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Review Article

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Advancements in Gastroretentive Floating Drug Delivery Systems: A Comprehensive Review on Famotidine-Based Formulations

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Abstract

GRFDDS have been of great interest because they can enhance the bioavailability and therapeutic efficacy of drugs absorbed in the stomach and upper gastrointestinal (GI) tract. One of the common antagonists of the H2-receptor is famotidine, which has shown to be effective in the treatment of the gastrointestinal disorders associated with acid. But it has low bioavailability due to its low retention time in the stomach. GRFDDS is designed to address this drawback and achieve a controlled and sustained release of drug, thus improving the effect of the therapeutic action of famotidine. This review will give a detailed discussion of the different categories of gastroretentive floating system namely famotidine in an effervescent, non-effervescent and other novel methods of delivering famotidine. The review continues to discuss the formulation strategies, major determiners of floating behavior, and benefits and challenges of such systems. Moreover, it emphasizes recent advances and future outlooks of the design and optimization of floating drug delivery systems, particularly famotidine. These systems can provide an excellent solution to the clinical efficacy of famotidine to improve patient compliance and disease control by increasing the gastric retention time.

Introduction

H2-receptor antagonist, famotidine, has been a critical drug in the management of the different acid-related gastrointestinal disorders. It is mainly employed to curtail the amount of gastric acid discharge and is normally adopted in the treatment of gastroesophageal reflux disorder (GERD), peptic ulcer, Zollinger-Ellison syndrome, and other diseases associated with acid. Famotidine acts by blocking histamine at the H2 receptor on the parietal cells of the stomach thereby decreasing the secretion of acid and causing healing of ulcer[1]. The drug works well in lowering stomach acid levels, the symptoms of acid reflux, and in healing ulcers. Famotidine has been found to be highly effective and selective compared to other H2 blockers and is therefore used in the treatment of acid-peptic disorders. Although famotidine is clinically active, it is not devoid of limitations, mostly because of its pharmacokinetic characteristics, which influence its bioavailability and efficacy of action[2].The relatively low bioavailability of famotidine, about 40-45% when given orally, is one of the primary issues in the delivery of this drug. This can be attributed to the fact that it is not easily absorbed in the gastrointestinal tract and the drug gets expelled out of the stomach at a high rate thus leading to low residence time in the gastric area. Consequently, famotidine is quickly absorbed in the small intestine and this can cause fluctuations in the effectiveness of the drug. Moreover, its uptake is very sensitive to the stomach pH[3]. The alterations in the gastric pH, which may occur as a result of meals or antiacid intake, may influence the absorption of the drug to a considerable extent and, consequently, its therapeutic effects. Hence, enhanced release formulations of famotidine to enhance its bioavailability and therapeutic efficacy is an important field of study in the pharmaceutical sciences.GRDDS has also become a promising solution to the shortcomings of drugs such as famotidine, which needs to spend a long time in the stomach to be effectively absorbed and have a therapeutic effect. GRDDS are created to increase the retention of the drug to the gastrointestinal tract, so that the drug will stay longer in the stomach, thereby increasing the absorption rate of drugs that are mainly absorbed in the stomach or upper gastrointestinal tract. The major aim of gastroretentive systems is to obtain a regulated, slow release of the medication, and it is capable of providing therapeutic effects, enhance bioavailability, and patient compliance by decreasing dosing frequency[4].

