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Innovations and advancements in floating tablet drug delivery systems: a comprehensive review

Abstract

Floating tablets, also known as gastro retentive drug delivery systems (GRDDS), are innovative formulations designed to prolong the retention of drugs in the gastrointestinal tract, particularly the stomach. This approach is highly beneficial for medications with a narrow absorption window in the upper GI tract, requiring extended action or optimal absorption in a specific pH range. The floating mechanism helps improve bioavailability, therapeutic efficacy, and offers controlled drug release, reducing dosage frequency. The formulation of floating tablets typically involves hydrophilic polymers and gas-forming agents like sodium bicarbonate, which ensure buoyancy in gastric fluids. Key preparation techniques include direct compression, wet granulation, and hot melt extrusion. These tablets are advantageous for medications such as furosemide and ofloxacin, which have poor absorption or are extensively metabolized in the first pass. Floating tablets also show potential in enhancing patient compliance, particularly for drugs with short half-lives or those requiring a controlled release. Despite the promising benefits, challenges such as variability in gastric emptying, tablet buoyancy, and large-scale manufacturing complexities exist. Innovations in materials, including biodegradable polymers and 3D printing, aim to address these issues. Market demand for floating tablets is increasing, driven by the rising incidence of chronic diseases, especially in regions like India.

In conclusion, floating tablets represent a significant advancement in gastro retentive drug delivery, offering improved therapeutic outcomes for a range of medications, though further research and development are needed to optimize their formulation and production.

Keywords: floating tablet, drug delivery systems, pharmaceuticals, moist granulation, dry granulation, GI tract

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Introduction

Floating tablets, also known as gastro retentive drug delivery systems (GRDDS), are novel formulations that extend the residence period of pharmaceuticals in the gastrointestinal tract, particularly the stomach.

This method is especially useful for medications that have a short absorption window in the upper GI tract, need prolonged action, or are best absorbed in a certain pH range.

Floating tablets use a variety of mechanisms to remain buoyant in gastric fluids, allowing for prolonged release and improved bioavailability, therapeutic efficacy, and may even allow for dose reduction due to consistent therapeutic levels of drugs, such as furosemide and ofloxacine.

Enhanced drug delivery: Floating tablets are especially advantageous for medications with limited therapeutic indices or that undergo substantial first-pass metabolism, resulting in a more effective and regulated release.

Market potential: There is a lot of room for floating tablet formulations in India, one of the biggest pharmaceutical markets in the world. The need for novel medicine delivery methods is fuelled by the rising incidence of chronic illnesses including diabetes and high blood pressure.

Manufacturing difficulties: Creating floating tablets calls for certain methods and supplies, including buoyant hydrophilic polymers. Manufacturers must spend money on R&D and manufacturing facilities.

Consumer awareness: In order for floating tablets to be accepted and used in clinical practice, it is essential to inform patients and medical professionals about their advantages.

Market strategies: Targeted marketing, awareness campaigns, and partnerships with healthcare providers can help these products launch successfully.[1–5] (Figure 1)

Figure 1 Floating Drug Delivery Systems (FDDS).

Classification of floating drug delivery system[6] (Figure 2)

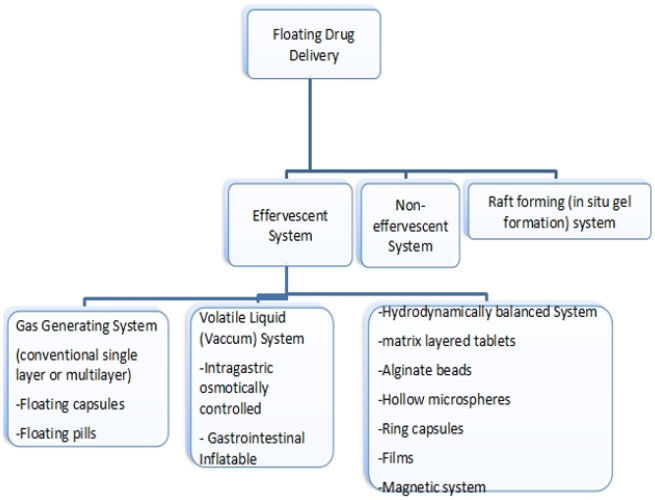

Figure 2 Classification of Floating Drug Delivery Systems.[6]

