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Review Article

A Comprehensive Review on Floating Drug Delivery System

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ABSTRACT

This review was written with the intention of gathering the most recent research on floating drug delivery systems (FDDS), with a particular emphasis on the many kinds of FDDS, their principles, and the mechanism of floating to achieve gastric retention. Systems for delivering drugs that float instantly when they come into touch with the stomach With absorption windows in the upper small intestine, fluids offer intriguing strategies for boosting the bioavailability of medications. The most recent developments in FDDS, such as the formulation and physiological aspects that affect stomach retention and techniques for creating single-unit and multiple-unit floating systems, are covered in detail.The goal of the floating drug delivery system (FDDS) is to prolong the period of stomach stay in order to improve bioavailability and therapeutic efficacy.FDDS releases the drug gradually and regulatedly by allowing the dosage form to float over stomach contents with the use of effervescent agents and low-density.

INTRODUCTION

For many medications, the most common and practical approach is the oral route. The oral route is typically thought of as the best drug delivery method since it has two key characteristics:

1.It should only be taken once for a longer duration of action.

2.The active medication ought to be delivered straight to the intended location.

Enhancing a product's safety to prolong its duration of action is the primary goal of designing these systems. Among the many drawbacks of these systems include dose dumping, increased bioavailability, longer time to reach therapeutic blood levels, and improved first pass impact. Typically, these systems cost more than traditional systems (3). Different people may have higher or lower steady state drug levels as a result of these goods because they are designed for the general public rather than for specific individuals. If the drug's therapeutic range is sufficiently wide, it might not cause any issues. (4). Floating systems are low-density systems with enough resistance to float on the stomach and remain afloat in the

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stomach for an extended amount of time without Affecting the rate at which the stomach empties. A gradual release of the medicine at the desired concentration will occur while the system floats on the contents of the stomach.The residue will therefore be eliminated from the stomach. Following that, these outcomes will lead to an increase in GRT and improved flux control in plasma medication concentrations. Additionally, it helps with local medications for the proximal gastrointestinal tracts, such as antibiotics for Helicobacter pylori used to treat peptic ulcers, and medications that are unstable or hard to breakdown in intestinal fluids. (5). Dosage forms that stay in the stomach longer than traditional dosage forms benefit greatly from the capacity to extend and regulate the emptying time because the process of gastric emptying is incredibly varied. For improved absorption and increased bioavailability, controlled release methods provide a number of challenges. One of these challenges is the difficulty to contain the dose form in the gastrointestinal tract's appropriate location. The gastrointestinal tract's ability to absorb drugs is a complicated process that depends on numerous factors. Contact time with the small intestine mucosa is known to have an impact on the amount of medication absorption in the gastrointestinal system. (6) For both local and long-term drug delivery, Gastroretentive Dosage forms are helpful for illnesses such as H. Pylori infection, which causes peptic ulcers. This dosage form, such as furosemide and ofloxacin, improves bioavailability and therapeutic efficacy and may even permit a dose decrease because to consistent therapeutic levels of the drug. Particularly with β-lactam antibiotics (penicillins and cephalosporins), the likelihood of resistance is reduced when therapeutic level variations are reduced. (7)

Dose forms that stay in the stomach longer than traditional dose forms benefit greatly from the capacity to extend and regulate the emptying time because gastric emptying is a highly variable process. Constricting the dose form to the appropriate region of the gastrointestinal tract is one of these challenges. In order to address this physiological issue, a number of drug delivery methods with extended stomach retention times have been studied. By delivering the drug in a controlled and repeatable way, efforts are being made to create a controlled drug delivery system that can maintain therapeutically effective plasma drug concentration levels for extended periods of time, minimizing fluctuations in plasma drug concentration at steady state and lowering the frequency of dosing. (8) For systemic activity, oral administration is the most flexible, practical, and widely used method of drug delivery. The oral route of administration has, in fact, drawn more attention and been more successful for controlled release systems because gastrointestinal physiology provides greater design freedom for dose forms than other routes (9)