Of the different classes of GRDDS, the floating drug delivery system (FDDS) has received significant interest because of their property to retain their buoyancy in the gastrointestinal tract. The floating systems are unique in that they are able to float on the surface of gastric contents, and this guarantees extended contact with the stomach lining. This property enables a longer release of the drug, thus enhancing bioavailability and therapeutic consequences. The different mechanisms of floating drug delivery systems are based on effervescent or non-effervescent systems that employ different excipients to regulate the buoyancy and rate of release of the drug. A floating system means that the systems will stay longer in the stomach even during peristalsis, which normally causes the speedy removal of traditional pills by the stomach[5].The most common and studied and most commonly used are the effervescent floating systems because of the effective mechanism of floating. They usually have a drug with effusive agents such as sodium bicarbonate or citric acid. The effervescent agents dissolve when the dosage form mixes with the gastric fluids, and the system floats. Non-effervescent systems, however, are based on the application of low density polymers, or other excipients, which are not dissolved but form a buoyancy network, which helps the formulation stay longer in the stomach. Both systems are developed to float in the acidic environment in the stomach and deliver a controlled release of famotidine and thereby potentially address the limitations of famotidine which includes its rapid absorption and short residence time[6].Floating drug delivery systems have a number of benefits in addition to their main role in increasing the bioavailability of drugs such as famotidine. These are a decrease in the number of side effects, increased compliance of patients as a result of a lower dosing schedule and predictability of therapeutic response. These systems also have the ability to control fluctuations in drug concentration, commonly linked with traditional immediate-release preparations by keeping the drug concentration constant in the gastrointestinal tract. This continuous discharge may be particularly useful with medications such as famotidine, which demand steady plasma assays to preserve their effectuality in treating acid-linked ailments. Moreover, the drug can be treated more effectively due to the controlled release, as it is necessary to treat chronic diseases such as GERD, which require long-term treatment[7].Nevertheless, despite the tremendous benefits of gastroretentive floating systems, there are challenges associated with this technology. To develop an efficient system of floating drug delivery, it is necessary to pay close attention to various aspects, such as the selection of excipients, the formulation design, and the production process. As an example, the buoyancy of the system should be maximized to make the formulation stay in the stomach as long as required. Also, the release profile of the drug should be well regulated in such a way that it should be released steadily to give a consistent effect of the drug. The performance of the floating drug delivery systems can also be affected by the gastric pH, the type of food present in the stomach and the presence of gastrointestinal diseases and this aspect has to be considered in the formulation development[8].

Types of Gastroretentive Floating Drug Delivery Systems

GRFDSSs are new pharmaceutical preparations that have been used to increase the retention period of drugs in the stomach. These systems find application especially in drugs which are predominantly absorbed in the upper gastrointestinal tract, with a small absorption window, or which are better soluble in acidic environments. The floating systems are not emptied quickly by the stomach because they are less dense than the stomach contents, thus enhancing drug bioavailability. One of these drugs is famotidine, which is greatly enhanced by gastroretentive preparations due to its low half-life and minimal intestinal absorption. Different methods have been created to attain gastric retention like effervescent systems, non-effervescent systems and some innovative floating systems. The various types have varied mechanisms of ensuring buoyancy and drug release. Such systems do not only enhance therapeutic effectiveness, but also lower the dosing schedule and increase patient adherence[9]. It is a matter of choice of a suitable floating system based on the physicochemical characteristics of the drug to be incorporated, the required release characteristics, and physiological factors of the stomach. Over time, there has been extensive research on enhancing these technologies to give it improved stability, floating capacity and longer drug release kinetics that can lead to optimal treatment outcomes[10].

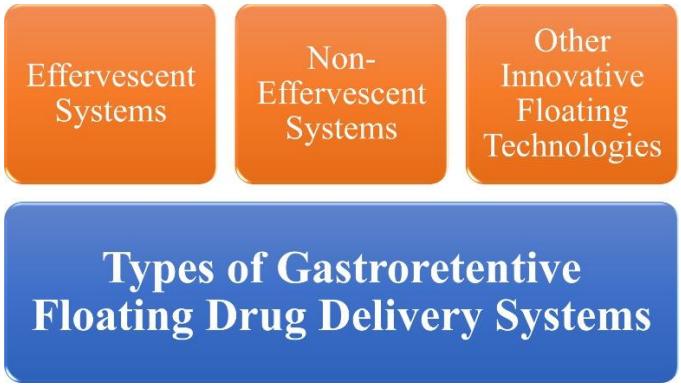

Figure 1 Types of Gastroretentive Floating Drug Delivery Systems

Effervescent Systems

One of the most prevalent gastroretentive systems is the effervescent floating drug delivery system because it has a good floating mechanism and is easily made. Such systems make use of agents that produce gases like sodium bicarbonate, calcium carbonate and citric acid, which combine with gastric acid to form carbon dioxide gas. The gas formed is trapped in the hydrated polymerse matrix of the dosage form which decreases its density and enables it to float on the gastric contents over a long period of time. This floating effect increases the gastric retention time and allows the release of drugs to be sustained[11].Swellable polymers are normally used in the formulation of effervescent systems; they include hydroxypropyl methylcellulose (HPMC), carbopol, chitosan, and sodium alginate. When these polymers come in contact with gastric fluid, they are hydrated and create a gel coating around the tablet or capsule. At the same time, the gas-producing agents create carbon dioxide, which is entraped in the gel layer and gives the system buoyancy. The moist matrix will release the drug slowly but in a controlled way as it stays suspended in the stomach[12].

