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A REVIEW ON: FOOD DRUG DELIVERY SYSTEM

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ABSTRACT

Recent technological and scientific research has been devoted to the development of rate-controlled drug delivery system to overcome physiological adversities such as unpredictable gastric emptying times and gastric residence time. FDDS are of particular interest of drugs that are locally active and have narrow absorption window in stomach. FDDS offers numerous advantages, specially the drugs having narrow absorption window in GIT, primary absorption in the stomach, Prolonged gastric retention improves bioavailability, reduces drug waste, and improves solubility for drugs that are least soluble in a high pH environment. This review summarizes the design of the FDDS systems, factors that affect floating system, advantages, limitations, evaluation parameters and applications. [1]

KEYWORDS: *Floating drug delivery systems, Gastro-retentive drug delivery system, GIT physiology]*

INTRODUCTION

Oral administration is the most versatile, convenient and commonly employed route of drug delivery for systemic action. Indeed, for controlled release system, oral route of administration has received the more attention and success because gastrointestinal physiology offers more flexibility in dosage form design than other routes [2]. Among the many oral route of administrations, floating drug delivery attains much attention to the researcher to develop and deliver the drugs which are highly soluble at acidic environment and drugs which are unstable at alkaline environment. The concept of floating drug delivery systems (FDDS) was first described in the literature in 1968 when Davis developed a method for overcoming the difficulty experienced by persons of gagging and choking while swallowing medicinal pills. He suggested that such difficulty could be overcome by providing pills with a density of less than 1g/cm such that the pill will float on the surface of water. FDDS are low-density systems that have sufficient buoyancy float over the gastric contents and remain in the stomach for a prolonged period. FDDS are preferred as they are economic and has improved patient compliance and they are advantageous for drugs absorbed from the stomach [3]. Gastroretentive drug delivery systems are designed to be retained in the stomach for a prolonged time and release their active ingredients and thereby enable sustained and prolonged input of the drug to the upper part of the gastrointestinal tract [4] . A modified release drug delivery system with prolonged residence time in the stomach is of particular interest for drugs- acting locally in the stomach; having an absorption window in the stomach or in the upper part of small intestine; those unstable in the intestinal or colonic environments; or those having low solubility at high pH values [5]. To formulate a successful gastroprotective drug delivery system, several techniques are currently used such as floating drug delivery system, low density systems, raft systems incorporating alginate gel, bio adhesive or mucoadhesive systems, high density systems, superporous hydrogel and magnetic system. Among these, the floating dosage forms have been most commonly used [6] . Floating dosage forms may be made as tablets or capsules by using appropriate excipients and including gas-generating agents, which give the dosage form buoyancy in gastrointestinal fluids. [7]

DEFINITION

Floating systems are low – density system that have sufficient resistance to float on the stomach and stay float in gastric without creating any effect on the gastric emptying rate for a long period of time. While the system floats on the gastric contents the drug will be released slowly at the desire concentration in the system.Thus, the residue will be cleared from the stomach. Then these results will conduct to GRT elevation and be better control of flux in plasma drug concentrations. It also useful for proximal gastrointestinal tracts local drugs for example antibiotics for Helicobacter pylori on the manage for a peptic ulcer and for drugs that difficult to dissolve or not stable in intestinal fluids [8] .

Physiology of stomach

The stomach is anatomically categorized into three distinct regions: the Fundus, Body, and Antrum (pylorus).

The proximal section, which includes the fundus and body, functions primarily as a storage area for undigested food, whereas the antrum is engaged in mixing movements and operates as a pump to facilitate gastric emptying through its propulsive actions. Gastric emptying takes place during both fasting and fed conditions. During fasting, a sequence of interdigestive electrical activities occurs cyclically within the stomach and intestines approximately every 2-3 hours. This sequence is referred to as the interdigestive myoelectric cycle or migrating myoelectric cycle (MMC), which can be further subdivided into four distinct phases.

