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An Overview on Floating Tablets

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ABSTRACT
Pharmaceutical technology has advanced significantly with the advent of Novel Drug Delivery Systems (NDDS), especially in the area of creating novel and creative formulations intended to increase therapeutic efficacy. In addition to improving the stability, bioavailability, and general safety of pharmaceutical substances, these advanced NDDS play a crucial role in protecting them against several types of degradation that may take place during storage or after administration. Among the wide variety of NDDS floating tablets, there are special benefits and mechanisms catered to particular medical requirements. Additionally, the developed floating tablets show off their exceptional ability to stay afloat in the stomach contents, allowing for the regulated release of medications over a longer time frame. This ultimately improves therapeutic outcomes and gastric retention.
The goal of this paper is to present a thorough analysis of floating tablets, covering their mechanism, preparation techniques, and assessment criteria. and conclusion. In order to achieve the best buoyancy and drug release kinetics, major formulation elements such polymer selection, gas-generation agents, and tablet density are essential. Floating methods are divided into effervescent and non-effervescent systems. The advantages of these sophisticated systems include not just improved drug absorption but also a notable decrease in unfavorable side effects for specific drug classes. Researchers and pharmaceutical professionals looking to create novel and potent floating tablet formulations might use this review as a resource.
Keywords: sustained release, controlled release, bioavailability improvement, floating tablets, oral drug delivery systems, extended period of gastric stay.

I. INTRODUCTION-

Low density systems with enough buoyancy to float over the contents of the stomach and stay there for an extended amount of time are known as floating systems. The medicine is delivered gradually at the desired pace as the system floats over the stomach contents, increasing the gastro-retention period and decreasing volatility.**(Wilson CG and Washington N 1989)**

Advantages-
1-Despite the alkaline pH of the colon, floating dosage forms, including tablets or capsules, will stay in the solution for an extended period of time
2-Aspirin and other similar medications may be administered using HBS/FDDS formulations because acidic substances like aspirin irritate the stomach wall when they come into contact with it.
3-The FDDS are beneficial for medications that are absorbed through the stomach, such as antacids and ferrous salts. enhanced GRT and longer duration of the dose form at the absorption site, which results in better drug absorption.
4-By distributing the medicine gradually, it reduces mucosal irritation. **(Narang N. 2011)**

Disadvantages-
1-A floating device is impractical for drugs that have problems with stability or solubility in the GI system.
2- For these system to float and function correctly, the stomach needs a lot of fluid.
3-Medications that undergo substantial first pass metabolism and are highly absorbed throughout the gastrointestinal system might not be the best options. For instance, nifedipine.
4-Unsuitable for medications that result in stomach lesions, such as non-steroidal anti-inflammatory medications
5- The adherence is uncertain since the mucus on the stomach walls is constantly renewing.
(Rathod H, et al., 2010)

CLASSIFICATION OF FLOATING DRUG DELIVERY-
A-Single Unit Floating Dosage Systems
a) Effervescent Systems (Gas-generating Systems)
b) Non-effervescent Systems
B-Multiple Unit Floating Dosage Systems

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a) Non-effervescent Systems
b) Effervescent Systems (Gas-generating Systems)
c) Hollow Microspheres
C- Raft Forming Systems
(Chandel et al.,2012)

A- Single Unit Floating Dosage Systems
a- Effervescent Systems (Gas-generating Systems)
These buoyant systems made use of matrices made with effervescent substances like sodium bicarbonate, citric and tartaric acids, polysaccharides like chitosan, swellable polymers like HPMC, or chambers filled with a liquid that gasifies at body temperature. According to reports, a stoichiometric ratio of 0.76:1 is ideal for gas formation between citric acid and sodium bicarbonate. These systems are typically prepared using resin beads coated with ethylcellulose 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 (Fig: 4). HPMC, polyacrylate polymers, polyvinyl acetate, Carbopol®, agar, sodium alginate, calcium chloride, polyethylene oxide, and polycarbonates are among the excipients most frequently utilized in these systems.
(Rubinstein A,1994)

