International Journal of Current Advanced Research
ISSN: O: 2319-6475, ISSN: P: 2319-6505, Impact Factor: 6.614
Available Online at www.journalijcar.org
Volume 11; Issue 06 (B); June 2022; Page No.1093-1099
DOI: http://dx.doi.org/10.24327/ijcar.2022.1099.0245

Review Article

EFFERVESCENT FLOATING DRUG DELIVERY SYSTEM: A REVIEW

Haarika Balusu*[1], Navya Mudapelly[2], Sumana Donthula[2] and Bhanu Priya Ch[2]

[1,2]Department of Pharmaceutics, Sarojini Naidu Vanita Pharmacy MahaVidyalaya, 12-5-31/32, Vijayapuri Colony, Tarnaka, Secunderabad - 500017, Telangana, India

A R T I C L E I N F O

Article History:

Received 15th February, 2022
Received in revised form 7th April, 2022
Accepted 13th May, 2022
Published online 28th June, 2022

Keywords:

Gastro retentive drug delivery system, Floating-Effervescent, Non- Effervescent, Mechanism, marketed formulations, Evaluation.

A B S T R A C T

In the recent years, scientific and technological advancements have been made in the research and development of novel drug delivery systems by overcoming physiological difficulty such as short gastric residence times and irregular gastric emptying times. Gastric emptying of dosage form is extremely variable process and ability to prolong and control the emptying time. Gastric transit time is valuable asset for dosage forms, which reside in the stomach for a long period of time than conventional dosage form. Many approaches at present uses the prolongation of the gastric residence times, including floating drug delivery systems, swelling and expanding systems, polymeric bio adhesive systems, modified shape systems, high density systems and other delayed gastric emptying devices. The drug from floating drug delivery systems can be absorbed in the upper parts of stomach, duodenum and jejunum. This is one of the best ideal approach for prolongation of gastric residence time of a drug for controlled and sustained release.

INTRODUCTION

The oral route is the most suitable and widely used route for the delivery of drugs to the systemic circulation[1]. Researchers keep studying about the drugs which show their action over an extended period of time, with a well-controlled release profile.

Even though it is less invasive, the real challenge is to increase the dosage in the gastrointestinal tract by increasing gastric residence time[2]. The stomach and upper small intestine are main sites for drug absorption: prolongation of the residence time to achieve higher drug bioavailability, reduces the frequent administration of drugs, and shows better patient compliance[3]. Gastroretentive systems can remain buoyant in the gastric region for several hours which prolongs the gastric residence time of drugs. The controlled gastric retention of solid dosage forms was achieved by different mechanisms of mucoadhesion, sedimentation, flotation and by the simultaneous administration of pharmacological agents that delay gastric emptying rate[4]. The most common and convenient method of drug delivery is the oral route of drug administration. All these are the foremost commonly used dosage forms. They supply safe and convenient ways of active pharmaceutical ingredients (API) administration with excellent physicochemical stability [4,6].

Gastroretentive Drug Delivery Systems

Gastro retentive dosage forms are drug delivery systems which remain in the stomach for an extended period of time and allow both spatial and time control of drug release.Basically, gastro retentive systems swells followingingestion and isretained in the stomach for more number of hours while it continuously releases the incorporated drug at a controlled rate to preferred absorption sites in the upper intestinal tract[5].Their application can be advantageous in the case of drugs that are absorbed from the upper part of GIT and unstable in the alkaline medium of distal intestinal regions. Drugs that would benefit from gastro retentive drug delivery systems (GRDDS) are CNS drugs (Parkinson disease, epilepsy, Alzheimer and migraine), antiviral products (for HIV, herpes and hepatitis), certain antibiotics, antihypertensive drugs, anti-diabetic agents for Type II diabetes, drugs for local treatment of GI infections and gastric enzyme replacement [4, 5].

