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Floating Drug Delivery System: A Promising Approach for Gastroprotective Drug Delivery

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ABSTRACT

Floating Drug Delivery Systems (FDDS) is a very recent approach in the development of oral drug delivery systems, which can be employed to control the gastric emptying time of filled device for both sustained and controlled release (CR) preparations, to locate the CR in a particular site, to minimize the drug loss and to improve drug delivery. These types of systems have a low density, are buoyant in gastric fluid, maintain longer residence time in the stomach with controlled drug release. FDDS can be prepared in tablets, capsules, powders, granules, films and microspheres and are especially valuable when dealing with highly water-soluble drugs with short half-life, having absorption window low in the gut or having instability at intestinal pH. There are several types of FDDS such as effervescent, non-effervescent, raft-forming, the hydrodynamically balanced and the inflatable system that uses different ways to float and consequent modification of release. Their performance is highly dependent upon physiological parameters, such as gastric pH, motility, meal content, age, and body position. FDDS have various advantages such as increased bioavailability, rapid onset of action, a lower frequency of dose administration, better patient compliance, and long site-specific action in the stomach, which is useful in the case of gastroesophageal reflux disease (GERD) and peptic ulcers. Nevertheless, gastric emptying variability and complexity of the formulation still pose obstacles. Newer excipients and polymers and newer carriers will continue to improve these systems, making FDDS a potential weapon for future gastroprotective and controlled-release therapies.

Keywords: Floating drug delivery systems, controlled-release preparations, gastroesophageal reflux disease, Migrating myoelectric complex, Hydrodynamically balanced systems

INTRODUCTION

Oral drug administration remains the most widely utilized route in pharmaceutical practice due to its numerous advantages, including high patience, ease of use, cost- effectiveness and formulation flexibility. These features allow for the design of various dosage forms tailored to meet patient-specific needs [1, 2] Despite these advantages, conventional oral drug delivery systems face several limitations including poor bioavailability of particular drugs, rapid gastric emptying, inability to achieve site-specific release of drug in gastrointestinal regions and others ([3 ,4]).To overcome these challenges FDDS was identified in 1968 by Davis.

Gastro retentive drug delivery systems are characterized by their low density less than 1.004 g/cm³ (the approximate density of gastric fluid) and high buoyancy [5,6], which enable them to remain afloat on gastric fluids in the stomach. while maintaining buoyancy within the gastric environment, the dosage form facilitates a sustained and regulated release of the active pharmaceutical ingredient. The extension of gastric residence time consequently permits enhanced drug exposure within the stomach, thereby optimizing systemic bioavailability and minimizing pharmacokinetic variability associated with plasma concentration fluctuations resulting in prolonged duration of action [7, 8].

Floating drug delivery systems (FDDS) can be formulated in various forms such as powders, granules, capsules, tablets, films, and microspheres with low density. These systems are particularly effective for medications with short half-life, required prolonged gastric retention or those with low bioavailability, have a short absorption window in the upper GI tract, or are best absorbed in a certain pH range [9,10].

Physiological aspect of the stomach

The stomach is a mixing and storage organ. About 1.5 L of 8 L fluid in the gastro intestinal system is produced in the stomach after food intake, while 25-50 ml is secreted during interdigestive states. There are numerous physiological factors such as pH, gastric enzymes, the volume and composition of gastric secretions and residence time which significantly impact metabolism and absorption of pharmaceutical agents [11,12].

Stomach pH can be as high as 6.0 if a large amount of food has just been ingested, but the mean pH is 2.0 ([13]. Gastric PH being influenced by numerous variables such as diet, disease, and presence of gases, fatty acids, and other fermentation products in gastric lumen, may impact oral drug absorption efficiency [14].Anatomically, the Stomach divided into two regions: proximal stomach that further consists of fundus and body which primarily act as reservoirs of ingested food. and the other region is distal stomach which consist of antrum and pylorus whereas antrum serves as a propulsive chamber aiding gastric emptying [15,16]. Gastrointestinal motility operates in two distinct patterns: the digestive and interdigestive states. Gastric emptying occurs not only in the fed state but also during fasting, though through a different mechanism characterized by a cyclical series of coordinated electrical events which pass every 2 to 3 hours in both stomach and small intestine. This process is referred to as the migrating myoelectric complex [17, 18].

Migrating myoelectric complex (MMC) often referred to as the inter-digestion myoelectric cycle (IDMC), is a series of electrical events that circulate through the stomach and intestine every two to three hours while a person is fasting [19],as illustrated in Figure 1 it goes through four repeating stages during periods between meals. Phase I is a calm phase with very little muscle movement, lasting about 30 to 60 minutes. Then comes Phase II, where there are occasional bursts of electrical signals and muscle contractions that grow stronger and more frequent over time. Phase III features a short burst of steady, powerful contractions lasting around 10 to 20 minutes.This phase helps move leftover food and waste from the stomach into the small intestine, which is why it's sometimes called the "housekeeping wave." Lastly, Phase IV is a short transition, lasting up to 5 minutes that marks the end of one cycle and the start of another [20.21].

