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NOVEL ADVANCED EMERGING PERSPECTIVES AND CURRENT STATE ON GASTRORETENTIVE DRUG DELIVERY SYSTEMS

Rohit Jaimini* and Dr. Manish Jaimini

Maharishi Arvind University, Mudiaramsar, Jaipur, Raj., Pin-302041

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***Corresponding Author:** Rohit Jaimini

ABSTRACT

The background of this review is to provide the information about the current state and innovation of gastro retentive drug delivery system leading with the future perspective to overcome the limitation of gastro retentive drug delivery system. In this context, a number of gastro retentive drug delivery systems have been employed to increase the therapeutic effectiveness of drugs with a limited window of absorption, unstable at alkaline pH, solubility in acidic conditions, and local stomach activity. The goal of this review was to study, compile, and concisely describe both new and older literatures, with a particular focus on strategies that are currently being used to extend gastric residency duration for narrow absorption, acidic (stable in stomach) but unstable at basic pH low aqueous solubility, short biological half life drugs to enhance bioavailability, patient compliance by decreasing side effects of drugs by use reduced dose of drug. The importance of *in-vitro* and *in-vivo* evaluation parameters of the various gastro retentive drug delivery systems, as well as their applications, is outlined. Future perspectives on this technology are also covered, including a brief discussion of the classification, formulation considerations for gastro retentive drug delivery systems, factors that control gastric retention, advantages, drawbacks, and applications of gastro retentive drug delivery systems to reduce the gastric emptying rate in both fasted and fed states. Overall, the formulation scientists who are designing the gastro retentive drug delivery systems may find this review useful and instructive.

1. Introduction

The oral route of drug administration is one of the most widely accepted routes. However, there are several physiological challenges in developing oral dosage forms, especially for certain drugs which have limited gastrointestinal transit, gastric emptying time, and absorption of several drugs in the upper part of the small intestine. Recent studies have reported an increased interest in developing a novel drug delivery system

that retains in the stomach for a significant period of time and provides a determined release profile. It has been reported that the gastric retention time of oral controlled release formulation is less than 12 hours. [1,2,3,4]

GRDDS is one of practical approaches for drugs that have limited absorption in the lower GIT, are unstable and poorly soluble at alkaline pH, have a short half-life, and exhibit local action at the upper section of the gut. Successful controlled release GRDDS have been developed using a variety of formulation techniques, including superporous hydrogel, bio/mucoadhesive, raft-forming, magnetic, ion-exchange, expandable, low- and high-density systems, and magnetic materials.[5]

This review's primary objective is to provide information about various GRDDS that have been developed till date, as well as the physiological condition of the stomach, potential treatment options, factors that may impact GRDDS, and in vitro and in vivo characterisation of GRDDS. The challenges and prospects for GRDDS in the future are also highlighted.

2. Gastroretentive Dosage Forms

1.1. Overview:

GRDDS improves the therapeutic efficacy and bioavailability of drug and may also reduce the dose of drug. Several factor that affect the absorption of the drug in the gastrointestinal tract are gastric transit time, gastric emptying process, site of drug absorption, and release of drugs from the dosage form.[6,7] There is a requirement of frequent dosing of these drugs to obtain a therapeutic level. Drugs with narrow absorption window in the upper portion of the gastrointestinal tract are unsuitable candidates for formulating a sustained release formulation as they have a brief gastric emptying time.[8] GRDDS helps in prolonging the gastric residence time. It allows the release of the drug at the specific site for systemic as well as local effects. These dosage forms are present in the stomach for a considerable period thereby significantly enhancing the time of retention of the drug in the stomach. The release of drug from GRDDS is controlled so that there would be continuous availability of the drug for absorption inside the stomach.[9]

1.2. Application of GRDDS:[10]

Some of the applications of GRDF are delivery of drugs that have narrow absorption window in the region of small intestine. Higher residence time in the gastric region could be beneficial for local effect in the upper area of the small intestine, for instance, peptic ulcer disease treatment. Improvement in the bio-availability is expected for drugs that are absorbed readily after released in the GI tract such as ciprofloxacin, cyclosporine, amoxicillin, ranitidine, captopril, etc. The bioavailability of drugs can be significantly enhanced through gastro retentive drug delivery system, especially for drugs that are metabolized in the upper GIT by this gastro-retentive drug delivery approach in comparison to the administration of non-gastro-retentive drug delivery.

