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Review Study on Gastro-Retentive Floating Drug Delivery System

K Charulatha[1], S Sowmitha*[2], Pselvamani[3], S Latha[4]
Department of Pharmaceutical Technology, University College of Engineering, BIT Campus, Anna University, Tiruchirappalli – 620024.
Corresponding Author: S Sowmitha[2]

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ABSTRACT
The aim of writing this review on Gastro Retentive Floating Drug Delivery Systems (GRFDDS) turned into collectthe recent literature review with distinctive focus on the floatationmechanismto attain the gastric retention. Drug administration by oral route wasthe regularly method due to ease of administration and patient compliance. Later the oral administration route of any drug, its bioavailability is affected by its residence time in stomach. NowGastro Retentive Drug DeliverySystems (GRDDS) have gatheredhuge recognition for narrow absorptionwindow drugs, decrease in stability at high alkaline pH, and increase in solubility at low pH. This approach expands a drug delivery system, which gets retained within gastric fluid medium, and thereby releasing its active principles in the stomach. Some methodologies are used to attain the drugs gastric retention comprise the effervescence agents use, magnetic material, mucoadhesive polymers, techniques and buoyancy enhancing excipient which form plug-like devices that resist gastric emptying. This review provides its background, classification, Approaches, Application, Advantages, limitation and factors.

Keywords: Bioavailability,Residence time, Gastric emptying, Buoyancy.

I.INTRODUCTION

Because of its convenience in terms of easier manufacturing, self-administration, and compactness the majorly used dosage forms are the tablet. However, by oral administration has only a limited use for essential drugs from various pharmacological classes which possess poorbioavailability, because of absorption in inadequate manner or degradation in the Gastrointestinal (GI) tract. Some of these drugs are labelled by a narrow absorption window at the gastrointestinal tract upper part. Fast and unresolved gastrointestinal transit could result in release of drug in incomplete manner from the device over the absorption zone, bring about to diminished efficacy of the administered dose[1].Todevelop the gastric retention time of drug, gastroretentive dosage forms (GRDF) can be enhanced[2].In long-durable therapy for the chronic disease conditions treatment, conventional formulations are need to be administered in multiple doses and hence they have various disadvantages[3].

II. BACKGROUND

Three decades ago, as the expense and difficulties involve in marketing new drug establishment have raised, with concurrent recognition of the therapeutic merits of controlled drug delivery, the purpose in the designing controlled / sustained drug delivery system is to reduce the dosing frequency or to raise drug's effectiveness by narrow at the targeted site, decreasing the dose required, or supplying uniform drug delivery[4].Gastro retentive dosage forms highly develops the GIT pharmacotherapy through local drug release, leading to high drug concentrations at the gastric mucosa (eradicating Helicobacter pylori) from the submucosal tissue of the stomach, making it possible to treat gastric and duodenal ulcers, oesophagitis etc lessening the risk of gastric carcinoma[5].

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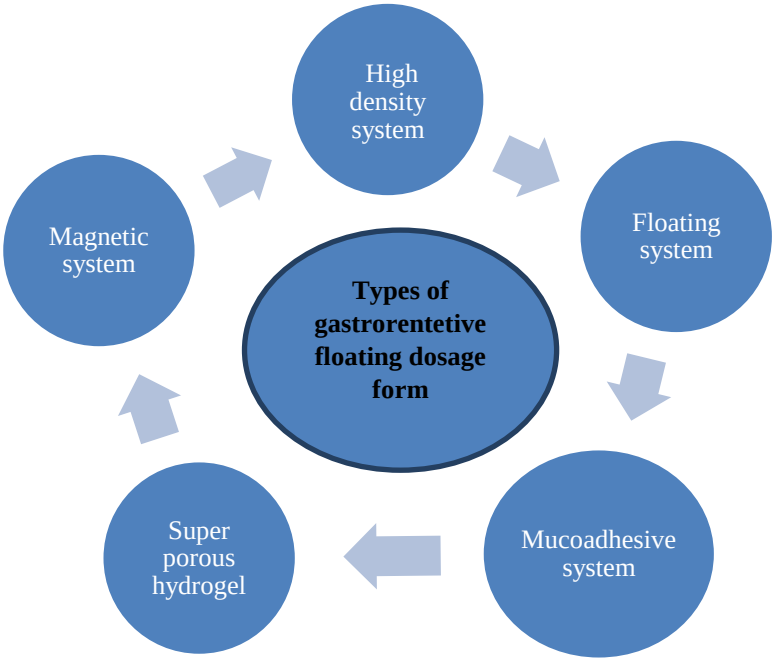
III. CLASSIFICATION OF GRFDDS[6,7]