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STOMACH ANATOMY

The basic operate of the abdomen is to method and transport food in tittle intestine the duration of food is tiny and largely protein square measure digestible. Structurally the abdomen is split into 3 regions: structure, body, and pylorus. the average pH in fasted healthy person is one .1±0.15, once intake of food the PH scale rises to the level of 3.0 to 4.0 [8].

Migrating myoelectric cycle (MMC) is further divide into four phases :

1. Phase I (basal phase)
2. Phase II (pre burst phase)
3. Phase III (burst phase)
4. Phase IV.

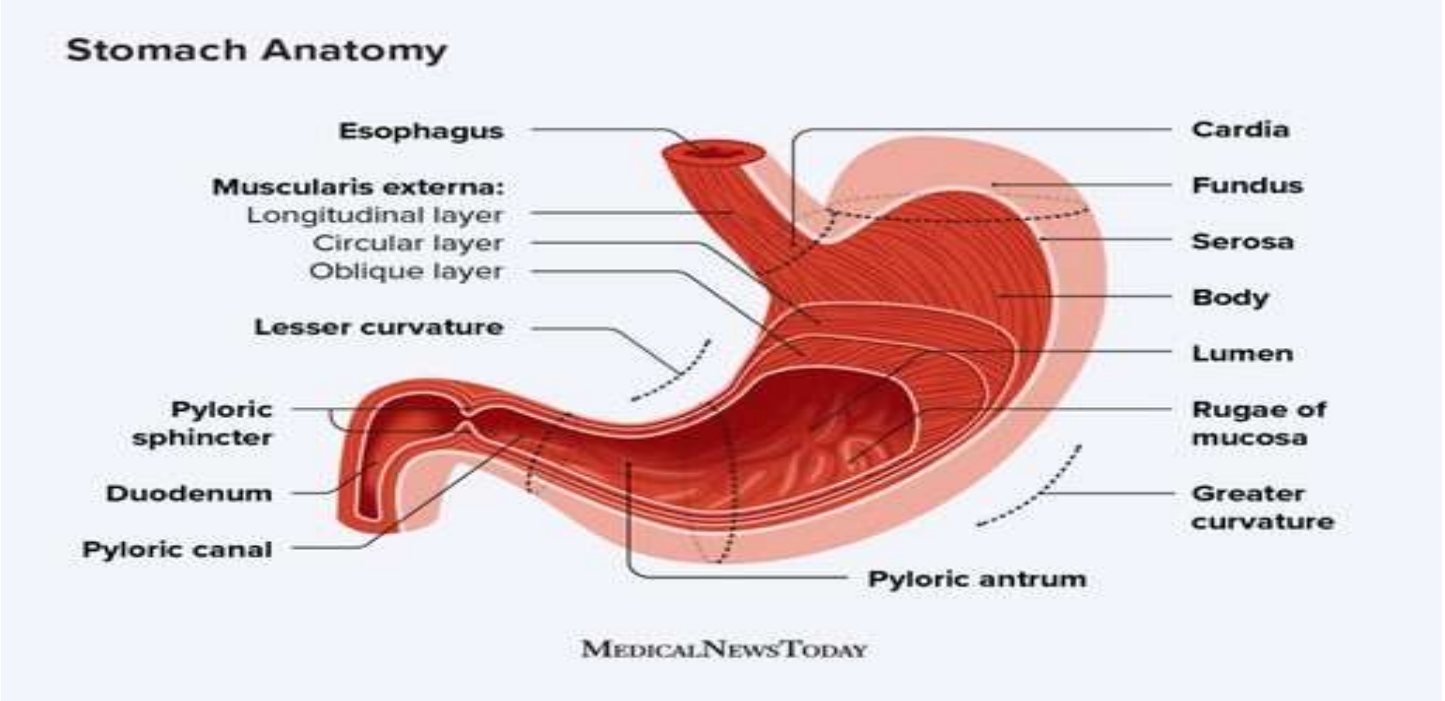


Fig 1. STOMACH ANATOMY

Phase I

In this phase the gastric emptying rate is slow as the onset of MMC is delayed. this phase usually lasts for 30 to 60 min. Contraction does not occur in this phase. it is also known as basal phase.

