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Review Article

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AN OVER VIEW OF GASTRO-RETENTIVE FLOATING DOSAGE FORM AND THEIR CLINICAL SIGNIFICATION

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Abstract

The purpose of writing review on Gastro-Retentive floating Dosage System (GRFDS) was to compile the recent literature with specific focus on the principal mechanism of floatation to achieve gastric retention. These systems are useful to overcome several problems encountered during the development of a pharmaceutical dosage form. Oral route of drug administration is the most convenient route and accepted route of drug delivery. It is probable that at least 90% of all the drugs given by oral route. There are different drug deliveries to cure the diseases through oral route. Among them Gastro-retentive drug delivery system plays an important and significant role in novel drug delivery systems. The floating systems, bio adhesive drug delivery system, expandable drug delivery system, high density systems, effervescent systems (Gas Generating systems), non-effervescent systems etc. are various approaches. The wide applications can be achieved through this delivery system are enhanced bioavailability, sustained drug delivery, site-specific drug delivery, absorption enhancement, mitigating adversity at colon etc. In addition to specified above, the advantages and disadvantages, drugs and polymers used and the method of evaluation is also summarized in this review. The most current advancements in GRFDS are reviewed in depth, along with the physiological factors and formulation factors impacting stomach retention, design strategies for single-unit and multiple-unit floating systems and their classification. The advantages and future prospects for drug delivery of the present technological breakthroughs of GRFDS.

Keywords: *Gastro-retentive systems, Floating drug delivery systems, Floating systems, site specific drug delivery, absorption enhancement, single-unit and multiple-unit floating systems bioavailability, gastric residence time.*

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1. INTRODUCTION

Gastro-Retentive Floating drug delivery systems (FDDS) also known as low-density systems have enough resistance to float on the stomach and remain there for an extended period of time without having any impact on the rate at which the stomach empties. These are low-density systems having sufficient buoyancy to float over the contents of the stomach and remain there for a long time. The medicine will release gradually at the desired concentration in the system while the body floats on the contents of the stomach. As a result, the stomach will be emptied of the residue. These outcomes will then lead to an increase in gastric residence periods (GRT) and better control of drug concentration flux [1].

The purpose of floating drug delivery systems is to increase absorption by extending the time the dosage form spends in the gastrointestinal tract. Drugs that are highly soluble in acidic conditions and have a specific absorption location in the upper section of the small intestine are more suited to these mechanisms. Floating multi-particulate are gastro-retentive drug free-flowing synthetic polymer powders, preferably smaller than 200 micro meters in size. Floating multi-particulate are effervescent and non-effervescent drug delivery methods that are gastro-retentive. The drug's gastric residence time will be greatly prolonged by gastro retentive systems, which will stay over several hours in the environment of the stomach. In a high pH situation, continuous stomach retention promotes bioavailability, lowers drug wastes and improves solubility for pharmaceuticals that are less soluble delivery systems based on non-effervescent and effervescent approach.

The ability of the system to exert some therapeutic control is referred to as "controlled release". It aids in maximizing efficiency and adherence [2]. The typical

stomach residence time is between 2-5 hours. A promising new dosage form that is fast gaining acceptance is floating dosage forms.

By incorporating gas-generating agents and the proper excipients, floating dosage forms can be created as tablets or capsules that float in gastrointestinal fluids. As the medication is floating on the contents of the stomach, it is slowly and effectively removed from the body. After the drug has been discharged, the stomach's residual system is emptied [3].

1. Physiology Of Stomach

The stomach is anatomically separated into three sections: the Fundus, the Body, and the Antrim (pylorus). The closest part produced FDDS (Floating drug delivery system) is one innovative strategy in this field. By continually releasing the drug for a protracted length of time prior to it reaching its absorption site, FDDS can enhance the controlled administration of medications that have an absorption window. FDDS help these medications by enhancing them. Bioavailability effectiveness of treatment and potential dose decrease. Long-term maintenance of therapeutic levels at the same level, resulting in less variation in the therapeutic levels lessen drug waste increases medication solubility Fundus and body act as a reservoir for undigested materials because they are less soluble in high pH environments (for example, weakly basic drugs like domperidone, papaverine), whereas the atrium is the primary location for mixing motions and serves as a pump for gastric emptying by pushing activities. Both when one is fasting and when one is eaten, the stomach empties [4].