1.3. Limitations of GRDDS:

The formulation requires floating in the stomach for effective drug delivery. Thus, there is a need for a high quantity of fluid in the stomach. During the sleeping position, there are contractile waves developed in the gastrointestinal system. Thus, if the dosage form is not of considerable size, it may sweep away. It is thus advisable that gastro retentive dosage forms should not be taken while going to bed. Certain drugs cannot be incorporated into the gastro retentive dosage forms. These include drugs with low solubility in an acidic environment, irritating the stomach mucosa, and acid-labile i.e. not stable in the acidic environment.

3. Developing Gastro Retentive Dosage Form: Physiological Consideration

3.1 Basic Gastro Intestinal Physiology:[11, 12]

The stomach is situated in the upper-left area of the abdominal cavity, under the diaphragm and divided into three regions which are fundus, body, and antrum. It is mainly composed of 3 types of cells, goblet cells, parietal cells, and chief cells. The proximal portion of the stomach is composed of the fundus. This acts as a reservoir for undigested materials. The antrum is the main region where the food particles are mixed and ground. It also regulates gastric emptying by its propelling action.

3.2 Gastric pH:

The gastric pH in humans varies with the regions of the GIT.[13] The variability in the pH of the stomach varies because of differences in the state of the stomach i.e it is fed or fasted. The mean value of the gastric pH in the fasted condition is measured to be 1.1± 0.15.[14] The mean gastric pH in the fed stomach is measured to be in the range of 3.6 ± 0.4.[15] Due to changes in physiological conditions of an elder person the gastric secretion may get affected. This may either result in decreased (achlorhydria) or increased (hyperchlorhydria) secretion of gastric acid.[16]

3.3 Gastric Emptying:

Gastric emptying means the emptying of the food particles into the small intestine. This is a completely motility-driven step. Gastric emptying signifies the time spent by a dosage form in the stomach. This is very important in the case of drugs whose site of absorption is in the stomach and proximal small intestine. Therefore, factors affecting gastric emptying will eventually affect the oral bioavailability of drug.[17] Since, it is a motility-driven step and the motility of the stomach is different in fasting and fed states.[18-19] Therefore, frequent feeding may increase the time of gastric emptying and as a result, the dosage form spends more time in the stomach. Thus the state of the stomach is also very important for modulating GRT.

4. Factors Affecting Gastro Retentive Drug Delivery System Efficacy

The gastric retention time can affect the absorption of the drug. Most of the absorption is limited to the stomach and duodenum region. The longer the drug remains in contact with the absorption region, the more will be the absorption. As a result, the efficacies of the dosage form will also increase.[20] Other formulation elements may be required, such as gas-generating agents in an effervescent floating tablet, sodium croscarmellose excipients with high swelling, and crospovidone for superporous hydrogels. Some of the factors affecting the gastro-retentive drug delivery system efficacy are:-

I.The density of dosage form:

It is a physical parameter that affects the gastric retention time in two ways. They are, sinking and floating.[21] Increasing the floating capacity of dosage form will increase the retention time but the effect may decrease in presence of food.[22] Increasing the density of the dosage form may cause an increase in gastric residence time.[23]

II.Size of dosage form:

The size of the dosage form can also be changed for increasing the residence time. This is done for a non-floating system. If the size of the non-disintegrating system is increased then its size will become more than the diameter of the pyloric sphincter.[24] This also increases the residence time of the dosage form.[25]

III.Extrinsic factor:

Extrinsic factors may include nature, frequency of food ingestion, the caloric content of food, taking drugs affecting the motility of the stomach, sleep, body mass index, posture, and physical activities.[25, 26, 27]

