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A REVIEW ON FLOATING DRUG DELIVERY SYSTEM

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Background:
The oral drug delivery system is widely preferred for its convenience. Floating drug delivery systems (FDDS) offer significant advantages for drugs primarily absorbed in the upper gastrointestinal (GI) tract, such as the stomach, duodenum, and jejunum. This review explores the various types, principles, mechanisms, and polymers used in FDDS. Both natural polymers like guar gum, chitosan, xanthan gum, gellan gum, and sodium alginate, as well as synthetic ones like HPMC, Eudragit, and ethyl cellulose, are commonly employed. These polymers help in prolonging gastric retention, enhancing the absorption and efficacy of drugs. FDDS has numerous benefits, such as improved bioavailability and therapeutic effectiveness. However, they also come with some limitations, such as their complexity and potential for irregular release profiles. Furthermore, infectious diseases caused by pathogens (viruses, bacteria, protozoa) can disrupt normal body functions and complicate treatments. Raising awareness about such diseases is vital for public health. The development of advanced drug delivery systems, particularly FDDS, represents a breakthrough in pharmaceutical sciences. Research continues to identify the most effective polymers for ensuring buoyancy and optimizing drug delivery. FDDS presents a promising solution to enhance drug bioavailability and improve overall treatment outcomes, offering substantial potential in the future of pharmaceutical therapies.

Keywords: Floating matrix, Gastrointestinal, Gastroprotective, Floating drug delivery systems, Gastric retention, Classification of FDDS, Novel methodologies, Evaluation of FDDS.

Introduction

Drug delivery system represents pure crude form of the drugs either in solid, liquid or semi-solid form, which should be therapeutically efficient, safe and stable enough to deliver a required amount of the drug to the specified site in the body to reach instantly, to achieve the correct concentration and then retain the adapted concentration. Many of the drug delivery system commercialized is oral drug delivery systems [1]. Due to low treatment costs, increased patient compliance and ease of administration oral drug delivery is mostly preferred despite of the multiple benefits, the frequency of dosing of a medication should be increased as it gets easily emptied from the stomach [2]. Floating drug delivery (FDDS) a invented to retain the drug in the stomach and applicable for drugs with poor solubility and low stability in intestinal fluids, The basis behind FDDS is making the dosage form less dense than the gastric fluids to make it float on them FDDS are Hydrodynamically controlled low density systems with sufficient buoyancy to float over the gastric contents and remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time [3]. Infectious organisms are emerging day by day through various adaptations and changes which lead to burden on global, social economics, environment and ecological factor [4-5].

Gastro Retention

Gastro Retention Basic Gastrointestinal Tract Physiology The presence or absence of food in the stomach influences the gastric retention time of the system. The presence of food increases the retention time and increases the absorption of the active agent by allowing it to stay at the absorption site for a longer time. Gastro retentive drug delivery systems are a good example; they emerged to enhance the bioavailability and effectiveness of drugs with

a narrow absorption window in the upper gastrointestinal tract and/or to promote local activity in the stomach and duodenum [6].

Basic Gastrointestinal Tract Physiology

Basic Gastrointestinal Tract Physiology Basic Gastrointestinal Tract Physiology Gastric emptying occurs during fasting as well as fed states. The pattern of motility is however distinct in the 2 states. 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), which is further divided into following four phases; 1. Phase I (basal phase) lasts from 45 to 60 minutes with rare contractions. 2. Phase II (preburst phase) lasts for 30 to 45 minutes with intermittent action potential and contractions. As the phase progresses the intensity and frequency also increases gradually. 3. Phase III (burst phase) lasts for 5 to 15 minutes. It includes intense and regular contractions for short period. It is due to this wave that all the undigested material is swept out of the stomach down to the small intestine. It is also known as the housekeeper wave. International Journal of Novel Research and Development 4. Phase IV lasts for 0 to 5 minutes and occurs between phases III and I of 2 consecutive cycles. After the ingestion of a mixed meal, the pattern of contractions changes from fasted to that of fed state. This is also known as digestive motility pattern and comprises continuous contractions as in phase II of fasted state. These contractions result in reducing the size of food particles (to less than 1 mm), which are propelled toward the pylorus in a suspension form. During the fed state onset of MMC is delayed resulting in slowdown of gastric emptying rate.

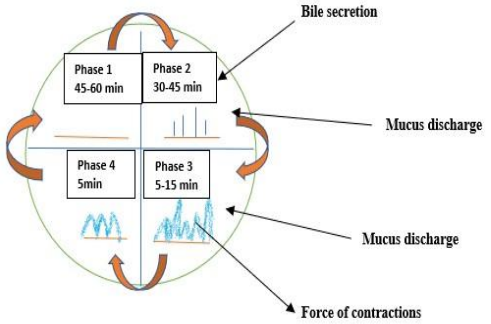

Figure 01: Motility pattern in GIT [7]

Mechanism of floating systems

Where, The drug is floating on the gastric contents (fig 2) the slow drug release is accompanied with requisite rate during the system flow on the gastric contents. The release is followed by removal of the residual system from the stomach. But, along with the appropriate level of floating force (F), minimum levels of gastric contents are needed to permit achievement of buoyancy retention principle and also to keep dosage form buoyant over meal surface.

