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Review Article

A Review on Floating Tablet

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Abstract

Floating drug delivery systems (FDDS) are designed with a lower bulk density than gastric fluids, enabling them to remain buoyant in the stomach for extended periods without affecting the gastric emptying rate. While floating on the stomach's contents, these systems release medication in a controlled and sustained manner. Once the drug is fully released, the system disintegrates or is emptied from the stomach. This mechanism increases the Gastric Residence Time (GRT), leading to improved control over fluctuations in plasma drug concentration. To achieve this, FDDS must possess sufficient structural integrity to form a cohesive gel barrier and release the drug gradually while maintaining a density lower than that of gastric fluids. These systems are typically developed using effervescent and non-effervescent approaches that rely on buoyancy mechanisms. Such methodologies are particularly beneficial for delivering drugs with a narrow therapeutic window. Our review aims to provide detailed insights into the pharmaceutical principles guiding the design, classification, and preparation of FDDS. It also explores factors influencing their performance, their advantages, applications, limitations, and potential future advancements in this innovative drug delivery system.

Keywords: Floating drug delivery system, Polymer, Gastroretentive system, Prolonged Gastric Retention, Controlled Drug Release.

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INTRODUCTION

A floating tablet is a gastroretentive drug delivery system (GRDDS) designed to remain buoyant in gastric fluid for an extended period, allowing controlled drug release and prolonged gastric retention time. Buoyancy is achieved using low-density polymers or gas-generating agents that react with gastric fluids to maintain the tablet's position in the stomach.[1]

FDDS are low viscosity systems that remain buoyant over the gastric contents without disturbing the gastric evacuating rate for a prolonged period.[2] These are useful for medicines that are inadequately answerable or unstable in intestinal fluids. When the system is floating on the gastric contents, the medicine is released at a controlled rate from the system and is voided from the stomach after the release of the medicine results in bettered gastric retention time had control of the oscillations in tube medicine attention, achieve lesser remedial benefit of the medicine substance. For illustration, medicines that are absorbed in the proximal part of the gastrointestinal tract (GIT) and medicines that are inadequately answerable in or degraded by the alkaline pH may profit from prolonged gastric retention. In addition, for original and sustained delivery of medicine to the stomach and proximal small intestine is used to treat certain conditions, dragged gastric retention of their medial half may offer very numerous advantages including bettered bio availability and remedial efficacy and possible reduction of cure size.[3] The ultimate thing of any medicine delivery is Effective complaint operation, minimal side goods, and lesser case compliance in cost-effective manner. Further than 50 of the medicine delivery systems available in the request are oral medicine delivery systems.[4] Controlled Release Drug Delivery Systems (CRDDS) ensure the controlled, predictable release of medication over an extended period, offering benefits such as consistent therapeutic drug levels, prolonged action for short half-life drugs, reduced side effects, and improved patient compliance. Gastric retention systems, like mucoadhesive, floating, swelling, or delayed evacuation systems, extend the drug's residence time in the stomach, enhancing bio availability, reducing drug waste, and improving solubility in less alkaline environments. These systems optimize therapy and provide significant benefits to patients.[5]

BIOLOGICAL ASPECTS OF CONTROL RELEASE GASTRO RETENTIONAL DELIVERY FLOATING SYSTEM:

Stomach Physiology

The stomach is distended section of the digestive tube between the oesophagus and small intestine. The wall of the stomach is structurally analogous to the other corridor of the digestive tube, with the exception that stomach has redundant, oblique sub caste of smooth muscle inside the indirect subcaste, which aids in the performance of complex grinding movements. In the empty state, the stomach is contracted and its mucosa and sub mucosa are thrown up into distinct crowds called rugae.[6]

There are images to four major types of clerk epithelial cells that cover the face of the stomach and extend down into gastric recesses and glands

1. **Mucous cells:** Release alkaline mucus that protects the epithelium against shear stress and acid.
2. **Parietal cells:** Release hydrochloric acid.
3. **Parietal cells:** Release pepsin, a proteolytic enzyme.
4. **G cells:** Release the hormone gastrin. The compression of gastric smooth muscle serves two introductory functions Ingested food is crushed, ground, mixed and liquefying to form Chyme. Chyme is forced through the pyloric conduit into the small intestine, a process called gastric evacuating.