Phase II

In this phase bile secretion and mucus discharge take place and intermediate contraction occurs. It lasts for 20- 40 mins. It is also known as pre- burst phase. The intensity and frequency increase gradually as the phase progresses.

Phase III

In this phase, regular and intense contraction take place for a short time. It last usually for 10-20 min. this phase also called as housekeeper wave as it tends to empty the fasting contents of the stomach. Large objective remains in the stomach in the stomach in the fed state but passed down to the intestine during this phase.

Phase IV

Last for 0 -5 minutes and occur between phase III and I of 2 consecutive cycle. After the ingestion of a mixed meal, the pattern of contractions changes from fasted to that of fed state. This also known as digestive motility pattern and comprises continuous contraction as in phase II of fasted state. During the fed state onset of MMC is delayed resulting in slowdown of gastric emptying rate [9].

Need for gastric retention:

- Drugs that are absorbed from the proximal a part of the canal (GIT). Drugs that are less soluble or are degraded by the alkaline pH they encounter at the lower a part of GIT. Drugs that are absorbed due to variable internal organ evacuation time. Local or sustained drug delivery to the abdomen and proximal bowel to treat bound conditions.
- Mostly very useful for the treatment of peptic ulcers caused by Helicobacter pylori infections [10] .

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APPROACHES OF STOMACH RETENTION

Various approaches are pursed to extended the retention of Associate in Nursing oral dose type within the abdomen for instance, bioadhesive approach during which the adhesive capability of some chemical compounds with conjugated protein is closely applied to the animal tissue surface of abdomen.

1. **High density approach :**For making ready such variety of formulation, the density of the pellets ought to be over the abdomen fluid. It might be a minimum of one 50 G / ml during this kind the drug will be coated or mixed with significant, nontoxic material like sulfate oxide, etc.
2. **Low density approach: floating systems come back:**Below tenuity approach during this approach, the density of pellets ought to be but one g/ ml thus on float the pellets or tablets within the internal organ fluid and unleash the drug slowly for a extended amount of your time.

FACTOR AFFECTING GASTRIC RETENTION

Factor affecting gastric emptying. The most vital parameters touching stomachal remotion and hence, the stomachal retention time of oral indefinite quantity forms include:

1. **Density**: GRT may be operated of indefinite quantity kind buoyancy that's obsessed with the density.
2. **Size**: indefinite quantity kind units with a diameter of quite seven. 5mm or reportable to possess Associate in Nursing exaggerated GRT compared those with diameter of 9mm .
3. **Single and multiple unit formulation:** Multiple unit formulations show a lot of inevitable unharness profile and insignificant impairing of performance thanks to failure of units, permit co administration of units with totally different unharness profiles.
4. **Fed or unfed state:** Under fast conditions the GI motility is characterised by periods of study motor active or the migrating myoelectric advanced (MMC) that happens each 1.5 to 2 hours.
5. **Nature of meal:** Feeding of inedible polymer or carboxylic acid salts will modification the motility pattern of the abdomen to a fed state decreasing the stomach remotion rate and prolonging drug release
6. **Calories content:** GRT is exaggerated by four to ten hours with a meal that's high in protein and fats.
7. **Frequency of feed:** The GRT will increase by over 400 minutes once sequent meals are given.
8. **Gender:** Mean mobile GRT in male (3.4 ± 0.6 hour) is a smaller amount compared with their age and race matched feminine counterpart (4.6 ± 1.2 hours)
9. **Age:** senior individuals, particularly those over seventy, have a considerably longer GRT.
10. **Biological factor:** polygenic disorder and Crohn's disease, stress etc.
11. **Posture:** GRT will vary between supine and upright mobile state of the patient. [11]

FLOATING DRUG DELIVERY SYSTEMS (FDDS)

These formulations have very low density and so float over gastric materials.

