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Formulation and In-Vitro Evaluation of Floating Tablets for Gastric Retention

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Abstract

Animal-based testing is important for understanding the performance, mechanism, and translational capacities of floating tablets and in-vitro testing for stomach retention, which is the focus of the current review. With a limited window for absorption in the upper gastrointestinal tract, drug delivery systems (FDDS) are designed to improve the residence time, bioavailability, and controlled release of medications. The recipes that employed gas-producing agents like sodium bicarbonate and citric acid, as well as hydrophilic polymers like HPMC, carbopol, and sodium alginate, demonstrated exceptional floating properties with a lag time of less than 12 hours. In vitro research studies showed sustained release profiles along the zero-order or non-Fickian kinetics, whereas in vivo testing in albino rats and rabbits showed long gastric retention and better pharmacokinetic results. Gastric safety and biocompatibility was confirmed by histopathological assessments. Direct compression was determined to have the best formulation through comparative analysis based on stable and efficient formulations compared to wet granulation. All in all, animal tests will be a critical preclinical base to determine optimal proportions of polymers, buoyancy, and release characteristics which will make floating pills safe and effective when applied to the clinical setting.

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Key Words:

Floating Drug Delivery System, Gastroretentive Tablets, Hydrophilic Polymers, In-vitro Evaluation, Gastric Retention, Drug Release Kinetics, Bioavailability

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1. INTRODUCTION

The development of controlled drug delivery mechanisms has transformed the therapeutic environment especially with the narrow absorption spectrum drugs in the upper GIT. One of these innovations is the floating drug delivery systems (FDSS) which has received a lot of

attention because they increase the bioavailability and gastric residence time. These systems are manufactured to be suspended on the gastric fluids and this will work to avoid the early expelling of the drug into the intestines and therefore the drug will be released slowly in the proximity of its main absorption site[1]. Animal model studies have revealed the effectiveness of these systems in enhancing the pharmacokinetic attributes of numerous drugs made up of ranitidine, ciprofloxacin, and famotidine. An example of this is the reported experiment in which formulations that were tested in rabbits had a high gastric retention of up to 12 hours with uniform floating properties, which confirms their potential use in clinical translation. The applicability of such findings to animal species points to the consistency of such models in preclinical testing[2].

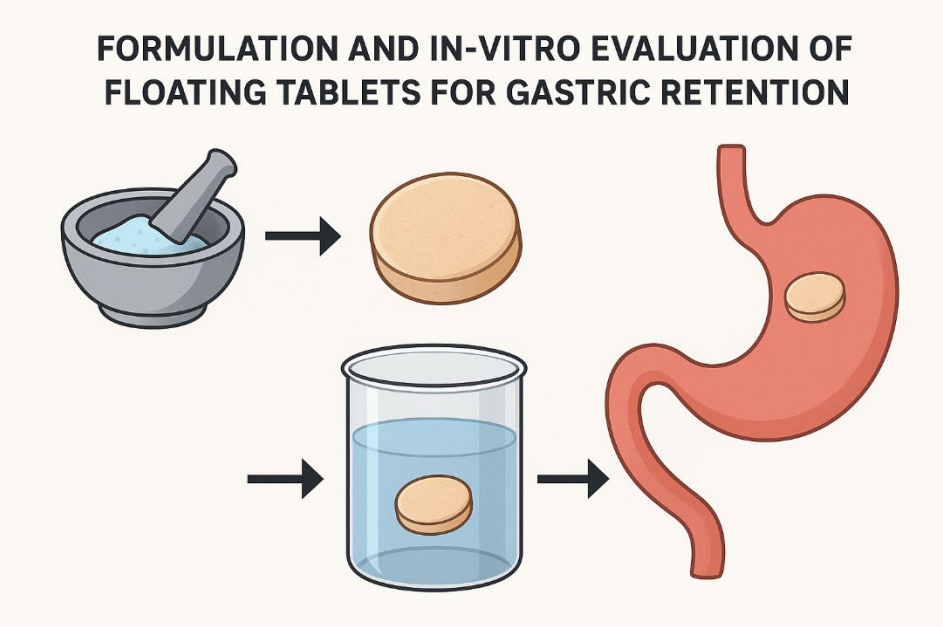

Figure 1: Schematic Representation of the Formulation and In-Vitro Evaluation Process of Floating Tablets for Gastric Retention[3]

