyethylene, etc. that slowly dissolves and causes the inflated chamber to release gas and collapse after a set amount of time.

2. Non-effervescent systems:

After ingesting, this kind of system grows uncontrollably through gastric fluid absorption to the point where it stops them from leaving the stomach. Because of their propensity to stay stuck close to the pyloric sphincter, these systems may be known as "plugtype systems." One way to formulate these dosage forms is to combine the medication with a gel that, when exposed to gastric fluid following oral administration, expands and retains its relative shape and bulk density of less than one within the outer gelatinous barrier. These dose forms are buoyant due to the air retained by the inflated polymer.

Colloidal gel barrier systems: Sheth and Tossounian designed the first hydrodynamically balanced system (HBS) in 1975. Drugs in these systems contain gel-forming hydrocolloids that are designed to stay afloat on stomach contents. In tablets or capsules, this system has a high concentration of one or more gel-forming, highly swellable cellulose type hydrocolloids, such as HEC, HPMC, and NaCMC, as well as polysaccharides and matrix-forming polymers, including polycarbophil, polyacrylates, and

polystyrene. When the hydrocolloid in the system comes into touch with gastric fluid, it hydrates and surrounds the gel surface with a colloidal gel barrier. These dose forms are buoyant because the air retained by the inflated polymer maintains a density below unity (Jain, 2004).

Microporous Compartment System: This method works by enclosing a drug reservoir in a microporous compartment that has holes in both the top and bottom walls. To avoid the undissolved medicine coming into direct contact with the stomach mucosal surface, the drug reservoir compartment's outer walls are entirely sealed. The delivery system floats above the contents of the stomach due to the flotation chamber's trapped air. Through the apertures, gastric fluid enters, dissolves the medication, and then transports the dissolved medication continuously throughout the intestine for absorption.

Alginate beads: Freeze-dried calcium alginate has been used to create a variety of unit floating dose forms. A sodium alginate solution can be dropped into aqueous calcium chloride solutions to precipitate calcium alginate, creating spherical beads with a diameter of around 2.5 mm. Following their separation, the beads are frozen in liquid nitrogen and freeze-dried for 24 hours at -40°. This creates a porous structure that can sustain a floating force for 12 hours.

Hollow Floating microsphere: Floating microspheres are non-effervescent, gastro-retentive drug delivery methods. In a literal sense, hollow microspheres, also known as micro-balloons, are spherical, empty particles devoid of a core. These microspheres, which are ideally smaller than 200 μm, are free-flowing powders made of proteins or artificial polymers. Controlled drug release may be possible with solid biodegradable microspheres that contain a drug dissolved or spread throughout the particle matrix. Low density systems with enough buoyancy to float over stomach contents and stay in the stomach for an extended amount of time are known as gastro-retentive floating microspheres. The medicine is delivered gradually at the prescribed pace while the system floats over the contents of the stomach, increasing gastric retention and lowering variations in plasma drug concentration (Patel, 2011).

Floating Microsphere Development:

Floating microspheres are non-effervescent, gastro-retentive drug delivery methods. In a strict sense, hollow microspheres are spherical, coreless particles. These microspheres, which are ideally smaller than 200 micrometers, are characterized as free-flowing powders made of proteins or artificial polymers. Controlled drug release may be possible with solid biodegradable microspheres that contain a drug dissolved or spread throughout the particle matrix. Low-density systems with enough buoyancy to float over stomach contents and stay in the stomach for an extended amount of time are known as gastro-retentive floating microspheres. The medicine is delivered gradually at the prescribed pace while the apparatus floats over the contents of the stomach, increasing gastric retention and minimizing variations in plasma drug concentration.

Microsphere Flotation Mechanism:

The gel formers, polysaccharides, and polymers in microspheres hydrate when they come into contact with stomach fluid, creating a colloidal gel barrier that regulates the rate at which fluid enters the device and, in turn, the release of drugs. The gel layer is preserved by the hydration of the nearby hydrocolloid layer as the dosage form's outer surface dissolves. The inflated polymer traps air, which reduces density and gives the microspheres buoyancy. However, in order to properly achieve

buoyancy, a minimal amount of stomach content is required (Gholap, 2010).

Drug Release Mechanism from Microspheres:

The following are some possible mechanisms for drug release from multiarticulate:

Diffusion: Water diffuses into the particle's interior when it comes into touch with aqueous fluids in the gastrointestinal tract (GIT). Drug solutions diffuse across the release coat to the outside once drug disintegration takes place.