5. Role of Excipients in Gastroretentive Drug Delivery System [28,29]

Table 1. Role of Polymer in GRDDS

Sr. No	Category	Polymer
1.	Hydrocolloids	These are gel-forming substances. When it comes into contact with gastric fluid, it swells and retains the shape and density of the dosage form. Examples:-Acacia, pectin, agar etc.[28]
2.	Inert fatty materials	A particular gravity exists for edible inert fatty materials. It is added to the formulation to reduce its hydrophilicity while enhancing its buoyancy.[28]
3.	Release rate accelerants	The addition of mannitol or lactose to the formulation can affect the release of active ingredients from the dosage form.[28]
4.	Release rate retardants	The addition of some insoluble excipients like calcium phosphate, talc and magnesium stearate decreases the solubility of the dosage form. As a result, the release of active ingredients is also delayed.[29]
5.	Effervescent agents	These are the agents which produce carbon dioxide when it comes in contact with the gastric fluid. Eg. Sodium bicarbonate, citric acid, and tartaric acid.[29]

6. Drugs Suitable for Gastro Retentive Drug Delivery Systems

Table 2. Suitable drug for Gastro-retentive Drug Delivery Systems

Sr. No	Drug	Challenges	BCS Class	Category	Delivery system
1.	Diazepam[31]	Low solubility at alkaline pH	I	Benzodiazepines	Controlled release floating system
2.	Misoprostal[31]	Narrow absorption window	I	*Prostaglandin analog*	Floating capsule
3.	Ciprofloxacin[31]	Plasma fluctuations	IV	Quinolone antibiotics.	Effervescent floating system
4.	Levodopa and benserzide[32]	Short half-life, narrow absorption window	I	Antiparkinson agents	Controlled release floating system
5.	Baclofen[33]	Low Solubility	III	Skeletal muscle relaxants	Swelling system
6.	Ferrous Sulphate[31]	--	I	Iron Content	Colloidal gel forming floating system
7.	Ofloxacin[34]	Low solubility at alkaline pH	II	Fluoroquinolone antibiotics	Effervescent floating system
8.	Carvedilol[34]	Poor Absorption from lower GIT	II	Beta-adrenergic blocking agents	Gastroretention with osmotic system

7. Types of Gastroretentive Dosage Forms

Gastro retentive dosage form are majorly classified in 5 types mentioned in Figure no. 1.