Development of a floating tablet involves proper choice of hydrophilic polymers, gas releasing agents, and matrix forming excipients in order to realize the desired buoyancy and release kinetics. In-vitro animal models have been very instrumental in measuring these parameters by using a controlled physiological environment to replicate the gastric environment. The floating lag time of the animal models of rats and rabbits has been reported to decrease significantly when effervescent agents like sodium bicarbonate are put in place where hydrophilic polymers like HPMC (Hydroxypropyl Methylcellulose) and carbopol are found to preserve the integrity of the matrix and control the release of drugs. Such results give the scientific basis to the creation of optimized gastroretentive formulations that will be able to enhance the efficiency of the therapeutic effect and decrease the number of doses. Besides, the biocompatibility and gastric safety of these formulations have been confirmed by histopathological analyses on animals to confirm that the tablets do not cause mucosal irritation during extended gastric retention.

1.1 Background Information and Context

The drug needs to be administered orally because this is the most desired route of administration because it is convenient, and cost-effective and the patient complies. Some drugs, however, have low bioavailability by oral route due to a low level of absorption in the lower intestine or due to rapid emptying of the stomach. To counter this, gastroretentive system has been invented which keeps the drug formulation in the stomach over long periods. Floating tablets, in particular, are the most beneficial ones as they can be kept in gastric fluids and gradually release the active ingredient over a few hours. The in-vivo tests on animal models particularly, albino rats and rabbits have continually shown that these formulations extend the gastric residence leading to increased absorption and better therapeutic effects. These experiments confirm the functionality principles and design parameters that are required to optimize the gastroretentive dosage forms in the case of the human use[4].

1.2 Objectives of the Review

The primary objectives of this review are threefold:

- To review animal research on the development and testing of floating tablets to be gastric retained.
- To examine how gas-generating agents and polymers affect the buoyancy and release characteristics of medications.
- To make a comparison between formulation methods and their influence on floating efficiency and release kinetics.
- To determine the in-vitro and in-vivo correlations and gastric safety in animals.
- To establish the research gap and propose future research directions in the direction of gastro retentive formulation developments.

The review will contribute to closing the gap between formulation science and preclinical evidence, thus providing the basis of translational research in gastro retentive delivery[5].

1.3 Importance of the Topic

The development and in vitro testing of floating tablets to be used in gastric retention is a vital aspect in creating efficient and consistent delivery systems of drugs. To evaluate the buoyancy property, gastric compatibility and release kinetics of these formulations under naturalistic biological environment, animal based research is used as a foundation. Floating systems has been developed and tested on rabbits and rats unlike traditional oral dosage systems that have a short-lasting gastric retention duration to provide controlled drug availability and enhanced bioactivity. What makes this topic so important is not only its pharmaceutical innovation but also its applicability in translation as animal tests can give the required preclinical data needed to determine how it will perform in a human system. Moreover, the results of animal in-vitro assessment inform subsequent formulation plans, and help in the creation of safer, better, and more convenient to patients gastroretentive dosage forms[6].

2. ANIMAL-BASED EVALUATION OF GASTRORETENTIVE FLOATING TABLET SYSTEMS

Animal experiments have validated that gastroretentive floating pills guarantee the long period of gastric retention, slow drug delivery and improved bioavailability. Such results confirm the safety, efficacy and therapeutic outcome enhancement potential of these before human trials[7].

