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Review Article

An Overview of Gastro Retentive Drug Delivery System

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ABSTRACT

Advanced technologies have contributed to the development of floating drug delivery devices. These devices may float on gastric secretions and increase the intestinal absorption and bioavailability of encapsulated drugs. The intestinal absorption and bioavailability of encapsulated drugs may be increased by the floating drug delivery devices' capacity to float above the gastric fluids thanks to the use of state-of-the-art technology. Gastroretentive Pharmaceutical Delivery Systems (GRDDS) are promising approach to increase therapeutic efficacy and bioavailability of oral drugs notably those having low solubility or restricted absorption window. The new drug delivery system is aimed at stomach residence time extension to improve drug release and absorption. Gastroretentive delivery systems for pharmaceuticals (GRDDS) is the novel approach to overcome the limitations of conventional oral drug delivery, notably for the drugs which are unstable at alkaline pH, having narrow absorption window or are poorly soluble in intestinal fluids. The objective of this review article is regarding the overview of GRDDS.

INTRODUCTION

A gastroretentive drug delivery device prolongs the gastric residence time to provide site-specific distribution of medicine in the upper gastrointestinal tract (GIT) to provide local or systemic action. Gastro-retentive dosage forms can remain in the stomach region for a prolonged time period, therefore enhancing the gastric retention time (GRT) of drugs to a greater extent.[1]

Gastro-resistant medications are innovative delivery methods that have the advantage of being retained in the stomach for extended periods of time. The fact that the medication is not given at a precise location is another drawback of traditional fast release pills.[1,2] In contrast, certain drugs are absorbed from particular sites and must be administered to those sites alone for effective absorption. It is based on several parameters such as the emptying process, the length of stay of the

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dosage form through the digestive system, the release of the medicine from the dosage form and the absorption site.[2]

When a medication is taken orally, it remains in the stomach to constantly provide the drug to the gastrointestinal tract's (GIT) absorption sites and release it in a regulated way. Short gastric retention time (GRT) and unpredictable short gastric emptying time (GET) are the two main issues with these drug delivery mechanisms. These issues can lead to incomplete drug release from the dosage form in the absorption zone (stomach or upper part of small intestine) and lower the effectiveness of the administered dose.[3]

Gastro retentive dosage forms (GRDFs) are designed to release active ingredients in the stomach for longer duration so that the medicine can be absorbed continuously in the upper gastrointestinal (GI) tract.[4] Understanding of the working of stomach is vital for creating gastroretentive delivery systems for drugs (GRDDS). The retention of a dose form depends on variables such as stomach architecture, pH variations, motility patterns and gastric emptying rates. These things also affect how a medicine dissolves, how it is absorbed, and how it acts in your body. [5]

However, these systems suffer from issues including short gastric retention time (GRT), unsteady gastric emptying time (GET), which might lead to insufficient drug release in the absorption site (stomach or proximal small intestine), and are less efficient in dose. A prolonged stomach residence time is helpful for site specific controlled release dose formulations. In addition, long stomach retention time could be useful for localized effects in the proximal small intestine especially in peptic ulcer treatment. [6]

The development of GRDDS technology has produced major improvements in the treatment of a variety of diseases, particularly those that need sustained drug levels or targeted delivery to the upper gastrointestinal tract. Such breakthrough has prompted a considerable amount of academic research toward the development of new formulation approaches and understanding the complicated interplay between dosage form design and physiological elements. [7]

There is some evidence that prolonging the amount of time a pharmaceutical spends in the stomach may

improve its absorption in the upper GI tract, its solubility in acidic environments, or its ability to reach the lower GI tract.[8]

Stomach Anatomy

The stomach is divided into four main parts. These include the cardia, fundus, body and pyloric portion. The area of the heart is located at the aperture of the upper stomach. Shaped like a circle, the fundus is located in the stomach above and to the left of the cardia; below it rests the body, the main structural element. The pyloric region is divided into three divisions. The first section, the pyloric antrum, is attached to the digestive tract. During a fast, your digestive system goes through a series of contractions known as the migrating myoelectric cycle. These contractions occur 120 to 180 minutes apart. Additionally, it is divided into four parts. A person's "digestive motility pattern" is the unique way their muscles contract after a meal. The sequence consists of a phase-1 (basal phase) with no contraction, a phase-2 (pre-burst phase) with occasional contraction, a phase-3 (burst phase) with regular contraction at maximal frequency that progresses distally, and a phase-4 period of transition between phases 3 and 2. Displays the movement patterns inside the digestive system. Normally, the stomach holds roughly 1.51 liters after eating, however this ranges from 250-500 ml in inter-digestive phases. The antrum is where most of the mixing takes place, whereas the fundus and body store undigested food. The lower part, the antrum, works as a pump to evacuate the stomach via a propulsive process. [1]

MECHANISMS OF GASTRORETENTION

Floating drug delivery system

These systems may float in the stomach for a longer period of time since they are less thick than gastric fluids, which extends the gastric residence time and promotes the drug's gradual release. There are two different types of floating systems. Effervescent and non-effervescent are the two varieties. Non-effervescent formulations are made by combining pharmaceuticals with gel-forming polymers or very absorbent cellulose derivatives. Effervescent materials are combined with calcium carbonate, sodium bicarbonate, citric acid, tartaric acid, and hydrophilic polymers.