In the case of famotidine, effervescent floating tablets have shown great enhancement in gastric retention and drug bioavailability. Because famotidine is less soluble in alkaline pH condition and the drug is mainly absorbed in the stomach and the upper intestine, it is best to keep the formulation in the gastrointestinal environment to improve its therapeutic action. Constant plasma drug concentration in famotidine through sustained release by effervescent systems helps to minimize variations in plasma drug concentration during dosage administration, as observed with traditional dosage forms[13].

Effusive systems have a number of benefits, such as ease of formulation, easy floating, extended gastric retention, and patient compliance. Such systems also minimize the number of dosing and decrease side effects due to the sudden release of drug. Nevertheless, there are also some limitations, including variability of floating behavior owing to gastric pH variations and food consumption. Overproduction of gases can also cause the dosage form to become unstable or to rupture. Notwithstanding such issues, effervescent floating systems are still among the most successful methods of gastroretentive administration of famotidine and other medications that need to be kept in the stomach over a long period[14].

Non-Effervescent Systems

Floating drug delivery systems that are not effusive are able to reach the surface without any gas-generating agent. The working principle of these systems is the use of swellable polymers and gel forming materials that have low density compared to gastric fluids. The polymers absorb water when exposed to gastric fluid and swell to become a hydrated matrix that can be retained in the air over a period of several hours. The swollen system has a low-density structure which allows it to float on the

contents of the stomach and gradually release the drug incorporated[15].Other hydrophilic polymers like hydroxypropyl methylcellulose (HPMC), polyethylene oxide, xanthan gum, carbopol and sodium carboxymethyl cellulose are typical of non-effervescent systems. When these polymers interact with gastric fluid they are quickly hydrated and create a sticky gel coating around the dosage form. The gel layer ensures the penetration of the gastric fluid into the system and the diffusion of the drug out of the matrix. The floating property and sustained drug release are sustained as new layers of polymer hydrates steadily enter the outer gel layer as the outer gel layer gradually dissolves[16].The hydrodynamically balanced system (HBS) is one of the significant varieties of non-effervescent system. In HBS formulations, the drug gets combined with hydrocolloids that form gels that hold the overall density of the dosage form lower than gastric fluid. These types of systems are very appropriate with drugs such as famotidine since they offer a longer gastric retention and controlled delivery of the drug without relying on the formation of gases.There are a number of benefits of non-effervesent systems over effervesent systems. They are mostly more stable, less sensitive to the environment and they are more easily produced. As there are no gas-forming agents, there is less risk of sudden expansion or structural rupture. The systems also deliver predictable and consistent drug release patterns[17].Non-effusive systems, however, are very reliant on the swelling behaviour and hydration capacity of the polymers employed. Poor swelling can decrease buoyancy and decrease the time of gastric retention. Moreover, the floating lag time can be increased as opposed to effervescent systems since the whole process of floating requires polymer hydration. Irrespective of these shortcomings, non-effervescent floating systems are an area of promising and well-studied future of the sustained gastric administration of famotidine and other such drugs[18].

Other Innovative Floating Technologies

However, over the past few years, a number of new gastroretentive floating technologies have been made to combat the shortcomings of traditional effervescent and non-effervescent systems. The purpose of these advanced methods is to enhance the floating efficiency as well as improve the control of drug release and also the increasing of the gastric retention time[19]. The modern floating technologies can be categorized as floating microspheres, hollow microspheres, raft-forming systems, floating beads, bioadhesive floating systems and expandable gastroretentive formulations[20].Hollow microspheres or microballoons Floating microspheres are hollow inside spherical particles that enable them to be buoyant in gastric fluid. Polymers like ethyl cellulose, Eudragit, and chitosan are used in these systems and are prepared by using the method of solvent evaporation. Floating microspheres offer long-term retention in the stomach and distribute the drug uniformly in the stomach. In the case of famotidine, microsphere formulations have demonstrated increased bioavailability and prolonged drug release[21].

Another innovative solution is raft-forming systems. These systems form a viscous cohesive gel, or “raft,” when they come in contact with gastric fluid. The raft is suspended on the gut contents and serves as a barrier to prevent acid reflux whilst gradually releasing the drug. Bicarbonate and sodium alginate are other commonly used ingredients in raft forming formulations. These systems are especially beneficial when treating gastroesophageal reflux disease (GERD), in which famotidine is a common prescription[22].Expandable and unfolding systems are tailored to become larger when they get to the stomach and thus cannot pass through the pyloric sphincter. Such formulations take long durations in the stomach and are gradually released as the drug. Likewise, bioadhesive floating systems represent a combination of buoyancy and mucoadhesion, allowing the dosage form to adsorb onto the gastric mucosa, and prolong the gastric retention time.The innovative floating technologies have many advantages, such as the opportunity to regulate the drugs release more thoroughly, increase the therapeutic effect, and patient compliance. Such systems also offer site-specific drug delivery and decreased dosing frequency. Their development is however usually characterized by complicated production processes, increased costs of production, and large-scale commercialization problems. Nevertheless, with these challenges, further breakthroughs in pharmaceutical technology are still ongoing to enhance the efficacy and usability of novel gastroretentive floating systems of famotidine and other medications[23].