Advantages

Biotic for helicobacter pylori infections, and gastric ulcer treatments. The drug's prolonged presence in the stomach ensures that it remains at the site of action for longer. Prolonged Gastric Retention: Floating tablets stay in the stomach for longer periods, extending pharmacological action, particularly for pharmaceuticals absorbed largely in the stomach or upper small intestine.[7–9]

I. **Improved bioavailability:** Extending gastric retention period allows for a wider absorption window, especially for medications having a small absorption window or unstable in the alkaline pH of the intestines.

II. **Sustained and regulated drug release:** Floating tablets release the drug slowly over time, resulting in a regulated and sustained release profile. This helps maintain consistent drug plasma levels and reduces the frequency of dosing.

III. **Controlled release of floating tablets** reduces drug concentration fluctuations, resulting in improved treatment outcomes and fewer adverse effects compared to immediate-release formulations.

IV. **Suitable for drugs with short half-lives:** Drugs with short half-lives may need frequent dosage to maintain therapeutic levels. Floating tablets can help by providing a consistent release of the medicine, decreasing the need for several dosages throughout the day.

V. **Improved patient compliance:** Floating tablets can improve patient compliance by reducing dosing frequency, particularly for medications that need several daily doses in conventional formulations.

VI. **Localized effect in the stomach:** Floating tablets are effective for pharmaceuticals that act locally in the stomach, such as antacids, antibiotics.

VII. **Suitable for poorly soluble drugs:** Floating tablets can benefit drugs with weak solubility in intestinal fluids but higher solubility in the acidic stomach environment, allowing for extended dissolution.

VIII. **Reduced possibility of dose dumping:** Floating pills' controlled release reduces the possibility of dose dumping, which can result in toxicity or reduced efficacy.

IX. **Reduced side effects:** Gradual medication release minimizes side effects associated with high peak plasma concentrations, resulting in a more consistent therapeutic response.

Technique for preparing a floating tablet

This is how to make floating tablet step-by-step: Supplies needed. The drug's active pharmaceutical ingredient (API) Gas-forming ingredients, like sodium bicarbonate or citric acid, make the tablet float. Polymers, including hydroxypropyl methylcellulose (HPMC), carbopol, or polyethylene oxide, offer the matrix and floating mechanism. Binders, including polyvinylpyrrolidone (PVP), that help tablet stay together Diluents (to supply bulk), like microcrystalline cellulose or lactose Lubricants, like magnesium stearate, are used to stop things from sticking additional excipients (based on the requirements of the formulation).[10,11]

Techniques for preparation

I. The direct compression technique

This is among the most straightforward and widely applied techniques.

Method:

i. Step 1:-Weigh each component, including the excipients, binders, gas-forming agents, polymers and API

ii. Step 2:-Combine the active medication with gas-forming agents (like sodium bicarbonate) and floating polymers (like HPMC).

iii. Step 3:-Include the lubricants, diluents, and binder (PVP) in the mixture.

iv. Step 4:-Use a blender or mixer to make sure the items are blended evenly.

v. Step 5:-Use a tablet press to compress the mixture into tablet.

vi. Step 6:-To regulate medicine release, you can choose to coat the tablet.[12]

II. The wet granulation method

Entail granule preparation prior to tablet compression.

Method:

i. Step 1:-Weight the polymers, gas forming agents, and active medication.

ii. Step 2:-In the blender, thoroughly combine the dry ingredient.

iii. Step 3:-To create a wet material, add a granulating agents, often water or an organic solvent.

iv. Step 4:-To create granules, pass the moist mixture through a sieve.

v. Step 5:-Use a fluidized bed dryer or an oven to dry the granules.

vi. Step 6:-Compress the grains into tablets after mixing with lubricants.[9]

III. Extrusions the hot melt

Useful for improving the solubility of medication that are not very soluble in water.