1. Bio Adhesive Systems

They are fix with stomach mucosa and hence, give the localized retention of the system.

2. Swelling Systems

These systems absorb water and get enlarged sized by swelling.

3. High Density Systems

These are stays in the stomach for longer period of time, by setting down to the folds of stomach.Floating systems are low density systems that have maximum buoyancy to float on the gastric material and remain in the stomach for the longer period of time. A minimum stomachic content required to allow proper achievement of the bouncy retention principle, a minimum floating force (F) is also to required to keep the dosage form to be buoyant on the surface of gastric content. The force equivalent to F that is required to maintain the submerged dosage form force F is on higher positive [10]

F=F (buoyancy) -F (gravity) = (DF-Ds) g.v --------(1)

Where ,

F= total vertical force

DF = fluid density

Ds = object density

V= volume and g= acceleration due to gravity

Mechanism of Floating System

Various attempts have been made up to retain the dosage form in the stomach as a way of increasing the retention time. These attempts include introduction floating dosage forms mucoadhesive systems, high – density system, modified shape system, gastric emptying delaying drugs. Among these the floating dosage forms are the most commonly used. Floating drug delivery systems FDDS. Have bulk density less than gastric fluids and so remain buoyant in the stomach without affecting the gastric emptying rate for a prolong period of time. While the system is floating on the gastric contents the drug is released slowly at the desired rate from the system.

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After release of drug the residual system is eliminated from the stomach.
This results in an increased GRT and a better control of the fluctuation in plasma drug concentration. oral dosage forms (capsule or tablet) that are designed to prolong the retention time of the drug within the GI tract. The recent literature survey shows that interest increased in academics and industrial research regarding the development of novel dosage forms that can be sustained in the stomach for a longer and predictable period of
time. [12]