Therefore, when it comes in touch with stomach juice, CO₂ is released and entrapped in a hydrocolloid framework modifying the release of the drug. [4]

Mucoadhesive Systems:

Dosage forms may be developed to stick to the stomach mucosa in order to extend their stay at the absorption site. This is achieved by bioadhesive or mucoadhesive formulations. The adhesion process encompasses several processes, including as wetting, diffusion, adsorption, and mechanical interlocking. These interactions take place between the polymer chains and the mucosal layer that coats the stomach. Mucoadhesion improves medication retention by counteracting stomach motility and inhibiting early expulsion.[5]

Swelling and Expanding Systems:

Systems that swell and expand are engineered to enlarge upon interaction with stomach fluid, obstructing their movement through the pyloric sphincter and hence extending gastric retention.[5]

High-Density Systems

Creating dosage forms with a density greater than that of stomach contents (~1.004 g/ml) is the essence of this technique. The medicinal ingredient is therefore coated or mixed with thick inert materials such as iron powder, zinc oxide, titanium dioxide or barium sulfate. These chemicals increase the overall density of the formulation and hence favor the extended gastric retention. [9]

Magnetic systems:

The magnetic apparatus includes a tiny internal magnet embedded in the dosage form, which engages with an external magnet situated on the abdomen above the stomach. Despite the apparent efficacy of this technique, the requirement for accurate positioning of the external magnet may influence patient adherence to maintaining the targeted site for two hours.

[10]

Raft-Forming Systems:

Raft-forming systems are liquid preparations that transform into a gel when they interact with stomach

fluid. These systems generally comprise alginate and bicarbonate, which interact to produce a thick gel (raft) that remains buoyant atop the stomach contents.[5]

CHARACTERIZATION OF GRDDS

In Vitro Characterization

The assessment of GRDDS includes many in vitro examinations aimed at evaluating essential performance metrics. Floating systems necessitate the assessment of floating lag time and length through the use of specialized dissolving equipment that replicates stomach conditions. The assessment of the swelling index, matrix erosion rate, and mucoadhesive strength offers understanding of the system's retention mechanism. Investigations of medication release conducted in biologically relevant conditions aid in the prediction of in vivo effectiveness.[7]

In Vivo Characterization

The in vivo assessment of GRDDS utilizes diverse imaging modalities and pharmacokinetic analyzes to validate stomach retention and treatment effectiveness. Gamma scintigraphy enables immediate observation of the positioning and dynamics of dose forms throughout the gastrointestinal system. The method entails integrating an appropriate radioisotope into the composition and tracking its progression via gamma.[7]

Advantages of gastro-retentive drug delivery systems[8.6]

For medications with comparatively brief half-lives, prolonged release can lead to a flip-flop pharmacokinetic profile and facilitate less frequent dosage, hence enhancing patient adherence. The use of gastroretentive drug administration allows for the slow and steady release of medicine from dosage forms, which allows for targeted therapy in the small intestine and stomach. Consequently, they are beneficial in addressing ailments associated with the stomach and small intestine. Gastroretentive medication administration can reduce the body's counteractive responses, resulting in enhanced therapeutic efficacy. The prolonged release mechanism of gastroretentive dosage forms facilitates an extended duration at a vital concentration, hence augmenting pharmacological efficacy and enhancing chemical results. Enhances patient compliance by



minimizing the dosage frequency. Enhances the efficient use of doses.

DISADVANTAGE OF GRDDS [4]

However, not all drugs or illnesses are suitable for gastroretentive devices, despite their benefits.

- Medications that are sensitive to acid and exhibit low solubility are inefficient for substances such as phenytoin, which poorly dissolve in acidic conditions, or for medications like erythromycin, which deteriorate swiftly in gastric acid.
- Gastric Irritants: Preparations that deliver NSAIDs or aspirin over prolonged durations may induce regional irritation and gastric lesions.
- Localized Regional Absorption: They provide no benefit for drugs that are specifically absorbed in the colon (such as corticosteroids) or those that are absorbed consistently over the whole gastrointestinal tract (such as isosorbide dinitrate and nifedipine).
- Fluid Dependence: Buoyant systems rely on sufficient fluid capacity within the stomach to maintain their floatation and operate well.