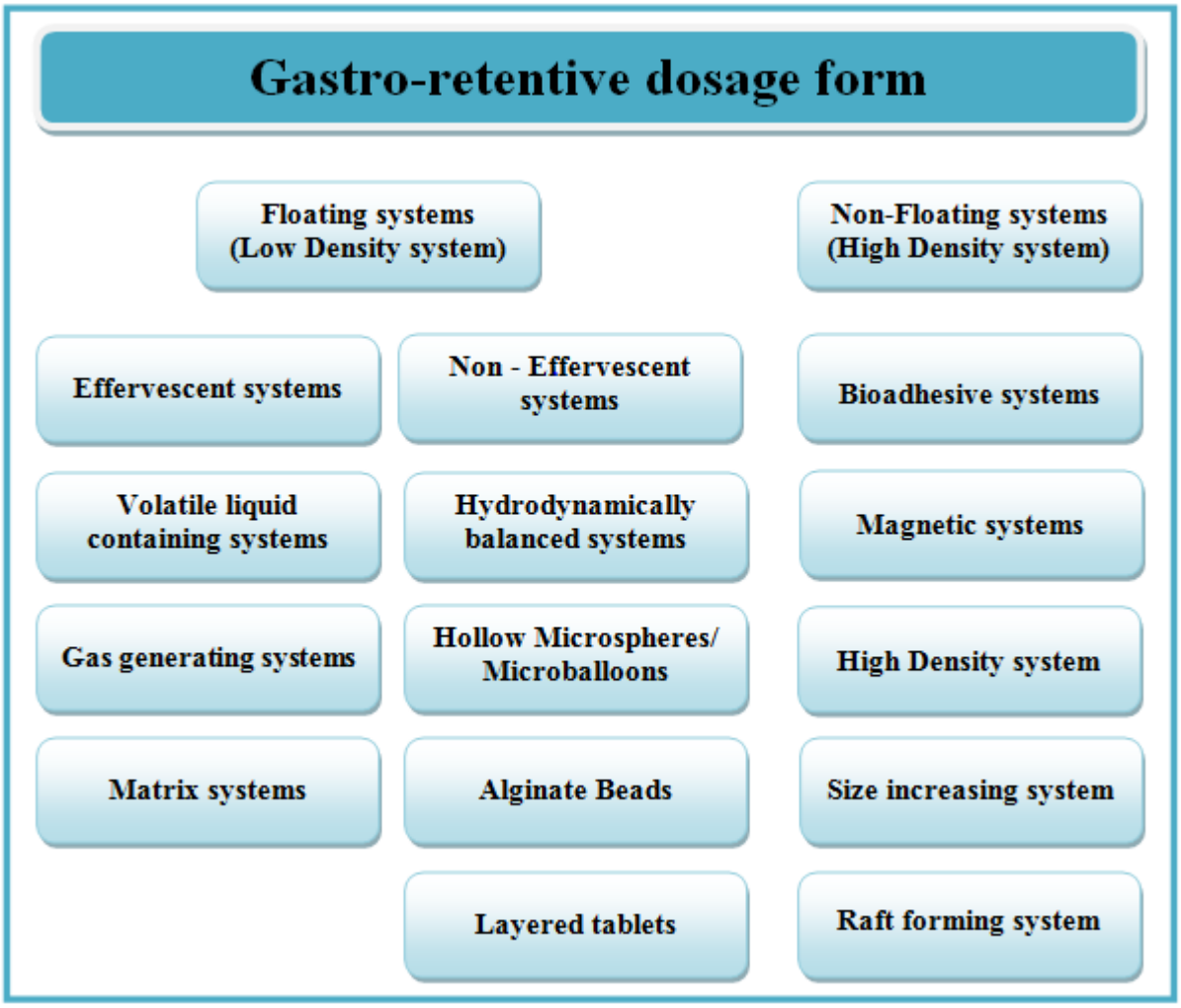

Figure 1. Gastro-retentive dosage forms[26]

7.1. High-density system: In this approach, the target is to develop a dosage form having a density greater than the density of normal stomach content. These types of formulations are made by mixing the drug with inert materials like iron powder, zinc oxide, and titanium dioxide.[30] Systems with a high density are denser than gastric juice. These systems frequently employ the excipients barium sulphate, zinc oxide, iron powder, and titanium dioxide. Due to their retention in the antrum rugae or folds, small high-density pellets can withstand gastric peristaltic movement, extending the length of the gastrointestinal tract from 5.8 to 25 hours. The creation of high-density pellets holding high-dose pharmaceuticals is challenging, despite the fact that this approach has the potential to increase GRT. The therapeutic importance of these systems is still debatable due to the lack of enough documented clinical trials on high-density pellet formulations in the literature. Therefore, future developments should emphasis on conducting animal studies to learn more about the therapeutic relevance of such dose formulations.

7.2. Floating system/Low-density system: Due to its low density, this kind of formulation does not settle down and keeps floating in the gastric fluid**.** This type of system provides prolonged release of the drugs. The dosage form having a low-density system does not affect the motility of the GIT. This is the reason this is widely circulated in the market.[31] The most practical and widely researched gastro retentive dosage forms are low-density/floating systems. This characteristic enables the system to float in the stomach for an extended period of time while the drug is eliminated from the body during the GRT at the appropriate

rate. Based on the mechanism of buoyancy, these systems are divided into two subtypes: non-effervescent floating and effervescent floating systems.

7.3. Super porous system: This is the swellable system but the swelling process is different from that of a conventional swelling system.[32] In this system the swelling occurs within minutes whereas takes up to hours in a conventional system. Swelling speed is increased because it has a pore size of >100µm.[33] The dosage form can be readily evacuated from the stomach because the conventional hydrogel system is a long and complex process that takes many hours to attain equilibrium. Instead, the superporous hydrogel systems expand by at least 100 times and have sufficient mechanical strength to withstand pressure from stomach contraction, increasing the GRT. In these systems, highly extendable polymers such sodium alginate and croscarmellose sodium are used. However, due to pH fluctuations and the structure's poor mechanical strength, these systems can be extremely sensitive to pH and swelling may be reversible.