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Method:

i. Step 1:- Combine the medication with plasticizers and polymers (such as HPMC).

ii. Step 2:- Melt the medication and polymers in the mixture by heating it.

iii. Step 3:- To create uniform bulk, run the molten mixture through and extruder.

iv. Step 4:- cut the extrudate into the appropriate size after it has cooled.[11]

IV. A floating effervescent tablets for buoyancy

This kind of floating tablets depends on gas production, such as CO_2.

Method:

i. Step 1:-Weigh and combine the medication, effervescent ingredients (like citric acid and sodium bicarbonate). And floating polymers (like HPMC).

ii. Step 2:-To guarantee even distribution, blend well.

iii. Step 3:-Use a tablet press to compress the mixture into tablets.

iv. Step 4:-The tablet floats because it produces CO2 when it comes into touch with gastric juices **(**Figure 3).[9,12–14]

Figure 3 Equipment used for dry granulation.

Evaluation of floating tablets[15–17]

The amount of time needed for the tablet to floats after coming into touch with stomach contents is known as the floating lag time.

Total floating time: The amount of time the tablet floats in the stomach environment.

Drug release profile: To assess the drug's controlled or prolonged release. The tablets can have a regulated medication release profile and longer stomach residence duration by employing the right technique and excipients.

Bulk density: - It is a ratio of mass of powder to bulk volume. The bulk density depends on particle size distribution, shape and cohesiveness of particles. Accurately weighed quantity of powder was carefully poured in to graduate measuring cylinder through large funnel and volume was measured, which is called initial bulk volume. It is expressed in gm/ml and is given by the formula:

Bulk density=M/Vo

Where, M = mass of the powder

Vo = bulk volume of the powder.

Tapped density: - 10 gm of powder was introduced into a clean, dry 100 ml measuring cylinder. The cylinder was then tapped 100 times from a constant height and the tapped volume was read. It is expressed in gm/ml and is given by:

Tapped density=M/Vt

Where, M = mass of the powder

Vt = final tapping volume of the powder.

Hausner's ratio: - Hausner's ratio is used to predict the flowability of the powders. This method is similar to compressibility index. Hausner's ratio can be represented by equation:

Hausner's ratio = Tapped density / bulk density

Hardness: - Tablet hardness and strength are the essential to see that the tablet can with the shock and stress during manufacturing packing and transportation, and while handled by the patient. To test the hardness of the tablet Monsanto tester, Strong-cobb tester, the Pfizer tester, the Erweka tester, the Schleuniger testers are used.

Friability: Friability is the tested for a tablet to see whether the tablet is stable to abrasion or not, it is tested by using Roche friabilator. This is made up of a plastic drum fixed with a machine which rotated at 25 rpm for 100 revolutions. And then the twenty tablets which were weighed prior to the test are taken out of the drum and cleaned with a cloth and weighed once again, the weight variation must not be less than 0.5 to 1.0% for a conventional tablet.

Size and shape: It can be dimensionally described & controlled. The thickness of a tablet is only variables. Tablet thickness can be measured by micrometer or by other device. Tablet thickness should be controlled within a ± 5% variation of standard value.

Weight Variation test (U.S.P.): Take 20 tablet and weighed individually. Calculate average weight and compare the individual tablet weight to the average. The tablet pass the U.S.P. test if no more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

Disintegration Test (U.S.P.): The U.S.P. device to test disintegration uses 6 glass tubes that are 3" long; open at the top and 10 mesh screens at the bottom end. To test for disintegration time, one tablet is placed in each tube and the basket rack is positioned in a 1-L beaker of water, simulated gastric fluid or simulated intestinal fluid at 37 ± 2 0 C such that the tablet remain 2.5 cm below the surface of liquid on their upward movement and not closer than 2.5 cm from the bottom of the beaker in their downward movement.

