INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA):IJPS00]
Journal Homepage: https://www.ijpsjournal.com

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Review Article

Floating Drug Delivery System: A Review

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ARTICLE INFO

Received: 03 Feb 2024
Accepted: 06 Feb 2024
Published: 07 Feb 2024

Keywords:
Floating drug delivery system, Gastro retentive Drug Delivery System, Gastric Residence Times, Gastric Emptying Times.

DOI:
10.5281/zenodo.10628440

ABSTRACT

The development of rate-controlled drug delivery devices to overcome physiological barriers such as short gastric residence times and unexpected gastric emptying times has been the focus of recent technology and scientific study. The behaviour of drug delivery and the duration of stomach residence are significantly impacted by variations in the gastric physiology, including motility and pH which show intra and inter-individual variability. The pharmaceutical industry has shown a great deal of interest in research on oral drug delivery, particularly with regard to the Gastro retentive drug delivery system known as the Floating Drug Delivery System (FDDS). This study goal is to analyse FDDS with an emphasis on its current advancements and future prospects. The aim of this review was to gather the latest research on floating drug delivery systems (FDDS) and to highlight the main mechanism of flotation for gastric retention. The most current advancements in FDDS are discussed in depth, along with the physiological and formulation factors influencing gastric retention, methods for designing single-unit and multiple-unit floating systems, and the characteristics of their classification and formulation. The goal of this review article is to provide comprehensive information on the pharmaceutical underpinning of floating tablet design, classification, advantages and disadvantages, and factors influencing the gastric residence time of FDDS. Floating drug delivery systems enhance both patient compliance and drug bioavailability by a prolongation of the gastric residence period and the regulation of drug release. The technological and scientific developments in floating systems are reviewed in this article

INTRODUCTION

Any drug delivery system aims to deliver a therapeutic dose of the medication to the right location in the body in order to quickly reach and then sustain the appropriate drug concentration. Viable dose options that can be supplied via several methods of administration have been made possible by recent technological developments. There are several different ways to provide drugs such as oral, topical, nasal, rectal, vaginal, and

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

ocular etc. However, among these methods oral medication delivery is seen to be the most popular and often utilized method for the following reasons: Low cost, simplicity of production and ease of administration[1]. Conventional oral dosage forms, like tablets and capsules generate significant changes in plasma drug levels and supply a specific drug concentration in the systemic circulation without allowing for any control over drug administration. Several efforts have been undertaken to create formulations for sustained release that have longer-lasting clinical benefits and require fewer doses. A common issue with Conventional sustained release dosage forms is that they lack control over drug administration and cannot be made to stay longer in the stomach, which causes variations in the medication's plasma level[2]. Dosage forms that stay in the stomach longer than Conventional dosage forms have the advantage of having the capacity to extend and regulate the emptying time, as gastric emptying is a highly variable process. There are a number of challenges in developing controlled release systems to improve absorption and boost bioavailability. The difficulty to limit the dose form in the intended gastrointestinal tract region is one of these challenges. The process of absorbing drugs from the digestive system is complex and diverse. It is well known that contact time with the small intestinal mucosa affects how much a medicine is absorbed through the gastrointestinal tract. Thus, Small intestinal transit time is therefore a crucial factor for medications that are not fully absorbed[3]. The low-density systems known as floating systems possess enough resistance to remain afloat in the stomach and do not alter the rate of gastric emptying for an extended duration. The medicine will be introduced gradually into the system at the desired concentration as the system floats on the contents of the stomach Consequently the stomach will be free of the residue. These findings will therefore lead to an increase in GRT and improved flux control in plasma medication concentrations. It is also helpful for local medications used in the proximal gastrointestinal system such as antibiotics used to treat Helicobacter pylori induced peptic ulcers, as well as medications that are difficult to dissolve or unstable in intestinal fluids[4].

DRUG CANDIDATES FOR GASTRO RETENTION[5]:

Usually, compounds with low colonic absorption but superior absorption qualities at the higher regions of the GIT provide good candidates for gastro retentive dose forms:

- The GI tracts narrow absorption window e.g., riboflavin and levodopa.
- For example, calcium supplements, chlordiazepoxide and cinnarizine are mostly absorbed from the stomach and upper portion of the GI tract.
- Medication that affects the stomach locally e.g., antacids and misoprostol.
- Drug that breaks down in the gut such as metronidazole and ranitidine HCl.
- Drugs that disrupt normal flora in the colon such as amoxicillin trihydrate.