Formulation Strategies for Famotidine-Based GRFDDS

Development of gastroretentive floating drug delivery system (GRFDDS) of drugs such as famotidine involves careful planning and formulation strategies to achieve long intestinal retention, drug retention and optimum therapeutic results. These systems are developed after a careful choice of the excipients, the selection of the best method of preparation and the description of the floating behavior to make sure that the system has the behavior desired. GRFDDS is of great advantage to famotidine which is relatively low in bioavailability and has a short half-life, thus prolonged presence in the stomach through GRFDDS may increase the absorption of famotidine. In this section, the strategies of formulation of famotidine-based GRFDDS are described, namely with the choice of excipients, the methods of preparation, and the definition of floating behavior[24].

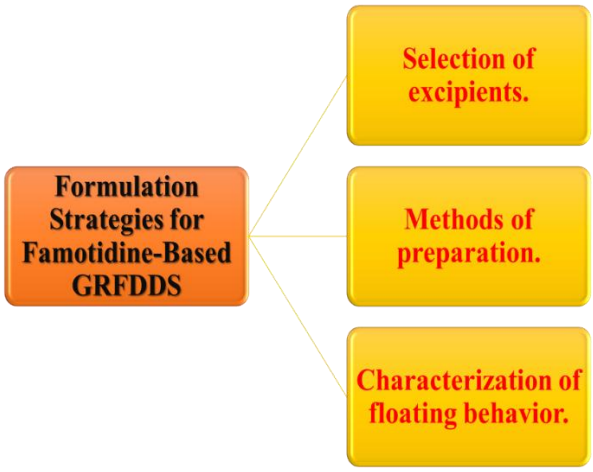

Figure 2 Formulation Strategies for Famotidine-Based GRFDDS

Selection of Excipients

Choices of excipients are critical to the development of floating drug delivery systems. In the case of famotidine-based GRFDDS, the excipients should be chosen based on their ability to provide the necessary buoyancy, controlled release, and stability of the dosage form in the acidic gastric environment. The main groups of excipients employed in GRFDDS formulations include polymers, gas-generating agents and other stabilizing agents[25].

Polymers: Floating drug delivery systems are based on hydrophilic and swellable polymers. These polymers assist in the creation of the gel matrix that gives the structural integrity required to support floating and also regulating the release of famotidine. Polymers commonly used are[26]:

Hydroxypropyl Methylcellulose (HPMC): This polymer is popular since it has good swelling characteristics and can form a gel when it is in contact with water. HPMC allows controlled release of drugs and makes the system to stay afloat over prolonged periods[27].

Carbopol: Carbopol is a cross-linked polymer that has gel forming properties and is employed to increase the viscosity and swelling ability of the system. It can also be used to regulate the rate of drug release[28].

Polyethylene Oxide (PEO): PEO is a polymer that is soluble in water and may swell to high extent and hence can be used to achieve buoyancy and to regulate the release of drugs in floating systems[29].

Chitosan: This biopolymer is often utilized because of its natural source, biocompatibility, and the capacity to create strong hydrogel which helps in delivering drugs and in floating[30].

Gas-Generating Agents: Gas-generating agents are necessary in developing the floating property of the dosage form. These agents are combined with the gastric fluid and release carbon dioxide which gets trapped in the system thereby lowering the density of the system and keeping it floating. There are some typical gaseous generating agents such as:

Sodium Bicarbonate: This compound reacts with the acidic conditions in the stomach to produce carbon dioxide that gives it the buoyancy to help it to be floated to deliver the drug.

Citric Acid: Citric acid together with sodium bicarbonate may also increase the amount of gas produced and floating properties of the system.

Calcium Carbonate: This also can be used to produce gas when it is mixed with stomach acid[31].

Other Excipients:

Plasticizers: These are added to the polymer matrix to enhance the flexibility and mechanical strength of the dosage form. Typical plasticizers are polyethylene glycol (PEG) and glycerin.