7.4. Mucoadhesive system: The dosage forms have a mucoadhesive system containing mucoadhesive polymers. These polymers get attached to the gastro-mucosal surface of GIT and increase the retention time of the dosage form. Some examples of mucoadhesive polymers are alginate, gelatin, guar gum etc.[34] These helps to bind the drug compounds to mucosal surfaces and extending the duration of drug residence at the application site. An ideal mucoadhesive polymer adheres to the mucosal surface, has site specificity, is inert, non-irritating, and non-toxic, and interacts with the mucin by electrostatic, disulfide, hydrogen, and hydrophobic bonding. The molecular weight, shape, flexibility of the polymeric chains, hydrogen bonding ability, cross-linking density, charge, concentration, or degree of hydration of the polymer all affect the polymer's mucoadhesive characteristics and interactions strength.

7.5. Magnetic system: Dosage forms having this type of system contains a small amount of magnetic property. A magnet is placed over the abdomen over the area of the stomach. This is done to increase the retention time of the dosage form.[35] A dosage form for magnetic systems comprises of an internal magnet, excipients, and the active pharmaceutical ingredient. The GRT can be impacted by the extracorporeal magnet's location and magnetic field intensity.

8. Floating Drug Delivery System

The floating drug delivery system is made to float in gastric fluid. This results in prolonged action of the dose. In this approach low-density system is used. In this system, the total density of the dose is lower than the density of the gastric fluid. The delivery system is expelled once it has released all the drug content.[36]

8.1. Mechanism of Floating Drug Delivery System

This dosage form is based on a low-density system. Due to its low density, it has buoyancy and remains floating over the gastric fluid for an extended time. This eventually results in increased gastric retention time. For the occurrence of these phenomena, a minimum level of gastric content and a minimum level of buoyancy force are also required.[37]

8.2. Classification of Floating Drug Delivery System

Floating Drug Delivery System is majorly classified into two types, effervescent and non-effervescent system and they are subdivided into several categories.

