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Review Paper

Floating Tablet A Gastro- Retentive Drug Delivery System: A Review

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ABSTRACT

Pharmaceutical research on oral drug delivery, particularly on the gastro-retentive drug delivery system known as the Floating Drug Delivery System (FDDS), has attracted a lot of interest from the pharmaceutical industry. GRDF stands for gastro-retentive dosage forms, which are dosage forms that can be retained in the stomach. With the help of GRDFs, the drug can be released to the upper portion of the GIT more continuously and for a longer period of time. This improves the bioavailability of drugs with limited therapeutic windows, lengthening the time between doses and enhance patient compliance. Drugs with a limited stomach absorption window and local activity are of special interest to FDDS. FDDS has many benefits, particularly for medications with a limited window for absorption in the GIT, main absorption in the stomach, For medications that are least soluble In a high pH environment, prolonged stomach retention increases solubility, decreases drug waste, and increases bioavailability. The goal of this study on floating drug delivery systems (FDDS) was to gather the most recent research on the topic, with an emphasis on the main mechanism of floatation to achieve gastric retention.

INTRODUCTION

The simplest and most popular way to administer any medication into the systemic circulation is oral route of administration. In order to attain better therapeutic benefits, including patient compliance, formulation flexibility, and ease of dosage administration, oral controlled release drug delivery has recently attracted more attention in the pharmaceutical industry. Tablets are the most widely used dosage form in medicines, mostly because of their easy handling, small size, user-friendliness, and simple manufacturing procedure. Low density systems having enough buoyancy to flow over the contents of the stomach and stay afloat in the stomach for an extended amount of time without influencing the gastric emptying rate are known as floating systems or dynamically regulated systems [2]. Increased stomach retention time and improved regulation of variations in

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plasma drug concentration are the outcomes of this.[3] Because of its many therapeutic benefits, oral controlled release dosage forms have been developed over the past three decades, including:

- Low cost therapy.
- Ease of administration.
- Patient compliance.

Gastro-retentive drug delivery system can stay in the stomach area for several hours, greatly extending the amount of time that medications are stay in the stomach. Long-term stomach retention increases solubility for medications that are less soluble in high pH environments, decreases drug waste, and increases bioavailability. [2] It can also be used to deliver drugs locally to the proximal small intestine and stomach. Improved bioavailability of new products with significant therapeutic potential and advantages for patients is made possible via gastro- retention. [4]

Basic Gastrointestinal Tract physiology :

Anatomically the stomach is divided into three regions that are as follows:

Fundus: It is proximal part of stomach.

Body: It acts as a reservoir for undigested material.

Pylorus: It is also called as antrum it is a site for mixing of contents and acts as a pump for gastric emptying by propelling actions.

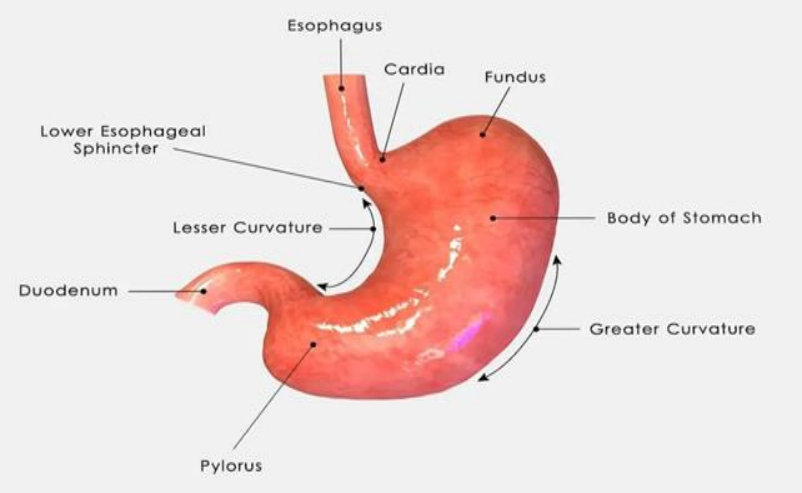

Fig 1: Anatomy of stomach

Gastric motility and emptying time:

Hormonal and neurological signals work together to regulate gastric motility. [4] GI tract is always in a state of continuous motility. Gastric emptying happens in both fed and fasting conditions. In case of fasting state inter digestive series of electrical events take place in cyclic manner both through stomach and small intestine in every 2-3 hours,which is called as interdigestive myoelectric cycle or migrating myoelectric cycle (MMC) which is further divided into four phases as follows:

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

2.Phase II (Preburst phase) : lasts from 20-40 mins with intermittent action potential and contractions.