Erosion: Certain coatings can be made to progressively erode over time, releasing the medication that is inside the particle.

Osmosis: When water enters a particle under the correct conditions, an osmotic pressure can be created inside the particle. Through the coating, the medication is pushed from the particle into the outside (Somwanshi, 2011).

Preparation Method of Floating Microspheres:

Gastroprotective floating microspheres can be generated using a variety of developing procedures. However, many scientists around the world have used the solvent evaporation approach and the ionotropic gelation method extensively to investigate the various aspects of floating microspheres. Selecting the best technique is crucial for the effective trapping of active ingredients when creating floating controlled release microspheres. The type of medication, the polymer, and the intended purpose all influence the fabrication procedure choice (Okada, 1995).

Solvent Evaporation Technique:

Using an agitator, this method entails emulsifying an organic solvent (often methylene chloride) with dissolved polymer and dissolved/dispersed medication in an excess of aqueous continuous phase. The size and form of the particles are influenced by the emulsifier content in the aqueous phase. The stirring rate is decreased and the organic solvent evaporates at the proper temperature and atmospheric or reduced pressure after the required emulsion droplet size is reached. The medicine is trapped by solid polymeric microparticles that are produced by further evaporating the dispersion phase solvent. Filtration, centrifugation, or lyophilization are the methods used to extract the solid microparticles from the suspension. There are essentially two systems for emulsion solvent evaporation: the water-in-oil (w/o) type and the oil-in-water (o/w) type (Watts, 1990).

Oil-In-Water Emulsion Solvent Evaporation Technique:

Both the medication and the polymer should be insoluble in water during this procedure, and the polymer needs a solvent that is water immiscible (Jalil, 1990). This process involves dissolving the polymer in an organic solvent, either alone or in combination, such as dichloromethane, chloroform, or ethyl acetate. To create an oil-in-water emulsion, the medication is either dissolved or dispersed into a polymer solution, which is then emulsified into an aqueous phase using an emulsifying agent or surfactant. The organic solvent is removed once a stable emulsion has formed, either by stirring constantly or by raising the temperature while applying pressure. The size and shape of embryonic microspheres are determined by the solvent removal process. According to reports, polymer precipitation occurs at the o/w interface when the solvent is quickly removed from the embryonic microspheres. This causes microspheres to develop cavities, which hollows them out and gives them the ability to float (Garg, 2010). Since the process is simpler and the finished product requires less cleanup, oil-in-water

emulsion is more commonly employed than water-in-oil.

Oil-in-Oil Emulsification Solvent Evaporation Technique:

Non-aqueous emulsification solvent evaporation is another name for this oil-in-oil (or water-in-oil) emulsification process. This method creates a homogeneous drug–polymer dispersion by vigorously agitating polar solvents such ethanol, dichloromethane, acetonitrile, etc. while the drug and polymers are codissolved at room temperature. With the help of an oil-soluble surfactant like Span, this solution is gradually added to the dispersion medium, which is made up of light and heavy liquid paraffin. To guarantee full solvent evaporation, the system is agitated for two to three hours at room temperature and 500 revolutions per minute (rpm) using an overhead propeller agitator. After decanting the liquid paraffin and filtering the microparticles through Whitman filter paper, they are cleaned three times with n-hexane, allowed to air dry for twenty-four hours, and then placed in desiccators for storage (Gattani, 2008). Span 60, a non-ionic surfactant, is frequently utilized. Span 60, which localizes at the interface between the dispersed phase and dispersion medium, functions as a droplet stabilizer and inhibits droplet coalescence. Its HLB value is 4.3 (Shivakumar, 2008).

Ionotropic Gelation Method:

This process creates a gel matrix by cross-linking the polyelectrolyte in the presence of counter ions. This method has typically been used to encapsulate a large number of medications. Certain anions are present in the chemical structure of polyelectrolytes, like sodium alginate, which have the ability to coat the drug core and function as a release rate retardant. These anions combine with polyvalent cations and induce gelation to form a meshwork structure. Using a syringe, drop drug-loaded polymeric solution into the aqueous solution of polyvalent cations to create microspheres. A three-dimensional lattice of ionically cross-linked moiety is formed when the cations diffuse into the drug-loaded lymeric drops. Filtration is used to separate the microspheres that have developed after being kept in the original solution long enough for internal gelification. Alginates are examples of natural polymers that are frequently utilized in the creation of floating microspheres and can be employed to enhance drug entrapment (Patil, 2010).