Mechanism of action

Low density: Due to the components used in its formulation, the tablet has a lower density than gastric juices, usually less than 1 g/ml. Polymers such as sodium alginate, hydroxypropyle methylcellulose (HPMC), and other gas-generating substances like bicarbonates are examples of common excipients.

Buoyancy: Tablet's contact with the stomach fluid after swallowing causes the gas- generating substances (such as sodium bicarbonate and gastric acid to react to release carbon dioxide it sweels and becomes buoyant, allowing the tablets to "float" on the surface of the stomach contents since the created gas is retained within the tablet matrix.

Extended holding in the stomach: The floating tablet avoids an early evacuation from the stomach through the pyloric sphincter by staying buoyant. By doing this, the tablet's gastric residence duration is extended, enabling the medicine to be released gradually over an extended length of time in the stomach.

Slow medicine release: As the floating tablet stays in the stomach, the medicine is gradually released, guaranteeing a prolonged release profile. This is particularly advantageous for medications that are unstable or poorly soluble in the alkaline environment of the intestines, or those are mostly absorbed in the stomach or upper small intestine.

Erosion or dissolution: The floating tablet progressively erodes or dissolves over time, delivering the medication into the stomach fluid in a regulated way.[18–21]

Important elements:[22,23]

Citric acid and sodium bicarbonate are effervescent chemicals that produce gas and cause the pill float.

Hydrophilic polymers: xanthan gum and HPMC (to limit drug release and provide the floating mechanism).

Lipid-based materials: For low density, certain formulations employ lipid-based excipients. For medications that require a longer absorption window or are absorbed in the stomach, this mechanism is very helpful because it improves bioavailability **(**Figure 4).

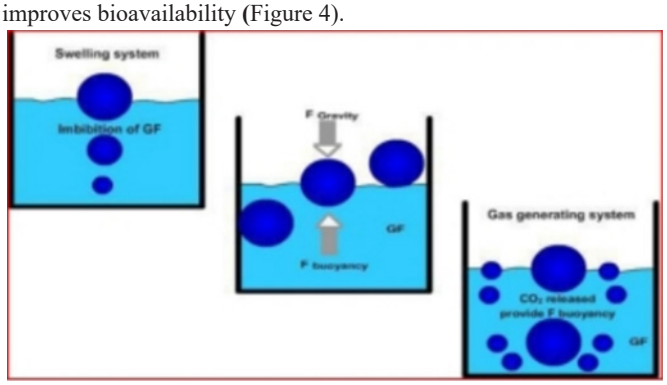

Figure 4 Mechanisms of buoyancy in Floating Drug Delivery Systems.

Proper tablet formulation requires balancing density and buoyancy: If the tablet's density is too high, it will sink rather than float, and if it is too low, it will float but make insufficient contact with the stomach lining, potentially affecting drug release and absorption.

Delayed onset in the fasting state: The stomach may empty more quickly. Floating tablets may not remain in the stomach long enough to full fill their intended purpose. Furthermore, the effervescent mechanism (in the case of gas-generating tablets) may not function properly on an empty stomach due to a lack of gastric contents to support the floating action.

Limited to certain drugs: Floating tablets are only acceptable for medications that are largely absorbed in the stomach or upper small intestine. Maintain a steady profile in acidic settings (stomach). Requires regulated or sustained stomach release. Drugs that are unstable in acidic environments or are largely absorbed in the intestines may not benefit from floating tablet formulations.

Difficulties in large-scale manufacturing: Producing a consistent formulation with exact buoyancy and medication release qualities might be problematic. Variations in tablet size, shape, and substance during manufacture may have an impact on floating ability and drug release profiles.

Effervescent systems: The use of gas-generating substances (such as sodium bicarbonate) that emit carbon dioxide when in contact with gastric acid, resulting in an abuoyant effect.

Non-effervescent systems: The use of swellable polymers (such as hydroxypropyl methylcellulose or sodium alginate) to absorb stomach fluid, swell, and lower tablet density.

Osmotic systems: These systems use osmotic pressure to slowly force the medication out while remaining buoyant **(**Figure 5).