GIT (Gastro Intestinal Tract) physiology

The term "human gastrointestinal tract" usually refers to the stomach and intestines, but it can also apply to the entire system, including the mouth and the anus. (The word "digestive system" is more inclusive and includes additional structures, such as the auxiliary organs of digestion.) The Gastrointestinal (GI) tract measures 5 meters (20 feet) in length in an adult male person.

The stomach basically intends at digesting and carrying food materials. The stomach offers for short term food reservation and rapid consumption of relatively large meal. The chief substantial metabolism of enzymes is enriched in stomach of proteins. The peristalsis of stomach mixes and break down consumed food with the natural secretions of the stomach, converting food in normal liquid form. The liquefied volume is passed to the small intestine for further digestive process.

Migrating Myoelectric Cycle (MMC)

The term "inter digestive myoelectric cycle" or "migrating myoelectric cycle" (MMC) refers to a sequence of electrical events that occur during the fasting condition and cycle through the stomach and intestine every two to three hours. The MMC is further broken into four parts. When a mixed meal is consumed, the pattern of contractions shifts from the fasted state to the fed state, which is also known as digestive motility pattern.

Phase 1- (Basic phase) lasts from 30-60 mins with rare contractions.

Phase 2- (Pre burst phase) lasts for 20-40 mins with intermittent action potential and contractions.

Phase 3- (Burst phase) last for 10-20 mints which includes intense and regular contractions for short period.

Phase 4-last for 0-5 mints and occurs between phase 2 and 1 of 2 consecutive cycles

In phase II of the fasting state, constant contractions are present in this pattern, which is also known as the digestive motility pattern. The size of the food particles is decreased by these contractions (to less than 1 mm) and they are then driven toward the pylorus in a suspension state. The fed state causes MMC to start later, which slows down the rate at which the stomach empties. Gastric emptying rates were determined using scanty graphic tests, which showed that controlled release dosage forms taken orally are primarily affected by two issues: short gastric residency duration and an unpredictably high gastric emptying rate.

2. APPROACHES TO DESIGN FLOATING DOSAGE FORM

1. Single-unit dosage forms:

The globular shells in the low-density method can be employed as a drug carrier for a controlled release of the drug because they appear to have a lower density than gastric fluid. These shells have been undercoated with sugar polymeric materials such cellulose acetate phthalate and methacrylic polymer. A further layer of a drug-polymer mixture is applied to these. Depending on the kind of release required, ethyl cellulose or hydroxypropyl cellulose can be the preferred polymer. Finally, the product floats on stomach fluid while slowly delivering the medication over an extended period of time [6].

A gas-filled floatation chamber may be incorporated into a micro porous component that contains a drug reservoir in fluid filled floating chamber dosage forms. Along the top and bottom sides, there are openings or apertures through which gastrointestinal tract fluid can enter to dissolve the medicine. The undissolved medicine is kept inside by sealing the other two walls that come into touch with the fluid. Any suitable gas, liquid, or solid with the proper specific gravity and inert behaviour can be used as the fluid in the presence, whether it be air, a partial vacuum, or another suitable fluid.

The gadget is small enough to be swallowed, floats for a long time in the stomach and after complete release, the shell disintegrates, travels to the intestine, and is expelled. Hydro dynamically Balanced Systems (HBS) are created to increase absorption by extending the time the dose form spends in the gastro intestinal tract. Such systems are ideally suited for medications with superior acid solubility as well as medications with a particular site of absorption in the upper region of the small intestine [7].

3. CIASSIFICATION OF GRFDS

A. Single Unit Floating Dosage Systems
   a. Effervescent Systems (Gas-generating Systems)
   b. Non-effervescent Systems
B. Multiple Unit Floating Dosage System
   a. Effervescent Systems (Gas-generating Systems)
   b. Non-effervescent Systems
   c. Hollow Microspheres
C. Raft Forming System

A. Single Unit Floating Dosage Systems:

Single unit dosage forms are easier to produce, however due to their all or no emptying from the stomach, they suffer from the risk of losing their effects too early and can therefore cause high variability in bioavailability and local discomfort due to a large volume of drug administered at a specific location of the gastrointestinal tract.

a. Effervescent Systems (Gas-generating Systems)

