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FLOATING DRUG DELIVERY SYSTEM CURRENT TRENDS, CHALLEGE AND FURTURE PRESEPECTIVES

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Abstract: The floating drug delivery system FDDS remains buoyant upon contact with gastric fluids, thereby improving the bioavailability of drugs intended for absorption in the upper small intestine. Immediate floating capability is only attainable when the components of the device are characterized by low density in their initial state. This review encompasses both in vitro methodologies and in vivo research investigations that are utilized by researchers to evaluate floating systems. Floating dosage forms can be administered in traditional formats such as tablets and capsules, supplemented with appropriate ingredients and a gas-generating agent. The review elucidates the techniques for creating floating systems, which include evaluation and characterization methods for pharmaceutical dosage forms via FDDS, while also detailing classification systems and all established as well as emerging techniques employed in the development of floating dosage forms. The review elucidates the techniques for creating floating systems, which include evaluation and characterization methods for pharmaceutical dosage forms via FDDS, while also detailing classification systems and all established as well as emerging techniques employed in the development of floating dosage forms.

Keywords: *Floating Drug Delivery System, single unit and multiple unit floating system, In vitro and in vivo evaluation, Novel advancements.*

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INTRODUCTION

The article concerning floating drug delivery systems (FDDS) seeks to showcase the current research on gastric retention utilizing floating techniques. The innovative designs of FDDS incorporate both single-unit and multiple-unit floating systems, alongside gastric retention studies that employ newly formulated polymers, taking into account existing physiological and formulation variances. The floating drug delivery system FDDS remains buoyant upon contact with gastric fluids, thereby improving the bioavailability of drugs intended for absorption in the upper small intestine [1]. Immediate floating capability is only attainable when the components of the device are characterized by low density in their initial state. This review encompasses both in vitro methodologies and in vivo research investigations that are utilized by researchers to evaluate floating systems [2]. Floating dosage forms can be administered in traditional formats such as tablets and capsules, supplemented with appropriate ingredients and a gas-generating agent. The review elucidates the techniques for creating floating systems, which include evaluation and characterization methods for pharmaceutical dosage forms via FDDS, while also detailing classification systems and all established as well as emerging techniques employed in the development of floating dosage forms [3].

1. NEED FOR FLOATING DRUG DELIVERY SYSTEMS

Illnesses. However, traditional delivery methods face several challenges, with the primary issue being the lack of site specificity.

- Certain medications are only absorbed at specific locations. They require a release at a targeted site or one that guarantees the maximum amount of medicine reaches the intended area.
- The pharmaceutical sector is currently focusing on these medications that necessitate site specific delivery.

One method for site-specific medication delivery to the stomach or intestines is gastro retentive delivery. This approach involves administering the medication while retaining the dosage form in the stomach, allowing for gradual release into the stomach, duodenum, or intestine at a predetermined site [4].

2. COMPONENTS OF FLOATING DRUG DELIVERY SYSTEMS (FDDS)

The gastric retention time (GRT) of a dosage form is influenced by various factors that
impact its effectiveness as a gastroretentive system.

- Density – The GRT is determined by the buoyancy of the dosage form, which is reliant on its density.
- Size – Dosage forms with a diameter exceeding 9.5mm have been observed to exhibit an enhanced GRT.
- Caloric content – A meal rich in proteins and fats can extend the GRT by four to ten hours.
- Frequency of feed – The GRT may increase by over 400 minutes when multiple meals are consumed in succession compared to a single meal, due to the reduced frequency of the MMC [5].

3. FACTORS AFFECTING GASTRIC RETENTION

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- Frequency of feed – The GRT may increase by over 400 minutes when multiple meals are consumed in succession compared to a single meal, due to the reduced frequency of the MMC.
- Gender – The average ambulatory GRT in males (3.4 ± 0.6 hours) is shorter than that of their age and race-matched female counterparts (4.6 ± 1.0 hours) [6].