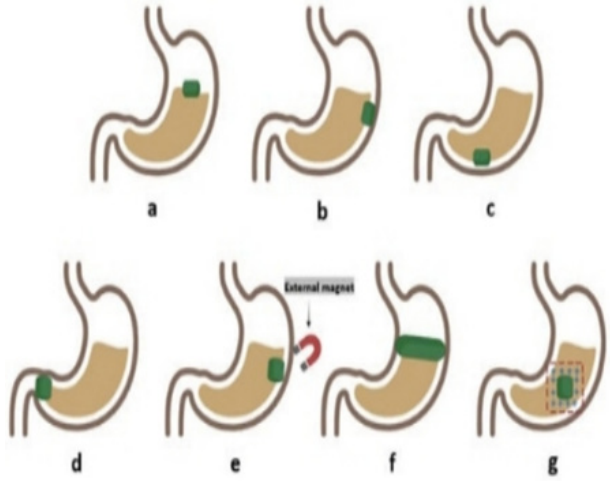

Figure 5 Mechanism of floating tablet in stomach.

Challenges in floating tablets[9]:

Variability in gastric emptying: Gastric emptying times can vary widely among individuals and even within the same person, depending on factors such as diet, posture, age, and disease status. This variability influences how long the floating tablet remains in the stomach and can result in irregular medication absorption.

Sufficient gastric fluid: Floating tablets require appropriate gastric fluid to act properly. In some situations, particularly in patients with gastroparesis or low stomach fluid volume, the tablet may not float or disintegrate as planned, resulting in unexpected medication release.

Tablet size: Larger floating tablets may be necessary to maintain buoyancy and release the medicine over time. Large tablets can be difficult to swallow, particularly for individuals who already struggle with oral medications.

Risk of tablet adhesion: There is a potential risk that floating tablets could adhere to the oesophagus or the stomach wall, which could cause discomfort or irritation and interfere with drug release. Effect of Food on Tablet Performance: Food in the stomach can impact the performance of floating tablets. For instance, food may affect the tablet's buoyancy.

Impact of food on tablet performs: Certain foods may change the pH of the gastrointestinal environment, influencing the drug's release rate. Food can also disrupt the floating process by reacting with the tablet, resulting in early sinking.

Formulation complexity: Creating a floating tablet necessitates precise formulation procedures. Polymer choices (for swelling and buoyancy), gas-generating agents (for effervescent formulations), and coating materials all require careful optimization. This complexity can lead to longer development times and higher costs.

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Issues with drug solubility and stability: Drugs with low solubility in stomach juices may not dissolve properly, limiting absorption. Furthermore, some medications can deteriorate in acidic environments, rendering them inappropriate for floating tablet formulations.

Potential for irritation: Prolonged gastric retention may cause stomach lining irritation or pain, especially for sensitive patients or those taking irritants.

Cost and development: Floating pills are more expensive and time-consuming to create and test than regular dosage forms. The necessity for specialized excipients, polymers, and coatings raises the expense and complexity of manufacturing.

Unintentional rapid release: If the tablet loses buoyancy or disintegrates too quickly due to formulation difficulties, it may cause unintentional rapid drug release, leading to dose dumping and possible side effects.

Ethical and regulatory issues: Floating pills may attract regulatory scrutiny due to their complicated and variable functioning. Extensive in vitro and in vivo testing may be necessary to verify safety, efficacy, and reproducibility, which can cause product approval delays and expense increases.