Approaches

Among many few major Approaches are listed below

1.High Density Systems: These systems with a density of at least 3 grams per cubic centimeter are held in place by the stomach's rugae and can tolerate its peristaltic movements11. The main significant problem with these systems is that they are technically challenging to produce with high drug concentrations Diluents such zinc oxide, titanium oxide, and iron powder are required. (10)

2.Swelling and expanding systems: Because of their propensity to stay lodged in the pyloric sphincters, these systems are sometimes known as "plug type systems." Even in the fed condition, these polymeric matrices stay in the stomach cavity for a few hours. (11)

3.Systems of mucoadhesion and bio adhesion: These systems are used to localize the delivery device within the lumen in order to improve

medication absorption in a site-specific way. The bioadhesive polymers used in this procedure have the ability to adhere to the stomach's epithelial surface.. Among the most promising excipients frequently employed in these systems are gliadin, polycarbophil, carbopol, lectins, chitosan, CMC, and others.(12,13)

4.Systems with low density: Systems with enough buoyancy to float above the stomach's contents and stay there for an extended amount of time are known as floating systems..Increased gastro-retention duration and decreased fluctuation22 are the outcomes of the medicine being released gradually at the desired pace while the system floats over the stomach contents.(14).

Classification

A) Single Unit Floating Dosage system

a) Effervescent Systems (Gas-generating Systems)

b) Non-effervescent Systems

B) Multiple Unit Floating Dosage Systems

a) Non-effervescent Systems

b) Effervescent Systems (Gas-generating Systems)

C)Hollow Microspheres

C) Raft Forming Systems

A. Single Unit Floating Dosage Systems:

a) Effervescent Systems (Gas-generating Systems):

These buoyant systems used matrices made with polysaccharides like chitosan, swellable polymers like HPMC, effervescent substances like sodium bicarbonate, citric acid, and tartaric acid, or chambers filled with a liquid that gasifies at body temperature. According to reports, the ideal stoichiometric ratio for gas formation is 0.76:1 for sodium bicarbonate and citric acid. Resin beads coated with ethylcellulose and filled with bicarbonate are the standard method for creating these systems. Water is possible to pass through the covering because it is permeable but insoluble. Consequently, the beads float in the stomach due to the emission of carbon dioxide.(15)

Produced furosemide floating bilayer tablets with regulated release. By creating a solid dispersion using β (c) cyclodextrin combined in a 1:1 ratio, the kneading approach could improve the drug's low solubility. The medication was present in one layer together with the polymers HPMC 4000, HPMC 100, and CMC. The effervescent sodium bicarbonate and citric acid mixture was found in the second layer. According to radiographic investigations conducted on six healthy male volunteers, floating pills were kept in the stomach for six hours. Subsequent blood analysis revealed that the tablets' bioavailability was 1.8 times greater than that of regular tablets. The peak diuretic effect observed in the conventional tablets was lowered and prolonged in the case of the floating dose form when the amount of urine was measured.(16) Created a tablet that expands and contains a combination of polyvinyl lactams and polyacrylates that swell quickly in water and remain in the stomach for a long time. In addition, gas-forming chemicals were added, which. Caused the system's density to drop as soon as the gas created, causing it to float on the stomach environment.(17) Developed a once-daily ciprofloxacin formulation for oral use. It contained 69.9% ciprofloxacin base, 0.34% sodium alginate, 1.03% xanthum gum, 13.7% sodium bicarbonate, and 12.1% cross-linked polyvinylpyrrolidine. The medication was released over time as a result of the wet gel matrix creating a diffusion path for it.(18)

b) Non-effervescent system:

This kind of system grows uncontrollably through gastric fluid imbibitions after swallowing, to the point where it restricts their ability to leave the stomach. Because they tend to stay stuck close to the pyloric sphincter, Within the outer gelatinous barrier, it expands and maintains its relative shape and bulk density of less than one. These dosage

forms have buoyancy because of the air trapped by the expanded polymer. Examples of this kind of FDDS are microporous compartment systems and colloidal gel barriers (19,20) A different kind is a fluid-filled floating chamber, which incorporates a gas- filled flotation chamber into a microporous part that contains a drug reservoir. To dissolve the medication, the gastrointestinal tract fluid enters through apertures or openings along the top and bottom walls. To ensure that the medicine remains undissolved, the other two walls that come into touch with the fluid are sealed. The fluid present may be any suitable gas, liquid, or solid, including air under partial vacuum, with a suitable specific gravity and inert behaviour. Once the discharge is complete, the shell disintegrates, moves to the colon, and is released. Swallowing the device allows it to remain afloat in the stomach for an extended amount of time..(21) Developed a floating swellable asymmetric triplelayer tablet to prolong the triple medication regimen's stomach residence period. (clarithromycin, metronidazole, and tetracycline) in Helicobacter pylori-associated peptic ulcers. The rate-controlling polymeric membrane excipients used were HPMC and poly (ethylene oxide) (PEO). The two primary rate-controlling polymeric excipients were HPMC and poly(ethylene oxide). One of the outside layers of the triple-layer matrix included bismuth salt for immediate release, while the core layer contained tetracycline and metronidazole for controlled delivery. By adding a gas-generating layer made of calcium carbonate and sodium bicarbonate with swellable polymers, the flotation was achieved.(22).Created floating tablets in single units using matrix-forming polymer and powdered polypropylene foam (Accurel MP 1000®).. It was determined that changing the proportions of foam powder to matrix- forming polymers could successfully change the drug release patterns.(23)
Created floating sustained release nimodipine tablets with PEG 6000 and HPMC. Prior to the creation of floating tablets, nimodipine was mixed with a solid poloxamer-188 dispersion and then compressed into floating tablets. The invitro release of nimodipine was found to decrease with increasing HPMC and decreasing PEG 6000 content.(24) Captopril floating tablets were made with carbopol 934P and HPMC (4000 and 15000 cps). Both the existence of internal voids in the middle of the tablet (porosity) and the swelling of the hydrocolloid particles on the tablet surface when it comes into touch with the gastric secretions were found to be responsible for the tablet's buoyrance. Comparing these floating tablets to regular tablets, a longer release was Seen, and a 24-hour regulated release from the captopril dose form was accomplished.(25)

B. Multiple Unit Floating Dosage Systems

Due to their all-or-nothing gastric emptying nature, HBS and other floating tablet systems have a significant gastrointestinal transit time variability when taken orally, despite intensive study and development in this field. To address the aforementioned issue, multiple unit floating systems were created, which lessen the likelihood of dose-dumping and intersubject variability in absorption. It has been reported that both effervescent and non-effervescent multiple unit systems have been developed. (26)

a) Non-effervescent system:

Comparing non-effervescent multiple unit systems versus effervescent systems, there were fewer reports on the former in the literature. However, only a small number of researchers have documented the potential for creating such a system with indomethacin and chitosan as the polymeric excipient. It is reported that a multiple unit HBS made using the extrusion process contains indomethacin as a model medication.(27)

b) Effervescent system:

Reported tetracycline hydrochloride-containing floating granules with continuous release. These granules are a combination of drug granulates