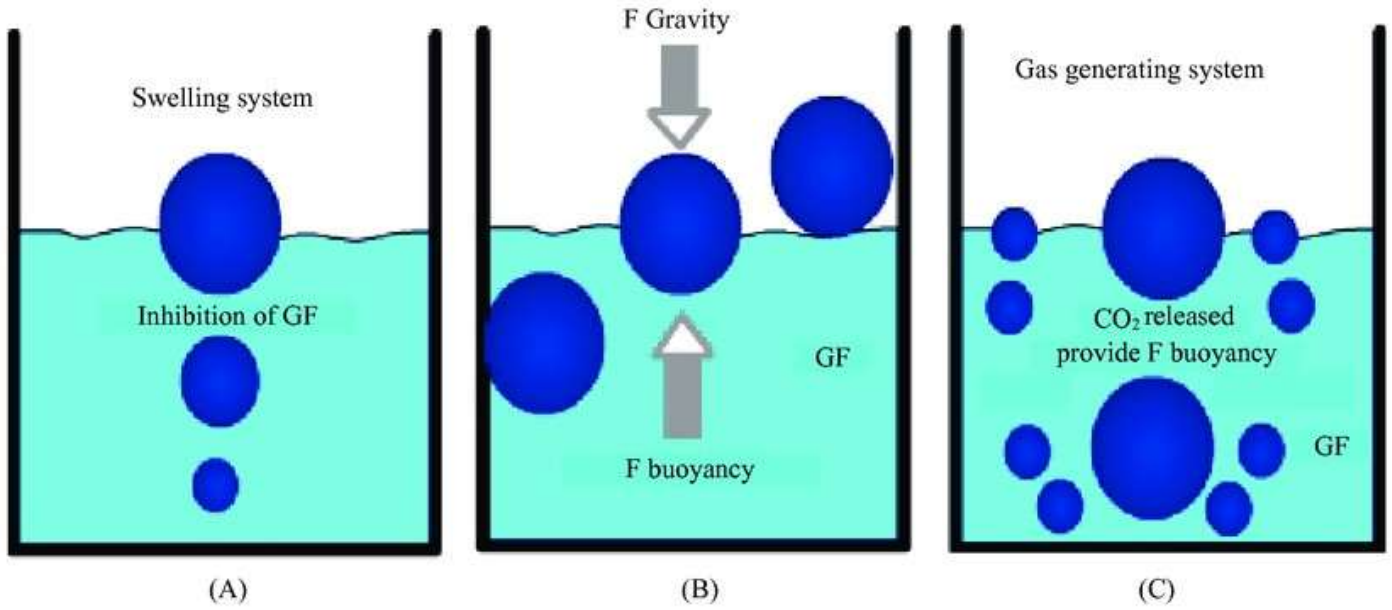


Fig 2 : Mechanism Of Floating Drug Delivery

Approaches to Gastroretention
Several techniques are reported in the literature to increase the Gastroretention of drugs. Among many few major approaches are listed below :

High Density Systems
These systems which have density of ≥3g/cm3, are retained in the stomach rugae of stomach and capable withstanding its peristaltic movements . The only major drawback with these systems is that it is technically difficult to manufacture them with large amount of drug (>50%) and to achieve required density of 2.42.8g/cm3. Diluents such as barium sulphate, zinc oxide, titanium oxide and iron powder must be used to manufacture such high-density formulations.

Swelling and Expanding systems
These systems are also as "Plug type systems", since they exhibit tendency to remain logged in the pyloric sphincters. These polymeric matrices remain in the gastric cavity for several hours even in the fed state.

Mucoadhesive and Bioadhesive Systems
Mucoadhesive and bioadhesive systems are used to localize the deliver with device within the lumen to enhance the drug absorption in a site-specific manner. This approach involves the use of bioadhesive polymers, which can adhere to epithelial surface in the stomach. Some of most promising excipients that have been used commonly in these systems include polycarbophil, carbopol, lectins, chitosan, CMC and gliadin etc.

Low Density Systems
Floating systems are low density systems that have sufficient buoyancy to float over the gastric contents and remain in the stomach for a prolonged period. While the system floats over the gastric contents, the drug is released slowly at the desired rate, which results in increased gastro-retention time and reduces fluctuation.

Classification of FDDS based on mechanism of bouncy
A . Non Effervescent Systems
These are single-unit dosage forms, containing one or more gel-forming hydrophilic polymers. Hydroxypropyl methylcellulose (HPMC) is the most commonly used excipient; although ethyl cellulose (HEC), hydroxypropyl cellulose (HPC), sodium carboxymethyl agar, carrageen or alginic acid are also used. The polymer is mixed with drug and usually administered in a gelatin capsule. The capsule rapidly dissolves in the gastric fluid, and hydration and swelling of the surface polymers produces floating mass. Drug release is controlled by the formation of a hydrated boundary at the surface. Continuous erosion of the surface allows

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water penetration to the inner layers, maintaining surface hydration and buoyancy. Incorporation of fatty excipients gives lowdensity formulations and reduced penetration of water, reducing the erosion. Effective drug delivery depends on the balance of drug loading and the effect of polymer on its release profile. [1]

Non effervescent system further classified into:

1. Colloidal gel barrier system
2. Hydrodynamically balanced systems (HBS)
3. Microballoons and Hollow microspheres.
4. Alginate beads.
5. Microporous compartment system.
6. Layered tablets.

B . Effervescent Systems

These are matrix type systems prepared with the help of swellable polymers such as Hydroxypropyl methylcellulose or polysaccharides and chitosan and various effervescent components like sodium bicarbonate, calcium carbonate, citric acid or tartaric. These dosage forms are developed in such a way that, when they come in contact with gastric juice in the stomach, Carbon dioxide is liberated and is trapped in the swollen hydrocolloids. This provides buoyancy to the do-sage form. The liberated carbon dioxide may intimately get mixed within the tablet matrix in case of single layered tablet. [1]

Effervescent system further classified into **:**

- •Gas generating system
- •Volatile/Vacuum containing systems.