UNSUITABLE DRUGS FOR GASTRORETENTION:[6]

- Medications with extremely low solubility such as NSAIDS and phenytoin.
- Medications that are unstable in the stomach environment e.g., erythromycin.
- Medications designed for the colon to release certain drugs selectively such as corticosteroids and 5-amino salicylic acid.

BASIC GIT PHYSIOLOGY:

The stomach is composed of three anatomical regions: the fundus, body and antrum (pylorus). The antrum is the primary location for mixing motions and functions as a pump for gastric emptying via thrusting actions whereas the proximal portion composed of the fundus and

body serves as a reservoir for undigested materials. In both the fed and fasted states gastric emptying happens. The term inters digestive myoelectric cycle also known as the migrating myoelectric cycle (MMC), refers to an interdigestive series of electrical events that occur during the fasting state and cycle through the stomach and intestine every two to three hours. MMC is further divided into four phases[7].

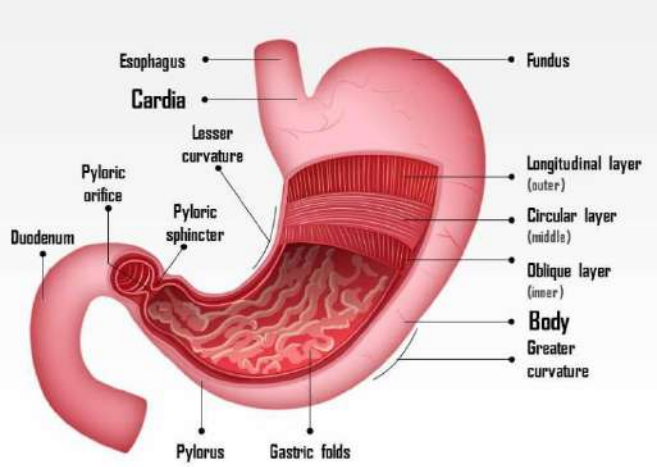

Figure 1: Anatomy of stomach

The pattern of contractions shifts from the fasted to the fed condition after consuming a mixed meal; this is also known as the digestive motility pattern. (figure2)

1. **Phase 1 (Basic phase):**
   Rare contractions that last for 30 to 60 minutes.
2. **Phase 2 (preburst phase):**
   sporadic contractions and action potentials that last for 20 to 40 minutes.
3. **Phase 3 (Burst phase):**
   This phase, which lasts for 10 to 20 minutes, is characterized by brief strong contractions.
4. **Phase 4**
   Takes place in between phases 2 and 1 in a two-cycle sequence and lasts for 0–5 minutes[8].

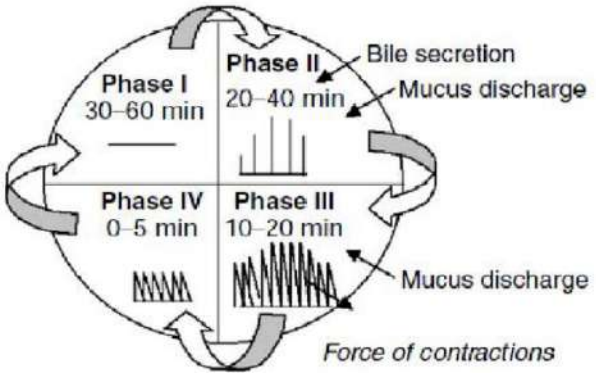

Figure 2: Motility pattern in the gastrointestinal tract.

MECHANISM OF FLOATING DRUG DELIVERY SYSTEMS :[9]

As shown in Figure 3(a), the system is floating on the stomach contents and the system flow is regulated to produce a gradual release of the medicine at the necessary rate. Removal of the leftover system from the stomach occurs after the release. To maintain the dosage, form buoyant above the meal surface and to enable the attainment of the buoyancy retention principle, minimum levels of stomach contents are also required in addition to the proper amount of floating force (F). The literature has described a novel device for determining resultant weight (RW) in order to quantify the kinetics of the floating force. If RW is higher on the positive side, the object floats more readily (figure 3(b)).This device maximizes FDDS and avoids its disadvantages, which include unpredictable intragastric buoyancy capacity fluctuations that affect stability and durability.