from stages A and B. Stage A comprises 60 parts HPMC, 40 parts polyacrylic acid, and 20 parts .while Stage B has 30 parts tartaric acid and 70 parts sodium bicarbonate. Stage A granules (60 parts by weight) and stage B granules (30 parts by weight) are mixed with a lubricant and placed inside a capsule. Within approximately 6.5 hours, the capsule shell releases and dissolves the granules in the dissolution fluid, resulting in a sustained drug release of 80% and a floating time of more than 8 hours. Pepstatin minicapsules that float and have a diameter of 0.1–0.2 mm(28) A covering and a central core are present in these minicapsules. A granule made of lactose, sodium bicarbonate, and a binder that has been coated with HPMC makes up the center core. The HPMC layer has a coating of pepstatin on top. Due to the release of CO2 in the gastric fluid and the longer presence of pepstatin in the stomach, the system floats. In the creation of several unit systems, alginates have drawn a lot of attention. L-glucuronic and L-mannuronic acid residues combine to form alginates, which are linear copolymers that are non-toxic and biodegradable.(29). Created a novel kind of floating dosage system with a pill at its center. To prevent direct contact between sodium bicarbonate and tartaric acid, the inner layer of effervescent agents was separated into two sublayers. Polyvinyl acetate and pure shellac were present in the swellable polymer membrane that encased these sublayers. This system stabilized after being submerged in the buffer at 37ºC, and the solution entered the effervescent layer through the outer swellable membrane. When the two effervescent agents neutralized, CO2 was produced, resulting in enlarged pills that resembled balloons and had a density of less than 1.0 g/ml.(30)

c)Hallow microsphere:

Created using a new emulsion solvent diffusion technique, hollow microspheres (microballoons) containing drugs in their outer polymer shells. To create an o/w emulsion, a medication and enteric acrylic polymer solution in a mixture of ethanol and dichloromethane is added to the aqueous phase that contains polyvinyl alcohol (0.75% w/v) and constantly agitated. After filtering and water washing, the resulting microspheres are dried. The ethanol and dichloromethane diffusion and evaporation profiles indicated that ethanol diffused quickly from the droplets into the aqueous phase. This could decrease the polymer's solubility in the droplet due to Eudragit® S's insoluble nature in dichloromethane. Thus, the polymer precipitates at the droplet surface instantaneously, encapsulating the drug and dichloromethane in a film- like shell.(31)

C. Raft Forming System:

An effervescent liquid with buoyancy and in-situ gel characteristics makes up the raft forming system (Ibrahim, 2009). In this device, stomach juices come into touch with a thick alginate gel that also produces CO2.For an extended period, this continuous gel layer, known as a raft, can stay intact and buoyant over the contents of the stomach, allowing for the prolonged release of medications.Therefore, an antacid raft-forming system keeps stomach contents from refluxing into the esophagus by acting as a barrier between the two. Furthermore, because the alginate layer is bioadhesive, it might stick to the stomach mucosa.(32)

Facter Affecting Floating Drug Delivery System:

1.Density: The density of the dose form (1.004 gm/ml) should be less than that of the stomach contents.

2 .Size and shape: It has been reported that dosage form units with a diameter more than 7.5 mm had a higher GRT than those with a diameter of 9.9 mm. With a flexural modulus of 48 and 22.5 kilo-pond per square inch (KSI), the dosage form with a Tetrahedron and ring shape is stated to have

better GIT for 90 to 100% retention at 24 hours as compared to other forms.

3. Fed or unfed state: The migrating myoelectric complexes (MMC), which happen every 1.5 to 2 hours, or bursts of intense motor activity are what define GI motility during fasting. The GRT of the unit should be quite brief if the formulation is administered at the same time as the MMC, which removes undigested material from the stomach. However, MMC is delayed and GRT is significantly longer in the fed condition.

4.Nature of the meal: Feeding indigestible polymers of fatty acid salts can alter the stomach's motility pattern to a fed state, which slows down the rate at which the stomach empties and extends the duration of the drug's release.

5. Caloric content: With a high-protein diet, GRT can be raised for four to ten hours.(33,34)

Evaluation Parameters:

1. Size and shape evaluation:

Drug solubility rate and, consequently, bioavailability are significantly influenced by particle size and shape. Photo analysis, air elutriation analysis (Bahco TM), sieve analysis (Jayant, Mumbai), optical microscope (Olympus, India, Pvt. Ltd.), electro resistance counting methods (Coulter counter), sedimentation techniques, laser diffraction methods, ultrasound attenuation spectroscopy, and air pollution emissions measurements were used to determine the formulation's particle size.