2.1 Summary of Key Research Studies

Animal studies have been done extensively to determine the in-vitro and in-vivo efficacy of the gastroretentive floating tablets. These were all studies that had repeatedly shown that floating tablets have the capability of being held in the gastric fluids long durations which in most cases are over ten hours and had the capacity to release the drug in a controlled and sustained manner. Most formulations exhibited zero-order or diffusion-controlled release behavior meaning that their release was constant regardless of drug concentration. Researchers noted a pronounced gastric residence time and bioavailability in in-vivo studies that were done on animal models including rabbits and rats in comparison to traditional immediate-release tablets.

Floating tablets can improve the therapeutic efficacy of medications with a limited window for absorption in the upper gastrointestinal system, according to all of the studies presented. By retaining the drug in the stomach for a longer amount of time, these systems improved the pace and degree of absorption, resulting in better pharmacokinetics and a lower dosing schedule. These findings demonstrate that floating drug delivery devices have the potential to be a promising treatment for medications that are poorly soluble or unstable in the intestinal environment[8].

2.2 Methodologies and Findings

The techniques that were used in animal-based studies consisted mainly of the wet granulation or direct compression of tablets. Hydrophilic polymers that were usually included in the formulations included: hydroxypropyl methylcellulose, ethylcellulose, carbopol and sodium alginate which dictated the behavior of both the buoyancy and release of the drug. In order to encourage floating by producing carbon dioxide when it came into touch with stomach juices, the majority of them added gas-generating substances like citric acid and sodium bicarbonate[9].

The floating lag time, overall floating time, swelling index, hardness, friability, and cumulative percentage medication release were the crucial evaluation metrics. In-vitro buoyancy tests conducted in simulated gastric fluid established that optimized formulations had short lag times- typically less than one minute- and could be suspended over twelve hours. The profiles of drug release showed that the concentration of polymer and the grade of viscosity used played a very important role in determining the rate and degree of release. In-vivo tests carried out on animal models showed that there was a significant increase in gastric retention and extended plasma drug levels, which are indicators of increased absorption[10]. Notably, gastric histopathological observations demonstrated no gastric mucosal irritation or tissue damage, and therefore the biocompatibility and safetyness of the formulations. These observations confirmed the uniformity, constancy, and clinical response of the developed floating tablet systems.

2.3 Critical Evaluation

The physiological and pharmacokinetic behavior of floating drug delivery systems has been found to be crucial with animal research[11]. These investigations formed crucial information about the correlation between gastric parameters dosage forms and different motility, pH, and enzyme activities. Nevertheless, regardless of their importance, there are problems with the direct extrapolation of animal data to the human system as there are interspecies differences in gastric emptying time, pH levels, and digestive physiology. These differences can cause changes in floating pattern, drug release pattern and bioavailability results[12].

However, animal models cannot be replaced during the preclinical stage because it offers essential information on the formulation optimization, safety testing, and performance predictability in advance before human testing. The combination of in-vitro and in-vivo represents a balanced and holistic method of gastric conditions in-vitro tests deal with the simulated conditions by providing a controlled environment, and in-vivo models deal with a realistic biological reaction. This combined evaluation system is also effective in the sense that floating tablet preparations are efficient, safe, and physiologically compatible[13].

Studies carried out on animals have also played a major role in fostering the gastro retentive floating drug delivery systems development. Their performance has made it easy to rationally design formulations with prolonged gastric residence, controlled drug release and enhanced bioavailability, which forms a robust basis in further clinical studies done on human beings[14].

3. EVALUATION OF ANIMAL-BASED FORMULATIONS AND PERFORMANCE STUDIES OF FLOATING TABLETS

Floating tablet animal research emphasizes the importance of polymers, methods of formulation, and parameters of evaluation to realize long-term gastric retention, targeted slowing drug release, and safety. These results guarantee successful transfer of optimized formulations between the preclinical and clinical stages of research[15].