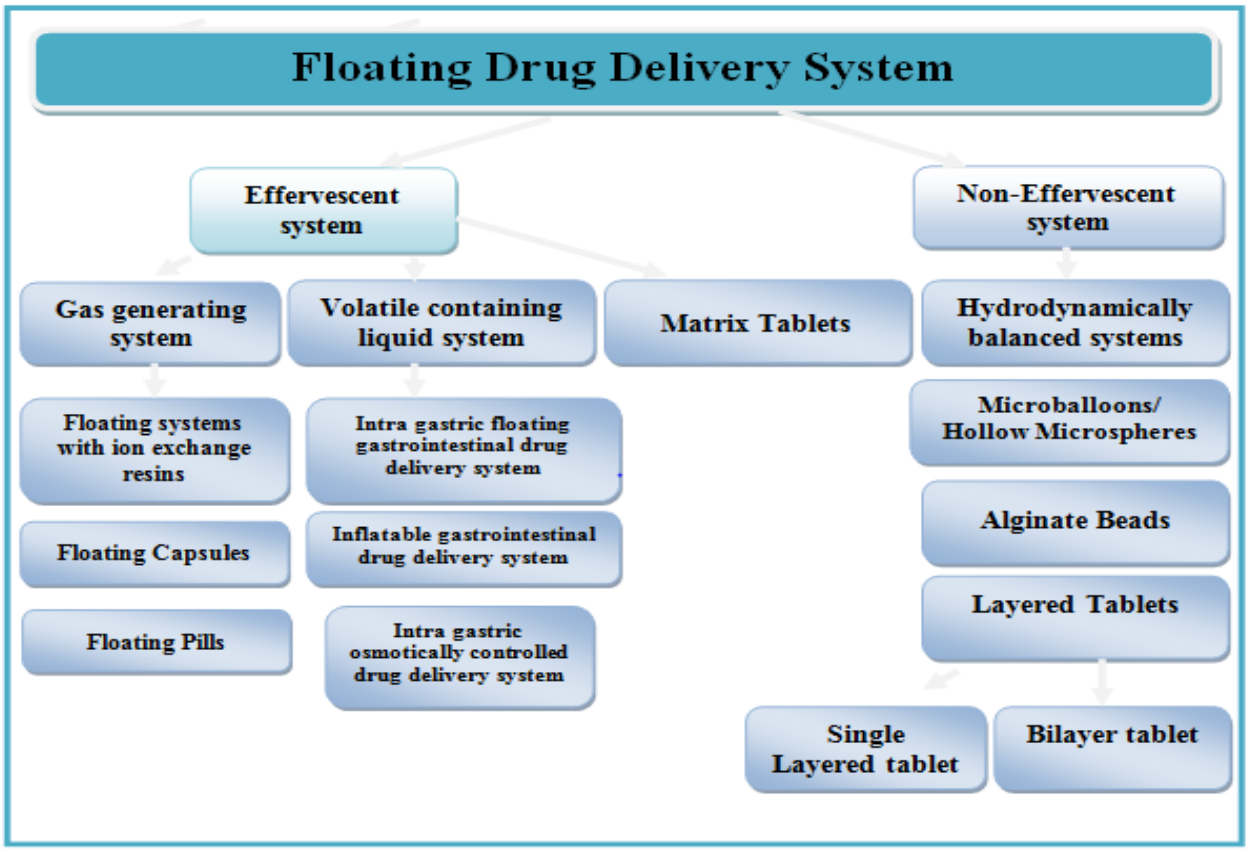

Figure 2. Floating Drug Delivery System

- **Effervescent system**

A gas-generating agent and volatile liquids are used in effervescent floating devices. Both single-unit systems and systems with many units have used this strategy. Effervescent ingredients such sodium bicarbonate, calcium carbonate, tartaric acid, and citric acid are mixed with hydrophilic polymers in the gas-generating floating system. Due to the effervescent agent's interaction with the stomach fluid when this system comes into contact with it, CO_2 is released. The hydrocolloid matrix, which gives the tablet buoyancy and affects the drug release characteristics, traps the released CO_2 gas. In volatile liquid systems, liquids that volatilize at body temperature, such as ether and cyclopentane, are delivered into an inflatable chamber, permitting inflation of the chamber in the stomach.[38]

I. **Gas generating system**: CO_2 gas is primarily evolved in this system. This is because of the reaction between sodium bicarbonate, tartaric acid, and citric acid. Due to production of. Gas the system becomes less dense and as a result, it floats in the gastric fluid.[39, 40, 41]

II. **Volatile liquid-containing system**: The dosage form belonging to this type of system has an inflatable space filled with liquid-like ether and cyclopentane. These gasify at body temperature and cause the dosage form to float into the stomach. This is an osmotically controlled floating system.[42]

- **Non-effervescent system.**

It is also a type of floating system but the gel-forming agents used in this are hydrocolloids and the polymers used to form the matrix are polycarbonate, and polystyrene. Highly expandable cellulose derivatives or gel-forming polymers are employed in non-effervescent systems. In non-effervescent systems, the medication is combined with a gel-forming polymer as part of the formulation process. The hydrodynamically balanced system (HBS), single- and double-layer floating tablets, and microballoons/hollow microspheres are a few examples of non-effervescent systems.