Drug Suitable For Gastro Retentive Drug Delivery System

- The drugs which are locally active in the stomach like antacidse.g. Misoprostol.etc
- Drugs showing narrow absorption window in gastrointestinal tract e.g. Riboflavin, furosemide, etc.
- Drugs showing instability in the colonic environment e.g. Ranitidine HCl, captopril.
- Drugs which are effective against normal colonic microbes e.g. Antibiotics against helicobacter pylori.
- Drugs which have low solubility at high pH values. e.g. Chlordiazepoxide, diazepam etc [4].

Corresponding author:* **Haarika Balusu
Department of Pharmaceutics, Sarojini NaiduVanita Pharmacy MahaVidyalaya, 12-5-31/32, Vijayapuri Colony, Tarnaka, Secunderabad - 500017, Telangana, India

Drugs Unsuitable For Gastroretentive Drug Delivery System

- Drugs which have very limited solubility in the acid medium e.g. Phenytoin etc.
- Drugs enduring instability in the gastric environmental conditions e.g. Erythromycin, etc.
- The drugs which are mainly employed for their selective release in the colon e.g. 5-amino salicylic acid and corticosteroids etc [5,6].

Floating Drug Delivery Systems

The system floats over the gastric contents, the drug is released slowly at the desired rate which results in prolonged gastric retention time and reduces frequency of dose[7]. Floating drug delivery systems provide local delivery to specific regions like the stomach and proximal small intestine. It shows good bioavailability, better therapeutic activity and substantial benefits to patients [8].

Advantages of FDDS

- Enhanced bioavailability
- Sustained drug delivery or controlled drug delivery reduced frequency of dosing[3].
- Targeted therapy for local ailments in the upper GIT.
- Reduced fluctuations of drug concentration.
- Improved selectivity in receptor activation.
- Reduced counter activity of the body[5,7].

Disadvantages of FDDS

- Not feasible for those drugs that have solubility or stability problems in gastric juices.
- They require a sufficiently high level of fluids in the stomach, then they float and work efficiently[9].

Drug candidates suitable for FDDS

- Drugs that have narrow absorption windows in GIT (e.g. L-DOPA, p-aminobenzoic acid, furosemide, riboflavin).
- Drugs those are locally active in the stomach (e.g. misoprostol, antacids)
- Drugs that are unstable in the intestinal fluid. (e.g. captopril, ranitidine HCl, metronidazole).
- Drugs that disturb normal colonic microbes (e.g. antibiotics like tetracycline, clarithromycin, amoxicillin).
- Drugs that exhibit low solubility at high pH values (e.g. diazepam, verapamil)[10,11] .

Mechanism of Floating Systems

Various attempts have been made to retain the dosage form in the stomach as a way of increasing the retention time. These attempts include: 1) Introducing floating dosage forms (gas generating systems or swelling or expanding systems), 2) Mucoadhesive systems, 3) High-density systems, 4) Modified shape systems, 5) Gastric-emptying delaying devices and 6) Co-administration of gastric emptying delaying drugs. Among these the floating dosage forms are the most commonly used dosage forms [8,31,32]. Floating dots have been made to retain the dosage form in the stomach as a way of increasing the retention time. These attempts include: 1) Introducing floating dosage forms (gas generating systems or swelling or expanding systems), 2) Mucoadhesive systems, 3) Drug delivery systems (FDDS) have a bulk density less than gastric fluids and so remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. While the system is floating on the gastric contents, the drug is released slowly at the desired rate from the system. After release of the drug, the residual system is eliminated from the stomach[9]. This results in an increased gastric retentive time (GRT) and control of the fluctuations in the plasma drug concentrations. 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 objects[25].The apparatus helps in optimising FDDS with respect to stability and durability of floating forces produced in order to prevent the drawbacks of unforeseeable intragastric buoyancy capability variations.

$F = F_{buoyancy} - F_{gravity} = (D_f - D_s)\, gV$

Where F=total vertical force, D_f =fluid density, D_s=object density, V=volume, g=acceleration due to gravity.

While the system is floating on the gastric contents, the drug is released slowly at the desired rate from the system. After the release of the drug, the residual system is eliminated from the stomach [19].This results in an increased gastric retentive time (GRT) and control of the fluctuations in the plasma drug concentrations. To measure the floating force kinetics, a novel apparatus for the 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 objects[22].The apparatus helps in optimising FDDS concerning the stability and durability of floating forces produced to prevent the drawbacks of unforeseeable intragastric buoyancy capability variation.