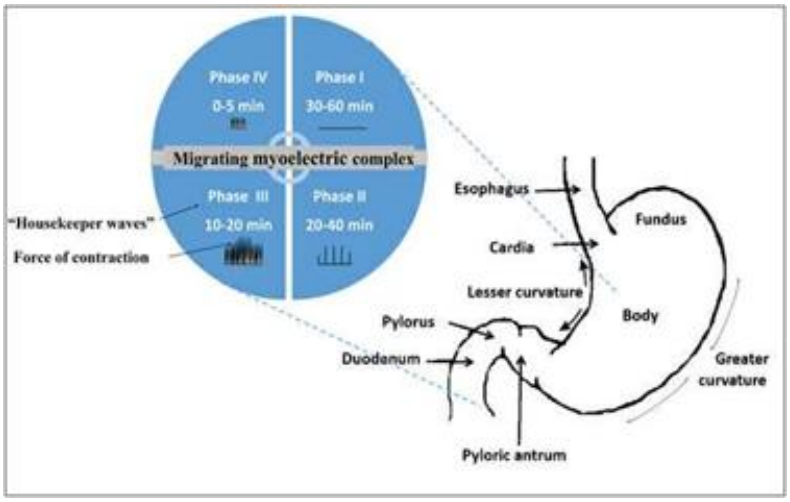

Figure 1: shows Migrating Myoelectric Complex phases

Drugs suitable for Floating drug delivery system

- Medication that acts locally in the stomach (Antacids, Misoprostol).
- Drugs having narrow absorption window in GIT (furosemide).
- Drugs that are poorly soluble at high pH levels (Chlordiazepoxide).
- Drugs unstable in the lower part of Gastro-intestinal tract (captopril).
- Drugs with variable bioavailability (Sotalol HCl).
- Drugs caused imbalance of normal colonic microbes (Antibiotics against H. Pylori) [22,23]

Classification of floating drug delivery system

FDDs can be classified into two broad types single-unit and multiple-unit formulations with different characteristics and therapeutic implications. While single-unit dosage forms are simpler and less expensive to produce, they are susceptible to variations because they either tend to stay in the stomach completely or get ejected completely [24,25]. This "all-or-none" effect may result in premature therapeutic effect loss, localized irritation due to the release of a high concentration drug at a single location along the gastrointestinal tract, and extreme bioavailability variations. Conversely, multiple-unit systems offer a superior option by dispersing numerous tiny floating subunits (e.g., microspheres, beads, and pellets) into the gastric milieu. This method minimizes both intra- and inter-subject variation in drug absorption, thereby reducing the likelihood of dose dumping incidents. Several design techniques are used in these systems, and these involve air spaces, hollow microspheres that are produced by solvent diffusion in emulsions, and beads that are produced via emulsion gelation techniques. Effervescent agents and swellable polymers play a significant role in sustaining buoyancy and for the controlled delivery of the drug. In summary, though single-unit systems present a straightforward approach to manufacturing, multiple-unit systems afford enhanced reliability, improved gastric retention, and more predictable pharmacokinetics. These advantages are especially appropriate for medications that necessitate stable plasma concentrations and extended gastric residency [26, 27].

Classification of floating drug delivery system based on floating mechanism

1-Effervescent System: It is categories into two types:

A) Gas Generating System: gas generating systems are prepared using swellable polymer like chitosan, methocel and methylcellulose also by using gas generating agents, carbonates (i.e. Sodium bicarbonate) and other organic acids (like citric acid and tartaric acid) found in the formulation.it come into contact with acidic gastric content they produce carbon dioxide (CO2) gas and entrapped in a swelling hydrocolloid, thus decreasing the system density and causing it to be floatable relative to the gastric juice [28,29]. In order to identify a mechanism for gas generation within the hydrocolloid layer, the carbon dioxide-producing components are combined in a single or multi-layered structure within the tablet matrix. Meanwhile, the drug in the other layer produces a sustained release effect as shown in Figure 2 [30, 31, 32].One example of a multi-unit floating system is the utilization of calcium alginate beads, which are encapsulated in a membrane fabricated from calcium alginate and polyvinyl alcohol (PVA) with an air gap between them [33,34]. When the system is exposed to water, PVA deteriorates, hence enhancing the permeability of the membrane while allowing space for the air gap essential for flotation. Enhancement of the molecular weight and concentration of PVA significantly enhances the buoyancy characteristic of the system. Freeze-drying is the process employed in the formulation of the current beads, resulting in a porous structure that facilitates buoyancy. In a human study utilizing gamma scintigraphy, the buoyant beads showed a prolonged gastric retention time, which was more than 5.5 hours when compared with non-buoyant controls [35,36,37].

B) Volatile liquid-vacuum comprising systems

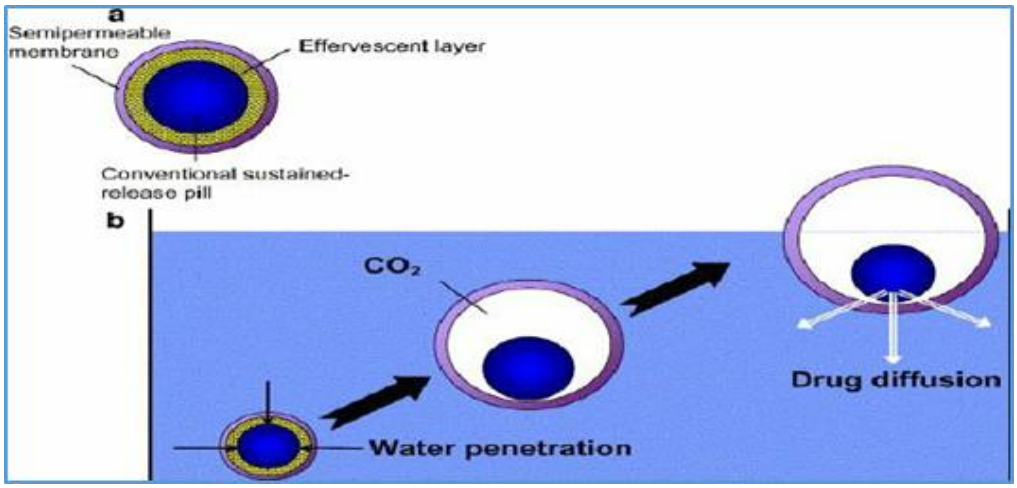

Figure 2: Illustrated Working principle of effervescent Floating Drug Delivery Systems