RW or 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.

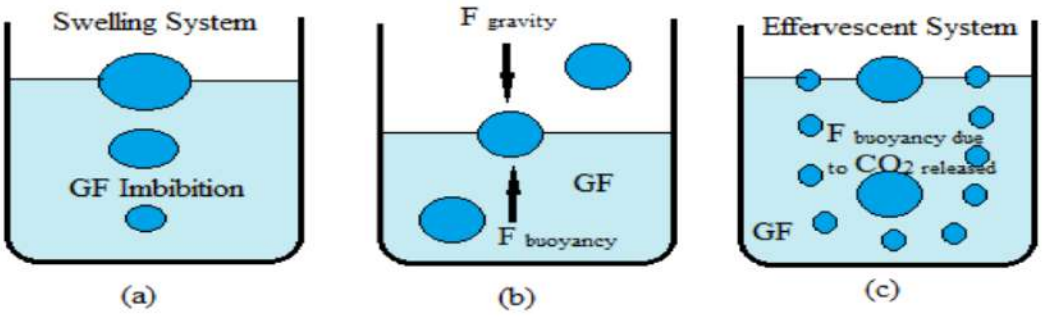

Figure 3: Mechanism of FDDS, GF: Gastric Fluid, CO2: Carbon Dioxide

CLASSIFICATION OF FLOATING DRUG DELIVERY SYSTEM[10]:

A. Effervescent FDDS

1. Gas generating system
2. Volatile liquid containing system

B. Non – Effervescent FDDS

a. Colloidal gel barrier system.
b. Micro porous compartment system
c. Hallow microspheres / micro balloons
d. Alginate floating beads

C. **Raft forming system**

A. **Effervescent FDDS**

The matrix-type systems that include swellable polymers such as polysaccharides or hydroxy propyl methyl cellulose (HPMC) and chitosan as well as effervescent components including sodium bicarbonate, citric acid, tartaric acid and calcium carbonate. When these dose forms interact with the stomach's gastric fluid, trapped CO2 is released from the enlarged hydrocolloids. This gives the dose form buoyancy. These buoyant delivery systems are made with effervescent substances like sodium bicarbonate, polysaccharides like chitosan and swellable polymers like methocel. The effervescent floating drug delivery system (EFDDS) employs several methods including[11]:

1. Gas generating system.

Based on the release of CO2 upon interaction with stomach fluids following oral administration low-density FDDS is used. The materials are designed so that when they reach the stomach and react with the acidic gastric fluid, they release carbon dioxide and become trapped in the gel-based hydrocolloid (fig. 4). The dose form rises as a result and its buoyancy is maintained. In the end, it lowers the dose form's specific gravity, which results in a float on the chime. The hydrocolloid layer of the tablet matrix is used to create a gas generating mechanism by mixing the CO2 generating components in a single layer or multi-layered form, while the medicine in the other layer produces a prolonged release effect[12].

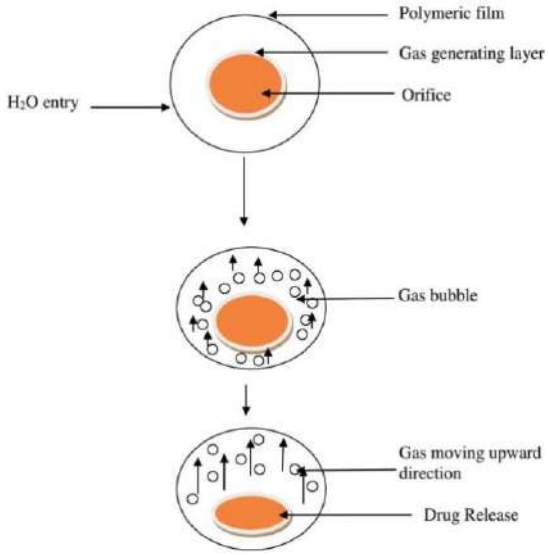

Figure 4: Mechanism of floatation via CO2 liberation

2. Volatile liquid containing system

The device, a floating system controlled by osmotic forces, consisted of a malleable hollow unit that could be lifted from a collapsed position after a significant amount of time. A first chamber and a second chamber internally divided by an impermeable pressure responsive movable bladder were part of the housing which was attached to the deformable unit. The drug reservoir can float