4. APPROACHES TO GASTRIC RETENTION

Various approaches have been pursued to increase the retention of an oral dosage form in the stomach. Practical approaches in designing FDDS – The idea of FDDS become first defined within side the literature as early as 1968, whilst Davis (1968) disclosed a way to conquer the problem skilled with the aid of using a few folks of gagging or choking after swallowing medicinal pills. The writer recommended that such problem might be conquer with the aid of using presenting tablet having a density of much less than 1.0g/cm3, in order that tablet will drift on water surface. Since then, numerous procedures were used to broaden a super floating drug transport system (Moya Nakagawa et al. 2006). Approaches to Design Single and Multiple Unit Dosage Form – The following approaches have been used for the design of floating dosage forms of single and multiple unit systems. (Yie W. et al, 1992) For Single Unit Dosage Forms (Eg: tablets) I. Floating lag time: It is the time taken by the tablet to emerge onto the surface of dissolution medium and is expressed in seconds or minutes [7]. In vitro drug release and duration of floating: This is determined by using USP II apparatus (paddle) stirring at a speed of 50 or 100 rpm at 37 ± 0.2 °c in simulated gastric fluid (pH 1.2 without pepsin). Aliquots of the samples are collected and analysed for the drug content. The time (hrs) for which the tablets remain buoyant on the surface of the dissolution medium is the duration of floating and is visually observed. III. In vivo evaluation for gastro retention: This is carried out by means of X-ray or Gamma scintigraphy monitoring of the dosage form transition in the GIT. The tablets are also evaluated for hardness, weight variation, etc. In low density approaches [8]. The globular shells reputedly having decrease density than that of gastric fluid may be used as a service like popcorn, price, polystrol for the drug for its managed launch. The polymer of preference may be both Ethyl cellulose or HPMC. Depending on kind of launch desired. Finally, the product floats at the gastric fluid whilst liberating the drug steadily over an extended duration. Fluid stuffed floating chamber kind of dosage paperwork consists of incorporation of a fuel line stuffed floatation chamber in to a micro porous thing that homes as a reservoir having apertures gift at pinnacle and backside partitions thru which the gastrointestinal tract fluid enters to dissolve the drug [9].

5. CLASSIFICATION OF FLOATING DRUG DELIVERY SYSTEM:

Based on the buoyancy mechanism floating systems are classified as follows

- Effervescent systems
- Non effervescent systems

Effervescent Systems Effervescent systems are matrix types of systems made with a variety of effervescent substances, including sodium bicarbonate, citric acid, and tartaric acid, together with swelling polymers like chitosan and methylcellulose. They are designed so that when they come into contact with acidic stomach contents, CO2 is Gel generating systems are of different types [10]. Floating capsules are made by blending a solution of sodium bicarbonate and sodium alginate. When exposed to an acidic environment, the carbon dioxide that is produced becomes trapped in the hydrating gel network, causing the capsules to float. Floating pills are composed of two layers: an outside swellable polymeric membrane and an inside effervescent layer containing tartaric acid and sodium

bicarbonate. To prevent sodium bicarbonate and tartaric acid from coming into physical touch, the inner layer is further separated into two sublayers. This tablet sinks to the bottom of the buffer solution at 37 °C, allowing the buffer solution to pass through the outer swellable membrane and into the effervescent layer. When sodium bicarbonates and tartaric acid mix, carbon released and lodges in swelling hydrocolloids, giving dosage forms buoyancy [11].

Gas generating System: In order to retain drugs, this system primarily uses agents that release carbon dioxide. The primary purpose of agents like sodium bicarbonate, citric acid, tartaric acid, and chitosan is to produce carbon dioxide, which lowers the drug's density and causes it to float in the stomach. This floating aids in the drug's longer-term retention [12], dioxide is produced, which causes swollen pills or balloons to form. The device floats because the created carbon dioxide is trapped in the delivery system. Floating systems with ion exchange resins are formulated by using ion exchange resin that is loaded with bicarbonate by mixing the beads with sodium bicarbonate solution [13-14].