3.1 Polymers and Excipients Used in Animal-Based Formulations

The use of polymers and excipients in floating drug delivery systems (FDDS) design and performance, especially in preclinical testing with animals, has a significant role. The most popular hydrophilic polymers in floating tablet formulations include hydroxypropyl Methylcellulose (HPMC K4M, K15M, K100M), Carbopol 934 and Sodium Alginate. When in contact with gastric fluids, they are hydrated and swelled to make viscoelastic gel barrier, and modulate the diffusion of drugs, and erosion of the matrix is not rapid. The gas generated is held in bubbles by this gel layer, lowering the density of the pills and making them be able to float[16].

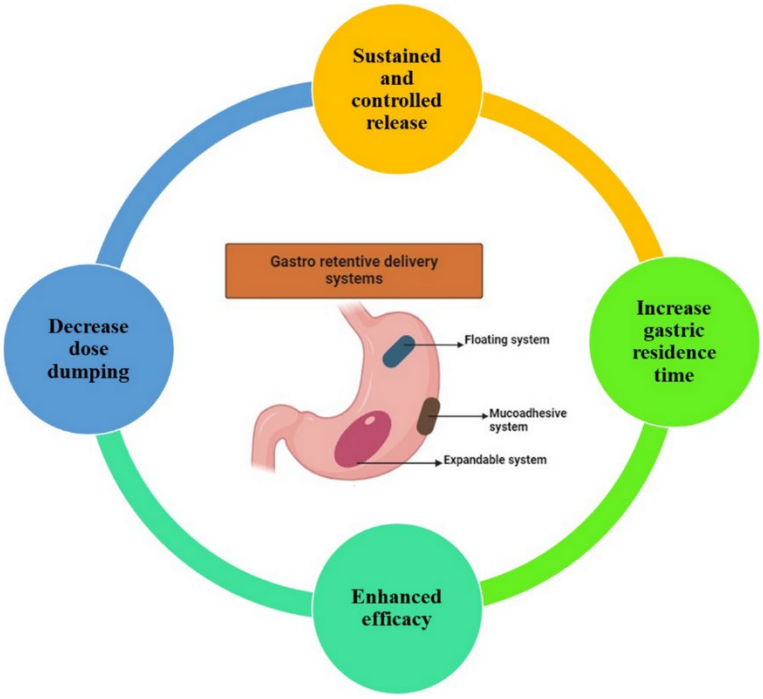

Figure 2: current developments in the delivery of gastro retentive drug[17]

Formulations based on animals sometimes contain gas-generating compounds, including sodium bicarbonate and citric acid, which react in the acidic gastrointestinal tract to form carbon dioxide and help with floatation. Polymer ratio and selection of polymer have a direct effect on the floating lag time (FLT) and total floating time (TFT). Swelling behaviour, long floating behaviour, and reliable release profile of HPMC K15M in rat models with or without Carbopol 934 formulations are improved. In such investigations, histopathological examinations found no definite mucosal irritation proving that the polymers applied in the gastric conditions are biocompatible. This indicates that hydrophilic matrix systems have the capacity of enabling controlled release without affecting the mucosal integrity, which is a critical factor to be considered prior to clinical translation[18].

3.2 In-vitro Evaluation Parameters

In-vitro testing is a preliminary procedure in projecting in-vivo characteristics of floating pills. There are a number of critical parameters that are periodically examined in order to determine the level of functional performance of animal-based formulations:

- **Floating Lag Time (FLT):** Determines the time of ascension of the tablet to the surface of the dissolution medium on immersion. Optimized formulations normally have an FLT of under one minute, which implies fast buoyancy[19].
- **Total Floating Time (TFT):** Measures the time that the tablet is floating, the longer the better, preferably over 12 hours making sure of a longer stay in the stomach.
- **Swelling Index:** Ascertains the level of hydration and expansion of the polymer, which have a direct effect on drug release and stability of the tablet when exposed to gastrointestinal conditions.