IV. BASIC GASTROINTESTINAL TRACT PHYSIOLOGY

The stomach is anatomicallyclassified into 3 regions: fundus, body, and antrum (pylorus). The proximal region made of fundus and body behave as a reservoir for undigested content, on the other hand the antrum is the important site for mixing motions and behave as a pump for gastric emptying by propelling actionsGastric emptying occurs during fasting as well as postprandial states [8].The pattern of motility is however distinct in the 2 states[9].During the fasting state an interdigitate series of electrical events take place, which cycle both through stomach and intestine every 2 to 3hours. This is called the interdigitate myoelectric cycle or Migrating Myoelectric Cycle (MMC), which is further divided into following 4 phases as described by **Wilson and Washington**[10].

a) Phase I (basal phase) lasts from 40 to 60 minutes with rare contractions.
b) Phase II (preburst phase) lasts for 40 to 60 minutes with intermittent action potential and contractions. As the phase progresses the intensity and frequency also increase gradually.
c) Phase III (burst phase) occurs for 4 to 6 minutes. It involves intense and regular contractions for short period. It is due to this wave that all the undigested content is swept out of the stomach down to the small intestine. It is otherwise known as the housekeeper wave.
d) Phase IV occur 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 (to 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. Scintigraphy studies determining gastric emptying rates revealed that orally administered controlled release dosage forms are subjected to basically twocomplications, that of short gastric residence time and unpredictable gastric emptying rate [11].

V. APPROACHES TO GASTRIC RETENTION FLOATING DRUG DELIVERY SYSTEM

FDDS also known as hydro-dynamically balanced system is technologically efficacious to extend the gastric residence and to increase the drug optimum bioavailability. Formulation buoyancy character in stomach is attained by

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reducing its bulk density as equated to gastric fluid density. This character advantage is which it doesn't alter gastric emptying rate for a prolonged time duration and the release of drug happened in slow rate from the system, controlling of plasma drug concentration change. Floating drug delivery system is categorised based upon the mechanism of buoyancy [25]. These systems retain in the gastric region for long hours and therefore significantly extend the gastric residence time of drug. Prolonged gastric retention improves bioavailability, reduces drug waste, and improves solubility of drugs that are less soluble in the high pH environment of the small intestine.[26,27]

5.1 High Density System

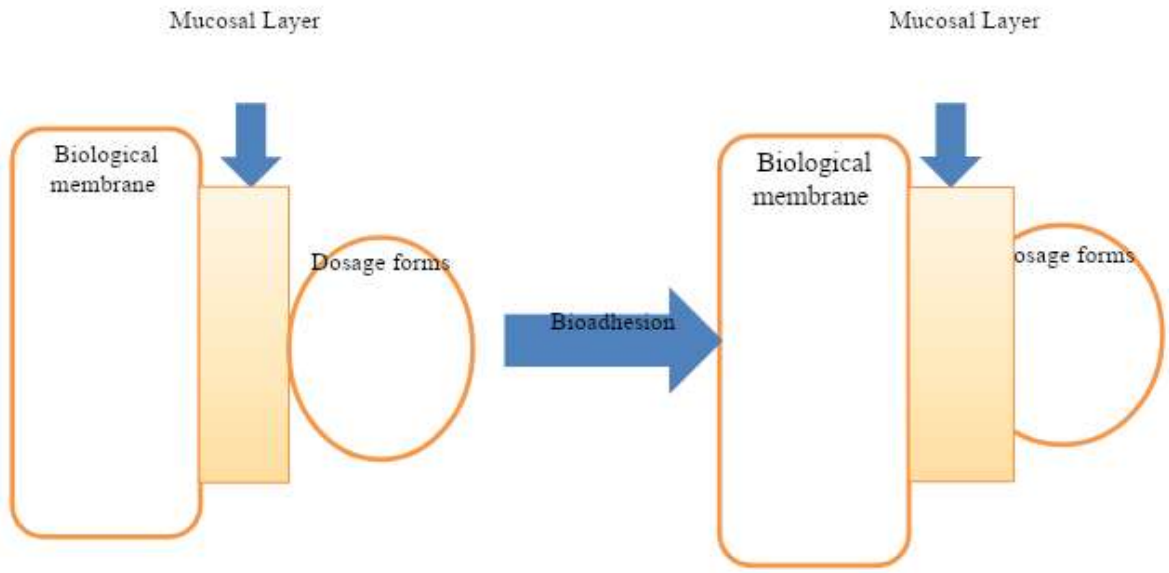
The dosage form's density performs a major aspect in the formulation of the GRDDS. A high-density system utilizes its weight as a mechanism. To increase the gastric residence of a drug, its density must beat the normal stomach content (1.004 g/mL) [12]. Clarke et al. [13], used gamma scintigraphy and analysed gastrointestinal transit of placebo pellet systems of varying densities. They described that GRT of such a formulation can be elongated from an average of 5.8 to 25 hours, based higherdensity than on the diameter of the pellets.