2-Inflatable system

The inflatable drug delivery system is designed with a chamber containing a volatile liquid such as ether that evaporates at body temperature, resulting in gas formation that inflates the chamber and enables the system to float in the stomach [38]. The expanded state typically comprises a biodegradable polymer i.e., polyvinyl alcohol or polyethylene, which degrades gradually in the gastric environment. When the medication is taken orally, the entire system—which consists of an inflatable chamber and a drug reservoir that may contain the medication in its pure form or encased in a polymeric matrix—is placed within a gelatin capsule [39,40]. Upon reaching the stomach, the capsule disintegrates, enabling the inflation of the chamber and the entrapment of the drug reservoir within the gastric fluid. As the polymeric substance gradually breaks down, the therapeutic agent is continuously released into the gastric milieu, ultimately causing the degradation of the system by loss of structural integrity of the chamber [41, 42].

3-Intragastric floating system

It has a chamber filled with vacuum, air or a harmless gas, with a microporous section that acts as a drug reservoir, thereby it tends to float in the stomach [43].

4-Intragastric-osmotically controlled system:

Is an osmotically controlled floating drug delivery system containing a flexible, collapsible module. Internally, it is divided into two compartments by an impermeable, pressure-sensitive membrane. One compartment holds the active medication, the other contains volatile liquid—ether or cyclopentane—with a vaporization point at body temperature which generating as and causes the device to float in the stomach. A bioerodible plug subsequently permits vapor release, facilitating the collapse of the device and subsequent removal from the gastrointestinal tract [44, 45, 46].

5-Non effervescent systems

Non-effervescent systems rely on polymers capable of swelling or gelling upon contact with gastric fluids such as HPMC, polyacrylate, and sodium alginate. These polymers absorb water and form a hydrated matrix of bulk density less than the density of gastric contents, causing the dosage form to float. The entrapped air in the swollen form imparts buoyancy, while the matrix also serves as a diffusion barrier to achieve sustained drug release [47, 48, 49].Such systems are commonly prepared by intimately mixing the drug with the gel-forming polymer for uniform distribution [50].Of the advanced formulations, bilayer and multilayer floating tablets are improved non-effervescent systems. In bilayer systems, one layer sustains an immediate release of the drug, while a second, comprised of swellable polymer, absorbs gastric fluid and provides buoyancy. Multilayer tablets consist of at least one drug layer and two barrier layers of erodible polymers. Upon exposure to gastric fluids, the tablet swells and erodes gradually, providing controlled exposure of the drug. A gas-forming agent is typically included in one of the barrier layers to promote flotation and prolong gastric retention time ([51, 52,53].

6-Raft forming drug delivery systems

Raft-forming drug delivery systems have received much interest in the management of gastrointestinal infections and disorders, mainly gastroesophageal reflux [54]. These systems are usually composed of a gel-forming agent such as sodium alginate and carbonates or bicarbonates. Upon contact with gastric fluid, the solution swells to form a cohesive and thick gel that entraps carbon dioxide bubbles [55]. This chemical reaction creates a low-density buoyant "raft" layer that floats on the surface of the gastric contents. The raft is a physical barrier that prevents the retrograde flow of gastric acid and enzymes into the esophagus while providing prolonged release of the active pharmaceutical ingredient [56, 57]. Drugs like calcium carbonate or aluminum hydroxide are usually incorporated into these preparations so as to decrease gastric acidity and increase the healing action of the raft system [58].

7-Hydrodynamically balanced systems (HBS)

HBS are single-unit dosage forms designed specifically to improve gastric retention by forming a floating matrix within the stomach [59]. These systems typically composed of gel-forming hydrophilic polymers, with hydroxypropyl methylcellulose (HPMC) being the most notable, although others like hydroxyethyl cellulose (HEC), hydroxypropyl cellulose (HPC), sodium carboxymethyl cellulose (NaCMC), agar, and alginic acid are also used [60,61]. The drug is incorporated into the polymer blend, which is most often encapsulated in a gelatin

capsule. Upon administration, the capsule disintegrates quickly in gastric fluid, causing the hydrophilic polymers to swell up with water, thus forming a buoyant gel layer. As a result, the floating matrix floats in the stomach, extending the residence time of the drug while improving its solubility and absorption properties [62,63]. These formulations were originally called "Hydrodynamically Balanced Systems," and they utilize polymers that form a colloidal gel after hydration, serving as a physical barrier while at the same time being buoyant. A good example of this technology in action is Modopar LPR, a 1980s product designed in compliance with this delivery system [64].