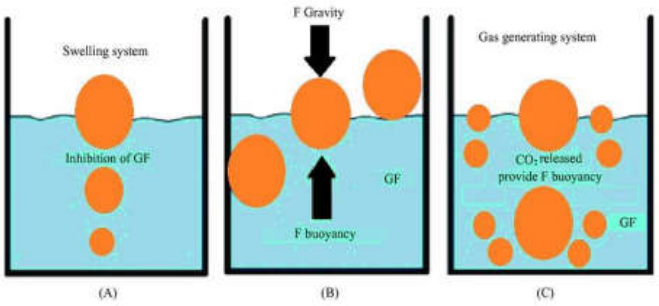

Figure 1 Representation of mechanism of floating tablets

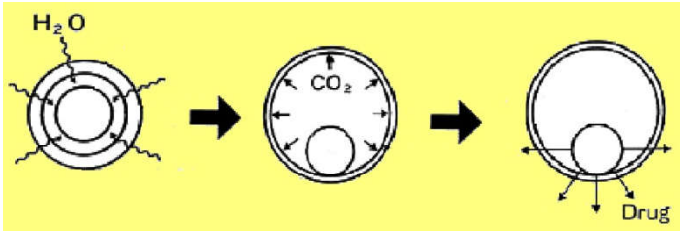

Figure 2 Mechanism of action in effervescent floating drug delivery system

Classification of FDDS

Effervescent systems

1. Gas generating system
2. Volatile liquid containing system[10]

Non-Effervescent systems

1. Colloidal gel barrier system.
2. Bi-layer floating tablets.

3. Microporous compartment system[11].
4. Floating Beads/ Alginate Beads.
5. Micro balloons/ Hollow Microspheres.
6. Raft forming system[12].

Effervescent systems

1. ***Gas-generating Systems:*** These buoyant delivery systems utilize effervescent reactions between carbonate/bicarbonate salts and citric/tartaric acid to liberate CO2, which gets entrapped in the gellified hydrocolloid layer of the systems which decreases its specific gravity and making it to float over chyme[25]. Some FDDS products available in the market are listed in Table 2.
2. ***Volatile liquid containing system:*** These system contain an inflatable chamber, which contains a liquid (ether, cyclopentane), that gasifies at body temperature to cause the inflatation of the chamber in the stomach. These devices are osmotically controlled floating systems containing a hollow deformable unit that can convert from a collapsed to an expanded position, and returns to collapsed position after an extended period[39].

Methods of Developing Floating Drug Delivery System

- **Direct compression technique:** The method involves compressing a tablet directly from powder content without chaning the substance's physical structure itself. Dicalcium trihydrate phosphate, tricalcium phosphate, etc. are the most widely used carriers.
- **Effervescent Technique:**An effervescent reaction between organic acid (citric acid) and bicarbonate salts to fill the floating chamber of the drug delivery system with inert gas (CO_2).
- **Wet granulation technique:** This technique Involves the massing of a mix of dry primary powder particles using a granulating fluid. Wet granulation shapes the granules by binding the powders together with an adhesive instead of compacting them[14].
- **Ionotropic Gelation Technique:** Gelation of anionic polysaccharide sodium alginate, the primary polymer of natural origin, was performed with opposite charged calcium ions (counter-ions) with the objective of forming instantaneous (immediate) micro particles.
- **Solvent evaporation technique:** It is the method where the drug is dissolved, dispersed, or emulsified into an organic polymer solution, then emulsified into an external aqueous or oil phase. Solvent evaporates from the dispersal surface to receive formed microspheres.
- **Spray Drying Technique:** Involves dispersing the core layer into the liquefied coating content and spraying the core coating mixture into the environment so that the coating is solidified by rapid evaporation by which the coating material is solubilized[15].
- **Melt Solidification Technique:** This method states that emulsifying the molten mass in the aqueous phase followed by cooling it to solidify. Lipids, waxes, polyethylene glycol, etc. are the carriers used in this technique.
- **Melt Granulation Technique:** This is the method that agglomerates the pharmaceutical powders using a meltable binder and does not use water or organic solvents for granulation[17,27,35].