b-Non-effervescent systems
After swallowing, this kind of system grows uncontrollably through gastric fluid imbibitions 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 referred to as "plug-type systems." One way to formulate these dosage forms is to mix the medication with a gel that swells when it comes into contact with stomach fluid. These dose forms are buoyant due to the air retained by the inflated polymer. Alginate beads, hollow microspheres, micro porous compartment systems, and colloidal gel barriers are a few examples of this kind of FDDS.
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. The top and bottom walls have apertures or openings that allow the fluid from the gastrointestinal tract to enter and dissolve the medication. To keep the undissolved medication inside, the other two walls that come into contact with the fluid are sealed. The fluid present could be air, under partial vacuum or any other acceptable gas, liquid, or solid with an appropriate specific gravity and an inert behavior. After the full discharge, the shell breaks down, travels to the colon, and is expelled. The device is swellable and stays afloat in the stomach for a long time. The drug release is controlled by a three-layer matrix in a more recent self-correcting floatable asymmetric configuration drug delivery device. By first maintaining a constant area at the diffusing front and then dissolving or eroding as the release process progresses, an asymmetric configuration drug delivery system has been developed to improve the 3-layer principle and achieve zero-order release kinetics. In order to increase the total transit time within the gastrointestinal tract environment with maximal absorptive capacity and, as a result, improved bioavailability, the system was developed to float to prolong the stomach residence duration in vivo.
This specific feature would apply to medications that are absorbed by active transport from the proximal or distal section of the small intestine, have a narrow window of absorption, and are pH-dependently soluble
(Desai S. 1984)

B- Multiple-unit floating systems
Because of their all-or-nothing gastric emptying character, hydrodynamically balanced systems and other floating tablets have a significant disadvantage of having a considerable degree of variability in gastrointestinal transit time when taken orally, despite extensive study and development in this area. Multiple unit floating systems were created to address this issue, which lessens the likelihood of dose-dumping and inter-subject variability in absorption (Fig. 1) The creation of both effervescent and non-effervescent multiple unit systems has been reported. area

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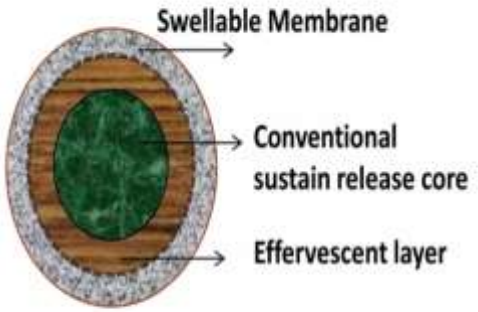

Fig. 1: Multiple unit of oral FDDS

a)Non-effervescent Systems-

Compared to effervescent systems, there were very few reports on non-effervescent multiple unit systems in the literature. Few researchers have, however, documented the potential for creating a system using indomethacin that uses chitosan as the polymeric excipient. An extrusion-prepared multiple unit HBS with indomethacin as a model medication is described. A needle is used to extrude a drug, chitosan, and acetic acid mixture; the extrudate is then chopped and dried. By altering the drug-polymer ratio, the necessary drug release might be achieved since chitosan hydrates and floats in acidic solutions**. (Tardi P and Troy H 2002)**

b) Effervescent Systems (Gas-generating Systems)-

Tetracycline Hcl-containing sustained release floating granules have been reported. The granules are a combination of medication granulates from stages A and B. Stage A comprises 50 parts sodium bicarbonate and 30 parts tartaric acid, while Stage B has 60 parts HPMC, 40 parts polyacrylic acid, and 20 parts drug. Together with a lubricant, 60 parts by weight of stage A granules and 30 parts by weight of stage B granules are combined and put inside a capsule. The capsule shell dissolves and releases the granules in dissolving media; the granules demonstrated a floating time of over 8 hours and a sustained medication release of 80% in roughly 6.5 hours.