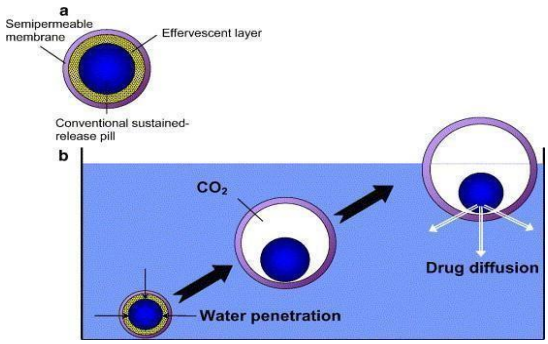

Figure 02: Mechanism of drug action in FDDS [8]

Advantages

1. Floating dosage forms such as tablets or capsules will remain in the solution for prolonged time even at the alkaline pH of the intestine.
2. FDDS shows vigorous intestinal movement and in diarrhea to keep the drug in floating condition in stomach to get a relatively better response.
3. Acidic substance like aspirin causes irritation on the stomach wall when come in contact with it hence; FDDS formulations may be useful for the administration of aspirin and other similar drugs [9].

Disadvantages

1. Floating systems are not feasible for those drugs that have solubility or stability problems in gastric fluids.
2. Drug which is well absorbed along the entire GI tract and which undergo significant first-pass metabolism, may not be suitable candidates for FDDS since the slow gastric emptying may lead to reduced systemic bioavailability. Ex: Nifedipine
3. In case of FDDS patient requires a sufficiently high level of fluids in the stomach to make the floating of drugs in stomach [10].

Classification of floating drug delivery system

1. Single Unit Floating Dosage Systems

a) Effervescent Systems (Gas-generating Systems)

b) Non-effervescent Systems

2. Multiple unit dosage form

1. Single unit floating dosage system

Single-unit dosage forms are simpler to manufacture, but because they empty completely or partially from the stomach, they run the risk of losing their effects too soon, resulting in high variability in bioavailability and local discomfort due to a large volume of drug administered at a specific location in the gastrointestinal tract [11].

(a) Effervescent Systems (Gas-generating Systems)

These are matrix forms of systems made with effervescent substances like sodium bicarbonate, citric acid, and tartaric acid, as well as swelling polymers like chitosan and methylcellulose.

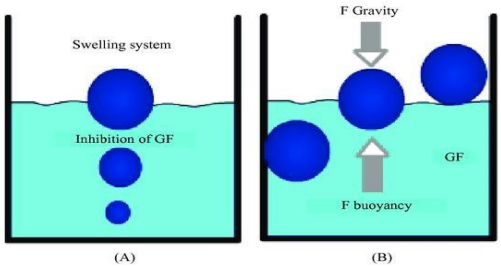

Figure 03: Effervescent systems (gas generating system) [12]

(b)Non-effervescent Systems

Polysaccharides, hydrocolloids, and matrix-forming polymers such as polyacrylate, polycarbonate, polystyrene, and polymethacrylate are used to generate a gel-forming or swelling cellulose type in non-effervescent floating dosage forms. A straight forward strategy to completely combine the medication and the hydrocolloid-forming gel is included in the formulation method. Following oral administration, this dosage form swells in contact with stomach juices and achieves a bulk density of 1. The air contained within the swelling matrix provides buoyancy to the dose form.

Multiple unit dosage form

In spite of extensive research and development in hydro dynamically balanced systems and other floating tablets, these systems has an important drawback of high variability of gastrointestinal transit time, when orally administered, because of their all-or nothing gastric emptying nature [13]. In order to overcome this problem, multiple unit floating International Journal of Novel Research and Development International Journal of Novel Research and Development (www.ijnrd.org) c335 systems were developed, which reduces the inter-subject variability in absorption and lowers the probability of dose- dumping [14].

Methods of Developing Floating Drug Delivery System

(1)Solvent evaporation technique

Solvent evaporation technique is a flexible method of particle preparation, in which various macromolecules and drugs may be employed. Parameters of emulsion obtained as first step of particle preparation are crucial in terms of particle size, drug loading, and morphology.

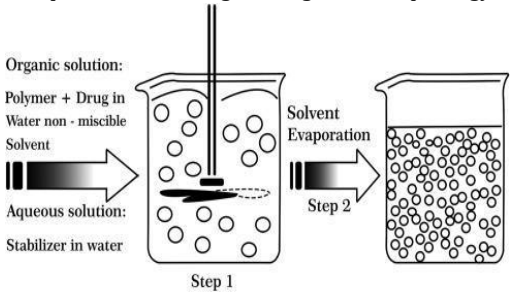

Figure 09: Solvent evaporation technique [15]

(2) Effervescent Technique:

An effervescent reaction between organic acid (citric acid) and bicarbonate salts will fill the floating chamber of the drug delivery system with inert gas (CO2). Effervescent tablets were designed to produce solutions that release carbon dioxide simultaneous

(3) Wet granulation technique:

Wet granulation involves the massing of a mix of dry primary powder particles using a granulating fluid. The fluid contains a solvent which can be removed by drying, and should be non-toxic. Typical solvents include water, ethanol and isopropanol and methylene chloride either alone or in combination. It involves wet powder massaging, milling or drying. Wet granulation shapes the granules by binding the powders together with an adhesive rather than compacting them.