Table 1 List of Drugs Formulated as Singleand Multiple Unit Forms of Floating DrugDelivery Systems

Dosage Form	Drugs
Tablets	Furosemide, Cholrpheniramine maleate, Theophylline,Ciprofloxacin, Captopril, Acetylsalicylic acid, Nicardipine, Nimodipine, Amoxycillin trihydrate, Verapamil HCI, Isosorbide di nitrate, Isosorbide mononitrate, Acetaminophen, Ampicillin, Cinnarazine, Dilitiazem, Florouracil, Prednisolone, Aspirin, Griseofulvin, and p-nitroanilline, Ketoprofen, Iboprufen, Terfenadine
Microspheres	
Granules	Indomethacin, Diclofenac sodium, Prednisolone
Films	Cinnarizine

Floating Agents

Floating drug delivery systems (FDDS) are invented to retain the drug in the stomach and are applicable for drugs with poor solubility and low stability in intestinal fluids. The basis behind FDDS is making the dosage form less dense than the gastric fluids to make it float[9].

FDDS are hydro-dynamically controlled low-dense systems with sufficient buoyancy to float over the gastric contents and remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time .The residual system is emptied from the stomach along with the release of the drug [27,15].

Basically the stomach is divided into three regions: fundus, body, and antrum (pylorus). The proximal part made of fundus and body acts as a reservoir for undigested material, the antrum is the main site for mixing motions and acts as a pump for gastric emptying by propelling actions. Gastric emptying occurs during fasting as well as fed states. The pattern of motility is however distinct in the two states. During the fasting state, an inner digestive series of electrical events take place, which cycles both through the stomach and intestine every 2 to 3 hours. This is called the interdigestive myoelectric cycle or migrating myoelectric cycle (MMC) which is further divided into the following 4 phases[13,18,33].

a. **Phase 1:**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 the basal phase[8].
b. **Phase 2:** In this phase bile secretion and mucus discharge take place and intermediate contraction occurs. It lasts for 20 to 40 min. It is also known as the pre-burst phase. The intensity and frequency increase gradually as the phase progresses[13].
c. **Phase 3:** In this phase, regular and intense contraction takes place for a short time. It lasts usually for 10 to 20 min. This phase is also called a housekeeper wave as it tends to empty the fasting contents of the stomach. Large objectives remain in the stomach in the fed state but passed down to the small intestine during this phase [9,13,31].

d. **Phase 4:** Lasts for 0 to 5 minutes and occurs between phases III and I of 2 consecutive cycles. After the ingestion of a mixed meal, the pattern of contractions changes from fasted to that of fed state. This is also known as digestive motility pattern and comprises continuous contractions as in phase II of fasted state. These contractions result in reducing the size of food particles (less than 1 mm) which are propelled toward the pylorus in a suspension form. During the fed state onset of MMC is delayed resulting in slowdown of gastric emptying rate [21,31].