There have been reports of pepstatin floating minicapsules with a 0.1–0.2 mm diameter. These minicapsules have a covering and a core in the middle. Granules made of lactose, sodium bicarbonate, and a binder make up the central core, which is covered in HPMC polymer. The HPMC layer is covered with pepstatin. Because CO2 is released into the gastric fluid and pepstatin stays in the stomach for a long time, the system floats. Alginates have drawn a lot of interest in the creation of several unit systems.**(Gholap et al. 2010)**

C- Hollow Microspheres-

Since of the center hollow space inside the microsphere, these buoyant systems are thought to be among the most promising since they have the distinct advantages of numerous unit systems in addition to superior floating properties. Simple solvent evaporation and solvent diffusion and evaporation are two main methods used in their preparation (Fig. 2). The kind of polymer, plasticizer, and solvents used in the formulation are the primary determinants of the drug release and improved floating qualities. Hollow microspheres were created using polymers such polycarbonate, cellulose acetate, and Eudragit®. By adjusting the polymer-plasticizer ratio and the polymer quantity, the medication release can be controlled..

Using the solvent evaporation process, polycarbonate-based sustained release floating microspheres were created. Griseofulvin, pnitroaniline, and aspirin were employed as model medications. **(Paterson et al.,2018)**

d) Raft Forming Systems-For the delivery of antacids and medications for gastrointestinal infections and illnesses, raft-forming systems have drawn a lot of interest. In contact with the stomach fluids, a viscous cohesive gel forms, and each part of the liquid expands to create a continuous layer known as a raft (Fig. 3). This is the fundamental mechanism underlying raft formation. The raft acts as a barrier to stop the reflux of stomach contents like HCl and enzymes into the oesophagus and floats due to the buoyancy produced by the generation of CO2. In order to make the system less dense and float on the stomach juices, it typically contains a gel forming agent and alkaline bicarbonates or carbonates that cause the formation. **(Mayavanshi AV and Gajjar SS 2008)**

MECHANISM OF FLOATING SYSTEM-

Because floating drug delivery systems (FDDS) have a lower bulk density than gastric fluids, they stay afloat in the stomach for an extended amount of time without influencing the rate at which the stomach empties. The medication is gradually removed from the system at the appropriate pace while it is floating on the contents

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of the stomach. The residual system is removed from the stomach following medication release. As a result, the GRT rises and the variations in the drug concentration in plasma are better managed. To retain the buoyancy of the dosage form on the meal's surface, a minimal amount of floating force (F) is also necessary in addition to a minimal gastric content that permits the correct achievement of the buoyancy retention effect.(Fig. 2) A unique apparatus for determining the resultant weight has been reported in the literature to measure the kinetics of the floating force. The device works by continually measuring the force equal to F (as a function of time) needed to keep an object submerged.

If F is on the upper positive side, the object floats more easily. In order to avoid any unexpected changes in intragastric buoyancy, this device aids in optimizing FDDS with regard to stability and sustainability of floating forces generated.

F = Fbuoyancy – Fgravity = (Df – Ds) g v

Where, F= total vertical force

Df = fluid density

Ds = object density

v = volume

g = acceleration due to gravity

(Mayavanshi AV and Gajjar SS 2008)

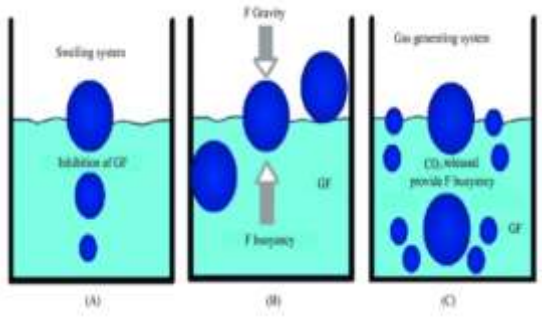

Fig. 2:Mechanism of floating systems

POLYMERS USED IN FLOATING SYSTEM-

In order to target medicine delivery at a particular area of the GI tract, such as the stomach, polymers are utilized in floating systems. The floating drug delivery system uses both natural and synthetic polymers.

Guar gum, chitosan, xanthan gum, gellan gum, sodium alginate, and other natural polymers are utilized in floating systems. HPMC, Eudragit, ethyl cellulose, and other synthetic polymers are utilized for floating medication delivery.**(Kumar G 2013)**

1 Natural Polymers-Natural gums are high molecular weight hydrophilic carbohydrate polymers that are derived from plants. In general, they are insoluble in organic solvents such as ether and hydrocarbons. In cold water, gums can either dissolve in water or absorb it and swell or disperse to form a jelly or viscous solution Natural polymers and their sources are summarized in Table 1 below.