because the second chamber's volatile liquid such as ether or cyclopentane vaporizes to form a gas at body temperature. An active medication is present in the first chamber. The device's biodegradable plug let the vapor out and enabled the device to exit the stomach[13].

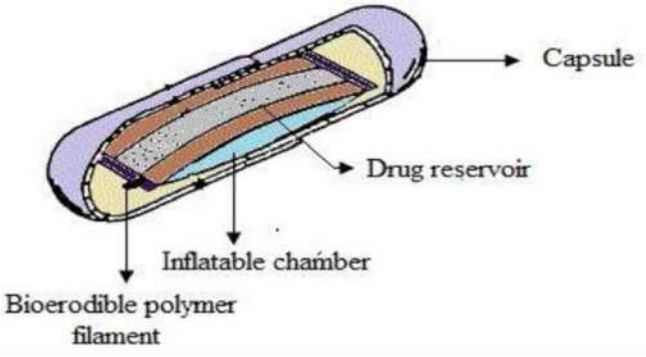

Figure 5:Volatile liquid containing system

B. Non – Effervescent FDDS

After swallowing, this kind of system absorbs so much gastric fluid that it causes the stomach to enlarge to the point where the food cannot pass through. Such dosage forms are prepared by mixing the medication with a gel that upon contact with gastric fluid expands and retains its relative shape integrity and bulk density of less than one behind the outer gelatinous barrier. These dose forms buoyancy comes from the air that the inflated polymer traps. The most often utilized excipients in these systems include polyvinyl acetate, Carbopol agar, sodium alginate, is partially dissolved to prevent the drug from existing and is then carried by the dissolved drug for continuous transit through the intestine for absorption[15].

3. Hollow microspheres / micro balloons

A unique emulsion-solvent diffusion approach is used to create hollow microspheres also known as micro balloons, that are loaded with medication within their outer polymer shells. An agitated aqueous solution of PVA that is thermally polyethylene oxide, polycarbonates, hydroxypropyl methyl cellulose (HPMC) and poly acrylate polymers. There are four more subtypes of this system that can be identified[14].

1. Colloidal gel barrier system :

This type of system includes a medication that gels hydrocolloids so it floats on stomach contents. This increases the amount of drug that reaches the absorption site in solution form for quick absorption and prolongs the gradient relaxation time (GRT). The system includes high concentrations of polysaccharides matrix-forming polymers like polycarbophil, polystyrene and polyacrylate and gel-forming, highly soluble cellulose hydrocolloids like HPMC. The hydrocolloid in the system hydrates when it comes into contact with GI fluid forming a colloid gel barrier surrounding its surface.

2. Micro porous compartment system :

The basis of this technology is the encapsulation of a medication reservoir inside a microporous compartment that has pores all the way along its walls at the top and bottom. The outer wall the medication reservoir compartment is fully enclosed to avoid any direct stomach surface in contact with the undissolved medication. The delivery system floats over the gastric content in the stomach due to the entrapped air in the flotation chamber. Through the aperture, gastric fluid enters regulated at 40˚C is filled with the drug's ethanol: dichloromethane solution along with an enteric acrylic polymer. An internal cavity is formed in the polymer microsphere containing drug by the gas phase that is produced in the dispersed polymer droplet by the evaporation of dichloromethane. For nearly 12 hours, the micro balloons remain suspended above the surface of acidic dissolving medium that contains surfactant[16].