These systems are of the matrix kind prepared with the use of several effervescent chemicals and swellable polymers, including methylcellulose and chitosan. Ex: citric acid, tartaric acid, sodium bicarbonate. These are matrix forms of systems that are prepared using swelling polymers such as chitosan and methylcellulose, as well as several effervescent compounds such as sodium bicarbonate, citric acid and tartaric acid. They're made such that CO2 is produced when it comes into touch with acidic gastric contents and becomes lodged in swollen hydrocolloids, giving dose kinds buoyancy [8].

b. Non-effervescent Systems

Non-effervescent floating dosage forms use polysaccharides, hydrocolloids and matrix-forming polymers such as polyacrylate, polycarbonate, polystyrene and polymethacrylate to form a gel forming or swelling cellulose type. The method of formulation includes a simple approach to thoroughly mixing the drug and the hydrocolloid-forming gel. This dosage form swells in contact with gastric fluids following oral administration and achieves a bulk density of < 1. The air trapped within the swollen matrix imparts the dosage shape with buoyancy. The swollen gel-like structure formed in this way acts as a reservoir and allows the gelatinous mass to sustainably release the drug [9].

B. Multiple Unit Floating Dosage Systems

Multiple unit dosage forms may be an appealing alternative, as it has been shown that inter- and intra-subject differences in drug absorption are reduced as well as the risk of dose dumping is reduced. Several multiple unit floating systems were created utilizing concepts such as a multiple unit system of air compartments, hollow microspheres made using the emulsion solvent diffusion method, and beads made using the emulsion gelation process. Another technique for planning multiple unit GRFDS is the use of effervescent and swellable polymers [10].

C. Raft Forming System

For the administration of antacids and medications for gastro-intestinal infections and illnesses, raft-forming systems are receiving a lot of interest. Here, a gel-forming solution (e.g., carbonate or bicarbonate containing sodium alginate solution) swells and forms a viscous cohesive gel on contact with gastric fluid containing trapped CO2 bubbles. Antacids such as calcium carbonate or aluminium hydroxide are often usually used in formulations to minimize gastric acidity. They are also used for gastro oesophageal reflux treatment since raft forming systems create a coating on the top of gastric fluids. The preparation of a viscous cohesive gel in contact with gastric fluid, where the liquid swells in each part, forming a continuous layer known as a raft, is one of the mechanisms involved in raft formation. This raft floats on stomach juices due to its low density and the production of carbon dioxide.

4. Method of Preparation of GRFDS

1. Direct compression technique

It means compressing tablets directly from powder content without altering the substance's physical structure itself. Dicalcium trihydrate phosphate, tricalcium phosphate, etc. are the most widely used carriers.

2. Effervescent Technique

An effervescent reaction between organic acid (citric acid) and bicarbonate salts will fill the floating chamber of the drug delivery system with inert gas (CO2).

3. Wet granulation technique

Involves wet powder massaging, milling or drying. Wet granulation shapes the granules by binding the powders together with an adhesive rather than compacting them.

4. Ionotropic Gelation Technique

Gelation of anionic polysaccharide sodium alginate, the primary polymer of natural origin, was accomplished with opposite charged calcium ions (counter-ions) with the objective of forming instantaneous micro particles.

5. Solvent evaporation technique

Continuous phase ability is inadequate to remove the entire amount of liquid dispersal solvent. Solvent evaporates from the dispersal surface to receive hardened microspheres.

6. Spray Drying Technique

Involves dispersing the core layer into the liquefied coating content and spraying the core coating mixture into the environment so that the coating is solidified by rapidly evaporating in which the coating material is solubilized.

7. Melt Solidification Technique

This method involves emulsifying the molten mass in the aqueous phase followed by cooling it to solidify.

Lipids, waxes, polyethylene glycol, etc. are the carriers used for this technique.

8. Melt Granulation Technique

This is the method that agglomerates the pharmaceutical powders using a meltable binder and does not use water or organic solvents for granulation.

5. MECHANISM OF GRFDS

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 [11].

1. Gas generation:

One of the primary mechanisms involved in the buoyancy of GRFDS 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. [12]. By decreasing the density, the dosage form becomes buoyant and floats on the surface of the gastric contents, thus enhancing the gastric residence time. 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 [13].

2. Swelling:

The swelling mechanism is another critical factor contributing to the buoyancy and sustained release characteristics of GRFDS. 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 [14].

3. Density:

Reduction The use of low-density polymers is another mechanism that contributes to the floating properties of GRFDS. 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 [15]. 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 [16].