Stabilizers: Magnesium stearate and silica gel are excipients that can be used to aid in the stability of the floating system. These stabilize the formulation and prevent premature degradation.

The optimal mix of excipients guarantees that the formulation offers good floating and controlled release of famotidine during a prolonged duration[32].

Methods of Preparation

GRFDDS (preparation using famotidine) can be prepared in a number of ways, which is determined by the kind of floating system being prepared, either effervescent or non-effervescent. These techniques are selected with the aim of maximizing the swelling, gas production and controlled release of the drug. The common preparation methods used are[33]:

Tablet Compression: It is also one of the most utilized techniques of preparing floating drug delivery systems. The preferred excipients (polymers, gas-generating agents, and stabilizers) are combined with famotidine in this technique and then pressed into tablets. Compression also makes sure that the active pharmaceutical ingredient (API) and excipients are uniformly distributed. Sodium bicarbonate or citric acid is usually used as the gas-generating agents in the effervescent systems and swelling polymers in the non-effervesent systems, enabling the tablet to float when it comes in contact with gastric fluid[34].

Granulation: Granulation is the process of forming granules by blending the drug and excipients with an

appropriate binder and compressing the granules to make tablets or stuffing the granules into a capsule. This technique is applicable to achieve homogenous particle sizes and improving flow characteristics of the formulation. The effervescent system is one area where granulation is especially advantageous, as it is necessary to have a consistent distribution of gas-forming substances to achieve predictable floating properties[35].

Coacervation: Coacervation refers to a phenomenon in which a polymer-rich phase is separated into a polymer-poor phase forming a gel-like coating to the drug particles. This method is often used for producing floating microspheres or microballoons that can be filled with famotidine. The coacervation process contributes to the gradual release of the drug out of the microspheres as they stay afloat in the stomach[36].

Spray Drying: Spray drying is the process of turning a drug-polymer solution or suspension into a fine powder by spraying it into a high temperature air stream. The method frequently finds application in the formation of floating microspheres, where hollow, porous structures are formed that are not only buoyant, but can release drugs as well. Famotidine may be added to the solution or suspension and on drying, it forms microspheres that float in gastric fluid[37].

Solvent Evaporation: In this technique, the drug and polymers are dissolved in a volatile organic solvent and then the solvent is evaporated under controlled conditions. The floating beads or microspheres which result may be loaded with famotidine and then tested further on their buoyancy and release characteristics[38].

Hot Melt Extrusion: In this process, the drug and excipients are subjected to mixing and heating to a molten form followed by extrusion to create a solid homogeneous matrix. In the fabrication of non-effervescent systems, in which a particular polymer behavior is necessary, e.g. swelling to establish the gel matrix, hot melt extrusion is a good choice. This technique is especially useful in making systems of famotidine in which delayed gastric retention is required[39].

These techniques have varying benefits and are selected according to the needs of the formulation, including the desired floating capabilities, rate of drug release and scalability of the process.

Characterization of Floating Behavior

The definition of floating behavior is necessary to determine the functioning of gastroretentive systems. The floating property of a formulation on the gastric contents and its ability to stay afloat throughout the necessary duration has a direct influence on the efficacy of a formulation in enhancing drug bioavailability and therapeutic efficacy. A number of tests and methods are used to assess the floating behavior of famotidine-based GRFDDS[40].

In vitro Floating Time: Floating Time is one of the most important parameters to determine the floating behavior of the system and it is defined as the period the formulation is floated in the stomach. This is usually assayed in a model in vitro model where the dosage form is suspended in a simulated gastric fluid (SGF) at 37 o C. The time required by the system to sink or float is noted and the duration to float is timed. A formulation is said to be successful when it floats a few hours, simulating the situation in the stomach[41].

Floating Lag Time: This is the period taken by the dosage form to enter the simulated gastric fluid and the time of beginning to float. A low floating lag time is desirable because it means that the system will be able to become buoyant quickly after it has been introduced to the stomach. This may be measured by observing the time it takes the system to rise after being immersed in the fluid[42].

Determination of Buoyancy: Buoyancy is a very important attribute of the floating system and should be determined. The percentage of the dosage form that is above the liquid surface can be used to quantify this. Factors that affect the buoyancy of the system include the density of the system, the swelling power of the polymers and the quantity of gas-generating substances that are added to the formulation[43].