5.2 Low Density System

An Alternatemanner to improve gastric residence is to reduce the dosage form density than the normal gastric content.The particular systems remain buoyant because of lower density and provide continuous drug release.Accordingly, they enhance the GRT of the drug and better its bioavailability [14].

5.3 Mucoadhesive and Bioadhesive System

A bio adhesive and mucoadhesive system utilize its adhesive properties to target a drug to a specific region of the body for an extended period. The underneath figure displays a mucoadhesive system of GRDDS. Here, mucoadhesive or bio adhesive polymers are mostly used [15].



Polymers obtained from natural method (i.e.)sodium alginate, guar gum, gelatine etc., and semisynthetic polymers such as HPMC, carbopol, lectins and sodium carboxymethyl cellulose are vastly used for mucoadhesion. The adhesion is interfered by hydration, receptor interactions or bonding [16,17]. Madgulkaret al. [18],confirmed gastric retention and sustained drug release for six hours in albino rats.

5.4 Swelling System

The particular systems, when they come in contact with gastric fluid, their size enhances remarkably than that of the pyloric sphincter and thus, after swelling, being logged in the stomach. The above mentioned also called a "plug type system". Sustained and Controlled drug release is obtained utilizing an appropriate excipient. The swelling polymer ability mainly expect the degree of cross-linking of hydrophilic polymer network

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[19]. The high nature of cross-linking maintains the integrity of the system, this period a less degree of cross-linking original extensive swelling resulting in rapid dissolution of the polymer [20].

5.5 Superporous Hydrogel System

Superporous hydrogels are a hydrophilic polymer of three-dimensional network that possess numerous super-size pores inside them. The superporous hydrogels swelling occurs by the capillary wetting mechanism through interconnected open pores. To design superporous hydrogels, few of the ingredients like initiators and cross-linkers are utilized to begin the cross-linking. Some other ingredients were foaming aids, foam stabilizers, and foaming agents.[21] Desu et al[22],developed a superporous hydrogel system using cross-linking operator as N', N'-methylene bisacrylamide and composite specialist called polyvinyl alcohol, as an initiator pair named ammonium persulfate and N, N-tetramethylenediamine and Span 80 as a surfactant. The above-mentioned components are used as a froth stabilizer to produce a permeable structure using the gasfoaming method.

5.6 Magnetic System

In this system, by utilizing strong magnet with a powerful magnetic field towards the body surface, the movement of gastroretentive formulation with a small internal magnet is prolonged. Many reports talk about the positive results of this system, but the success of this system depends upon the selection of the magnet position with very high precision[23].Gröning et al.[24],developed peroral acyclovir depot tablets with an internal magnet. An extracorporeal magnet was used to prolong the GRT of the dosage form and to influence the duration of absorption of acyclovir. They performed an in vivo study with five healthy male subjects and determined the plasmaconcentration-time profiles of acyclovir. Computer simulations were carried out to display the influence of GRT of acyclovir depot preparations on the plasma concentration-time profiles of acyclovir.

VI.APPLICATIONS OF FLOATING DRUG DELIVERY SYSTEM

Floating drug delivery provides numerous applications for drugs have very less bioavailability due to the narrow absorption window of the upper part of the gastrointestinal tract. It attains the dosage form at the absorption site and therefore it increases the bioavailability. These are explained briefly as below.