- **Drug Release Kinetics:** Kinetic models like Higuchi, Korsmeyer-Peppas and zero-order models are used to interpret data on drug release to determine the diffusion and erosion mechanism[20].

In-vitro studies that have been conducted using animal preparations and formulation containing ciprofloxacin, amoxicillin and metformin have shown that the concentration of polymer as well as the presence of gas forming agents has a significant effect on the buoyancy and drug release profile. An increase in the proportion of HPMC and Carbopol increased gelation and release retention, whereas high amounts of effervescent reduced the integrity of the matrix. These results highlight the fine line that exists between the composition and performance of formulation, especially in the extrapolation of animal data to human systems.

3.3 Animal Models in Gastric Retention Studies

Animal models would also be important in the assessment of the gastroretentive ability and pharmacokinetic performance of floating tablet before advancing to clinical phases. The most prevalent species used in the laboratory are albino rats, rabbits and beagle dogs all of which are chosen in relation to the physiological and anatomical factors.

Rats are mainly used in preliminary release, safety and mucosal irritation experiments because of their small gastrointestinal mass and rapid gastrointestinal passage. The reason why rabbits are used as intermediate models is their rather closer gastric pH and motility to humans. Instead, beagle dogs are used to conduct higher pharmacokinetic and bioavailability studies as the stomach size is larger and the gastric emptying activity resembles that of human beings[21].

An example of this is in-vivo X-ray imaging and gamma scintigraphy of rabbits has been successfully applied to visualize and confirm sustained buoyancy of floating formulations over 8 hours of sustained gastric retention, and release of the drug at controlled rates. These studies confirm the stability and activity of the delivery system under active gastrointestinal conditions and give essential information on optimization of dose and safety analysis.

3.4 Comparative Evaluation of Formulation Techniques

The method of formulation has a bearing on the physicochemical and in-vivo performance of floating tablets; this is because different methods of formulation are used including direct compression, wet granulation, and hot-melt extrusion. Of these, direct compression is the most desirable that is simple, cost effective and offers a better control of the tablet density and uniformity. It is especially applicable where the drug is thermolabile or moisture-sensitive because it lacks moisture or depends on heat-sensitive stages.

There is also animal research evidence indicating that directly compressed floating tablets have a reduced floating lag time, increased hardness and longer floating lives than wet-granulated preparations. As an illustration, ciprofloxacin floating tablets made by the direct compression technique were characterized by an FLT of about 40 seconds and TFT of over 14 hours in-vitro, which was confirmed by radiographic images of rat models with prolonged gastric retention. Direct compression is a reliable method of scaling up animal-approved formulations to clinical prototypes because of the reproducibility and mechanical stability obtained.

Comparative analyses therefore bring to light the fact that formulation methodology plays a critical role in the release kinetics, floating behavior as well as the pharmacological behavior of gastroretentive systems. Ongoing optimization on the basis of animal evidence leads to the enhanced translation of preclinical results into efficient human applications.

4. MECHANISM OF FLOATING AND DRUG RELEASE BEHAVIOR

The complex interaction between buoyancy generation and controlled drug release behavior is the main determinant of the performance and therapeutic efficacy of floating tablet as a method of gastric retention. The mechanism that enables the dosage form to have a lower density than gastrointestinal fluids is based on the idea of gas generation and entrapment into a hydrated polymeric network[22]. This buoyancy ensures that the tablet remains in the upper portion of the stomach for an extended amount of time, extending the residence duration and improving the bioavailability of medications that have limited absorption in the upper gastrointestinal system.