I. **Floating microspheres:** Hollow microspheres are the most promising and dependable floating systems because of the hollow space present them. These hollow microspheres are then loaded with the drug in its outer layer of polymer.[43]

II. **Alginate floating beads:** For preparing this type of system, the sodium alginate solution is dropped into the aqueous medium of calcium chloride. The beads formed by this method are approximately 2.5 mm in diameter.[44]

III. **Microporous compartment:** A drug reservoir is encapsulated in a microporous compartment having apertures at its top and bottom. The peripheral walls of the compartment are sealed using an appropriate aid.[45]

Table 3. Current Available studies on GRDDS

Sr. No	Drug	Polymer	Delivery system
1.	Metoprolol Tartarate[45]	Hydroxypropyl Methylcellulose	Floating Tablets
2.	Ranitidine Hydrochloride[45]	HPMC K15M, HPMC K100M, Polyethylene Oxide	Floating Tablets
3.	Valacyclovir Hydrochloride[45]	Ethylcellulose	Floating Microspheres
4.	Stavudine[45]	HPMC K4M, HPMC K15M, HPMC K100K, Ethyl Cellulose	Floating Matrix Tablet
5.	Ofloxacin[45]	Psyllium Husk, HPMC K100M, Crospovidone	Sustained Release Tablets
6.	Venlafaxine Hydrochloride[45]	Carbopol 971P, Ethyl Cellulose, Eudragit RS-PO	Mucoadhesive Tablets
7.	Famotidine[45]	Eudragit RL100, Cellulose Acetate	Hollow Microspheres
8.	Ranitidine Hydrochloride[45]	HPMC, Carbopol 934P, Ethyl Cellulose, Chitosan, Sodium Carboxymethyl Cellulose	Superporous Hydrogel

9. Advancements in Floating Drug Delivery System

- **Dual working system:** this system is based on two types of working principles. They are either floating, bio-adhesion or swelling. Floating drug delivery systems are made to make the dosage form float on the gastric fluid when the stomach is fed. Therefore, when the stomach is empty and the dosage form reaches the floor, in that case, the buoyancy of that dosage form is reduced. That is why the buoyancy of the FDDS

in the stomach is only for about 3 to 4 hours. A dual working system can overcome the limitations faced by floating, swelling, and bio-adhesive systems. [46]

- **Floating pulsatile system:** Pulsating drug delivery system delivers the drug completely and rapidly after a certain time. Uncertainty about this system is that sometimes it may get expelled out without releasing the drug. To overcome this limitation the Floating pulsatile system has been made. [47]
- **Floating osmotic system:** This system uses the principle of osmotic pressure to float in the gastric fluid. This system has 3 parts, an osmotic core, a shape-retaining semipermeable membrane, and an outer compression coating. This has gas generating and gel-forming agents. CO_2 is generated when this system comes in contact with the gastric fluid. Due to this, the density of the dosage form decreases and it starts to float. The major advantage of this system is that it delivers drugs without getting affected by the physiological conditions for example pH of the stomach.[48]

10. Evaluation Of Dosage Form Formulated Through Floating Dose Drug Delivery System

The performance of GRDDS can be estimated using in vitro evaluations. Assessments of tablet tensile strength, weight variation, friability, drug content, content uniformity, and in vitro drug release are among the standard ways of evaluating gastro retentive tablets. The evaluation of dosage form formulated through a floating dose drug delivery system can be done by the following methods:-

10.1. In-*vitro* Buoyancy test:

The floating property of the tablets was determined visually in triplicate. The floating lag time and total floating time were measured in the USP dissolution apparatus with 0.1 N HCl (pH 1.2, 37±0.5°C). Floating lag time was defined as the time it took for the tablet to rise to the surface of the medium and float. The total floating time was determined by the length of time the dose form stayed constant on the surface of the medium. [49]

10.2. In-*vitro* Dissolution test:

The drug release from the tablets was investigated using a type I USP dissolution apparatus (basket method). A tablet was submerged in a dissolution vessel (n = 6) containing 900 ml of 0.1 N HCl (pH 1.2) utilised as dissolution medium at 37±0.5 °C and agitated at a speed of 100 rpm. The amount of drug released was assessed after 0.5, 1, 2, 3, 4, 6, 8, 10, 12, 14, and 16 hours.