Swelling Index: In non-effervescent systems, the swelling index is a significant parameter, because it is used to indicate the capability of the system to swell and be able to remain in a state of buoyancy. The swelling index is determined by measuring the increase in the size of the dosage form after immersion in simulated gastric fluid. Increased swelling values tend to be associated with improved floating[44].

In vivo Studies: To gain complete insight into the floating behavior in real-world scenario in vivo studies are frequently carried out. These are studies that entail the retention period of the gastric and the release of the drug in animals or humans. The formulation is usually observed in the stomach by visualizing it with imaging methods such as X-ray or MRI[45].

The description of the floating attribute plays a crucial role in guaranteeing that the famotidine-based GRFDDS works

as intended and gives the drug a prolonged release and increased bioavailability in the gastric milieu[46].

Factors Influencing Floating Behavior

The floating nature of the gastroretentive drug delivery systems (GRFDDS) particularly with drugs such as famotidine depends on a number of factors. These factors play a crucial role in determining the effectiveness of floating systems in prolonging gastric residence time, controlling drug release, and improving bioavailability. The key variables that affect the floating behavior are formulation variables, physiological factors, and environmental conditions. All of these factors affect the buoyancy, stability and release kinetics of the system and knowledge of these effects is the key to optimising GRFDDS formulations[47].

Influence of Formulation Variables

One of the most crucial variables in floating behavior of GRFDDS is formulation variables. These are the type and concentration of excipients, polymers selection and preparation method. Hydrophilic and swellable polymers like HPMC, carbopol and polyethylene oxide can have a significant influence on the swelling potential and gel formation which play a major role in the assurance of buoyancy. Polymer concentration also influences the gel strength and rate of drug release, as an increase in concentration can lead to a reduced rate of drug release but an increased buoyancy. Gas-generating agents such as sodium bicarbonate, citric acid are also crucial in triggering the effervescence reaction in effervescent floating systems, which helps in sustaining buoyancy. Further, the drug loading capacity, the shape and size of the formulation play an important role in defining the floating time. Higher or smaller sized tablets can sink quicker, whereas those with smaller and lighter doses can be in suspension longer, giving a longer-lasting release of medication. Accordingly, the choice of the correct excipients and concentrations used should be optimized with each drug, such as famotidine, to attain the desired floating and release properties[48].

Physiological Factors

GRFDDS exhibits a floating behavior that is greatly affected by the physiological aspects in the gastrointestinal tract. The gastric pH is one of the most significant components that may influence the solubility of gas-generating agents and drug delivery. An example of this is famotidine, which is most soluble in an acidic environment, so a change in pH in the stomach is a critical factor to GRFDDS. Another physiological factor that has a central role to play is the rate of gastric emptying. Rapid gastric emptying would decrease the duration the dosage form is in the stomach, thus limiting its floating tendency. On the contrary, slow gastric emptying can enhance floating retention but might result in irregular drug absorption and release. Furthermore, food in the stomach can also modify the pH and gastric motility. The food intake could slow down the gastrointestinal emptying which can be beneficial in increasing the floating time. It can also influence drug release; however, food can influence the viscosity and hydration of the floating system. Lastly, gastric fluids, such as bile, mucus, and enzymes, may interact with the formulation, affecting its buoyancy and stability. Understanding these physiological factors is crucial for designing GRFDDS that can maintain gastric retention and optimize the therapeutic action of drugs like famotidine[49].

Environmental Conditions

The floating behavior of GRFDDS can also be greatly influenced by the environmental conditions in the stomach. These requirements involve the contents and the volume of gastric fluids, the speed of gastric peristalsis and the presence of enzymes or other substances that may affect the performance of the formulation. The solubility of the active drug (famotidine) and the excipients, especially the gas-forming agents in the effervescent systems, depends on the amount and composition of gastric fluids, i.e., hydrochloric acid and digestive enzymes. The buoyancy and floating capacity of the system can be affected by variations in the amount of gastric fluid, and the presence of food or liquids. The peristalsis rate, or the contractions of the stomach muscles, may also have an effect on the floating dosage form movement and the retention time. More vigorous gastric contractions may cause premature expulsion of the formulation whereas weaker contractions may result in prolonged retention. Also, other substances like antacids or antibiotics may have an influence on the gastric pH and change the floating behavior of the drug delivery system. Environmental factors are extremely dynamic, and the floating behavior of GRFDDS in various individuals or when exposed to various meals or treatments is difficult to predict. The external factors should thus be always taken into consideration whenever formulating gastroretentive formulations so that they can be effective in the various clinical environments[50].