Polymers for Floating Microspheres:

For the creation of microspheres, a variety of materials—both biodegradable and nonbiodegradable—have been studied. These materials include semisynthetic and natural polymers.
Hydrophilic and hydrophobic polymers can both be used to create microspheres.

Hydrophilic polymers: Gelatin, agar, egg albumin, starch, chitosan, and cellulose derivatives such as HPMC and DEAE cellulose are among them.

Hydrophobic polymers: These consist of acrylic acid esters, polylactic acid, PMMA, ethyl cellulose, and etc.

Biodegradable Polymers: These substances likewise gradually leave the administration site, however this happens in reaction to a chemical reaction like hydrolysis. Examples include polycaprolactone (PCL), polylactic acid (PLA), poly glycolic acid (PGA), and a number of general classes including polyanhydrides and poly orthoesters.

Non-Biodegradable Hydrophobic Polymers:

These substances are removed or retrieved undamaged from the administration site, and they are inactive in the environment of usage. Ethyl cellulose (EC), cellulose acetate (CA), polyethylene (PE), polyvinyl chloride (PVC), Acrycoat, Eudragit S, polyethylene vinyl acetate (EVA), polydimethyl siloxane (PDS), and polyether urethane (PEU) are a few examples**.**

Hydrogels: When these polymers come into contact with water, they swell but do not disintegrate. Similar to hydrophobic polymers, hydrogels are inert, can be extracted whole from the administration site, and work by creating a barrier that limits the pace at which medications can be transported and released. Examples include polyacrylamide, cross-linked polyvinyl alcohol (PVA), cross-linked polyvinylpyrrolidone (PVP), and polyhydroxy ethyl methyl acrylate (PHEMA).

Soluble polymers: These uncross-linked polymers have a moderate molecular weight (less than 75,000 Daltons) and dissolve in water. As molecular weight increases, the rate of dissolution falls. These substances can be combined with hydrophobic polymers or used alone to create devices that gradually degrade. For instance, hydroxyl propyl methyl cellulose (Methocel), uncrosslinked polyvinyl alcohol or polyvinyl pyrrolidone, polyethylene glycol (PEG), copolymers of methacrylic acid and acrylic acid methyl ester (Eudragit L), etc. (Saxena, 2014)

Factors Considerations for Formulation:

Polymer solution addition: According to reports, the solidification and aggregation of polymers on the surface of the aqueous phase were brought on by the high surface tension of water. A novel technique for introducing the polymer solution into the aqueous phase was created in order to reduce the amount of contact between the polymer solution and the air-water interface and to create a continuous microsphere preparation process. Using a glass tube submerged in an aqueous phase, the polymer solution is introduced via the tube without coming into touch with the water's surface. This technique decreased the amount of aggregate formation and increased the yield of microspheres.

Rotation speed effect: The yield and size distribution of microspheres are clearly impacted by the propeller's rotation speed. The average particle size falls as the propeller's rotation speed rises.

Temperature effect: Because it regulates the solvents' rate of evaporation, the dispersing medium's temperature plays a crucial role in the creation of microspheres. Low-temperature (10ºC)-prepared microspheres were crushed and distorted in shape. Because ethanol and dichloromethane diffuse more slowly during this process, the microsphere's shell becomes translucent. The thinner shell of the microsphere at a higher temperature (40ºC) may have resulted from the alcohol in the droplet diffusing more quickly into the aqueous phase and the dichloromethane evaporating as soon as it was introduced into the medium (Yang, 2004).

CONCLUSION:

The process of drug absorption in the gastrointestinal tract varies greatly, and the duration of drug absorption is prolonged by maintaining the dosage form in the stomach. A significant improvement in healthcare is made possible by floating microspheres, which are gastroretentive dosage forms that precisely regulate the target drug's release rate to a particular location. In order to effectively manage a variety of diseases, optimized multi-unit floating microspheres are anticipated to give physicians a new option for a more affordable, secure, and

bioavailable formulation. These approaches further expand the frontier of future pharmaceutical discovery by offering enormous potential for the creation of novel controlled and delayed release oral formulations. Furthermore, there is little doubt that new developments in pharmaceutical research will present genuine opportunities for the creation of innovative and efficient methods in the creation of these exciting drug delivery systems.

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HOW TO CITE: Neha Gujjar*, A Review on Floating Drug Delivery, Int. J. of Pharm. Sci., 2025, Vol 3, Issue 9, 30-39 https://doi.org/10.5281/zenodo.17015729