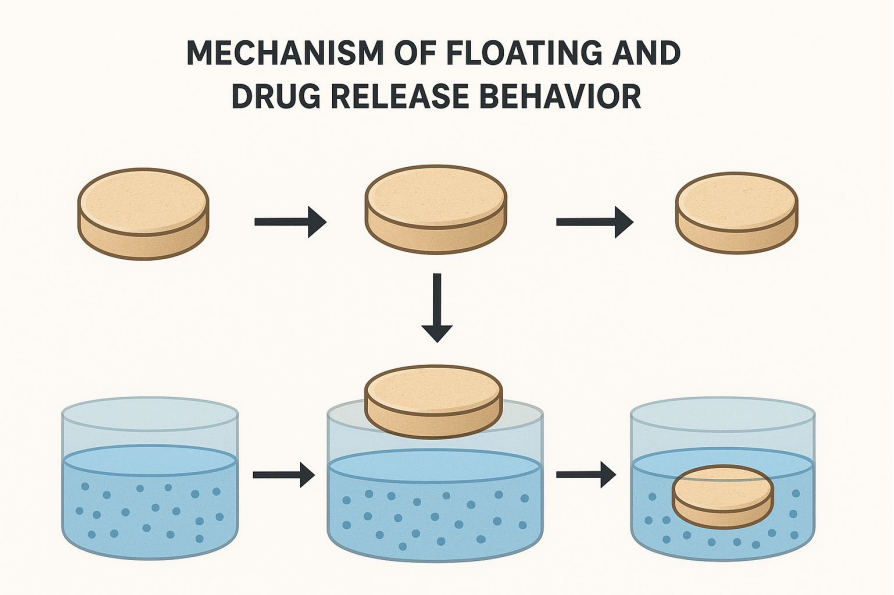

Figure 3: Mechanism Of Floating and Drug Release Behavior[23]

In such formulations, the gas-generating systems like sodium bicarbonate and citric acid reacts when exposed to the acidic gastric fluids to form carbon dioxide (CO_2)[24]. The gas is entraped into the distended polymer network, making the density of the pill lower and floating. The effectiveness of this action is measured by two key values (FLT) which is the period taken by the tablet to get to the surface, and (TFT), which is the period that the tablet stays in suspension. The idealization of these parameters means that there is uniform gastric retention and not premature sinking or breakage[25].

Investigations on the animal system using rabbit models and albino rats have proven that the ratio of the polymer to the effusive system is vital in controlling the aspects of buoyancy and drug release[26]. An increased amount of hydrophilic polymers like HPMC (K4M, K15M, K100M), Carbopol 934 and Sodium Alginate allows the formation of a thick viscous gel layer on hydration. This layer does not only maintain the floating nature, but also controls the infiltration of the gastric fluids, diffusion of the drug. On the other hand, excessive concentration of effusive

substances may impair the integrity of the matrix resulting in premature rupture of the gel layer and non-uniform discharge of the drugs. Therefore, to have a long-lasting buoyancy and equal diffusion of drugs, a perfect balance between gas generation and swelling of matrix is crucial[27].

The swelling index is crucial in release and the mechanism of buoyancy. The hydration of the polymer causes the expansion of the polymer into a gel barrier that regulates drug movement. In evaluations that involve animals, the higher the swelling index of the formulation, the stronger it is in mechanics and the longer it can release. This gel system acts as a dynamic diffusion barrier, which retards the rate of drug delivery and permits a constant release to take place over a prolonged time. The diffusion-erosion-controlled process is usually the mechanism of drug release by floating tablet. When put in gastric fluid, the outer polymeric layer is swollen and partially eroded, leaving the inner core intact[28]. These two steps lead to sustained release by a combination of Fickian diffusion and non-Fickian transport, under which the polymer matrix composition and kinetics of hydration depend on each other. Optimized formulations have already been demonstrated in-vitro in simulated gastric fluid (pH 1.2) to sustain a controlled release of 12-14 hours, which is in-vivo consistent with gastric retention profiles of rat and rabbit test vectors (imaging and pharmacokinetic) to optimize their use in medicine and food applications[29].