Gastric motility

Gastric motility is controlled by a complex set of neural and hormonal signals. Nervous control originates from the enteric nervous system as well as parasympathetic (generally vagus caprice- whams) and sympathetic systems. A large battery of hormones has been shown to impact gastric motility- for e.g. both gastrin and cholecystokinin act to relax the proximal stomach and enhance condensation in the distal stomach. The gastric volume is important for dissolution of the tablet form in vivo. The resting volume of the stomach is 25- 50 ml. There is a large difference in gastric caching of normal and achlorhydric individualities. Gastric pH also has pronounced effect of absorption of drug from delivery system. The pH of fasting stomach is 1.2-.2.0 and in fed conditions 2.0- 6.0.[7]

Gastric empty rate

Gastric evacuating occurs during fasting as well as fed conditions. The pattern of motility is still distinct in the 2 countries. During the fasting state an interdigestive series of electrical events take place, which cycle both through stomach and intestine every 2 to 3 hours. This is called the interdigestive myloelectric cycle or migrating myloelectric cycle (MMC).[8]

CLASSIFICATION OF FLOATING TABLET [9]

Non-Effervescent Floating Drug Delivery System (FDDS): The non-effervescent FDDS relies on the swelling properties of polymers or their bioadhesive interactions with the gastrointestinal (GI) mucosa to achieve gastric retention. These systems utilize gel-forming agents or highly swellable hydrocolloids, such as cellulose derivatives, along with matrix-forming polymers like polycarbonate, polyacrylate, polymethacrylate, and polystyrene. Additionally, bioadhesive materials like chitosan and carbopol enhance adhesion to the stomach lining, prolonging the system's retention and ensuring sustained drug release.

Effervescent Floating Drug Delivery System (FDDS) Effervescent FDDS employs gas-generating components, such as sodium bicarbonate, in combination with organic acids like citric acid or tartaric acid. Upon contact with gastric fluid, these ingredients react to produce carbon dioxide (CO_2), reducing the system's density and enabling it to float on the stomach's contents. Alternatively, the formulation may incorporate a matrix with liquid components that generate gas through evaporation at body temperature, further aiding buoyancy and controlled drug release.

Volatile liquid-containing systems: Volatile liquid-containing systems use an inflatable chamber filled with fluids to enable sustained gastric retention in medication delivery. These systems contain volatile liquids like cyclopentane and ether, which gasify at body temperature, causing the stomach chamber to expand. They consist of osmotically regulated floating structures called hollow deformable units. The system is divided into two compartments: one holds the medication, while the other contains the volatile liquid.

Bilayer floating tablet: Bilayer floating tablet consists of two layers: an immediate-release layer for the initial drug dose and a sustained-release layer that absorbs gastric fluid, forming a gel barrier to maintain buoyancy in the stomach.

Micro-porous compartment system: Micro-porous compartment system contains a drug reservoir sealed on the sides, preventing direct contact with the gastric surface. Entrapped air in the floating chamber keeps it buoyant, while gastric fluid enters through an aperture, dissolving the drug for intestinal absorption.

Raft-forming systems: Raft-forming systems are used for antacid delivery and treating gastrointestinal infections. They work by forming a viscous gel upon contact with gastric fluids, creating a floating raft. This raft buoyed by CO_2 formation acts as a barrier to prevent acid reflux into the esophagus. The system typically includes a gel-forming agent and alkaline bicarbonates or carbonates, which reduce density and ensure flotation on gastric fluids.

Colloidal Gel Barrier System: Colloidal Gel Barrier System developed by Sheth and Tossounian, is a hydrodynamically balanced system that remains buoyant in the stomach to enhance gastric retention time (GRT) and drug absorption. It uses gel-forming hydrocolloids and matrix-forming polymers like polystyrene and polycarbophil, along with cellulose-based hydrocolloids such as hydroxyethyl, hydroxypropyl, and hydroxypropyl methylcellulose to maintain flotation and controlled drug release.

FACTORS AFFECTING GASTRIC RETENTION

The gastric retention time (GRT) of capsule form is controlled by several factors that affect their effectiveness as a gastroretentive system.

Density – GRT is a function of capsule form buoyancy that is dependent on the density.[10]

Size – capsule form units with a fringe of further than 9.5 mm are reported to have an increased GRT.[11]

Shape of dosage form – Tetrahedron and ring- shaped bias with a flexural modulus of 48 and 22.5 kilopounds per square inch (KSI) are reported to have better GRT. 90 to 100 retentions at 24 hours compared with other shapes.

Single or multiple unit formulation – Multiple-unit formulations offer more predictable release profiles, reduce the risk of dose dumping, enable co-administration of incompatible substances, and provide greater safety compared to single-unit forms.