3.Phase III (Burst phase) : lasts for 10-20 mins which includes intense and regular contractions for short period of time.

4.Phase IV : lasts for 0-5 mins and occurs between phases III and I of 2 consecutive cycles.

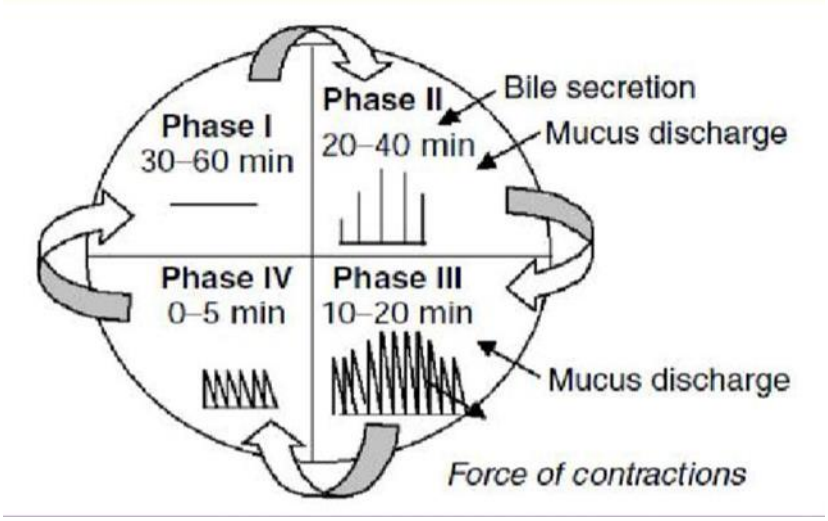

Fig 2: Motility pattern of GIT

Classification of floating tablets :

Floating tablets are classified as effervescent floating tablets and non – effervescent floating tablets.

1.Effervescent floating tablets:

Swellable polymers like chitosan and methylcellulose, as well as different effervescent substances including citric acid, sodium bicarbonate, and tartaric acid, are used to create these matrix-type systems. They are made in a way that releases CO2 when it comes into contact with the stomach's acidic contents and traps it in swelling hydrocolloids, giving the dosage forms buoyancy.

2. Non – Effervescent floating tablets:

Non-effervescent floating tablets are made up of hydrocolloids of the gel-forming or swellable cellulose type, polysaccharides, and matrix-forming polymers such as polystyrene, polycarbonate, polyacrylate, and polymethacrylate. One straightforward step in the formulation process is to completely mix the medicine with the hydrocolloid that forms gel. after being taken orally. This dosage form achieves a bulk density of less than one after swelling when it comes into contact with stomach contents. The buoyancy of the dosage form is provided by the air trapped in the expanded matrix. The resulting swelling gel-like structure serves as a reservoir and permits the medicine to be released gradually through the gelatinous mass.[11]

METHODS TO PREPARE FLOATING TABLETS:

Direct compression method:

Direct compression is the method of compressing tablets directly from powdered ingredients without changing the materials' physical composition. Dicalcium trihydrate phosphate, tricalcium phosphate, etc. are the most widely used carriers. Using tablet machines, compressed tablets are made by a single compression.when a certain amount of granulated or powdered tabletting material flow into a die, the material is compressed

by the tablet machine's upper and lower punches at a high pressure.

Dry granulation method:

Slugging is the process by which granules are prepared when tablet ingredients are moisture-sensitive or cannot tolerate high drying temperatures.