Mechanism of FDDS

Since the system is suspended in the gastric contents, the drug is released slowly at a controlled rate from the delivery system. When the drug is released, the rest of the system is ejected from the stomach. Apart from the minimum gastric content necessary for buoyancy maintenance, a certain minimum quantity of floating force is needed for the dosage form to remain buoyant consistently on top of the meal as shown in Fig 3. A new device that was developed to measure the dynamics of the floating force was reported in the literature. The device operates by continuously measuring the force equivalent to F as a function of time, which is needed to buoy submerged objects. The device plays a critical role in optimizing the FDDS with respect to the stability and longevity of the floating forces developed, thus overcoming the possible difficulties linked with random variations in intra gastric buoyancy capacity [65, 66].

$$F = F\,\text{buoyancy} - F\,\text{gravity} = (Df - Ds)gv$$

Where; F = Total vertical force, Df = Fluid density, Ds = Object density, g = Acceleration due to gravity, v = Volume.

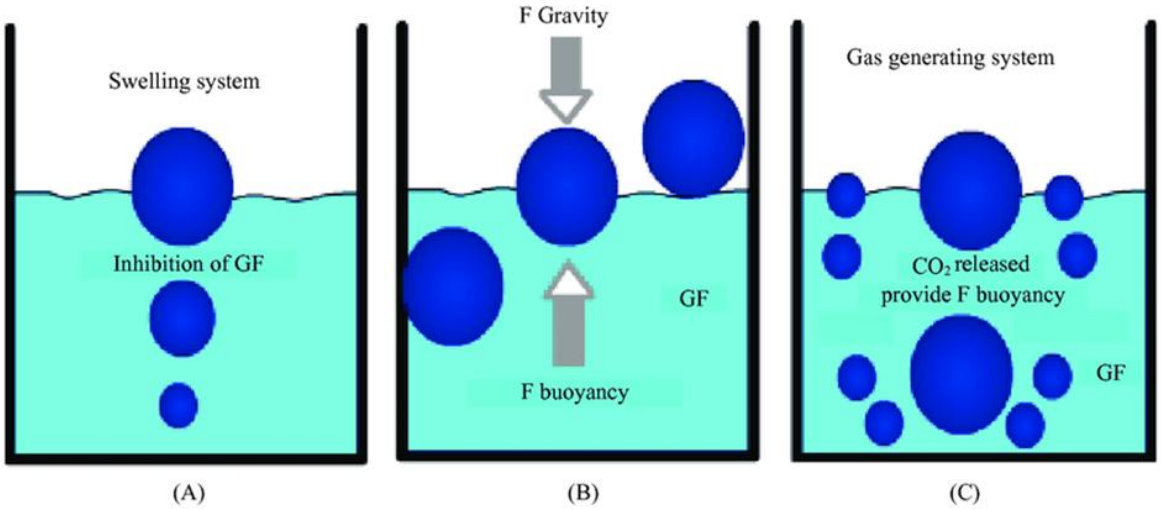

Figure 3: Mechanism of Floating Drug Delivery Systems.

Factors Affecting FDDS

Size of the dosage form

To enable transit via the pyloric valve into the small intestine, the particle size must range from 1 to 2 mm. In general, larger dosage forms tend to have better gastric retention time (GRT). However, the larger the dosage form, the longer it takes to clear the pyloric antrum and move into the intestine. Larger tablets are eliminated during the housekeeping waves, whereas smaller tablets can leave the stomach during the digesting phase [67,68].

Shape of the dosage form

Devices that are tetrahedron and ring-shaped have a better buoyancy compared to other shapes. These shapes can retain for 24 hours with 90 to 98 percent higher retention rate [69].

Density

The ability to float is dependent on density. The density of the dosage form should be less than the density of gastric contents (1.004 gm/ml) [70].As such, dosage forms with lower density than gastric contents will float while those with higher density will sink to the bottom of the stomach.

Formulation of single or multiple units:

Compared to single unit dosage forms, multiple unit formulations provide a greater margin of safety against dosage form malfunction [71].

Fed or unfed state

In the absence of food, gastrointestinal (GI) motility has strong motor activity along with gaps known as the migrating myoelectric complex (MMC), whose phases alternate every 1.5-2 hours. The MMC cleanses undigested substances [72].

Nature of meal

The intake of complex indigestible carbohydrates or salt forms of fatty acids can shift the stomach's motility pattern to a fed state, thereby reducing the gastric emptying rate and extending the release of drugs [73].

Caloric content

High-protein and high-fat meals can enhance gastric retention time (GRT) by 4 to 10 hours.

Frequency of feed

Gastric retention duration exceeds 400 minutes because the frequency of migrating myoelectric complex (MMC) decreases with subsequent meals compared to a single meal [74].

Gender

The mean ambulatory gastric retention time for men is 3.4 to 0.6 hours less than that of their age-matched counterparts, whereas it is 4.6 to 1.2 hours longer for females of the same race. These numbers are unaffected by body surface area, height, or weight [75].

Age

Elderly persons have a longer gastro-retentive time, particularly those above 70. This slows down the time it takes for the stomach to empty.

Posture

While average GRT remains largely unchanged with posture, floating systems are likely to stay in the upper stomach while a person is upright which increases retention. In the supine position, however, floating forms are likely to be emptied more rapidly than in upright posture [76].

Gastric fluid amount

The volume of liquids given has an impact on the stomach evacuation time. When the volume is large, the evacuation process proceeds more quickly. While stomach evacuation is slowed down by colder fluids, it is accelerated by warmer ones.

Biological factors

The floating drug delivery system is impacted by biological variables such as diabetes and Crohn's disease [77].