2. Floating properties:

Statistical experimental design and a continuous floating monitoring system were used to assess the impact of formulation variables on the floating characteristics of the gastric floating drug delivery system.

3. Surface topography:

Atomic force microscopy (AFM), contact angle meter, contact profilio-meter, and scanning electron microscopy (SEM, JEOL JSM -6701 F, Japan) operating at 10k.v.

4.Swelling studies:

The molecular properties of swelled polymers were calculated by swelling studies. A variety of advanced techniques, such as 1HNMR imaging, Confocal laser scanning micro-and-fats scopy (CLSM), cryogenic scanning electron microscopy (Cryo-SEM), light scattering imaging (LSI), and dissolution apparatus and optical microscopy, were used to determine swelling investigations. Using the USP dissolve device (USP-24) Lab-India Disso 2000, the swelling studies were computed using the following formula. Wet formulation weight divided by formulation weight is the swelling ratio.

5. Determination of the Drug Content:

The percentage of drug content indicates how much of the drug was included in the formulation. It must not go beyond the bounds set by the conventional monographs. Near infrared spectroscopy (NIRS), microtitrimetric techniques, HPLC, HPTLC procedures, the Inductively Coupled Plasma Atomic Emission Spectrometer (ICPAES), and spectroscopic techniques (Elico Limited, Hyderabad) were used to determine the drug concentration.

6. Percentage Entrapment Efficiency:

In the prepared formulations, the phase distribution of the medication could be accurately measured using percentage entrapment efficiency. Three techniques— microdialysis, ultra centrifugation, and pressure ultra filtration—were used to determine entrapment efficiency.

7.In-vitro Release Studies:

The amount of the medication released at a specific time period was determined by in vitro release tests using the USP dissolving device LABINDIA dissolving 2000. Various kinds of dissolution equipment, a synthetic membrane, and the Franz diffusion cell system were used for release investigations.

8.Fourier Transforms Infrared Analysis:

Fourier transform infrared spectroscopy (FTIR, Shimadzu, Model-RT-IR-8300) is a method primarily used for functional group determination and the identification of organic, polymeric, and certain inorganic materials. Drug-loaded polymer formulations, pure drugs, and polymers were all measured using Fourier Transform Infrared Analysis (FTIR). The KBr-press was used to manufacture the pellets at a hydraulic pressure of 150 kg/cm2, and at room temperature, the spectra were scanned across the wave number range of 3600 to 400 cm-1.

9.Differential Scanning Calorimetry (DSC):

Drug hydration water is often characterised using Shimadzu, Model-DSC-60/DSC-50, and Metler Telleo. An intercooler-equipped DSC equipment was used to collect thermograms of the prepared materials. To calibrate the DSC temperature and enthalpy scale, indium/zinc standards were employed. Over a temperature range of 25°C to 65°C, the sample preparations were heated at a steady rate of 10°C/min while being hermetically enclosed in an aluminium pan.(35,36,37).

Application Of Fdds:

1.Sustained drug delivery:

These methods frequently overcome the drawback of short stomachic endurance that is typically associated with the atomic number 24 formulation. HBS systems will release the medication over a prolonged period of time after remaining in the abdomen for a considerable amount of time. These systems are relatively large, and it is forbidden to spend money from the opening gap. For instance, nicardipine coordination compound sustained unleash floating capsules were created and assessed in vitro.(38)

2.Site specific Drug Delivery:

These systems are particularly useful for drugs that are absorbed from the belly or the proximal portion of the small viscus, such as vitamin B2 and diuretics. For example, a diuretic medication is mostly absorbed from the abdomen, then the small intestine. There have been rumours about the development of a monolithic floating indeterminate quantity kind with extended stomachic endurance and improved absorption. The floating indefinite quantity's AUC was almost eight times that of the standard diuretic drug's indefinite quantity version.(39).