Wet granulation method:

In wet granulation, the disintegrants, diluents, and active component are thoroughly combined or mixed. Wet granulation includes wet powder drying, grinding, or massaging. By using an adhesive to bind the particles together instead of compacting them, wet granulation forms the granules.

PRINCIPLE:

Floating tablets slowly release the drug into the stomach by floating on the contents of the stomach. This helps to regulate variations in the drug's plasma levels and enhance its bioavailability. Floating drug delivery system have sufficient buoyancy to float over gastric contents and remain in the stomach for a long period of time. This results in increased gastric retention and better control of drug concentrations.

MECHANISM OF ACTION:

Floating drug delivery systems (FDDS) can float in the stomach for an extended period of time without affecting the gastric emptying rate because their bulk density is lower than that of gastric fluids. The drug is slowly removed from the system at the appropriate speed while the system is floating on the stomach contents . Following drug release, the stomach's residual system is emptied. As a result, the GRT rises and the variations in the drug concentration in plasma are better managed.

However, besides a minimal gastric content needed To allow the proper achievement of the buoyancy Retention principle, a minimal level of floating Force (F) is also required to keep the dosage form Reliably buoyant on the surface of the meal.To Measure the floating force kinetics, a novel Apparatus for determination of resultant weight has Been reported in the literature. The apparatus Operates by measuring continuously the force Equivalent to F (as a function of time) that is Required to maintain the submerged object. The object floats better if F is on the higher positive Side. This apparatus helps in optimizing FDDS with Respect to stability and durability of floating forces Produced in order to prevent the drawbacks of Unforeseeable intra-gastric buoyancy capability Variations.[25]

$$F = F_{buoyancy} - F_{gravity} = (Df - Ds)\,gV$$

Where, F= total vertical force, Df = fluid density, Ds = object density, V = volume and g = Acceleration due to gravity.

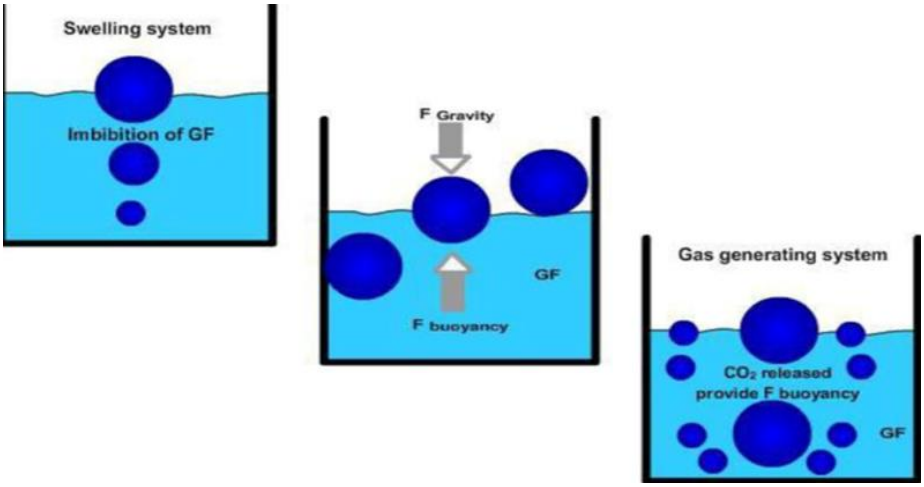

Fig 3: Mechanism of floating drug delivery system

ADVANTAGES OF FLOATING DRUG DELIVERY SYSTEM :

1. The floating drug delivery systems are advantageous for drugs Absorbed through the stomach or proximal part of the small Intestine. E.g. Ferrous salts, furosemide.

2. The floating drug delivery systems are advantageous for drugs Meant for local action in the stomach. E.g. antacids

3. Reduced fluctuations of drug concentration.

4. Acidic substances like aspirin cause irritation on the stomach wall when come in contact with it. Hence HBS formulation may be useful for the administration of aspirin and other similar drugs.

5. Enhanced bioavailability.

6. Reduced counter-activity of the body.

7.Sustained drug delivery reduced frequency of dosing.