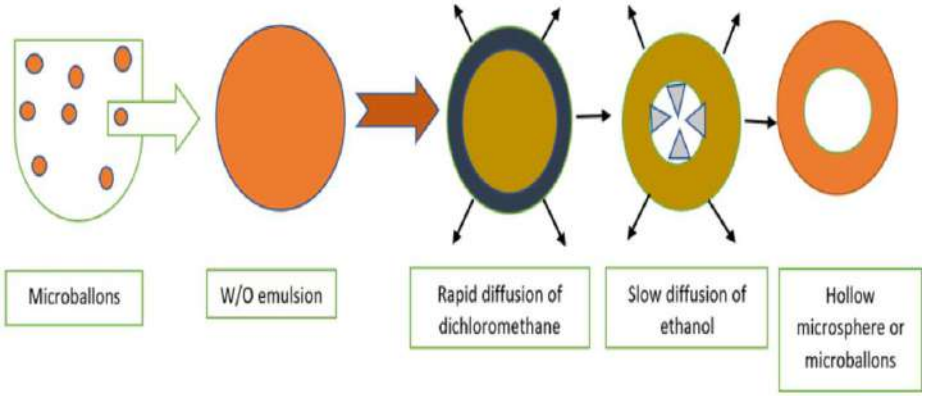

Figure 6: Hollow microspheres or micro Ballons

4. Alginate floating beads

Calcium alginate that has been freeze dried has been used to create multiunit floating dosage forms. By dropping a sodium alginate solution into an aqueous calcium chloride solution. calcium chloride precipitates forming spherical beads with a diameter of around 2.5 mm. Beads were taken out of the solution and snap-frozen in liquid nitrogen once the interval gelation was finished. They were then freeze dried for 24 hours at -40˚C. The weight measurements that followed indicated that these beads continued to have a positive buoyant force for more than 12 hours. There have also been produced floating systems that consist of an air-separated calcium alginate core from a calcium alginate membrane or calcium alginate/polyvinyl alcohol (PVA)[17].

C. Raft forming system

Here, gastric fluid containing trapped CO2 bubbles reacts with a gel-forming solution (such as carbonate or bicarbonate-bearing sodium alginate solution) to cause it to swell and create a viscous cohesive gel. In order to reduce stomach acidity, antacids like calcium carbonate and aluminum hydroxide are frequently employed in formulations. Because raft forming devices provide a covering on top of gastric fluids, they are also employed in the treatment of gastrooesophageal reflux disease. One of the mechanisms underlying raft creation is the production of a viscous cohesive gel in contact with gastric fluid, where the liquid expands in each portion forming a continuous layer known as a raft. Because stomach secretions are low in density and produce carbon dioxide this raft floats on them[18].

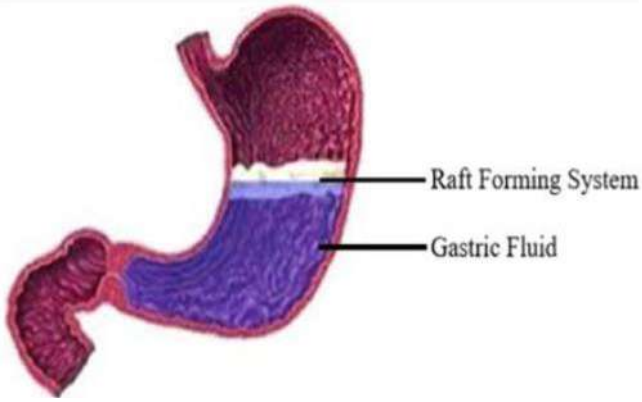

Figure 7 : GRDDS based on Raft Forming System.

FACTORS AFFECTING THE FLOATING DRUG DELIVERY SYSTEM: [19]

1. **Density:**
   A dosage forms density controls its buoyancy and hence its floating efficiency. The density of the dose form should be less than the gastric contents (1.004 gm/ml).
2. **Shape of dosage form:**
   The floating potential of tetrahedron and ring-shaped devices is higher than that of other shapes. Their percentage of 24-hour retention is 90-98% greater.
3. **Fed or unfed state:**
   Migrating myoelectric complexes (MMC), which happen every 1.5 to 2 hours in

abstinence settings are periods of strong motor activity that define GI motility.