The scientific foundation of rational formulation design has been aided in understanding these interrelated mechanisms. Researchers can tightly control the floating behaviour, drug release kinetics and gastric retention efficiency by controlling the factors of polymer ratio, viscosity, effervescent concentration and compression pressure. These preclinical results of animal models are the basis upon which in-vivo performance of human beings can be predicted making it easier to transfer laboratory-scale devices to clinical applications as floating drug delivery systems.

Table 1: Summary of Literature on Formulation and Evaluation of Floating Tablets for Gastric Retention[30]

Author's and Year	Study Title	Focus Area	Methodology	Key Findings
Schneider et al. (2019)[31]	In vitro and in vivo test methods for the evaluation of gastroretentive dosage forms	Evaluation of testing techniques for gastroretentive systems	Review of existing in-vitro and in-vivo test methods; comparison of floating, swelling, and mucoadhesive systems	Highlighted inconsistencies between in-vitro and in-vivo data; emphasized development of biorelevant test models to better predict gastric residence and performance.
Shaikh et al. (2018)[32]	Formulation and evaluation of ibuprofen gastro-	Development of floating ibuprofen tablets	Formulation utilizing gas-generating agents	Optimized formulation exhibited

	retentive floating tablets		and hydrophilic polymers; assessment of drug release, buoyancy lag time, and hardness	prolonged floating time and sustained drug release, enhancing gastric retention and bioavailability.
Singhal et al. (2020)[33]	Preparation and in vitro characterization of solid dispersion floating tablet by effervescent control release technique	Enhancement of solubility and floating efficiency	Solid dispersion technique with hydrophilic carriers and effervescent agents; in-vitro characterization	Showed improved solubility, buoyancy, and sustained drug release with zero-order kinetics; validated solid dispersion and effervescence synergy.
Soni et al. (2018)[34]	Development and in vitro evaluation of an oral floating tablet of metronidazole	Controlled release formulation for gastric retention	Formulation using HPMC and carbopol; in-vitro buoyancy and release studies	Achieved short lag time, prolonged buoyancy (>8 h), and controlled release; suitable for sustained local gastric action of metronidazole.
Taha et al. (2019)[35]	Formulation, evaluation, and in vitro characterization of gastroretentive floating tablet of diclofenac sodium	Development of swellable and effervescent floating tablets	Formulation with hydrophilic polymers; evaluation of floating time and release kinetics	Demonstrated buoyancy and controlled drug release up to 10 hours; release followed Higuchi kinetics; improved drug retention and reduced side effects.
Teaima et al. (2020)[36]	Promising swellable floating bupropion tablets: formulation, in vitro/in vivo evaluation and comparative pharmacokinetic study	Design and pharmacokinetic evaluation of bupropion floating tablets	Formulation using hydrophilic polymers; in-vitro buoyancy and human pharmacokinetic study	Proved enhanced bioavailability and extended drug absorption; established strong in-vitro/in-vivo correlation; improved therapeutic

				efficacy and compliance.

1. DISCUSSION

Animal studies also support the board stating that floating tablets promote longer gastrointestinal retention, regulated drug release, and safety, which implicates gastroretentive delivery of drugs in translation. More developed models, new polymers, and real-time imaging should be studied in the future to make the research more predictable and clinically operational[37].

5.1 Interpretation and Analysis of Findings

Studies of floating tablet formulations conducted on animals have demonstrated the great efficacy of gastroretentive drug delivery systems (GRDDS) in promoting stomach residency and achieving controlled drug release. Combining hydrophilic polymers like HPMC, carbopol, and sodium alginate with effervescent agents like sodium bicarbonate has been shown to provide the best matrix for sustained floatation and diffusion-controlled release in animal models. A direct correlation between the viscosity of the polymer and the retention time in the gastrointestinal tract was discovered, and the swelling of these polymers had an immediate impact on the floating lag time and overall floating duration. The histopathological outcomes also proved the fact that these formulations are biocompatible and safe because no mucosal irritation or tissue damage could be seen in rat and rabbit stomach lining[38].