Non-Effervescent System Non-effervescent floating dosage forms include matrix-forming polymers such as polycarbonate, polyacrylate, polymethacrylate, and polystyrene, as well as gel-forming or swellable cellulose type hydrocolloids trapped in the enlarged matrix. The resulting inflated, gel-like structure serves as a reservoir for the drug's continuous release through the gelatinous mass.

a) Microporous Compartment System: In this technology, a drug reservoir is encapsulated inside a microporous compartment with pores along its top and bottom walls. The peripheral walls of the drug reservoir compartment are completely sealed [15].

b) Alginate Beads: The freeze-dried calcium alginate has been utilized to create floating dosage forms with multiple units. Calcium alginate can be precipitated by dropping sodium alginate solution into an aqueous solution of calcium chloride, resulting in spherical beads with a diameter of around 2.5 mm [16].

c) Hollow Microspheres: A unique emulsion solvent diffusion approach was used to create hollow microspheres loaded with medication in their outer polymer shelf. The distributed polymer droplet experiences the formation of an interior cavity in the polymer microsphere containing medication due to the evaporation of dichloromethane [17].

6. MECHANISUM OF FLOATING DRUG DELIVERY SYSTEM

Among these, floating dosage forms are the most utilized. Due to the lower bulk density of gastric fluids compared to Floating Drug Delivery Systems (FDDS), these forms remain buoyant in the stomach without hindering the gastric emptying rate. The medication is gradually released from the system at the intended rate while it floats on the gastric contents. Following the release, the residual system of the drug is expelled from the stomach. Consequently, fluctuations in plasma drug concentration are more effectively controlled, and gastric retention time (GRT) is increased. However, to maintain the buoyancy of the dosage form on the surface of the meal, a minimum level of floating force (F) is required, in addition to the necessary stomach content to achieve the buoyancy retention effect effectively [18]. A specialized apparatus for calculating the resultant weight has been documented in the literature to assess the kinetics of floating force. This device operates by continuously measuring the force F (as a function of time) required to keep an object submerged [19].

7. METHODS OF DEVELOPING FLOATING DRUG DELIVERY SYSTEM

7.1. Compression Technique: It means compressing tablets directly from powder content without altering the substance's physical structure itself. Dicalcium trihydrate phosphate, tricalcium phosphate, etc. are the most widely used carriers.

7.2. Spray Drying Technique: Involves dispersing the core layer into the liquefied coating content and spraying the core coating mixture into the environment so that the coating is solidified by rapidly evaporating in which the coating material is solubilized.

7. 3. Melt Solidification Technique: This method involves emulsifying the molten mass in the aqueous phase followed by cooling it to solidify. Lipids, waxes, polyethylene glycol, etc. are the carriers used for this technique.

7. 4. Melt Granulation Technique: This is the method that agglomerates the pharmaceutical powders using a meltable binder and does not use water or organic solvents for granulation.

8. EVALUATION OF FLOATING DRU DELIVERY SYSTEM

8.1. Bulk density: This refers to the ratio of a powder's total mass (m) to its bulk volume (Vo). The formula is Db=m/Vo.

8.2. Tapped density: This is defined as the ratio of the total mass of the powder (m) to its tapped volume (Vi). The formula is Dt = m/Vi.

8.3. Compressibility index: The bulk density (o) and tapped density (t) of the powder, along with the rate at which it compacts, can be utilized to evaluate the flowability of the powder.

8.4. Hausner's Ratio: This is determined by dividing the tapped density by the bulk density, as shown in the formula below. Hausner's Ratio = Tapped density / Bulk density. 5. Angle of repose: In this procedure, a funnel is filled with a precisely weighed mixture of powder, granules, and microparticles.