8. Targeted therapy for local ailments in the upper GIT.

DISADVANTAGES OF FLOATING DRUG DELIVERY SYSTEM :

1. Floating system is not suitable for those drugs that have Solubility or stability problem in GI tract.

2. The drug substances that are unstable in the acidic Environment of the stomach are not suitable candidates to be Incorporated in the systems.

3. These systems require a high level of fluid in the stomach for Drug delivery to float and work efficiently.

4. Drugs which are irritant to Gastric mucosa are also not Desirable.

5. Drugs such as nifedipine, which under goes first pass Metabolism may not be desirable for the preparation of these types of systems.

6. The dosage form should be administered with the full glass of water (200-250 ml).

POLYMERS USED IN FLOATING DRUG DELIVERY SYSTEM :

Table 1. Polymers used in floating drug delivery

Category	Materials
Polymers	**Cellulose polymers:** HPMC K4 M, HPMC K15, HPMC K 100 and HPMC 4000 etc. **Eudragits :**Eudragit S 100, Eudragit RL,Eudragit RS, Eudragit S etc. **Alginates:** Calcium alginate, sodium alginate etc. **Others:** PEO, PVA, PEG, PVP, carbopol, polycarbonate, acrylic polymer etc.
Effervescent agents	Citric acid, citroglycine, di-sodium glycine carbonate, sodium bicarbonate, tartaric acid etc.
Low density material	Glyceryl palmitostearate, glyceryl behenate, polypropylene foam powder etc.
Buoyancy increasing agents (upto 80%)	Ethyl cellulose.
Inert fatty materials (5%-75%)	Beeswax, fatty acids, long chain fatty alcohols, gelucires® 39/01 and 43/01 etc.
Release rate retardants (5%-60%)	Di-calcium phosphate, talc, magnesium stearate etc.
Release rate accelerants (5%-60%)	Lactose, mannitol etc.

FACTORS AFFECTING ON FLOATING DRUG DELIVERY SYSTEM:

1.**Density of tablets :** Density of the dosage form should be Less than the gastric contents (1.004gm/ml).

2.**fed or unfed state :** Under fasting conditions, the GI motility is characterized by periods of strong motor Activity or the migrating myoelectric complex (MMC) that occurs every 1.5 to 2 hours.

3.**Size and shape of dosage form:** Dosage form unit with a diameter of more than 7.5 mm are Reported to have an increased GRT competed to with those with a diameter of 9.9 mm. The dosage form with a Shape tetrahedron and ring shape devises with a flexural modulus of 48 and 22.5 kilopond per square inch (KSI) Are reported to have better GIT for 90 to 100 % retention at 24 hours compared with other shapes.[10]

4. **Age:** people over 70 years old have much longer GRTs.

5. **Nature of meal :** Feeding of indigestible Polymers of fatty acid salts can change the Motility pattern of the stomach to a fed state, Thus decreasing the gastric emptying rate and Prolonging the drug release.

6. **Posture :** Floating can vary between supine and upright ambulatory states of the patient.

7. **Caloric content :** GRT can be increased Between 4 to 10 hours with a meal that is high In proteins.

8. **Feeding Frequency :** Due to the low frequency of MMC, the GRT can increase by over 400 minutes when multiple meals are given in succession rather than a single meal.

PREFORMULATION PARAMETERS:

Angle of repose: Angle of repose is the maximum angle between the surface of the pile of powder and the horizontal plane. The granules are allowed to flow through the funnel fixed to a stand at fixed height (h).The angle of repose is calculated by measuring the height and radius of the heap of granules formed.

Angle of repose (Θ)=tan1 h/r

Bulk density : Bulk density is the ratio of mass of powder to bulk volume. Accurately weight quantity of powder and poured into graduated cylinder then note the level of volume (bulk volume). It is expressed in gm/ml.

Bulk density= Mass of powder/ bulk volume of powder

Tapped density : Tapped density is the ratio of total mass of powder to the tapped volume. Accurately weight 10gm of powder and poured into a clean, dry 100ml of measuring cylinder.Then the cylinder was tapped 100 times from a constant height and tapped volume was noted.It is expressed in gm/ml.