Marketed overview

Floating tablets have acquired popularity in the pharmaceutical sector, especially for medications that require gastro retentive delivery. Several goods are now available[24, 25]:

Table 1 Examples of commercially available floating drug delivery systems

Name	Company	Type and Drug	Remark
MadoparHBS (PropalHBS)	Roche, USA	Floating Capsule, Levodopa and Benserazide	Floating CR Capsules
Valrelease	Hoffman LaRoche, USA	Floating Capsules, Diazepam	Floating Capsules
Topalkan	Pierre Fabre Drug, France	Floating Antacid, Aluminium and Magnesium mixture	Effervesents Floating liquid Alginate Preparation
Conviron	Ranbaxy, India	Ferrous Sulphate	Colloidal gel Forming FDDS
Cifran	Ranbaxy, India	Ciprofloxacine (1gm)	Gas Generating Floating Form
Cytotech	Pharmacia, USA	Misoprostol (100mcg/200mcg)	Bilayer Floating Capsules

Recent innovation and trends[26,27]:

Polymer innovations: Novel biocompatible and biodegradable polymers are being developed to improve buoyancy and medication release properties. These advancements aid in the drug's long-term retention in the stomach.

3D printing techniques: Using 3D printing to create floating tablets allows for exact control over the structure and drug release rates, resulting in individualized treatment.

Nano formulations: Adding nanoparticles to floating tablets improves the solubility and bioavailability of poorly soluble medicines, increasing therapeutic efficacy

Sustainable materials: Research into sustainable, biodegradable materials for floating tablets seeks to lessen environmental impact while retaining effective drug delivery.

Combination drug therapies: Recent research has focused on creating floating tablets containing various active components, which can increase therapeutic outcomes and patient compliance.

Biodegradable polymers: The usage of ecologically friendly ingredients in the composition of floating tablets is increasing, addressing efficacy and sustainability problems.

Metformin SR: Extended-release versions of Metformin use a floating mechanism to keep therapeutic levels in patients with type 2 diabetes, improving glucose control and patient compliance.

Ciprofloxacin extended release tablets: Ciprofloxacin floating formulations improve its bioavailability, allowing for less frequent dose and better patient adherence to treatment.

Ranitidine and famotidine: These H2 receptor antagonists used to treat GERD and peptic ulcers benefit from increased stomach retention, which leads to better therapeutic results.

Domperidone: Floating formulations of this antiemetic drug provide improved control of nausea and vomiting by guaranteeing a more consistances therapeutic impact (Table 1 & Figure 6).

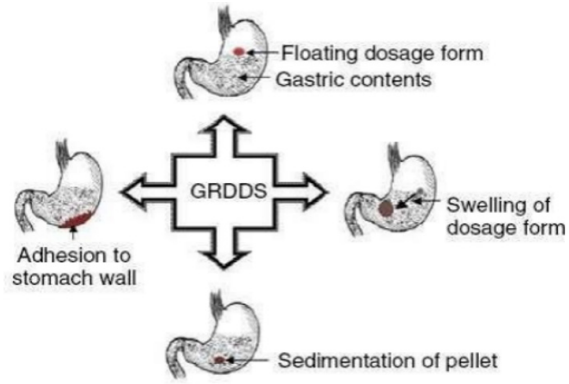

Figure 6 Mechanisms of gastro retentive drug delivery systems.

Conclusion

Floating tablets, also known as gastro retentive drug delivery systems (GRDDS), are novel formulations that extend the residence period of pharmaceuticals in the gastrointestinal tract, particularly the stomach. This technology is especially useful for medications that have tight absorption windows, require continuous action, or are better absorbed in a certain pH range. Floating pills are especially advantageous for medications with narrow therapeutic indices or that undergo considerable first-pass metabolism, resulting in more effective and regulated release. Because of the rising prevalence of chronic diseases such as diabetes and hypertension in India, one of the world's largest pharmaceutical markets, there is a significant opportunity for floating tablet formulations. However, the introduction must adhere to the regulatory framework established by the Central Drugs Standard Control Organization (CDSCO) in India.

Manufacturing issues include specialised processes and materials, as well as consumer awareness and market tactics. Direct compression, moist granulation, and hot melt extrusion are three preparation methods. Collaborations with healthcare providers, targeted marketing, and awareness campaigns could all help to speed up the adoption of floating tablets in India. As the pharmaceutical

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industry continues to investigate gastro retentive technology, floating tablets will play an increasingly crucial role in improving.

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Conflict of interest

The authors declare that there is no conflict of interest.

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