Gender – Mean ambulatory GRT in males (3.4 ± 0.6 hours) is less compared with their age and race-matched womanish counterparts (4.6 ± 1.2 hours), anyhow of the weight, height and body face.

Age – Elderly people, especially those over 70, have a significantly longer GRT.

Posture – GRT can vary between supine and upright ambulatory countries of the case.[12]

Biological factors – Diabetes and Crohn's complaint.

POLYMERS USED IN FLOATING DRUG DELIVERY SYSTEM[13-15]

1) Natural Polymers

Chitosan: Biodegradable, biocompatible, and forms a gel in acidic pH, promoting sustained medicine release and buoyancy.

Guar gum: Provides gel- forming capability and helps sustain medicine release.

Xanthan gum: Used as a thickening agent and stabilizer, promoting floating and controlled release.

Alginates: Form hydrogels that swell in the stomach, enabling floatation and controlled medicine delivery. **Hydroxypropyl Methylcellulose (HPMC):** A extensively used polymer for controlled release phrasings due to its gel- forming capability. Different grades (e.g. HPMC K4M, K15M) can conform medicine release rates.

Methylcellulose: Provides buoyancy and a prolonged floating effect due to its high water immersion capacity.

Ethylcellulose: frequently used in combination with other polymers to modify medicine release and enhance floatation.

2) Synthetic Polymers

Eudragit (Methacrylic acid copolymers):

a) Eudragit RL and RS give controlled medicine release and help maintain buoyancy.

b) Eudragit NE 30D used in coatings for floatable phrasings.

Polyvinyl Alcohol (PVA): Biocompatible, forms stable hydrogels, and aids in floatation.

Polyethylene Oxide (PEO): Offers high lump capacity, perfecting the floatation and release profile.

Polylactic-co-Glycolic Acid (PLGA): Used in advanced FDDS to achieve sustained release.

METHOD FOR PREPARATION OF FLOATING TABLET

The preparation of floating tablets typically involves one of the following methods:

1. **Direct Compression:** Ingredients, including the drug, floating agents (e.g. sodium bicarbonate, citric acid), polymers (e.g. HPMC) and excipients are mixed and directly compressed into tablets.[16]

2. Wet Granulation: The drug and excipients are mixed with a granulating agent (e.g. water, ethanol). The wet mass is granulated, dried and compressed into tablets.[17]

3. Effervescent Technique: Effervescent agents like sodium bicarbonate and citric acid are incorporated to produce CO_2, allowing the tablet to float. These are combined with the drug and compressed into tablets.[18]

4. Hot-Melt Extrusion: Polymers are melted and mixed with the drug, shaped into tablets, and cooled. This method is used for controlled-release floating tablets.[19]

ADVANTAGES OF FLOATING DRUG DELIVERY SYSTEM[20-22]

1. Increases the oral bio availability of medicine.
2. Enhanced first pass bio-transformation.
3. Sustained medicine delivery/ reduced frequency of dosing.
4. Reduced oscillations of tube medicine attention.
5. Bettered receptor activation selectivity.
6. Give advanced effectiveness due to reduced counter-activity of body.
7. Extended time over critical (Effective) attention.
8. Minimized adverse exertion at the colon.
9. Targeted remedy for original affections within the upper GIT.
10. Point specific medicine delivery.

LIMITATIONS OF FLOATING DRUG DELIVERY SYSTEM[23-27]

1. Medicines having solubility or stability problem in GIT are not suitable for FDDS.
2. Medicines like Nifedipine, Propranolol etc. which are well absorbed throughout GIT and which undergoes first pass metabolism are not be desirable seeker.
3. Medicines which are irritant to Gastric mucous also are can't desirable.
4. Medicines that are unstable in the acidic terrain of the stomach are not suitable in this type of systems.
5. High position of fluid in the stomach is needed for maintaining buoyancy; float and work efficiently.

APPLICATION OF FLOATING DRUG DELIVERY SYSTEM

1. **Sustained Drug Delivery**: Floating systems prolong gastric residence, enabling controlled drug release over time. E.g., sustained-release floating capsules of nicardipine showed effective in vivo performance.[28]
2. **Site-Specific Delivery**: Ideal for drugs absorbed in the stomach or upper intestine, like diuretics and vitamin B2, enhancing bioavailability significantly.[29]
3. **Absorption Enhancement**: Improves bioavailability for drugs with site-specific absorption in the upper GI tract. E.g., floating formulations showed superior absorption compared to conventional forms.[30]
4. **Constant Blood Levels**: Ensures steady drug release, maintaining consistent blood levels, with easy administration and better patient compliance.[31]

FORMULATION OF FLOATING TABLETS[32-35]

1. **Active Pharmaceutical Ingredient (API):** The drug intended for controlled or sustained release.