Tapped density: mass of powder /tapped volume of powder

Compressibity index : Compressibility index can be calculated for evaluating floawability of powders. Compressibility index Calculated as follows :

Tapped density – bulk density/Tapped density ×100

Hausner's ratio : It is used to predict the floawability of powders.It is calculated by the formula given as follows :

Hausner's ratio= Tapped density/ Bulk density

EVALUATION PARAMETERS:

Hardness:

Hardness of the tablet was tested using Monsanto's hardness tester. Hardness shows the capability of a tablet to face up mechanical shocks while transport and handling. The tablet was placed between two anvils, force applied to the anvils and the crushing strength that will cause the tablet to break was recorded. It was expressed in kg/cm2.

Dimensions:

Thickness and diameter of the tablet was measured by using Vernier caliper.Tablet was placed between lower jaws of Vernier caliper then reading was noted.

Friability

Friability was expressed in percent(%). 10 tablets were weighed and transferred into chamber of friabilator. The Friabilator were operated at 25 rpm for 4 minutes or run as much as 100 revolutions.The tablets were weighed again . The % friability was then calculated by using formula:

% Friability= weight of tablet before test – weight of tablet after test /Weight of tablet before test×100

Desirable friability limit is 1%.

Weight variation test:

20 tablets were weighted individually. Average Weight was calculated from the total weight of all Tablets. The individual weights were compared With the average weight. The percent deviation Was calculated.

% Deviation = Individual weight -Average weight× 100

Average weight

In- vitro buoyancy/ Floating lag time and total floating time:

The time between introduction of tablet into the medium and its rise to upper one third of the dissolution vessel is term as floating lag time. The test were estimated in 100ml beaker containing 0.1N HCL. The total time for which the dosage form floats is termed as floating time/ Total floating time.

Swelling index:

Tablets are weighed (W1) and placed in a glass beaker containing 200ml of 0.01N HCL. Then each and every hour the tablet were taken out from beaker and reweighed until 8 hrs . The excess water or liquid was carefully removed by tissue paper or filter paper , re- weigh it and calculate swelling index using the formula:

Swelling index (%)= W2- W1× 100

W1

W2= Final weight of tablet after immersion.

W1= Initial weight of tablet before immersion.

Disintegration test:

The device consist of 6 glass tubes that are 3" long ; open at the top and 10 mesh screens at the bottom end. To test for disintegration time one tablet is placed in each tube and the basket rack is positioned in a 1- 1.Beaker of water or HCL or simulated gastric fluid at 37± 2°c such as tablet remain 2.5cm below the surface of liquid on their upward movement and not closer than 2.5cm from the bottom. Floating of tablet can be prevented by placing perforated discs on each tablet . Disintegration time: Uncoated tablet : 5-30 min and for coated tablet: 1 -2 hours .

Dissolution test:

In vitro release studies was carried out by using USP dissolution testing Apparatus II (Paddle type). The dissolution test was carried out using 900ml 0.1 N HCL, at 37± 0.5°c and 50 rpm was maintained. A 5ml sample of solution was taken from the dissolution apparatus at every hr for 12 hrs ,and the samples were replaced with fresh dissolution medium . The samples were passed via whatman's filter paper and the absorbance of these solutions was measured.

CONCLUSION:

Absorption of drug in the gastrointestinal tract is a extremely variable process and prolonging gastric retention of the dosage form increase the time for drug absorption. Floating drug delivery system have emerged as an powerful means of enhancing the bioavailability and controlled delivery of many drugs.Sustained release floating tablets which release drug over a long period of time within therapeutic concentration would be the best possible approach to achieve prolonged and better effect of drug.floating drug delivery system will increase patient compliance, avoid night time dosing also avoid multiple frequency of dose. These systems have special advantage for the drug that are primarily absorbed from upper part of GIT. So there is a lot of future scope for designing of optimum floating drug delivery system.

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