4. **Formulation of a single or multiple units:** Comparing multiple unit formulations to single unit dosage forms, a greater margin of safety against dosage form failure is possible.
5. **Nature of meal:**
   The stomach's motility pattern may change to a fed state when indigestible polymers or fatty acid salts are fed to it. This will slow down the emptying of the stomach and extend the time that medication acts.
6. **Calorie content:**
   A high-protein, high-fat meal might add four to ten hours to your floating duration.
7. **Frequency of feed:**
   The GRT (Gastric Residence Time) will rise by more than 40 minutes when consecutive meals are given rather than a single meal (MMC) due to the low frequency of migrating myoelectric complex.
8. **Age:**
   Individuals over 60 who are considered elderly have much longer floating times.
9. **Biological factor:**
   Floating may differ based on an individual's physiological state or state of health. For example, floating time is impacted by diabetes and Crohn's disease.

APPROACHES TO DESIGN FLOATING DRUG DELIVERY SYSTEM:[20]

For Single Unit Dosage Forms (Ex: Tablets):

A. Floating Lag Time:

This is the amount of time expressed in seconds or minutes, that it takes for the tablet to surface on the dissolving media.

B. In-vitro drug release and floating duration:

This is computed by using stirrers (USP II devices, paddles) at 50 or 100 rpm and 37±0.20C to replicate gastric fluid (pH 1.2, no pepsin). After then, the samples are regularly gathered and their drug content is examined. Visual observation of the floating duration measured in hours occurs when the tablets stay buoyant on the surface of the dissolving solvent.

C. In-vivo Gastro-Retention Assessment:

This is achieved by measuring the dose form transition in the GIT using gamma-scintigraphy or X-ray technology. The tablets are also examined for hardness, weight variation etc.

Hydrodynamically Balanced System:

The purpose of the delivery system is to improve absorption and prolong the duration of certain medicine kinds in the gastrointestinal tract. The HBS system generates medications with a specific absorption location in the upper section of the small intestine and increased solubility in acidic environments. The dosage form must release the medication continuously and have a bulk density of less than "1" in order for the medication to stay in the stomach for a prolonged amount of time.

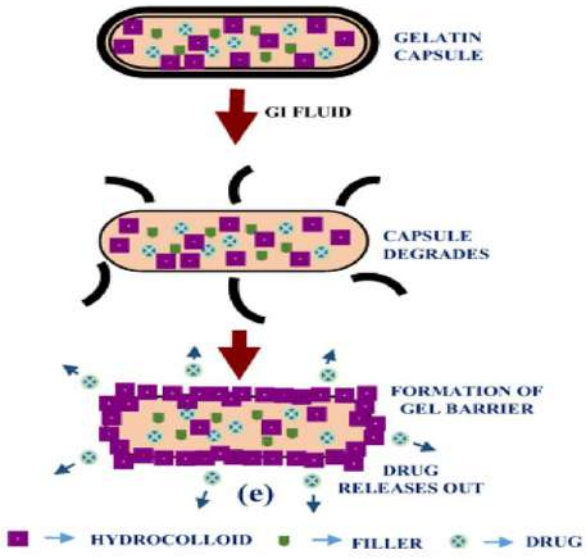

Figure 8 : Working principle of Hydrodynamically Balanced

METHODS OF DEVELOPING FLOATING DRUG DELIVERY SYSTEM[21]:

1. Direct compression technique

It entails compressing tablets straight from their powdered form without changing the materials physical composition. The most widely used

carriers include tricalcium phosphate, dicalcium trihydrate phosphate, etc.

2. Effervescent Technique

The floating chamber of the drug delivery technique will be filled with inert gas (CO2) through an effervescent reaction between organic acid (citric acid) and bicarbonate salts.

3. Wet granulation technique

It involves rubbing, grinding or drying wet powder. Instead of compacting the powders, wet granulation forms the granules by gluing them together using an adhesive.