Example: Metformin, Ciprofloxacin.

2. **Polymers:**

a) **Hydrophilic Polymers:** Control drug release and form the matrix.

Examples: Hydroxypropyl methylcellulose (HPMC), Carbopol.

b) **Effervescent Agents:** Generate gas for buoyancy.

Examples: Sodium bicarbonate, citric acid.

3. **Buoyancy Enhancers:** Provide low density.

Examples: Low-density materials like polyethylene oxide or ethyl cellulose.

4. **Binders:** Ensure tablet integrity.

Examples: Polyvinylpyrrolidone (PVP), starch.

5. **Lubricants and Glidants:** Facilitate manufacturing.

Examples: Magnesium stearate, talc.

6. **Gas-Generating System:** Sodium bicarbonate and organic acids (e.g., citric acid) react in the gastric medium to release CO_2.

EVALUATION OF FLOATING DRUG DELIVERY SYSTEMS (FDDS)[36-50]

The evaluation of Floating Drug Delivery Systems (FDDS) is crucial to ensure their efficacy and performance. The assessment is broadly categorized into two main parts:

(a) In-vitro Evaluation

1. Floating Lag Time and Total Floating Duration

Floating lag time refers to the time taken by the dosage form to begin floating on the gastric fluid.

Floating time is the total duration for which the formulation remains buoyant.

These studies are typically conducted in 0.1N hydrochloric acid (HCl) (900 mL) at 37°C.

2. Dissolution Studies

Dissolution testing is conducted using simulated gastric fluid in compliance with the USP dissolution apparatus or modified methods.

Samples are withdrawn at predetermined intervals, replaced with fresh medium, and analyzed to determine drug release percentage.

3. Resultant Weight Test

This test assesses the floating ability of FDDS using specialized in-vitro measuring equipment.

4. Differential Scanning Calorimetry (DSC)

DSC evaluates the thermal properties of the formulation, helping to analyze drug-polymer interactions and stability.

5. Particle Size Distribution

This parameter helps in understanding the uniformity of the formulation, which can influence dissolution, floating behavior, and drug release kinetics.

6. Surface Morphology

Techniques like scanning electron microscopy (SEM) provide insights into the texture, porosity, and integrity of the floating dosage form.

7. Mechanical Properties

Evaluates the tablet's strength, hardness, and friability to ensure durability and proper functionality.

(b) In-vivo Evaluation

1. X-ray / Gamma Scintigraphy

These imaging techniques track the position and movement of the dosage form within the gastrointestinal tract.

X-ray imaging involves incorporating a radiopaque marker in the formulation, while gamma scintigraphy utilizes a stable isotope for tracking.

2. Gastroscopy / Ultrasonography

Gastroscopy: A fiber-optic endoscopic method allows direct visualization of the dosage form's behavior in the stomach.

Ultrasonography: Uses sound waves to generate images of the abdominal area, identifying the floating dosage form based on differences in acoustic impedance.

3. Pharmacokinetic Studies

These studies assess drug absorption and bioavailability by analyzing parameters such as:

Cmax: Maximum drug concentration in plasma, indicating absorption rate.

Tmax: Time taken to reach Cmax.

AUC (Area Under Curve): Represents the total drug exposure over time.

CONCLUSION

Floating drug delivery systems, particularly floating tablets, represent a promising approach in the field of pharmaceutical science for enhancing the bioavailability of drugs with narrow therapeutic windows or those affected by gastric emptying times. These systems offer significant advantages, including prolonged gastric retention, localized drug release, and improved patient compliance. The design and formulation of floating tablets depend on various factors, such as the choice of excipients, polymers, and the method of preparation, which can significantly influence their performance. Despite the progress made in this field, challenges remain, including the variability in gastric conditions, the need for precise control over drug release, and the stability of the dosage form over time. Future research should focus on optimizing formulation strategies, exploring new materials for better floating properties, and conducting clinical studies to validate the efficacy of floating tablets in diverse therapeutic areas. Overall, floating tablets continue to offer exciting potential in advancing oral drug delivery systems and improving patient outcomes.

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