Concomitant drug administration

Prokinetic drugs like metoclopramide and cisapride, opiates like codeine, and anticholinergic drugs like atropine all have an impact on the gastric emptying and hence gastric residence time of an oral dosage form [78].

Advantages of FDDS

•Ease of administration with greater patient compliance
• Treatment of gastrointestinal diseases like GERD.
• Aspirin which is an acidic substance that can cause inflammation and irritability of the stomach wall when come in contact with it. Hence HBS formulation may be useful for the administration of such drugs.
• Suitable for medications with short half-lives: Multi-dosage may be necessary for medications with short half-lives in order to maintain therapeutic levels. Floating tablets can help by releasing the medication gradually, which eliminates the need for several doses throughout the day.
•Floating tablets can be useful for medications that are poorly soluble in intestinal fluid but more soluble at the stomach's acidic pH, which allows for a longer dissolving time.
• FDDS dosage forms are advantageous in diarrhea and severe intestinal movement due to the fact that they maintain the drug in a floating condition within the stomach for enhanced response.
• The active agent is targeted directly to the site of action, thereby reducing or avoiding the side effects
• Fluctuations are minimized due to continuous input of the drug [79,80,81].

Disadvantages of FDDS

• Require high volume of fluids in the stomach.
• Different Factor such as gastric motility, pH and presence of food affects the gastric retention and they are never constant. Therefore, the buoyancy cannot be predicted.
• High variability in gastric emptying time because of its all (or) non-emptying process.
• Patients are not supposed to be administered floating forms shortly before bedtime.
• Drugs that cause irritation to the mucosa of the stomach should not be utilized in the development of the floating drug delivery device.
• Drugs that undergo substantial first-pass metabolism and are well absorbed throughout the GI tract would not be good candidates for FDDS because of the potential for decreased systemic bioavailability due to delayed gastric emptying. For example, nifedipine [82].

EVALUATION PARAMETERS

1-Drug-excipient interactions:

Fourier Transform Infrared Spectroscopy (FTIR) may be utilized to examine drug-excipient interactions. A (DE) interaction is signaled by the disappearance or appearance of new peaks of identifiable peaks of the drug or excipient. Furthermore, methods such as Hot Stage Polarizing Microscopy and Differential Scanning Calorimetry may be utilized in assessing the effects of aging [83,84].

2-Weight variation test:

From each batch, twenty tablets were chosen at random and weighed individually to check for weight variations. A small variance in tablet weight is allowed by the USP [85].

$$\text{Weight Variation} = \frac{\text{Iw} - \text{Aw}}{\text{Aw}} * 100\%$$

Where, Iw = Weight of tablet, individual; Aw = Average weight of tablet

3-Tablet density:

One important factor for floating tablets is tablet density. Only when the density of the tablet is less than that of gastric fluid will it float (1.004) [86].

We can calculate the density by using the formula;

$$V = \pi r2h$$

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

4-Bulk density

A known volume of powder is poured into a graduated cylinder to determine the bulk density. This blend's bulk volume is then measured, enabling bulk density to be calculated using the formula:

$$Bulk\ density = Total\ mass\ of\ powder / Bulk\ volume\ of\ powder$$

5-Tapped Density

Following standard procedures, a measuring cylinder is filled with a known weight of the blend is tapped for a specified period of time and from a specific height [87]. The tapping procedure is repeated after recording the cylinder's initial volume. The tapped density may be determined from the formula:

$$Tapped\ density = Total\ powder\ mass\ /\ Tapped\ powder\ volume$$

Hausner's ratio: - Hausner's ratio is utilized for the prediction of the flowability of the powders. This is a similar technique to compressibility index [88]. Hausner's ratio can be expressed by equation:

$$Hausner's\ ratio = Tapped\ density\ /\ bulk\ density$$

6-Compressibility Index

The bulk density (ρo) and tapped density (ρt) can be compared, and the rate of packing can be observed, to evaluate the powder's flow properties.The relation between compressibility and index property shown in Table 1 .The following formula determines the compressibility index:

$$\boldsymbol{Compressibility\ index}\ (\%) = (\boldsymbol{\rho t} - \boldsymbol{\rho o}) / \boldsymbol{\rho t} \times \mathbf{100}$$

Where, ρo represents bulk density in g/ml, and ρt indicates tapped density in g/ml.

Table 1: Relation between compressibility and index property

Compressibility	**Index Properties**
≤10	Excellent
11-15	Good
16-20	Fair
21-25	Passable
26-31	Poor
32-37	Very poor
>38	Very Very poor

7-Buoyancy / Floating Test; It is known as Floating Lag Time (FLT) or Buoyancy Lag Time (BLT) when the dosage form emerges on the medium's surface, and Total Floating Time (TFT) is the total amount of time the dosage form is afloat. To simulate in vivo settings, a study of floating behavior was carried out in a USP XXIII dissolving apparatus type II (Paddle) at a speed of 50 RPM in 900 ml SGF at 37±0.50C for 12 hours [(89)].

8-Hardness:

Tablet strength and hardness are crucial for ensuring that the tablet can endure shock and strain during production, packaging, and transportation, as well as when the patient handles it. The Monsanto testing tablet's hardness is measured in kilograms per centimeter. Additionally, Schleuniger, Erweka, Pfizer, and Strong-Cobb testers are used.