6.1. Targeted drug delivery

Few of the drugs which are particularly absorbed from stomach or small intestine at proximal region, for those drugs this type of system is favoured. Example: furosemide and riboflavin. AUC attained with the floating tablets was almost high when contrasted with conventional dosage tablets. By targeting delivery in slow rate of misoprostol to the stomach, desired therapeutic levels could be attained and drug waste could be decreased [28].

6.2. Sustained Drug Delivery

Hydrodynamically balanced system can be in the stomach region for prolonged time and hence it can release the drug over an extended time period. The trouble of short gastric residence time encountered with an oral CR formulation hence can be overthrow with these systems. These systems possess bulk density of <1 As afinal result of which they are able to go with the float at the gastric contents. These systems sizes are relatively large and passing from the pyloric opening is prevented [29].

6.3. Absorption Enhancement

Drugs that possess low bioavailability due to its specific site of absorption from the gastrointestinal tract's upper part are promising candidates to be formulated as floating drug delivery systems, thereby boosting their absorption.[30,31]

VII. ADVANTAGES OF FDDS

7.1. Targeted therapy for local ailments in the upper GIT

The controlled and extended administration of the drug from FDDS to the stomach might convenient for local therapy in the stomach region.

7.2. Improved Receptor activation selectivity

FDDS lowers the drug concentration fluctuation over a critical concentration and thus enhances the pharmacological effects and improves the clinical results.

7.3. Reduced counter-activity of the Body

Release of the drug in slow manner into the body reduces the counter activity leading to higher drug efficiency.

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7.4. Site specific Drug Delivery

A floating dosage form is a vastly approved approach specifically for drugs which possess finite absorption sites in upper part of small intestine[32,33].

VIII. LIMITATIONS[34,35,36]

a) Most appropriate for drugs that own stability or solubility problem in GIT.
b) Drugs which are inconvenience to gastric mucosa and cause irritation are also not suitable and desirable.
c) With a glass full of water only the dosage form is administered.
d) The drug substances which are unsteady in the acidic medium of the stomach are unfit candidates to be incorporated in the systems.
e) Unsuitable for drugs with limited acid solubility. E.g., Phenytoin
f) Unsuitable for drugs that are unstable in acidic environment. E.g., Erythromycin
g) Drugs that disturb or causes gastric lesions on slow release. E.g., Aspirin & NSAID's
h) Drugs that absorb selectively in colon. E.g., Corticosteroid
i) Drugs that absorb equally well through GIT. E.g., Isosorbide dinitrate, Nifedipine.

IX. DRUG PROFILE SUITABLE FOR FDDS[37,38,39]

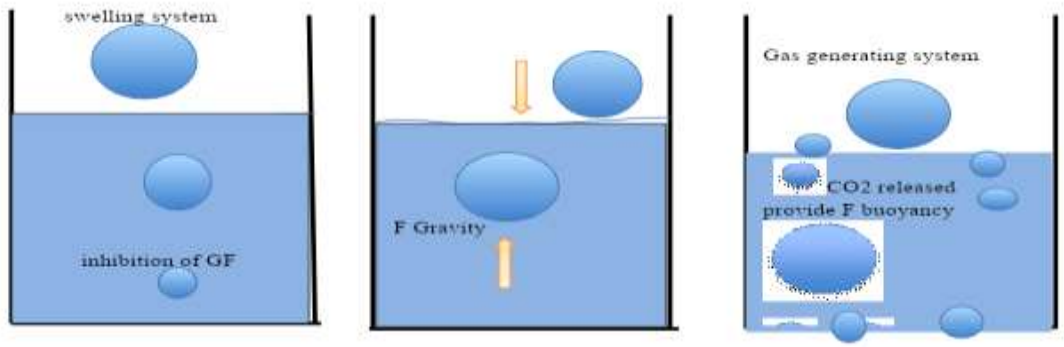
a) Drugs those are locally active in the stomach. Example, antacids.
b) Drugs that exhibit low solubility at high pH values. Example, diazepam, verapamil.
c) Drugs those are unstable in the intestinal or colonic environment. Example, ranitidine HCl, metronidazole.