4. Ionotropic Gelation Technique

In order to create instantaneous microparticles, the anionic polysaccharide sodium alginate, the main polymer derived from nature, was gelled using oppositely charged calcium ions or counter-ions. This process is referred to as a physicochemical way of polyelectrolyte chelation with polyvalent ions to produce microdroplet hardening. This type of chelation results in the formation of a shell around the polyelectrolyte molecules in a polymeric system that is widely used. It works by gelating aqueous sodium alginate, gellan or carrageenan and then adding divalent cations like calcium, barium or potassium chloride which causes the polymers to cross-link and instantly forms discrete solid microparticles. This technique minimizes dose-related adverse effects and extends the drug's release potential by creating robust, spherically shaped, narrow, high-yield microparticles that are then used as the carriers of numerous NSAIDs.

5. Solvent evaporation technique

There is not enough continuous phase capability to completely remove the liquid dispersal solvent. To receive the hardened microspheres, the solvent evaporation from the dispersal surface occurs. This method allows the dispersion or dissolution of the core material by dissolving the polymer in a volatile organic water-impermeable solvent such as chloroform or dichloromethane. In order to create tiny polymer droplets surrounding encapsulated material the resultant solution is then added drop-wise to a stirring aqueous solution with an inappropriate stabilizer like polyvinyl alcohol. Evaporation or solvent extraction can be used to harden the created microsphere.

6. Melt Solidification Technique:

This process involves cooling the molten mass to solidify after emulsifying it in the aqueous phase. For this approach lipids, waxes, polyethylene glycol, etc. are used as carriers.

EVALUATION OF THE FDDS[22]:

1. **Friability:**

The USP friability test apparatus is used to measure the friability of each formulation. The Roche Friabilator used to test the pellet formulations friability across 5 g of samples at 25 rpm for 4 minutes. The formulation weights is precisely recorded both before and after the test and the following equation is used to compute the friability ratios. In order to determine the percent friability (% F). It is commonly accepted that functional coating can result in weight loss of less than 1%.

2. **Bulk Density and Tapped Density:**

Before any pellet agglomerates formed, 5 gm of each formulation is gently shaken. Ten milliliter measuring cylinders is filled with this amount. A measurement of the apparent volume (V0) to be taken after the pellets is precisely leveled without compacting it. The tapped volume of the sample-containing cylinder is then calculated to the closest graded unit after 500 taps is made on it using a Tap Density Tester. The following formula is used to determine LBD and TBD:

LBD = Weight of the pellets / Volume of packing.

TBD = Weight of the pellets / Tapped Volume of the packing.

3. **Hausner ratio:**

It provides an indication of the degree of densification which could result from vibration of the feed hopper. Hausner ratio = Tapped density/

Bulk Density Lower the Hausner ratio better is the flow property.

4. **Compressibility index:**

Carr's Compressibility Index is used to determine the granules' compressibility.

Carr's compressibility index (%) = [(TBD-LBD) X 100] / TBD

Where,

TBD (Tapped Bulk Density or Tapped Density), LBD (Loose Bulk Density or bulk Density)

5. **Content uniformity of coated pellets:**

The drug content is calculated three times for each formulation. 50 milligrams of the coated pellets to be measured ground in a mortar and then added to a 100-millilitre volumetric flask. It is then mixed to with 100 cc of methanol. Following a one-hour stirring period and filtration through Whatman filter paper No.41, the drug content is measured spectrophotometrically .

6. **Scanning Electron Microscopy (SEM)**

The pellets form and surface features is examined and captured on camera using scanning electron microscopy. Pellets Surface is assessed at magnifications of 40X, 45X, 100X and 350 X before and after coating.

7. **Floating ability:**

Using a 250 ml beaker filled with 50 ml of 0.1N HCl, the coated effervescent-layered pellets floating abilities is determined. Twenty pellets is added to the medium and the amount of time needed for them to float also known as the floating time is determined visually. Using the formula below, the proportion of pellets floating is determined.

Floating pellets (FT %) = number of floating pellets at the measure time / Initial number of the pellets × 100

8. **Dissolution study :**

The drug release from the multiarticulate FDDS is investigated utilizing the USP type-I (rotating basket) dissolving test apparatus at 37.0±0.5˚C, 50 rpm and 900 ml of 0.1N HCl. For the dissolving investigation medication pellets with an equivalent weight of 20 mg is employed. At predetermined intervals of 0.5 hours, a 5 ml aliquot of the dissolution medium is removed and replaced with an equivalent volume of fresh medium maintained at the same temperature. The aliquot solutions are filtered using Whatman filter paper no. 41. The filtrates are examined using a UV-visible spectrophotometer.