9-Friability:

The Roche friabilator is used to test tablets to determine their stability against abrasion. This was made up of a plastic drum that was fixed to a machine that turned 100 times at 25 rpm. The twenty tablets that were weighed prior to the test are then taken out of the drum, cleaned with a cloth, and weighed once more. For a typical tablet, the weight variation should not be less than 0.5 to 1.0% [(90)].

$$\%\ Friability = Initial\ weight\ of\ tablets - Final\ weight\ of\ tablets\ /\ Initial\ weight\ of\ tablets \times 100$$

10-Swelling index;

Is measured by measuring weight increase or water uptake (WU) after being submerged in an aqueous medium—specifically, 0.1 M HCl—for a predetermined amount of time. Weight changes are computed in relation to time after the dosage form is removed at regular intervals [91]. WU is calculated as a weight increase percentage:

$$WU = (Wt - Wo) * 100 / Wo$$

Where Wo and Wt are initial weight of dosage form and weight at time t, respectively.

11-X-Ray technique

X-ray has become a very common evaluation metric for floating dosage forms nowadays. Together with the prediction and connection of stomach emptying time and dosage form passage in the GIT, it aids in the placing of dosage forms in the GIT. X-ray imaging is made possible by the addition of a radio-opaque substance in a solid dose form [92].

APPLICATION

In the pharmaceutical industry, floating tablets have become more and more common, especially for medications that require gastro-retentive distribution. A number of products are now on the market

1-Metformin SR: Metformin extended-release formulations use a floating mechanism to keep therapeutic levels stable in type 2 diabetics, improving patient compliance and glucose control [93].

2-Ciprofloxacin extended-release tablets: Floating formulations of ciprofloxacin increase its bioavailability, allowing for less frequent dosage and better patient adherence to treatment [94].

3-Ranitidine and famotidine: The benefit of using these H2 receptor antagonists to treat GERD and peptic ulcers is that they prolong stomach retention, which improves therapy results [95].

4-Domperidone:

This antiemetic medication's floating formulations show improved control over nausea and vomiting by guaranteeing a more steady therapeutic impact [96].

Work on floating drug delivery system

A lot of work has been done on the development of floating drug delivery system. Some of them are cited below. The floating ability and sustained release features of a multiple unit kind of floating dosage form containing aminobenzoic acid were assessed *in vitro* by Ichikawa M. *et al.* Regardless of the buffer medium's pH and viscosity, the system floated entirely in ten minutes and roughly 80% of it did so for five hours. It also followed zero order drug release [97]. Timmermans J. *et al s*tudied floating force kinetics of peroral polymeric matrix dosage forms using a new *in-vitro* resultant-weight measuring device. The floating curves demonstrated that the dosage form's bulk density was not the best metric to describe its buoyancy properties. The resulting weight measurements precisely reflected and tracked these capacities. The findings showed that the amount of floating strength can change over time and typically diminishes after the dosage forms is submerged in the fluid, which leads to the development of its hydrodynamic equilibrium [98].

For the oral controlled delivery of calcium, Shoufeng Li *et al.* created an ideal gastric floating drug delivery system. HPMC loading, citric acid loading, and magnesium stearate loading were the three formulation variables

utilized in a central, composite Box-Wilson design for the regulated release of calcium. Release properties were shown to be considerably impacted by all three formulation factors. For floating properties, only HPMC loading was determined to be important [(99)]. Amoxycillin trihydrate oral sustained release floating tablets were created by Hilton AK, et al., who also conducted an *in vitro-in vivo* assessment. According to the tests, the drug diffuses out of the floating matrix tablet in the stomach and then slowly moves toward the proximal intestine, where absorption takes place. It enhanced antibiotic delivery, leading to more consistent antibiotic levels after fewer oral doses [(100)]. Ozdemir N. *et al.* created a floating bilayer tablet comprising the inclusion complex of furosemide and cyclodextrin. After adding BaSO4, they used radiography to calculate the gastric residence duration and found that the tablet remained in the stomach for six hours. Additionally, there was a notable in vitro-in vivo correlation found, and the bioavailability of furosemide from floating tablets was almost 1.8 times that of normal tablets. There have been reports of propranolol in a floating dose form with both rapid and prolonged release characteristics [(101)].

By creating floating microparticles using the emulsion solvent diffusion technique, El-Kamel was able to extend the duration of Ketoprofen's residency in the stomach without coming into touch with the mucosa. The flow characteristics, packability, and drug release rate of each floating microparticle formulation were assessed [(102)].The effect of the solvent evaporation approach on Piroxicam's floating type hollow polycarbonate microspheres—which could float on simulated stomach fluid—was investigated by Joseph NJ et al. The bioavailability of Piroxicam hollow microsphere was approximately 1.4 times that of the free drug, according to pharmacokinetic studies, and 4.3 times that of the dosage form that included the loading dose in addition to the microsphere. Three times the elimination half-life of the free drug was observed [(103)].

Hydroxypropyl methyl Cellulose was used in the development of floating matrix tablets by Baumgartner S. *et al.* These tablets, when taken orally, are intended to boost the bioavailability, decrease the adverse effects of irritating medications, and extend the stomach residence duration. Examined were the significance of composition optimization, formulation considerations, and tablet characterization. The analysis revealed that the floating and drug release characteristics of the tablets are significantly influenced by their mechanical strength and content. They came to the conclusion that non-Fickian transport accounted for the drug release from the tablets [(104)]. Piretinide or atenolol were used as the model drugs in a study by Roughe N. *et al*. to assess the variables that enhance the floating minitablets' *in vitro* buoyancy and drug release profile. Either the excipients swelled or sodium bicarbonate, a gas-generating agent, was added to give the minitablets buoyancy. According to the study's findings, minitablets with either atenolol or piretinide can be made with adequate release profiles and a positive weight over a period of more than six hours [(105)].