C . Raft Forming system

Here, a gel-forming solution (e.g. sodium alginate solution containing carbonates or bicarbonates) swells and forms a viscous cohesive gel containing entrappedCO2 bubbles oncontact with gastric fluid. Formulations also typicallycontain antiacids suchas aluminiumhydroxide or calcium carbonate to reduce gastric acidity. Because raftforming systems produce a layer on the top of gastric fluids, they are often used for gastroesophageal reflux treatmentas with Liquid Gaviscon (GlaxoSmithkline). [1]

- **Advantages of floating drug delivery system :** [13]

1. Increases the oral bioavailability of drug.
2. Enhanced first pass biotransformation.
3. Sustained drug delivery/ reduced frequency of dosing.
4. Reduced fluctuations of plasma drug concentration.
5. Improved receptor activation selectivity.
6. Provide higher efficiency due to reduced counter-activity of body.
7. Extended time over critical (Effective) concentration.
8. Minimized adverse activity at the colon.
9. Targeted therapy for local ailments within the upper GIT.
10. Site specific Drug Delivery.

Limitations of floating drug delivery system : [14]

1. Drugs having solubility or stability problem in GIT aren't suitable for FDDS.
2. Drugs like Nifedipine, Propranolol etc. which are well absorbed throughout GIT and which undergoes first pass metabolism aren't be desirable candidate.
3. Drugs which are irritant to Gastric mucosa also are not desirable.
4. Drugs that are unstable in the acidic environment of the stomach aren't suitable in this type of systems.
5. High level of fluid in the stomach is required for maintaining buoyancy; float and work efficiently.

Benefits of FDDS : [15]

1. Floating dosage forms, such as tablets or capsules, will stay in the fluid for an extended period of time when the intestines have an alkaline pH.
2. FDDS are benefits for medications designed to operate locally in the stomach, such as antacids.
3. FDDS dosage forms have the advantage of keeping the medicine in a floating state in the stomach during diarrhea and agitated bowel movements, which results in a relatively better reaction.
4. Since aspirin and other similar medications might irritate the stomach wall when they come into touch with them, FDDS formulation may be helpful for their administration.
5. The FDDS offers benefits for medications that are absorbed through the stomach, such as ferrous salts.
6. Slow drug absorption into the body reduces antagonistic effects, increasing drug effectiveness.
7. FDDS improve clinical results by reducing drug concentration variation over a critical concentration, which enhances the pharmacological effects.

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8. A floating dose form is a generally acknowledged method, especially for medications with a narrow upper small intestine absorption site

Evaluation of stomach specific FDDS

Determine of floating lag time

The basic mechanism behind floating was carbonated is present within the formulation as insoluble dispersion and have become soluble within the acidic medium. Released metal ions and carbonic acid gas, caused gelation of compound and discharged gas get entrapped in gel matrix, that caused matrix system to float. [16]

Gelling capacity

The gelling capability made up our minds by placing 10 cubic centimetre of solution in a hundred cubic centimetre of stirred up stomachic fluid freshly ready and equilibrated at 37±0.5 ˚c and visually assessing the gel formation and nothing the time for gelation and therefore the time taken for the gel shaped to dissolved, totally different weights were assigned as per the gel integrity, weight and rate of formation of gel with respect to time. [17]

In Vitro Gelling Capacity

To evaluate the formulation for their in-vitro gelling capability by visual technique, coloured solution of in place gel forming drug delivery system were ready. The in-vitro gelling capability of ready formulation was measured by putting 5 ml of gelation resolution in a very 15ml salt glass tubing and maintained at 37±1˚c temperature. 1 ml of coloured formulation resolution was added with the assistance of measuring system. The formulation was transferred in such some way that places the measuring system at surface of fluid in tubbing and formulation was slowly free from the measuring system. Colour was incorporated to allow visualised look to fashioned gel. The in vitro gelling capability was ranked in 3 classes on idea of gelation time and fundamental measure that they fashioned gel remains. Gels once couple of minutes, spread rapidly gelation immediate remains for 12 hours gelation immediate remains for over 12 hours. [18]