ADVANTAGES OF FDDS[23]:

1. For medications that are absorbed through the stomach such as antacids and ferrous salts the gastroretentive systems are beneficial.
2. When acidic materials such as aspirin, come into contact with the stomach wall they irritate it. Therefore, the administration of aspirin and other comparable medications may benefit from the use of HBS formulation.
3. When tablets or capsules with a prolonged release floating dose form are administered, the medication will dissolve in the stomach juice. When the stomach's contents are emptied, they dissolve in the gastric fluid and become absorbable in the small intestine. Because of this, it is anticipated that a medication in floating dosage forms will be completely absorbed if it stays in solution form even at the intestinal pH of alkaline.
4. Medication intended for localized action in the stomach benefits from the gastro retentive systems such as antacids.
5. FDDS reduces dosage frequency which enhances patient compliance.

DISADVANTAGES[24]:

1. Unsuitable for medications having a low acid solubility. For example, phenytoin.
2. Unsuitable for medications that lose their stability in an acidic environment. For example, Erythromycin.
3. Medication that when released slowly, irritates the stomach or produces sores. Such as aspirin and NSAIDs.

4. Medications that the colon selectively absorbs. For example, corticosteroid.
5. Medication that passes through the GIT equally well such as nifidipine and isosorbidedinitrate.

APPLICATIONS[25]:

The limited absorption window in the upper gastrointestinal system has numerous applications for medications with low bioavailability, which can be addressed through floating drug delivery. It increases the bioavailability by keeping the dose form where it is absorbed. Below is an overview of these.

1. **Better bioavailability:**

Drugs that are not well absorbed from the upper part of the gastrointestinal tract due to site-specific absorption could be designed as floating drug delivery devices to maximize absorption. For example, an important increase in the bioavailability of floating dosage forms (42.9%) could be attained in comparison to enteric coated LASIX-long product (29.5%) and commercially available LASIX tablets (33.4%).

2. **Improved biotransformation in the first pass:**

Rather than a bolus intake, the presystemic metabolism the tested substance may be markedly boosted when the medication is delivered to the metabolic enzymes (cytochrome P-450, specifically CYP-3A4) in a continuous way.

3. **Lower frequency of dosage and prolonged medication administration:**

The drugs having short biological half-life a sustained and slow input from FDDS may result in a flip-flop pharmacokinetics and it reduces the dose frequency. This feature is associated with improved patient compliance and thus improves the therapy. HBS systems can remain in the stomach for long periods and hence can release the drug over a prolonged period of time.

4. **Targeted treatment for local illnesses in the upper gastrointestinal tract:**

For local therapy in the stomach, the medicine from FDDS may be administered for an extended period of time and continuously.

5. **Decreased medication concentration fluctuations:**

By minimizing variations in plasma drug concentration-dependent side effects linked to peak concentrations can be avoided. This characteristic is especially crucial for medications with a limited therapeutic index.

6. **Enhanced selectivity in receptor activation:**

FDDS minimizes drug concentration fluctuations, enabling specific selectivity in the pharmacological response produced by medicines that activate distinct receptor types at varying doses.

CONCLUSION

In order to increase bioavailability and provide controlled release of the dosage form, formulation of FDDS is an effective and promising strategy for stomach retention of dosage forms. The most crucial requirement to be considered while creating an FDDS is that the dosage forms density should be lower than that of stomach fluid. Consequently, it can be said that these dosage forms are the most useful for treating disorders related to the gastrointestinal tract and for extending the duration of a medication with a short half-life. Despite the many challenges that still need to be resolved to achieve prolonged gastric retention, a significant number of businesses are concentrating on commercializing this method. It is seen from the volume of profitable items and patents issued in this area

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HOW TO CITE: Nagendra R. , Divyashree P. , Venkatesh K. , Hanumanthachar Joshi, Nanditha V. V. , Floating Drug Delivery System: A Review, Int. J. of Pharm. Sci., 2024, Vol 2, Issue 2, 164-175. https://doi.org/10.5281/zenodo.10628440