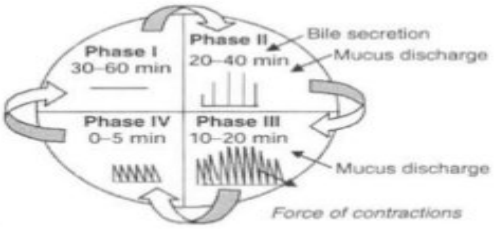

Figure 3 Phases of floating agents

Effervescent Floating Tablets

Effervescent tablets are tablets which are developed to dissolve in water, and release carbon dioxide. To use them, they are dropped into water to make a solution[8]. These tablets along with the active medicament, also contain ingredients like sodium bicarbonate, citric acid and tartaric acid. when tablets are dropped in the presence of water, liberating carbon dioxide and producing effervescence leading to the dissolution of the tablet, thus fastening solution formation and increasing the palatability, for example, Histac (Ranitidine). These effervescent formulations are also available in powders as well as in granules in the market. Effervescent tablets are becoming increasingly popular in a variety of sectors including supplements and pharmaceutical use due to the ease with which they can be consumed[9]. Effervescent tablets are designed to break in contact with liquid such as water or gastric juices, often causing the tablet to disintegrate and dissolve into a solution. This makes effervescent tablets the preferred choice of many, including people who are taking tablets for medical purposes as well as for dietary supplements. Effervescent tablets consist of a soluble organic acid and an alkali metal carbonate salt, one of which is often the active pharmaceutical ingredient (API). Carbon dioxide is formed if this mixture comes into contact with water. Typical examples of the acids include citric acid, tartaric acid, malic acid, fumaric acid, adipic acid and alkalis include sodium carbonate, sodium bicarbonate, sodium sesquicarbonate, potassium carbonate, potassium bicarbonate etc[12,19].

Advantages of Effervescent Tablets

- It can be administered to patients who have problems swallowing tablets and capsules.
- It is readily absorbed and the bioavailability is high because it is administered as a Solution1[4,20].
- Drugs that are unstable when stored as aqueous solutions are more often stable in the effervescent granules or tablet forms[10]
- Buffered effervescent aspirin tablets have a less irritant effect on the gastric mucosa and cause less gastrointestinal tract blood loss than conventional tablets.
- It is administered as a palatable sparkling solution[16].
- Fast onset of action.
- Good stomach and intestinal tolerance.
- Improved palatability.
- Superior stability.
- To obtain rapid drug action, for example, analgesics and antacids.
- To facilitate drug intake, for example vitamins [20].

Advantages of Effervescent Tablets over Conventional Tablets

- Pleasant taste compared to regular tablets..
- Distributed more evenly[11].
- Increased liquid intake.
- Easy alternative to conventional tablets.
- Simple and easy to measure[10,11].

Disadvantages of Effervescent Tablets

- The unpleasant taste of some active ingredients.
- Tablets having larger doses require special packaging.
- Relatively expensive to produce, due to large amounts of more or less expensive excipients and special production facilities are required.
- Its high sodium or potassium content makes it unsuitable for administration to patients with heart failure or cardiac insufficiency, chronic kidney diseases, uncontrolled diabetes and dehydration and so on[11,12].

Methods of Preparation of Floating Effervescent Tablets

- Dry granulation
- Direct compression
- By wet granulation

Dry granulation: The process of dry granulation is also called double compression or pre compression granulation .This method involves the manufacturing of tablets by converting the tablet formulation into slugs. These slugs are subjected to screening to form uniform sized granules[21].

Direct compression: This is a dry process in which powdered material is directly compressed into tablets without changing its physical nature[24].

Wet granulation: Wet granulation involves the accumulation of a mix of dry primary powder particles by using granulating fluid. The fluid contains solvent which can be removed by drying and should be non toxic. It involves [23,24]

- Powder wetting.
- Nucleation.
- Further nucleation or agglomeration.

Factors Affecting the Gastric Residence Time of Effervescent Floating Drug Delivery System

- ***Nature of Meal:*** Motility pattern of the stomach can change to fed state when indigestible polymers or fatty acid salts are fed and because of this the gastric emptying rate is decreased and drug release is prolonged[2,4].
- ***Frequency of Feed:*** when successive meals are given, the GRT can increase by over 40 minutes compared with a single meal because of the low frequency of migrating myoelectric complex[21].
- ***Gender:*** Mean GRT of a male in meals (3.4±0.4 hours) is less compared to the female of the same age and race (4.6±1.2 hours), regardless of the height, weight and body surface of the two.

- ***Age:*** Elderly people have a significantly longer GRT, especially those who are over 70 years of age[24].
- ***Fed and Unfed State:*** under fasting conditions, the GI motility is characterised by periods of strong motor activity or the migrating myoelectric complex (MMC) that occurs every 1.5 to 2 hours. The MMC sweeps undigested material from the stomach and, if the timing of the administration of the formulation coincides with that of the MMC the GRT of the unit can be expected to be very short. However, in the fed state, MMC is delayed and GRT is considerably longer[1,4,25].