Table 1: -Natural polymers used in floating tablets and their sources

S.NO	Polymer	Source
1	Guar gum	Endosperm of seed of cynopsis tetragonolobus
2	Chitosan	Shell of marine invertibrates
3	Xanthum gum	Fermentation of glucose by Xanthomonas compestris
4	Gellan gum	Pseudomonas elodea
5	Sodium alginate	Laminaria hyperboria

1-Guar gum ...

Guar gum is utilized in pharmaceuticals as a polymer in floating drug delivery systems and as a disintegrant.

The characteristics of guar gum

1. It is insoluble in organic solvents but soluble in water.
2. The feature of strong hydrogen bonds
3. Outstanding emulsion, film-forming, and thickening properties.
4. The capacity to regulate rheolog

(Singh and A. Kumar 2012)

2. Chitosan

Chitosan, a naturally occurring polymer, is produced by deacetylating chitin. Its beneficial biological qualities include nontoxicity, biodegradability, and biocompatibility. It can be delivered to specific sites because it is a bioadhesive polymer with antibacterial qualities. Chitosan has a pka value of 6.2-7, making it a polycationic weak base with a high molecular weight. It becomes buoyant and offers controlled release when combined with neutral media or an acidic pH of 1.2.

(Kumar, G.2013)

The rate of chitosan film release can be reduced by making it thicker.

(Singh, A. Kumar 2012)

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3-Gellan gum-
Spingomonas elodea ferments to produce gellan gum.
Advantages of Gellan gum:
1 It has outstanding stability, high gel strength, and taste release.
2. When positively charged ions are introduced, it gels.
3. It serves as a stabilizing or thickening agent in food products.
(Singh, A. Kumar 2012)

4-Sodium alginate-
The sodium salt of alginic acid, a mixture of polyuronic acids made up of leftovers of d'mannuronic acid and L guluronic acid, makes up the majority of sodium alginate.**(Raymond R, Sheskey P 2009)**

2-Synthetic polymers-
The use of synthetic polymers in therapeutics is growing in significance. Synthetic polymers are used as film coating agents, binder, and other applications. Large macromolecules with a diversity of functional groups are called polymers. There are two types of synthetic polymers: fully synthetic and semi-synthetic, which are modified forms of natural polymers.
1-Hydroxypropyl methyl cellulose
2-Eudragit
3-Ethyl cellulose
(Darekar D. 2013)

1-Hydroxypropyl methyl cellulose-
Hydroxypropyl methylcellulose ethers are part of a large family of odorless, water-soluble, white to off-white polymers that bind, hold water, thicken, create films, and lubricate. This semi-synthetic, inert, viscoelastic polymer is utilized in a number of commercial goods as an excipient and controlled-delivery ingredient in oral medications..
Synonyms: Hypromellose, Methocel, Metolose, Pharmacoat, Benecel MHPC, E464 etc **(Milanovic et al, 2010)**
Advantages -
1. The most prevalent and water-soluble polymer in nature
2. Applied as a water retension agent, film forming, and thickening
3. The most straightforward sustained release method for oral dose forms is hydrophilic matrix.
(Phadtare et al, 2014)

2-Eudragit
Nonproprietary names: BP: Methacrylas polymerisatum et methylis methacrylicum 1:2 USPNF: Copolymer of methacrylic acid
Polymeric methacrylates are synonyms.
Category of function: Tablet diluents, tablet binder, and film former

Description-
Synthetic cationic and anionic polymers of methacrylic acid, dimethylaminoethyl methacrylates and methacrylic acid esters in different ratios are called polymethacrylates. There are a number of commercially accessible varieties that can be acquired as an organic solution, an aqueous dispersion, or a dry powder. The most widely used organic solvent is a 60:40 blend of acetone and propan-2-ol. Eudragit S 100 is a powder that is soluble in intestinal fluid starting at pH 7 and is applied as an enteric coating material. The solvents utilized for this are 95% acetone and alcohols.
Eudragit L and S are anionic copolymerization products of methacrylic acid and methyl methacrylate, which are also known as methacrylic acid copolymers in the USPNF 23 monograph. In Eudragit L (Type A), the ratio of free carboxyl groups to the ester is roughly 1:1, while in Eudragit S (Type B), it is roughly 1:2. Film coats that are resistant to gastric media but soluble in intestinal fluid are made possible by the fact that both polymers are easily soluble in neutral to mildly alkaline environments (pH 6–7) and combine with alkalis to create salts. White powders that flow freely, Eudragit L-100 and S-100 contain at least 95% dry polymers.
(Raymond R and Sheskey P 2009)