The *in vitro* floating and bioadhesive properties of sotalol for oral administration were devised and studied by Jimenez-Castellanos *et al.* The active component was combined with sodium carboxymethyl cellulose, hydroxy propyl cellulose, and a carbonate to produce gas in order to create the tablets. Tests for drug release, tablet floating, and bioadhesion were conducted *in vitro*. They came to the conclusion that this technology had favorable qualities for a regulated medication delivery system [(106)].

The formulation, dissolution, buoyancy, and *in vivo* release experiments of a double layer, sustained release oral tablet of riboflavin phosphate sodium hydrophosphate matrix with a carbon dioxide producing layer were detailed by Ingani HM *et al.*This floating tablet's *in vivo* behavior was then compared with that of a traditional hydrodynamically balanced capsule design. The residence period of the floating dosage forms was longer than that of the nonfloating tablet [(107)].

Using a factorial design, Menon A. et al. reported creating a monolithic floating dosage form for furosemide while maintaining the three parameters of drug to polymer ratio, polymer to polymer ratio, and polymer grade. It was discovered that the resulting improved formulation had an excellent *in vitro/in vivo* correlation [(108)].

Using riboflavin as a model medication, Park et al. created and assessed floating beads from sodium alginate solution that contained CaCO3 or NaHCO3 as gas-forming agents. CaCO3 outperforms NaHCO3 as a gas

producing agent in alginate bead preparations, according to in vitro release experiments. Their improved buoyancy and sustained release qualities make them ideal for floating drug delivery systems [109].

An in-vitro dissolution technique for a floating dosage form with biphasic release properties was described by Burns SJ, et al. For the assessment, a modified paddle dissolution was compressed. According to studies, the enlargement of the tablet and its subsequent expulsion from the stomach at the end of the drug release significantly decreased the likelihood of elimination through the pylorus [110].

Two medication formulations that floated in gastric juice were created by Machida S. et al. One was a buoyant pill made of sodium bicarbonate, medication, and powdered soybean protein. The other preparation, a laminated film, was made up of an outer drug release controlling time, an effervescent film that included sodium bicarbonate, and a drug film. As the model medicine, cinnarazine, an acid-soluble medication, was employed [111].

A matrix tablet covered in a permeable membrane makes up the innovative controlled release gastric retention technology that Deshpande AA et al. developed. Tablets with the poorly soluble medication Riboflavin and the soluble medication Chlorpheniramine Maleate [112].

A dynamic artificial gastrointestinal system was created by Blanquet S. et al. to investigate how an oral medicine dosage form behaves in different physiological settings. Two model medications, acetaminophen and paracetamol, were used in the study. The findings showed that the in vivo data and the invitro results were compatible [113].

Tetracycline-loaded chitosan microspheres were used by Shah S. et al. to create stomach-specific drug delivery for the treatment of Helicobacter pylori. The microspheres release the drug for 12 hours while the dosage form is in the stomach because of the chitosan's natural ability to gel in acidic environments and its bioadhesion qualities [114].

Metranidazole matrix tablets were made by Alderete ME, et al., with particle sizes ranging from 163 micrometers to 505 micrometers and HPMC viscosities between 15 cps and 30,000 cps. At a 10% polymer content, the inverse of the release rate and viscosity grade showed a linear connection. Additionally, a linear correlation between the release rate and the diameter particle size cube was found [115].

El-Gibaly created and contrasted traditional non-floating chitosan microspheres with melatonin-containing chitosan floating microcapsules. In vitro, floating microcapsules demonstrated zero order release kinetics and a floating time of over 12 hours. Additionally the drug release from these floating microcapsules was significantly delayed, lasting many hours, whereas that from traditional microspheres was nearly instantaneous [116].

Yang L and Hejazi R created a novel intragastric administration method to treat gastric ulcers linked to H. pylori. Using HPMC K4M and chitosan, they created an intragastric floating medication delivery system. They discovered that the method might boost treatment effectiveness and enhance patient adherence [117].

Clarithromycin sustained release tablets were created by Bhat SS et al. to increase efficacy. They found that the antibiotic concentration in the sustained release formulation is significantly higher than the minimum inhibitory concentration (MIC) and lowers drug resistance. Drug release from the tablet matrix followed zero order kinetics, according to statistical analysis [118]. Scaglione et al. examined the pharmacokinetic properties of clarithromycin and its metabolite and discovered that, regardless of dose or ethnic origin, maximal serum concentrations were attained in 3 hours. Food has no clinical impact on the pharmacokinetic characteristics of clarithromycin [119].Clarithromycin extended release pill was created by Darkes MJM et al. It demonstrated that compared to immediate release pills, extended-release tablets had lower maximum plasma concentrations and are achieved later [120].

Hu Yiqiao, Zhi Feng, Sun Minjie, and Xu Xiaoqiang develop one new substance used to treat hypertension is phenoporlamine hydrochloride. Because phenoporlamine hydrochloride has a limited biological half-life, the goal of this study was to create a sustained release tablet. Based on the gas producing agent, three floating matrix formulations of phenoporlamine hydrochloride were made. The hydrogel drug delivery system was created using Carbopol 971P NF and hydroxypropyl methylcellulose K4M. The tablet floated atop the simulated stomach fluid for nearly six hours after sodium bicarbonate was added to the matrix. In simulated stomach fluid, non-Fickian diffusion was evident in the dissolution profiles of every pill [(121)].