FACTORS AFFECTING[1]

Density: The dose influenced by the physical parameter of density impacts the gastro-retention duration by counteracting floating and sinking. **Size-dosage:** A dosage form with a diameter beyond 7.5mm exhibits a longer stomach retention duration compared to a 9.9mm diameter dosage form. **Fasted or unfed condition:** It exists during times of vigorous physical activity that transpire every 1.5 to 2 hours. The migrating motor complex (MMC) clears undigested substances from the stomach, and if the formulation training aligns with the MMC, the gastric residence time (GRT) of the unit can be very brief; conversely, when fasting, the MMC is postponed, resulting in an extended GRT. Single multiple units are advantageous due to their consistent release profile, the ability to co-administer several units, and an increased safety margin.

EVALUATION

Floating lag time (FLT), Total floating time (TFT) floating strength

For low-density system, raft-forming system

We measured the time it took to get the dosage form to buoyancy in the simulated fluid (SGF) at 37 °C, as well as the time it took for the dosage form to stay buoyant (TFT). The buoyant force is quantified with a specially engineered basket holder linked to an analytical balance. The decrease in mass on the analytical balance over time dictates the buoyant force.[3]

Gel strength

A high gel strength is favored for enhanced mechanical integrity.[4]

Viscosity and rheology

For raft-forming and mucoadhesion systems.

The viscosity of polymers influences the uniformity of the dosage form when it interacts with gastric fluid; Brookfield and Ostwald viscometers, along with texture analyzers, are frequently employed.[3]

Particle size, ion exchange capacity, moisture content

For ion-exchange resin system.

Particle size assessment has been conducted via a sieve shaker, laser diffraction, and a Colter counter analyzer. The ion exchange capacity is contingent upon the functional group present for cross-linking. The Karl Fischer method can be utilized to quantify moisture content.[3]

Swelling studies

For super porous hydrogel system, expandable system.

The examination is conducted by introducing the measured dose form into the swelling medium (0.01N HCl), followed by the assessment of weight, diameter, and length of the swelled samples at specified intervals. [3]

Stability study

The dosage-to-buoyancy ratio informed the selection of the optimal formulation for the manufactured microballoons that float. For a duration of ninety days, the



selected blend was stored in glass vessels with borosilicate screw tops, maintained at three distinct temperatures: $27\pm 2^{\circ}\text{C}$, $40\pm 2^{\circ}\text{C}$, and $5-8^{\circ}\text{C}$ under refrigeration. The samples were routinely examined for drug entrapment (drug content).[4]

In-vitro Dissolution Tests

In-vitro dissolution assessments are frequently conducted utilizing USP apparatus including a paddle, and GRDDS is consistently administered with other standard tablets. Nevertheless, when the craft is substantial and the paddles are positioned close to the bottom, the buoyant dosage form is inclined to remain on the surface owing to diminished paddle power. Neglecting to rotate the floating dosage form may result in erroneous and variable outcomes. Reproducible results have been attained by several dissolution assembly modifications. [4]

In Vitro Buoyancy Studies

The in vitro buoyancy experiments are undertaken to examine the floating property of gastroretentive formulations. Put the dosage form in a solution that mimics stomach acid (pH 1.2) and measure its floating lag time (the time it takes for the dosage form to rise to the top) and total floating duration (the time it stays buoyant) as part of these tests. An ideal floating system should have a low floating lag time and remain buoyant for a lengthy period. Buoyancy is influenced by elements such as polymer type, density, and gas producing components. These investigations are important for the prediction of the capacity of the dose form to stay in the gastrointestinal environment. [5]

In Vivo Imaging

In vivo imaging methods are employed to determine the real stomach retention and transit behavior of the GRDDS in human or animal models. X-ray imaging The incorporation of radiopaque markers (eg. barium sulfate) into the dose form can be used to visualize the location in the gastrointestinal system.[5]

CONCLUSION

Floating, mucoadhesive, swelling and raft forming formulations are some of the methods which have demonstrated a high potential in the improvement of

gastric retention and controlled medication release. To improve bioavailability and controlled administration of medications with an absorption window, gastroretentive drug delivery systems are currently being used. When treating gastrointestinal (GI) diseases or wanting to prolong the effects of a treatment with a short half-life, these dosage forms are excellent. The rate of medicine absorption varies significantly across different geographic regions. More uniform techniques of medication administration that optimize drug delivery by molecular mechanisms will be possible as our knowledge of the role of GIT physiology on drug delivery increases. More gastro-retentive pharmaceutical delivery systems will be possible as delivery technology advances, allowing for the optimization of the distribution of molecules with longer first pass metabolism, limited bioavailability, and absorption window.

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All the authors have contributed equally.

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