3. Ethyl cellulose-
For more than 50 years, the pharmaceutical industry has made extensive use of ethocel (ethylcellulose polymers). Pharmaceutical formulations have chosen to use ethylcellulose for a number of reasons, including solvent and extrusion granulation, moisture protection, stabilizer, extended release multiparticulate coating, micro-encapsulation of actives, taste-masking of bitter actives, and extended release binder in inert matrix systems.
(Hegyesi 2016)

METHODS OF PREPARATION-
Methodology for single layer floating tablets: Basically single layer floating tablets are

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prepared by compression methods. For this normally three basic compression methods are used. They are as follows-
1-Direct compression
2-Dry granulation
3-Wet granulation

1-Direct compression method: This technique compresses tablets straight from powdered materials without changing the physical properties of the components to create tablets. Crystalline compounds with good compressible characteristics and flow qualities, including potassium salt (chloride, chlorate, bromide), ammonium chloride, sodium chloride, methylamine, etc., are employed in this process. Tablet machines are used to create compressed tablets through a single compression process. The tablet machine's top and lower punches crush the powdered or granulated tabletting material under high pressure (~tons/in2) after it has flowed into a die.
(Dave et al, 2004; Deshpande et al, 1996)
2-Dry granulation -Slugging is the process by which granules develop when tablet ingredients are moisture-sensitive or cannot tolerate high drying temperatures.
(Drewe et al, 1992)

3-Wet granulation method-In wet granulation, a rapid mixer granulator (RMG) is used to thoroughly mix or blend the active ingredient, diluents, and disintegrants. The RMG is a multifunctional chopper that is used for high-speed dispersion of dry powders and aqueous or solvent granulations. It is made up of an impeller and a chopper. Large trays containing moist materials from wet milling processes are put in drying chambers with a thermostable heat controller and a circulating air current. Tray dryers and fluidized bed dryers are frequently used dryers. Following drying, the granules are passed through a smaller mesh screen to reduce their particle size. To encourage granule flow, the lubricant or glidant is then applied as a fine powder.

A tablet is then created by compressing these granules. The manufacturing process for dry granulation is quicker and less expensive than that of wet granulation. Dry granulation works particularly well for active substances that are labile to moisture and high temperatures or sensitive to solvents because it doesn't require heat or moisture.
(Fukuda et al, 2006)

METHOD OF EVALUATION-
1-Bulk density-It is the mass of the powder divided by the volume of the bulk. The size distribution, shape, and cohesion of the particles all affect the bulk density. The initial bulk volume was determined after a precisely weighed amount of powder was carefully poured via a huge funnel into a graduated measuring cylinder. It is provided by the formula and is represented in gm/ml.
Bulk density=M/Vo
where,
M = mass of the powder
Vo = bulk volume of the powder.
(Hancock et al, 2000)

2-Tapped density- A 10 mL graduated measuring cylinder was filled with precisely weighed batch (F1–F10) powder. At a distance of 14+2 mm, the cylinder was first tapped 100 times. To the closest graded unit, the tapped volume was measured. Once more, the closest graduated unit was used to measure the tap volume. The following formulas were used to determine the Dt in g/Ml
Dt =M/Vt
Where, Dt =Tapped density
Vt =Tapped volume of the powder
Dt =Tapped density
M=Mass of the powder
(Rashmitha et al, 2021)