Non-Effervescent Floating Tablets

The mechanism of the non effervescent system is polymer swelling, bio- adhesion of polymer. The most common excipients in this system are swell-able polymers, polysaccharides and matrix-forming polymers. In this system, the drug is mixed with gel-forming hydrocolloids3[8]. After oral administration when the dosage form comes in contact with gastric fluid, it swollen and gelatinous barrier forms on the surface and because of the air entrapped within the swollen polymer impart the floating of dosage form[39].

- ***Single Layer Floating Tablets****:* They are formulated by intimate mixing of drug with a gel-forming hydrocolloid, which swells in contact with gastric fluid and maintains bulk density of less than unity. They are formulated by intimate mixing of drug with low-density enteric materials such as HPMC35.
- ***Bi-layer Floating Tablets:*** A bi-layer tablet contain two layer one immediate release layer which releases initial dosefrom system while the another sustained release layer absorbs gastric fluid, formingan impermeable colloidal gel barrier on itssurface, and maintain a bulk density of less than unity and thereby it remains buoyant inthe stomach
- ***Alginate Beads:*** Multi-unit floating dosage forms were developed from freeze-dried calcium alginate. Spherical beads of approximately 2.5 mm diameter can be prepared by pouring sodium alginate solution into aqueous solution of calcium chloride, leads to formation of porous system with calcium alginate precipitates, which helps in flotation for over 12 hours. When compared with solid beads, which gave a short residencetime of 1 hour, and these floating beads gave a prolonged residence time of more than 5.5 hours.
- ***Hollow Microspheres:*** Micro balloons loaded with drug in their outer polymer shells are prepared by a novel emulsion-solvent diffusion method. The ethanol: dichloromethane solution of the drug and anenteric acrylic polymer is poured into anagitated aqueous solution of PVA that is thermally controlled at 40°C. The micro balloons float continuously over the surface surface of acidic dissolution media containing surfactant for more than 12 hours40.
- ***Micro porous compartment systems:*** The encapsulation of adrug reservoir inside a micro porous compartment with apertures along its top and bottom walls. The peripheral walls of the drug reservoir compartment are totally sealed to prevent any direct contact of the gastric mucosal surface with the un dissolveddrug.
- ***Raft Forming Systems:*** The mechanism involved in the raft formation includes the formation viscous cohesive gel in contact with gastric fluids, where in each portion of the liquid swells forming a continuous layer called raft. The system contains a gel forming agent (alginic acid), sodium bicarbonate and acid neutralizer, which forms a foaming sodium alginate gel (raft) when in contact with gastric fluids38.

Marketed Products of FDDS

Table 2 Marketed Products of FDDS

Dosage Form,	Drugs	Brand Name	Company Country
Floating Capsule	Diazepam	VALRELEASE	Hoffmann-LaRoche, USA
Effervescent Floating Liquid alginate Preparation	Aluminium hydroxide, Magnesium carbonate	LIQUID GAVISON	Glaxo Smith Kline, INDIA
Floating Controlled Release Capsule	Levodopa, Benserazide	MODAPAR	Roche Products, USA
Floating Liquid alginate Preparation	Aluminium-Magnesium antacid	TOPALKAN	Pierre Fabre Drug, FRANCE
Colloidal gel forming FDDS	Ferrous sulphate	CONVIRON	Ranbaxy, INDIA
Gas-generating floating Tablets	Ciprofloxacin	CIFRAN OD	Ranbaxy, INDIA
Bilayer floating Capsule	Misoprostal	CYTOTEC	Pharmacist, USA

Evaluation of FDDS

Pre-compression: Before compression process, granules were subjected to pre compression parameters (flow properties) such as angle of repose, bulk density, tapped density, hausner's ratio and carr's compressibility index.

Post-compression: After compression, tablets were subjected to tablet diameter, thickness, weight variation, hardness, friability, drug content, swelling index, buoyancy lag time, duration of buoyancy, cumulative percentage *in vitro* drug release and characterization of optimised tablets using FT-IR, SEM, DSC and X-RD.