X. EXCIPIENTS INCORPORATED IN DIFFERENT FLOATING DOSAGE FORM[40]

a) Effervescent Agents: Example citric acid, tartaric acid, Sodium bicarbonate, Di-SGC (Disodium glycine carbonate) CG(Citroglycine).
b) Release rate Retardants: Some substances such a Talc, Dicalcium phosphate, Magnesium stearate are used for retarding the release rate.
c) Inert Fatty Materials: Example, Beeswax, Long chain fattyalcohols, Fatty acids.
d) Release rate accelerants Eg. lactose,Mannitol etc.
e) Hydrocolloids: Example, Acacia, Alginates, B-cyclodextrin, Gelatin,Pectin, HPMC, Carbopol etc.
f) Buoyancy increasing Agents: Example, Polypropylene Foam and Ethyl Cellulose.

XI. MECHANISM OF FLOATING DRUG DELIVERY SYSTEM:

Floating drug delivery systems (FDDS) have a bulk density much less than gastric fluids andbuoyant withinside the belly without affecting the gastric emptying free for an extended length of time. While the system is floating on the gastric contents the drug is released slowly at the desired rate from the system. After drug release from the stomach, the residual system is emptied. Thisresults in araisedGRT and a good control of the fluctuations in plasma drug concentration. Minimum level of floating force (F) is likewise required to hold the dosage form shape reliably buoyant at the floor of the meal. 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 afunction of time) that is required to maintain the submerged object [41].



Mechanism of Floating System GF= Gastric fluid

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XII. FACTORS AFFECTING FLOATING DRUG DELIVERY SYSTEM:

12.1 Size and Shape

Dosage form unit with a diameter of more than 7.5 mm are reported to have an increased GRT competed to with those have a diameter of 9.9 mm. The dosage form with a shape tetrahedron and ring shape devices with a flexural modulus of 48 and 22.5 kilo-pond per square inch (KSI) are reported to have better GIT for 90 to 100 % retention at 24 hours compared with other shapes.

12.2 Caloric Content

GRT can be raised between 4 to 10 hours with a meal that is high in proteins nature.

12.3 Density

Dosage form density should be lesser than the gastric contents (1.004gm/ml).

12.4 Nature of the Meal

Feeding of indigestible polymers of fatty acid salts can alternate the motility order of the stomach to a fed state, to a fed state, for that reason reducing the gastric emptying charge and prolonging the drug release[42,43].

XIII. METHODS OF DEVELOPING FLOATING DRUG DELIVERY SYSTEM:

13.1Effervescent Technique

An effervescent response between organic acid (citric acid) and bicarbonate salts will fulfil the drug delivery system floating chamber with inert gas (CO_2).

13.2 Direct compression technique

It defines compressing tablets directly from powder content without changing the substance's physical structure. Dicalcium trihydrate phosphate, tricalcium phosphate, etc. are the most frequently used carriers.

13.3Ionotropic Gelation Technique

Gelation of anionic polysaccharide sodium alginate, the primary polymer of natural origin, was accomplished with opposite charged calcium ions (counter-ions) with the objective of forming instantaneous micro particles.

13.4 Wet granulation technique

Requires wet powder massaging, milling or drying. Wet granulation forms the granules by powder binding together with an adhesive rather than compacting them.

13.5 Solvent evaporation technique

Continuous phase ability is inadequate to remove the entire amount of liquid dispersal solvent. Solvent evaporates from the dispersal surface to receive hardened microspheres.

13.6 Spray Drying Technique

Requires dispersing the core layer into the liquefied coating content and spraying the core coating mixture into the environment hence the coating is solidified by quickly evaporating in which the coating material is solubilized.

13.6Melt Granulation Technique

This is the technique that aggregate the pharmaceutical powders employing a meltable binder and does not utilize water or organic solvents for granulation.

13.7Melt Solidification Technique

This techniquerequires emulsifying the molten mass in the aqueous phase continued by cooling it to solidify. Lipids, waxes, Polyethylene glycol, etc. are the carriers utilized for this technique[44,45,46].

XIV. CONCLUSION

Drug absorption happened in the gastrointestinal tract is a majorly variable process 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 technique. The most important criteria which has to be looked into for the productions of a floating drug delivery system is that the density of the dosage form should be less than that of gastric fluid. And hence, it can be concluded that these dosage forms serve the best in the treatment of diseases related to the GIT and for extracting a prolonged action from a drug with a short half-life.The novel drug delivery non effervescent based floating system is an emerging approach for receiving In-vitro buoyancy. Floating drug delivery system may be used for the possibility to replace the parenteral administration of drugs to oral pharmacotherapy that results in improved patient therapy. Hence, we can perform this study by developing the formulation in experimental tool design method. The correct formulation will be chosen and evaluated for further tests.

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