3-Angle of repose (θ)-It is the greatest angle that can exist between the powder pile's surface and the horizontal plane. The fixed funnel approach was applied. A graph paper was laid on top of a flat, horizontal surface, and a funnel was secured with its tip at a specific height "h." A funnel was used to delicately pour powder until the conical pile's apex barely touched the funnel's tip. The following formula was then used to get the angle of repose:17
Repose angle Ø = tan1(h/r)
(Jaimini M. 2007)
4-Weight Variation test (U.S.P.)-Weigh each of the twenty tablets. Determine the average weight of each tablet and compare it to the average. If no more than two tablets deviate from the percentage restriction and if no tablet deviates by more than twice the percentage limit, the tablet passes the U.S.P. test.
(Khan et al, 2009)

5- Hardness-The ability of a tablet to tolerate mechanical shocks while handling is indicated by its hardness. A Monsanto hardness tester was used

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to measure the tablets' hardness. The unit of measurement was kg/cm³.
(Timmermans j, Moes AJ 1994)

6-Drug content-Each batch's ten tablets were weighed and ground into powder. In a 100 ml volumetric flask, powder equal to the average weight of the tablet was precisely weighed and dissolved in an appropriate amount of 0.1 N HCl. After that, 0.1 N HCl was added to get the volume up to 100 ml, and it was filtered. A 100 ml volumetric flask was filled with 2 ml of filtrate, and 0.1 N HCl was added to adjust the volume. A UV spectrophotometer is used to measure the absorbance of the resultant solution at a drug-specific wavelength.
(Keshari et al, 2015)

7-Floating lag time and total floating time -With a paddle rotating at 50 rpm (pH 1.2) at 37 ± 0.5 °C, the floating lag time (FLT) and total floating time (TFT) of floating tablets were visually recorded in a dissolution apparatus type II that contained 100 mL of 0.1 N HCl.
(Mashadi AB and Newton JM 1987)

8-Dissolution Study- Using a USP dissolution equipment type II paddle type, the formulation's in vitro drug release was conducted at 37 ± 0.5 °C and a sink condition with a revolving speed of 50 rpm. 900 milliliters of 0.1NHCl were employed as the dissolving media. For six hours, the samples were taken out at prearranged intervals, refilled with freshly diluted medium, and examined using a UV/visible spectrophotometer. **(Ohwoavworhua F and Adelakun T 2004)**

9-Disintegration Test (U.S.P.)-.Six 3-inch glass tubes with ten mesh screens at the bottom and an open top are used in the U.S.P. equipment to test disintegration. One tablet is put in each tube, and the basket rack is set up in a 1-liter beaker of water, simulated gastric fluid, or simulated intestinal fluid at 37 ± 2 0 C so that the tablet stays 2.5 cm below the liquid's surface when it moves upward and stays no closer than 2.5 cm from the beaker's bottom when it moves downward. This is how the disintegration time is measured. At a rate of 28 to 32 cycles per minute, move the basket with the tablets up and down a distance of 5 to 6 cm.
Placing perforated plastic disks on each tablet will stop them from floating. The test requires that the tablet break up and that every particle flow through the 10-mesh screen within the allotted time. Any residue that is left over ought to have a soft bulk. Time of disintegration: Tablet without coating: 5 to 30 minutes pill with coating: 1-2 hours.
(Patel 2006)

Table 2 provides a list of commercially available floating formulations, along with their active ingredients and categories.

Table 2: Commercially available floating formulations

Name of the product	Active ingredient	Category
Madopar® HBS Capsule	Levodopa (100mg) and Beneserazide (25mg)	Anti-parkinsonial
Valrelease ® Capsule	Diazepam (15mg)	Anti-anxiety
Liquid Gaviscon	Al hydroxide (95mg) Mg carbonate (358mg)	Antacid (in reflux esophagitis)
Cytotec Bilayer capsule	Misoprostol (100mcg/200mcg)	(PGE1) analogue
Topalkan ®	Alginic acid, Aluminium and Magnesium salts	Antacid
Almagate flowcoat	Al-Mg antacid	Antacid

(Jain et al, 2005)

II. CONCLUSION-

Floating tablets have become a potent way to increase bioavailability, offer sustained release, and circumvent the negative side effects of numerous medications. In order to maximize absorption and improve absolute bioavailability, drugs with low bioavailability due to restricted absorption to the upper gastrointestinal system can be given effectively. One possible treatment for stomach retention has been found to be floating pills.

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CONFLICT OF INTEREST-

The author's have no conflict of interest.

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