The governing diffusion and erosion controlled mechanisms of drug release were observed to be of zero-order or non-Fickian kinetics which implies that the release rate is constant and predictable and does not depend on the drug concentration. The fact that in-vitro and in-vivo release patterns are similar which has been confirmed by animal experiments justifies the use of in-vitro models in predicting in-vivo performance. Additionally, formulation methods were comparatively assessed and it was found that direct compression produces tablets which have better mechanical stability, lag times, and extended buoyancy than wet granulation protocols. All these results confirm the effective functionality of optimized floating formulations in improving drug absorption and drug therapeutic effects in drugs with narrow absorption windows.

5.2 Implications and Significance

The consequences of these results have far reaching implications in the area of controlled drug delivery and pharmaceutical formulations design. Floating tablets help resolve the issues linked to drugs that have low solubility and stability in the intestinal milieu by maintaining the continuous presence of the drug in the stomach. Animal tests are necessary in order to help furnish the preclinical data, which should not only confirm the effectiveness of such systems but also supplement the knowledge of physiological interactions in the conditions of actual biological activity. These formulations have been shown to increase the retention duration of gastric content and bioavailability, implying that such formulations can be used to decrease the dosage and increase patient adherence, particularly with chronic therapeutic products. Besides, the significant association between in-vitro buoyancy parameters and in-vivo performance

underlines the necessity of the combination of polymer science with physiological modeling to predict accurately clinical outcomes. These findings support the clinical utility of animal-tested preparations, which provides an up-and-coming avenue to creating patient-specific, performance-optimized gastroretentive tablets[39].

5.3 Gaps and Future Research Directions

Despite the significant progress has been achieved based on the animal studies, there are still a number of research gaps that can be addressed by conducting more studies. The biggest constraint is that interspecies variability in gastric physiology is not completely studied-variability in gastric motility, gastric pH, and enzymatic activity between animals and humans can affect floating and drug release characteristics and induce an error in translatability. Future studies need to concentrate on the construct of computational gastric simulation models and physiologically based pharmacokinetic (PBPK) models as a way of predicting the human results of an animal data better. Also, larger-scale research in large-animal models, including beagle dogs and pigs, may help in the transition between small-animal research and human research.

Also, there is the necessity to consider new biocompatible and biodegradable polymers and regulate their swelling and erosion characteristics to further optimize the release kinetics and reduce variability. The combination of real time imaging methods such as the gamma scintigraphy and the MRI when conducting the in-vivo experiment would give more information on the dynamic behaviour of the floating systems when subjected to real gastric motility. Lastly, new directions should focus on optimization of formulation using machine learning and AI-based modeling, which will allow control of the floating duration, drug diffusion and polymer interactions predictively. These improvements would make floating tablet formulations much more reliable, safe, and scalable, leading to an effective clinical success and patient-centered therapeutic innovation[40].

2. CONCLUSION

Evaluations using animals show that well-designed gastroretentive floating tablets that incorporate hydrophilic polymers (HPMC, Carbopol, sodium alginate) alone or with a suitable effervescent agent is reliable and show buoyancy and sustained drug release (usually zero order/diffusion/erosion controlled) while providing improved gastric residence time and bioavailability for preclinical studies, while demonstrating good mucosal compatibility. Direct compression was the most reproducible, scalable method for creating tablets that had the best mechanical strength and shortest lag times compared to other approaches. Although the in vitro-in vivo correlations in rats and rabbits demonstrated some support for the predictive nature of preclinical work, the physiological differences across species should warn against direct translations to humans and suggest the need for more prudent steps in advancing to human studies, such as large animal studies, PBPK/gastric emptying simulations, real-time imaging, and new biodegradable polymer evaluations. Altogether, these data support floating drug delivery systems as an effective strategy for therapeutic delivery where the absorption window in the upper-GI tract is narrow and provide a rational approach towards an optimization of clinical development.

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