11. Innovations in GRDDS

Table 4. Innovative Technology on GRDDS

Sr. No	Innovative Technology	Description
1.	Oleotec™ and Soctec™ gastro-retentive technology[58]	OleotecTM was specifically developed for medications that require high therapeutic dosages that are incompatible with traditional dosage forms.
2.	The Accordion Pill™ Technology[58]	The Accordion PillTM is another gastro retentive formulation made of pharmaceutical biodegradable polymeric sheets. Under normal calorie diets, the Accordion PillTM unfolds and remains in the stomach for up to 12 hours.
3.	Gastro Retentive Innovative Device Technology[58]	The Gastro Retentive Innovative Device (GRID) is a once-daily system for drugs that

		would otherwise be absorbed only in the stomach or small intestine. GRID is designed to keep the drug in the stomach for at least eight hours.
4.	Acuform® Technology[58]	This method enables the targeted and controlled administration of medicinal components to the upper GI tract, which is the preferred absorption location for many oral medications. The special swelling polymers used by Acuform technology allow the tabet to be maintained in the stomach for eight to ten hours.
5.	Gastrointestinal Retention System Technology[58]	GIRESTM is a gastro-retentive technology that provides 16-24 hour retention durations in the stomach without the need of food. GIRES is a controlled-release dosage form enclosed in an inflatable pouch that is placed in a drug capsule for oral administration.
6.	Gastrodose Technology[58]	Gastrodose is a tablet that is retained in the stomach for long periods of time and is used to treat stomach or upper gastrointestinal tract diseases.

12. Gastroretentive Drug Delivery System: Challenges and Future Direction[59]

One of the aim challenges faced in conventional drug delivery system is to maintain the gastric retention time of the dosage form. This problem is faced especially in cases of drugs that are absorbed from the upper part of the stomach. This can be overcome by designing gastro-retentive drug delivery system. Several studies have been performed on gastro-retentive drug delivery system by making floating, mucoadhesive, and expandable systems. The variation in gastro-retentive time in fed and non-fed state stomach is still the most important challenge that is being faced by the researchers. Therefore, for minimizing the variations in GRT preparing a combination of systems is the best way. One of the factors influencing the bioavailability of oral drug delivery systems is the duration of the dosage forms' retention in the GIT. GRDDS is a condition that mostly affects the stomach. As a result, maintaining the delivery system in the stomach or upper section of the small intestine for a long period until all the medications have been delivered at a specified pace is the key issue in constructing a GRDDS. Gastric emptying time is a very varied process. It mostly relies on the dose type as well as whether the stomach is fed or fasting, among many other variables. In a fed condition, the stomach retention period is prolonged; in a fasted state, it is shortened. In a fed condition, the stomach retention period is prolonged; in a fasted state, it is shortened. The kind of food, caloric amount, gender, and age, along with other physiological obstacles, significantly affect how quickly the stomach empties. High-fat meals considerably delay stomach emptying due to their high caloric content. Fatty acid salts or indigestible polymers can also change how the stomach moves when it is fed, which can slow down how quickly the stomach empties. =Therefore, in order to create an ideal GRDDS, it is necessary to resolve issues with the gastric emptying rate of the stomach as well as sustain a proper drug release rate for a long time before the medication is metabolised in the body.

13. Conclusion

Gastro retentive drug delivery systems have emerged as current approaches of enhancing bioavailability and controlled delivery of drugs that exhibit an absorption window. Gastro retentive drug delivery approaches comprised mainly of floating, bioadhesive, swelling, magnetic, and high density systems. These systems not only provide controlled release of the drug but also present the drug in an absorbable form at the regions of optimal absorption. Even though a number of GRDDS, including bio/mucoadhesive, magnetic, low-, and high-density systems, have been described in the literature, further research is still needed to determine their therapeutic importance. Innovative technologies for gastro-retentive drug delivery systems present indubitable benefits for drug administration. This review attempts to compile latest innovative technology regarding gastroretentive drug delivery systems developed by pharma companies. It can be inferred that the gastroretentive system is most suited for possible pharmaceutical candidates. Recent technical developments in drug research have produced novel therapeutics with more benefits and fewer negative effects. In order to increase product quality from a pharmacological perspective, future GRDDS techniques may need to focus on a combination strategy.

14. Conflict of Interest

We declare that we have no conflict of interest.

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