Advantages of Gastroretentive Floating Systems

The gastroretentive floating drug delivery system (GRFDDS) has various benefits, especially in improving the therapeutic effect of drugs such as famotidine that are absorbed in the upper gastrointestinal tract. These are created to ensure that these remain in the stomach over a longer duration and provide many advantages regarding gastric retention, bioavailability, therapeutic effect and the minimization of side effects. The main benefits of such systems are that they can increase the time of gastric

retention, enhance the absorption of drugs, and optimize the release profile, which makes them an attractive option of controlled drug delivery[51].

Enhanced Gastric Retention Time

Among the major benefits of gastroretentive floating systems, is the fact that they increase the gastric retention period. The traditional drug delivery methods are emptied quickly out of the stomach into the small intestine, where they are absorbed to a large extent. This fast transit time could however result in unabsorbed drug or partial absorption of drugs that demand an acidic environment or have a narrow absorption window. Floating systems, however, are not absorbed by the small intestine, but instead, they are retained in the stomach, and they do not pass into the small intestine. This long gastric retention will make sure that the drug remains longer in the stomach and this longer stay will be able to give a better therapeutic effect by allowing the drug to be more fully absorbed[52].

This is especially advantageous in the case of famotidine, which is absorbed in the stomach and upper gastrointestinal tract and the solubility is dependent on the pH. Floating systems increase the chance of famotidine to dissolve in the acidic stomach and thus have better bioavailability by staying longer in the stomach. Besides, longer gastric retention time offers more therapeutic period and the drug stays in the system long enough to treat an acid related disease, like GERD or peptic ulcers[53].

Improved Bioavailability and Therapeutic Efficacy

The second major benefit of gastroretentive floating systems is that the systems may enhance the bioavailability of poorly-absorbed or a short half-life drug. In the same way as most drugs, famotidine has low bioavailability, and also has a short gastric emptying half-life and low absorption in the small intestine. Floating systems ensure that the drug stays longer in the stomach and thus it is best absorbed where famotidine is most effective.The prolonged release of floating systems also means that famotidine is steadily released over a long duration, which guarantees the same plasma concentrations and eliminates the peaks and valleys of immediate-release preparations. This leads to a more predictable therapeutic effect, which can be used to manage such conditions as acid reflux or ulcers. The added advantage of floating drug delivery systems is reduced dosing frequency, better patient compliance and less chances of missing doses.Also, due to the controlled release mechanism of floating systems, the drug release can be optimized, which means that famotidine should be present in the gastrointestinal tract as long as possible. It may lead to increased clinical activity, because the drug is always present to act upon its target receptors in the stomach, and the drug is longer-acting in relief of the symptoms, and the drug is more active in healing the gastrointestinal lining[54].

Reduced Side Effects and Optimized Drug Release

The benefit of gastroretentive floating systems is that they have fewer side effects than traditional drug delivery systems. The rapid change in the concentration of drug in the bloodstream is one of the major causes of side effects with conventional drug formulations. Floating systems reduce such variations by a constant and regulated production of the active drug over time, and, in this way, can reduce the incidence of side effects, such as nausea, dizziness, or gastrointestinal irritation, that are commonly related to high peak concentrations[55].In the case of famotidine, constant levels of the drug are imperative in reducing any possible side effects. Conventional immediate-release preparations may cause excessive levels of the drug in the blood, potentially with undesirable effects, particularly in patients with delicate gastrointestinal systems. Floating systems guarantee gradual release of famotidine, which not only increases the overall therapeutic effectiveness, but also minimizes the risk of adverse events.In addition to that, floating systems are used to optimize the drug release profile to suit the needs of a patient in terms of treatment. When famotidine is used, the controlled release makes the drug remain longer in the stomach allowing a constant rate of acid suppression without sudden spikes in the drug concentration. This sustained release assists in attaining a more stable pharmacokinetic profile, which offers protracted relief against conditions like GERD and peptic ulcers as well as reduces side effects and enhances patient quality of life.To sum up, the benefits of gastroretentive floating systems are high, especially when it comes to drugs that have sustained release and longer gastric retention such as famotidine. These systems do not just enhance bioavailability and therapeutic efficacy, but also provide increased patient compliance, a decrease in side effects, and increased predictability of drug release. Floating systems are promising with further developments in formulation techniques, as they are likely to be used to optimize the delivery of a broad variety of drugs[56].

Challenges and Limitations

Although gastroretentive floating drug delivery systems (GRFDDS) have a lot of benefits, development and clinical practice of these systems have been coupled with a number of limitations and challenges. These challenges include the problem of stability, patient response variability, technological and manufacturing complications. These issues are important to consider when maximizing the usefulness and scalability of these systems to be useful to the masses[57].