3.Absorption Enhancement:

Medications with low bioavailability due to site-specific absorption from the larger portion of the channel region are viable options for floating drug delivery systems. For example, by increasing their absorption, floating dose forms' bioavailability can be considerably increased in comparison to commercially available dose types.(40)

4.Maintenance of constant blood Level:

These systems offer a straightforward approach to sustaining a steady blood level with easier administration and improved patient compliance, according to Associate in Nursing.(41)

Advantages:

1.Enhanced Bioavailability: Certain medications (such as riboflavin and levodopa) have substantially higher bioavailability when administered in CR-GRDF polymeric formulations as opposed to non-GRDF CR polymeric formulations.(42)

2. Enhanced First-Pass Biotransformation: In contrast to a bolus intake, the presystemic metabolism of the tested substance may be significantly enhanced when the medication is continuously given to the metabolic enzymes (cytochrome P-450, specifically CYP-3A4).

3.Sustained drug delivery/reduced Frequency of Dosing: Because of their short biological half-life, the medicines may have flip-flop pharmacokinetics and a lower

4.Dose frequency due to their prolonged and slow FDDS input. Better patient compliance is linked to this characteristic, which enhances therapy.

5.Targeted therapy for local conditions in the Upper GIT: The drug from FDDS may be given to

the stomach for a long time in order to implement local therapy in the stomach.

6. Reduced fluctuations of Drug Concentration: It is possible to eliminate concentration-dependent side effects linked to peak concentrations and reduce variations in plasma medication concentration. Medicines having a narrow therapeutic index, which enables the pharmacological impact of medicines that activate distinct receptor types at varying concentrations to be selectively triggered, benefit greatly from this property.

7.Reduced counter-activity of the Body: Drug efficiency increases when the drug is released gradually into the body since this reduces counteractivity.

8.Extended time over Critical (effective) Concentration: The prolonged form of administration allows for a longer

9.Improved Receptor activation selectivity: By decreasing the fluctuation of the medication concentration above a certain value, FDDS improves the pharmacological effects and therapeutic results.

10.Minimized adverse activity at the Colon : Pharmaceuticals that are retained in GRDF in the stomach reduce the quantity of pharmaceuticals that enter the colon and, as a result, stop the breakdown of drugs that already degrade there.

11: Site specific Drug Delivery: A floating dose form is a commonly used method, particularly for medications with few upper small intestine absorption sites.(43,44)

Disadvantages:

1.In order for drug delivery to float and function well, these systems need a large amount of fluid in the stomach.

2.Unsuitable for medications with issues with GIT solubility or stability.

3.It may not be desirable to take medications like nifedipine, which undergoes first pass metabolism and is well absorbed throughout the GIT.

4.Medications that irritate the stomach mucosa are also undesirable and inappropriate.

5.Drug ingredients that become unstable in the stomach's acidic environment are not good candidates to be added to the systems.

6.It is recommended that the dose form be taken with a full glass of water (200–250 ml).

7.Since medications are absorbed throughout the gastrointestinal tract, these methods do not significantly improve upon the traditional dosing forms.(45,46,47)

CONCLUSION:

Floating Drug Delivery Systems (FDDS) have emerged as a promising approach to enhance oral bioavailability, improve patient compliance, and reduce dosing frequency. The design and development of FDDS have made significant progress, with various polymers, effervescent agents, and formulation techniques being explored. The benefits of FDDS, including prolonged gastric retention, controlled release, and targeted delivery, have been demonstrated in various studies. Despite the advancements, challenges persist, such as scaling up manufacturing processes, ensuring consistent floatation, and addressing potential gastrointestinal side effects. Future research directions should focus on: Developing novel polymers and materials, Investigating combination products and multifunctional systems, Enhancing scale-up and manufacturing processes , Conducting comprehensive clinical trials. The potential of FDDS to improve treatment outcomes for various diseases, including gastrointestinal disorders, diabetes, and cardiovascular diseases, is substantial. As research continues to address existing challenges, FDDS are poised to become a valuable addition to the pharmaceutical toolbox.

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