Jain, Ashish K. Agrawal, Govind P.; Yadav, Awesh; Jain, Sunil K. created a calcium silicate-based controlled release floating granular delivery system for ranitidine hydrochloride. The formulation showed promising drug release and floating properties *in vitro.*Albino rats were used for the *in vivo* asessment in order to determine the pharmacokinetic parameters. Throughout the experimental period, the floating granules of RH maintained a higher plasma concentration. The floating nature of the dose form may be the cause of the improved bioavailability and elimination half-life seen in this investigation. According to the findings, calcium silicate is a helpful carrier for the advancement of sustained release and floating preparation.

Recent advances in 3D printing for floating drug delivery platforms

Currently, 3D printing has been used in various fields, and its applications continue to expand. The concept of 3D printing has been initiated in 1970; 3D-printed products were fabricated using high-energy beam to solidify the powdered material layer by layer, and this process is called “selective laser sintering”

Several advantages of 3D printing over conventional manufacturing have been reported in the pharmaceutical field. First, 3D printing can improve productivity. The 3D printing is faster than traditional methods for fabricating pharmaceutical products, such as prostheses and implants, with the added benefit of improved resolution, repeatability, precision, and consistency (Schubert et al., 2014). Second, 3D printing is suitable for customized and personalized products and pharmaceutical dosage forms. Last, the objects created by 3D printing are inexpensive. With all materials practically affordable, 3D printing is advantageous for small-scale production units or enterprises that manufacture complicated products or parts (Mertz, 2013) [(122,123,124)].

CONCLUSION

Floating Drug Delivery System (FDDS) is a remarkable development in oral drug delivery, providing a viable and efficient approach to prolong gastric retention and increase drug absorption in the upper gastrointestinal (GI) tract. Being capable of providing sustained and controlled drug release, it is particularly useful for drugs with a narrow absorption window or those having a short half-life. Although there are some limitations concerning physiological factors and formulation design, ongoing research and development have helped in alleviating most of these problems. With developments in new polymers and drug carriers, FDDS has great potential in maximizing therapeutic efficacy and patient compliance in future pharmaceutical therapies.

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نظام توصيل الدواء العائم: نهج واعد لتوصيل الأدوية الواقية للمعدة

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الخلاصة

تعد انظمة توصيل الدواء العائمة نهجا حديثا جدا في تطوير انظمة التوصيل الفموية للادوية. والتي يمكن استخدامها للتحكم في وقت إفراغ المعدة للجهاز المملوء، وذلك لكلٍ من مستحضرات التحرر المُستَمِر والتحرر المُتحَكَّم به، لتحديد موقع التحرر المُتحَكَّم به في موقع معين، وتقليل هدر الدواء وتحسين توصيله. تمتلك هذه الأنظمة كثافة منخفضة، مما يمكنها من الطفو على سوائل المعدة، والاحتفاظ بفترة بقاء أطول في المعدة مع تحرر مُتحَكَّم به للدواء. يمكن تحضير أنظمة التوصيل هذه على شكل أقراص، أو كبسولات، أو مساحيق، أو حبيبات، أو أغشية، أو كريات دقيقة، وهي ذات قيمة خاصة عند التعامل مع الأدوية عالية الذوبان في الماء ذات العمر النصفي القصير، أو التي تمتلك نافذة امتصاص في الجزء السفلي من الأمعاء، أو التي تظهر عدم استقرار عند درجة الحموضة الخاصة بالأمعاء. هناك عدة أنواع مثل: الأنظمة فوارة، وغير الفوارة، ومُشَكِّلة الطوف، والمتزنة هيدروديناميكياً، والنظام القابل للنفخ، والتي تستخدم طرقاً مختلفة للطفو وما يترتب على ذلك من تعديل في تحرر الدواء. يعتمد أداؤها اعتماداً كبيراً على المعايير الفسيولوجية، مثل درجة الحموضة في المعدة، وحركيتها، ومحتوى الوجبة، والعمر، ووضعية الجسم. تمتلك أنظمة التوصيل العائمة مزايا متنوعة، مثل: زيادة التوافر الحيوي، وبدء مفعول سريع، وتقليل تكرار الجرعات، وتحسين امتثال المريض للعلاج، وفعل خاص طويل الأمد في موقع معين في المعدة ,وهو أمر مفيد في حالات الأمراض المعدية مثل مرض الارتداد المعدي المريئي والقرحات الهضمية.ومع ذلك، لا تزال التباينية في إفراغ المعدة وتعقيد التركيبة الدوائية يشكلان عقبتين رئيسيتين. وسوف تسهم المواد المساعدة (الإكسيبيانات) والبوليمرات والحوامل الأحدث في الاستمرار بتحسين هذه الأنظمة، مما يجعل من أنظمة التوصيل الدوائية العائمة سلاحاً واعداً في مستقبل علاجات الحماية المعدية والعلاجات ذات التحرر الدوائي المُتحَكَّم به.

الكلمات المفتاحية: أنظمة التوصيل الدوائية العائمة, مستحضرات التحرر المُتحَكَّم به, داء الارتداد المَعِدّي المريئي, المجمع الكهربائي الحركي المهاجر, الأنظمة المتزنة هيدروديناميكيًا