Stability Issues

The stability of the gastroretentive floating systems under different conditions is one of the key challenges in the development of the gastroretentive floating systems. The floating systems should be able to stay afloat in the acidic gastric environment over a long period of time. Nevertheless, some excipients, especially the gas-generating agents, may cause instability with time. As an illustration, effervescent systems based on agents such as sodium bicarbonate and citric acid might experience early gas release or degradation leading to the loss of buoyancy and early release of the drug. This may result in poor drug delivery and therapeutic ineffectiveness. Moreover, the stability of floating systems can be undermined by elements like humidity, changes in temperature, and exposure to light, particularly when kept over some time[1].

The polymer matrix in the non-effusive systems also affects formulation stability. The commonly used polymers such as HPMC and carbopol, which are swelling and floating polymers, may experience alteration in their physicochemical properties with time. This may cause them to lose some of their swelling capacity and buoyancy that is likely to decrease the lifetime of the system in the stomach. To counteract these stability issues, sophisticated stabilization methods like applying protective coating, moisture-resistant packaging and appropriate storage environments are required[2].

Variability in Patient Response

Another important issue with floating systems is that the response of patients is not very predictable. Gastric physiology is individual and the floating behavior and drug release profile may be affected by issues like gastric pH, motility and the presence of food. As an example, patients whose gastric pH is abnormal (altered by medications or some medical conditions) may have varied floating behavior than healthy people. Likewise, the gastric emptying rate may be altered according to whether the patient is fasting or has just eaten and this may affect the performance of floating systems[3].

Furthermore, the age, gender, and gastrointestinal diseases (e.g., GERD or irritable bowel syndrome) may contribute to unequal absorption of the drug, which complicates even more the forecast of therapeutic effects. This inconsistency complicates the development of a universal solution to GRFDDS since such systems should be flexible to a broader physiological spectrum to deliver the same drug and therapeutic effects to diverse populations of patients.

Technological and Manufacturing Challenges

Technologically and on manufacturing side, the invention of GRFDDS has a number of challenges. The intricacy of designing a floating system where a balance exists between offering both buoyancy and controlled drug release necessitates careful choice of excipients and optimization of their concentrations. Also, manufacturing processes of the production of floating systems and in particular production on a large scale have to be uniform and consistent. The differences in the formulation process, including the compression force, granulation method, or drying process will lead to a large difference in the final product performance[6].

The cost and time of development and manufacturing of such systems is also another major challenge. The addition of special excipients like gas-generating agents and complex polymers can raise production costs. Moreover, production itself may prove to be more complex than conventional dosage form and involves specialized machinery and quality control measures. This also presents a challenge since the formulations are difficult to scale up to mass production, which can restrict the commercial use of floating systems to a wide range of clinical use.

To sum up, although gastroretentive floating drug delivery systems have significant potential, the important issues of stability, variability among patients, and manufacturing complexities have to be tackled in order to implement them successfully. Continued research and development in formulation methods, custom medicine methods and new manufacturing technologies will play a key role in eliminating these challenges and achieving the full potential of these systems[8].

Conclusion

GRFDDS are a promising answer to the problems associated with drugs such as famotidine that are poorly absorbed and need to spend long periods of residence in the stomach in order to be effective therapeutically. These systems have a greater gastric retention, and by using excipients, gas-generating agents and polymers, drugs can stay longer in the stomach. This enhanced retention enhances the absorption of famotidine, especially in acidic pH-dependent solubility range, leading to increased bioavailability and uniform therapeutic response. GRFDDS has the following major benefits; increased gastric retention time: this will enable famotidine to stay in the stomach longer and deliver a sustained release that increases the therapeutic effectiveness of the drug. This controlled release lowers peaks and troughs in the drug concentration with the conventional formulations which reduce side effects and enhance patient compliance by lowering the dosing frequency. Floating systems have become an excellent solution due to their ability to

maximize the release of drugs and reduce adverse effects, thus being the best option in the management of chronic acid-related conditions such as GERD and peptic ulcers. Nevertheless, their potential still faces a number of challenges. The problems with stability, especially of gas-generating agents, may cause premature loss of buoyancy and uneven drug release. The efficacy of these systems is further complicated by variability of response of patients, which depends on factors like gastric pH, motility and ingestion of food. Moreover, the technological and manufacturing complexity of creating floating systems on a large-scale poses a cost and consistency challenge.

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