6. EVALUATION OF FLOATING TABLET [5]

1. Weight variation test:

Twenty tablets were chosen at random from each batch and measured separately to see if there was any weight difference. The USP allows for small variation in the weight of a tablet. The percentage deviation in weight variance allowed is as follows. The tablet weight was greater than 324 mg in all formulations, allowing for a maximum difference of 5% (16).

2. Hardness test:

The hardness of a tablet determines its ability to endure mechanical shocks while being treated. The Monsanto tester was used to assess the hardness (kg/cm2) tablet. The average of five replication determinations was used in all cases. (17).

3. Friability test:

This was determined by weighing 26 pills after dusting, placing them in the Roche Friabilator, and rotating the plastic cylinder vertically at 25 rpm for four minutes, according to Indian Pharmacopoeia (IP). The total remaining weight of the tablets was reported after dusting, and the percentage friability was calculated using the equation below.

The acceptable Friability of tablets= < 1%.

4. In vitro buoyancy study:

The period between the introduction of the dosage form and its buoyancy on the SGF, as well as the time the dosage form stays buoyant, were all measured. The time it takes for the dosage form to appear on the medium's surface is known as Floating Lag Time (FLT) or Buoyancy Lag Time (BLT), and the total time it takes for the dosage form to stay buoyant is known as Total Floating Time (TET).

5. X-Ray method:

Nowadays, X-Ray has become a very common evaluation parameter for floating dosage forms. It aids in the location of dosage forms in the GIT, as well as the prediction and correlation of gastric emptying time and dosage form passage in the GIT. The incorporation of a radio-opaque substance into a solid dosage shape allows for X-ray visualization.

6. Swelling index:

The weight assignment determines the swelling activity of the measurement device. When using a pH 6.8 buffer dissolution medium at 370.5 °C, the tablet swelling index correlates to the tablet site in the dissolution tool basket. At each time point, the trials were repeated three times [18].

7. Tablet dimension:

A calibrated vernier caliper was used to measure thickness and diameter. Three tablets of each formulation were chosen randomly, and their thicknesses were determined separately.

8. TABLET DENSITY:

Tablet density is considered as an important parameter for floating tablets. The tablet will float

only when its density is less than that of gastric fluid (1.004). We can determine the density using following formula,

$$V = r2\,h\,d = m/v$$

Here, v= Tablet's volume (cc)
r = Tablet's radius(cm)
h = Tablet's crown thickness(g/cc)
m = Tablet's mass

7. CHALLENGES AND LIMITATIONS

1. The drawback of floating systems is that they need a lot of fluids in the stomach to function properly and float. Thus, a higher water intake is advised when using this dose form.
2. If the floating dose form is not larger in size and is in a supine position (such when sleeping), contractile waves may sweep it away. Therefore, the patient shouldn't take a floating dose form right before night.
3. Drugs that have a difficult time remaining stable in highly acidic environments, have a very poor solubility in acidic environments, or irritate the intestinal mucosa cannot be included into Gastro-retentive Floating Drug Delivery System (GRFDDS).
4. Numerous elements, including stomach motility, pH, and the presence of food, might affect gastric retention. Since these variables are never consistent, it is impossible to forecast buoyancy. Drugs that have issues with stability and solubility in the gastrointestinal tract are not good choices for these kinds of systems [19].

8. CONCLUSION

The review briefly describes the mechanism, types of floating system, advantages, limitation, factors affecting floating system, drug candidates suitable for floating, evaluation parameters and application of the system. These systems are useful to several problems encountered during the development of a pharmaceutical dosage form and the future potential of GRFDDS. Due to its capacity to increase delivery system effectiveness and decrease potential adverse effects, hydrodynamically balanced systems are becoming more and more common in the medical and medication delivery fields. This is accomplished by stabilizing the fluid flow inside the system, lowering turbulence, and assuring reliable medication administration. Gastro-retentive Floating delivery systems have been demonstrated to enhance the efficacy of drug delivery systems overall, improve the bioavailability of pharmaceuticals, and improve the precision of dosage. For instance, floating delivery systems may be utilized to carry medications to the body's specified locations, making distribution more accurate and regulated. Floating devices can be employed in a variety of medical settings, including haemodialysis, where they can enhance the elimination of waste from the blood and lower the risk of problems. To completely comprehend the advantages and restrictions of these systems in various disciplines, more study is necessary.

19. AUTHOR CONTRIBUTIONS

All authors are contributed equally.

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