Weight variation: A group of 20 tablets were taken from each formulation randomly selected and weighed using an electronic balance and the average weight of the tablets was determined. The individual tablet weights were compared with average weight [9,10].

Percentage weight variation = (Average weight-initial weight/Average weight)x100

Hardness of tablets: The hardness of the tablet was measured by tablet hardness tester [7,11].

Friability: It is a measurement of the mechanical strength of a tablet. A pre-weighed group of 20 tablets was charged in the fabrilator and subjected to 100 revolutions. The dusted tablets were then reweighed. Compressed tablets must not drop more than 1% of their weight[8].

It is expressed by

$$F = W_{initial} - W_{final} / W_{initial} \times 100$$

Drug content

20 tablets were randomly selected and weighed. The average weight was noted. Tablets were crushed in a mortar, powder equivalent to 100mg drug was taken, diluted up to the necessary concentrations and measured the absorbance and calculate the drug content [6].

Swelling index

Tablets were weighed individually and placed in a glass beaker, containing 200 ml of 0.1 N HCl, placed in a water bath at 37 ºC ± 0.5 ºC. At fixed time intervals, the tablets were removed and the excess surface liquid was carefully removed using tissue paper. The swollen tablets were then re-weighed. The percentage swelling Index (SI) was calculated using the formula[8].

$(SI\%) = W_{final}\text{-}W_{Initial}/W_{final}$ x100

Buoyancy lag time

Three tablets were taken randomly and placed in a beaker containing 200 mL of 0.1 N HCl with a temperature at 37±0.5 ºC using a water bath. The time required for the tablet to rise from the bottom of the beaker to the surface and float was determined [7].

Duration of buoyancy

The time during which the tablet remains buoyant, was recorded to be the Floating Lag Time (FLT) and the duration of time in which the tablet constantly floated is called Total floating time [11,12].

Cumulative percentage in vitro drug release

USP dissolution apparatus type II was used for *in vitro* drug release. 900ml of 0.1 N HCl was used as a dissolution medium and the paddle was rotated at 100 rpm for 24hr. 10ml of the sample from each basket was withdrawn at predetermined time intervals and the same 10 ml was replaced with fresh 0.1 N HCl as medium to maintain the sink conditions. The collected samples at different intervals were analysed. The dissolution study data from optimized formulation was subjected to release kinetics[12]..

CONCLUSION

Drug absorption in the gastrointestinal tract is a highly variable procedure and prolonging gastric retention of the dosage form extends the time for drug absorption. FDDS promises to be a potential approach for gastric retention. Although there are number of difficulties to be worked out to achieve prolonged gastric retention, a large number of companies are focusing toward commercializing this method. The currently available polymer-mediated effervescent FDDS and Non effervescent designed on the basis of delayed gastric emptying and buoyancy principles appear to be a very much effective approachto the modulation of controlled oral drug delivery. The FDDS become anadditional advantage for drugs that are absorbed primarily in the upper part of GI tract, i.e., the stomach, duodenum, and jejunum. Some of the unresolved, critical issues like the quantitative efficiency of floating delivery systems in the fasted and fed states, role of buoyancy in enhancing gastric residence time of FDDS and more than that formulation of an ideal dosage form to be given locally to eliminate H.Pylori, responsible for gastric ulcers world wide. It seems that to formulate an efficient FDDS is sort of a challenge and the work will go on and on until an ideal approach with industrial applicability and possibility arrives.

Acknowledgment

The authors wish to thank management of sarojini Naidu Vanita Pharmacy Maha Vidyalaya, Hyderabad for providing all the facilities.

Conflict of interest: The authors declare that there is no conflict of Interest.

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How to cite this article:

Haarika Balusu *et al* (2022) 'Effervescent Floating Drug Delivery System: A Review', *International Journal of Current Advanced Research,* 11(06), pp. 1093-1099. DOI: http://dx.doi.org/10.24327/ijcar.2022.1099.0245

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