9. BENEFITS OF FLOATING OF DRUG DELIVERY SYSTEM

1. Floating dosage forms, such as tablets or capsules, will stay in the fluid for an extended period when the intestines have an alkaline pH.
2. FDDS are benefits for medications designed to operate locally in the stomach, such as antacids.
3. FDDS dosage forms have the advantage of keeping the medicine in a floating state in the stomach during diarrhoea and agitated bowel movements, which results in a relatively better reaction.
4. Since aspirin and other similar medications might irritate the stomach wall when they come into touch with them, FDDS formulation may be helpful for their administration.
5. The FDDS offers benefits for medications that are absorbed through the stomach, such as ferrous salts.
6. Slow drug absorption into the body reduces antagonistic effects, increasing drug effectiveness.

10. APPLICATION OF FLOATING DRUG DELIVERY SYSTEM

Floating drug delivery presents numerous applications for medications with low bioavailability due to the limited absorption window in the upper gastrointestinal tract. It maintains the dosage form at the absorption site, thereby improving bioavailability. The key points are summarized as follows [20].

1. Sustained Drug Delivery: Floating Drug Delivery Systems (FDDS) can remain in the stomach for extended durations, allowing for prolonged drug release. This addresses the issue of short gastric residence time typically faced by oral controlled release formulations. These systems possess a bulk density that is advantageous for drugs with poor bioavailability due to site specific absorption in the upper gastrointestinal tract. For instance, a notable increase in the bioavailability of floating dosage forms (42.9%) was observed compared to commercially available LASIX tablets (33.4%) and enteric-coated LASIX-long products (29.5%). 4. Enhanced Bioavailability: The bioavailability of riboflavin in Controlled Release-Gastro Retentive Drug Formulations (CR-GRDF) is significantly improved when compared to the administration of non GRDF controlled release polymeric formulations. Various processes related to the absorption and transit of the drug within the gastrointestinal tract work simultaneously to affect the extent of drug absorption [21].

11. LIMITATIONS

These systems necessitate a significant amount of fluid in the stomach for effective drug delivery to float and function efficiently.

- They are not appropriate for drugs that exhibit solubility or stability issues within the gastrointestinal tract.
- Medications like Nifedipine, which are well absorbed throughout the entire gastrointestinal tract and undergo first-pass metabolism, may not be ideal.
- Drugs that irritate the gastric mucosa are also considered undesirable or unsuitable.
- Drug substances that are unstable in the acidic conditions of the stomach are not suitable candidates for incorporation into these systems
- The dosage form should be taken with a full glass of water (200-250 ml).

12. FUTURE PERSPECTIVES IN FLOATING DRUG DELIVERY SYSTEM

Among the medicine presently in medical use are numerous narrow absorption window drugs that can gain from compounding right into a fdds. Changing parenteral administration of medicine to oral pharmacotherapy might extensively enhance treatment. It is predicted that fdds can also additionally enhance this possibility. Moreover, it is anticipated that the fdds technique can be used for lots potentially active agents with narrow absorption window, whose improvement has been halted because of loss of suitable pharmaceutical fdds technologies.

13. CONCLUSION

The development of an effective gastro-retentive dosage form for targeted drug delivery within the stomach is a current project. Floating Drug Delivery Systems provide the advantage of improved absorption for medications that are absorbed in the upper region of the stomach, thereby enhancing the bioavailability and controlled release of numerous drugs, offering new and essential therapeutic options. This results in less frequent dosing and a more effective treatment regimen. Enhanced stability and superior drug release compared to traditional dosage forms render such systems more reliable. A critical factor to consider in the production of a floating drug delivery system is that the density of the dosage form must be lower than that of gastric fluid. Consequently, it can be concluded that these dosage forms are most effective in treating gastrointestinal diseases and in prolonging the action of drugs with a short half-life.

14. AUTHOR CONTRIBUTIONS

All authors are contributed equally.

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16. DECLARATION COMPETING INTEREST

The authors have no conflicts of interest to declare.

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