9. Evaluation of Patient Information Leaflet

Patient information leaflet (PIL) was prepared in two parts Signs and symptoms and prevention and control as per the standard guidelines of WHO and tested for quality by Electronic Questionnaire for Investigations Processing (ensuring quality information for patients) method and by the Flesch Readability formula and interpretation of data was done for individual criterion and for different group of respondents FRE readability scale was used for estimation readability and complexity of PIL [16]. High response score indicates better quality and low response score indicates poor quality. There are different methods to evaluate Patient information leaflet.

10. Basic Gastrointestinal Tract Physiology

Basically stomach is divided into 3 regions: fundus, body, and antrum (pylorus). The proximal part made of fundus and body acts as a reservoir for undigested material, the antrum is the main site for mixing motions and act as a pump for gastric emptying by propelling actions (Desai, 1984). Gastric emptying occurs during fasting as well as fed states. The pattern of motility is however distinct in the 2 states [17]. During the fasting state an inter-digestive series of electrical events take place, which cycle both through stomach and intestine © 2012 Chandel et al.; licensee Saki Publishing Club.This is called the inter-digestive myloelectric cycle or migrating myloelectric cycle (MMC), which is further divided into following 4 phases as described by Wilson and Washington (Wilson and Washing ton, 1989)

Phase I (Basal Phase)

Lasts from 40 to 60 minutes with rare contractions.

Phase II (Pre-Burst Phase)

Lasts for 40 to 60 minutes with intermittent action potential and contractions. As the phase progresses the intensity and frequency also increases gradually.

Phase III (Burst Phase)

Lasts for 4 to 6 minutes. It includes intense and regular contractions for short period. It is due to this wave that all

the undigested material is swept out of the stomach down to the small intestine. It is also known as the housekeeper wave [18].

Phase IV

Lasts for 0 to 5 minutes and occur between phases III and I of 2 consecutive cycles. After the ingestion of a mixed meal, the pattern of contractions changes from fasted to that of fed state. This is also known as digestive motility pattern and comprises continuous contractions as in phase II of fasted state.

Applications of Floating Drug Delivery System

1. Improved Bioavailability-Enhances the amount of drug that enters systemic circulation effectively.
2. Enhanced Metabolism in the Liver-Increases first-pass biotransformation for better drug efficacy(19)
3. Prolonged Drug Release-Reduces dosing frequency by providing sustained delivery.
4. Targeted Treatment for Upper GIT Conditions-Focuses therapy on local ailments in the upper gastrointestinal tract.
5. Stabilized Drug Concentration-Reduces fluctuations in drug levels in the bloodstream.
6. Consistent Drug Levels-Minimizes variations in drug concentration to maintain efficacy.
7. Reduced Body's Counter-Response-Lowers the chances of the body counteracting the drug.
8. Extended Effective Concentration Time-Maintains drug levels above the minimum effective concentration for longer.
9. Minimized Side Effects in the Colon-Reduces adverse effects by controlling drug activity at the colon.
10. Precision Drug Delivery-Ensures site-specific delivery for improved therapeutic outcomes [20].

Conclusion

The development of floating drug delivery systems (FDDS) aims to prolong the gastric retention time of the dosage form and control drug release, offering a viable strategy for extended and predictable drug delivery profiles in the gastrointestinal tract. This technology provides new therapeutic options, especially for drugs absorbed primarily in the upper GI tract, such as the stomach, duodenum, and jejunum. Prolonging gastric retention extends the time available for drug absorption, improving bioavailability and reducing drug loss, as well as minimizing side effects. The use of polymeric excipients plays a crucial role in the technology of floating dosage forms, with characteristics such as significant swelling, stable gel formation, and low density ensuring gastroretention and modified release. Among the most promising approaches for achieving buoyancy in FDDS are one-component gas-forming systems, typically involving semi-synthetic and synthetic polymers like HPMC, NaCMC, carbomers, and PEO. These polymers are capable of forming matrices that retain their shape over time, erode, and maintain controlled release without collapsing due to CO_2 formation. Additionally, multicomponent systems utilizing polymers such as NA, chitosan, and pectin, or EC and polymethacrylates, offer effective buoyancy through pores or low-density matrices. Another innovative direction involves the use of 3D printing techniques, particularly extrusion-based (FDM) printing, which allows for the creation of floating delivery systems using thermoplastic polymers like HPC, PLA, PEG, PVA, and PVP. There is also growing interest in using materials previously not widely utilized in pharmacy, such as hydrophilic polymers (e.g., hyaluronic acid, albumin) or insoluble substances like polycarbonates and polypropylene.

Author Contributions

All authors are contributed equally

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Declaration of Competing Interest

The Authors have no Conflicts of Interest to Declare.

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