Measurement of water uptake by the gel

The water uptake by the gel of the chosen formulation of metal alginate were determined by a straight forward methodology. during this study the inplace gel fashioned in forty millilitre of 0.1 N

i. HCL was used. Form every formulation the gel portion from the 0.1 N HCL was separated and therefore the excess HCL resolution was obliterated with a paper. The initial weight of the gel taken was weighed and to the present gel 10 ml of water was added and once each half hour of the interval water was decanted and therefore the weight of the gel was recorded and therefore the distinction within the was calculated and then reported. [19]

Invitro Drug Release study

The in vitro unharness rate of levetiracetam from sustained release in place gel was performed using USP equipment fitted with paddle over disk at 37±zero. 50C using 500cc of 0.1 N HCL as a dissolution medium. This speed was slow enough to avoid the breaking of gelled formulation and was maintaining the gentle agitation condition believed to exist in vivo. The predetermine time interval, five cc sample were withdraw filtered, diluted and assayed at given wavelength using a ultra violet light 1800 double beam spectrophotometer. Accumulative share drug release was calculated using an equation obtained from a standardization curve.

pH Measurement

The pH was measured in each of the solution of Na alginate based in place solutions, using a mark digital pH meter at 27˚c. [20]

Physical Appearance

All the prepared in place gel was check for their clarity and also the type time required for gel formation duration of floating and type gel formed. the measurement of every information was in triplicate and average conclusion was taken. [21]

Determination of drug content

Accurately 10ml of in-suit gel from different batches were measured and transferred in to a 100ml of volumetric flask to the current 50-70 ml 0f 0.1N HCl was more and sonicated for 30 mins. Volume was adjusted to a 100ml. Complete dispersion of contents were ensured visually and filtered using what man filter paper. From this answer 10 ml of sample was withdrawn and diluted to a hundred ml with 0.1 N HCl. contents of metoclopramide HCl determine spectrophotometrically with using reference wavelength double beam UV - visible photometer. [22]

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Table I : List of marketed formulation aavailable in market

Brand name	Drug	Type of formulation
Madopar	Levodopa & Benserazide	Floating CR capsule
Valrelease	Diazepam	Floating capsule
Liquid Gaviscon	Al-Mg antacid	Effervescent floating liquid alginate preparation
Topalkan	Al-Mg antacid	Floating liquid alginate preparation
Amalgate flot coat	Al-Mg antacid	Floating dosage form
Conviron	Ferrous sulphate	Colloidal gel forming FDDS
Cifran OD	Ciprofloxacin	Gas generating floating form
Cytotec	Misoprostal	Bilayer floating capsule

Considerations Of FDDS : [15]

1. For the drug delivery system to float and function well, the stomach needed to contain a high amount of fluid. Not suited for medications with GIT solubility or stability issues.
2. It might not be advisable to use medications like Nifedipine (a calcium channel blocker), which is well absorbed throughout the GIT and goes through first pass metabolism.
3. Drugs that irritate the stomach mucosa are also undesirable or inappropriate.
4. It is not advisable to use drugs that are unstable in the stomach's acidic environment.
5. Drink a full glass of water together with the dosage form.
6. A full glass of water (200-250 ml) should be consumed along with the dosage form.
7. Many substances, such as chlordiazepoxide, cinnarizine, and calcium supplements, are mostly absorbed from the stomach and upper GI tract.

CONCLUSION

Developing an efficient FDDS is a real challenge and the drug delivery system must remain for a sufficient time in the stomach. Various techniques and approaches have been employed to develop FDDS has emerged as one of the most promising gastro-retentive drug delivery system. we are as close as we have ever been to see a greater transition of gastric retention devices from developmental level to the manufacturing and commercial level.

The floating drug delivery framework was set up in an exertion the gastric maintenance time of the measurements structure and to control tranquilize discharge. One of the most doable methodologies for accomplishing a delayed and unsurprising delved conveyance profiles in the gastrointestinal tract is to control the gastric living arrangements time, utilizing gastro- retentive dose frames that will furnish us with new and significant helpful alternatives.

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