International Journal of Pharmaceutical Research and Applications
Volume 9, Issue 1 Jan-Feb 2024, pp: 478-490 www.ijprajournal.com ISSN: 2249-7781

Insights into NovelGastroretentive Floating Film Drug Delivery Systems: A Comprehensive Review.

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Submitted: 05-01-2024 Accepted: 15-01-2024

ABSTRACT: This review critically explores the advancements and applications of Gastroretentive Floating Film Drug Delivery Systems (GRFFDDS), aiming to elucidate their role in optimizing drug delivery through prolonged gastric retention. The study systematically investigates the need for gastroretention, delves into gastrointestinal anatomy and physiology crucial for effective drug delivery system design, and examines various factors influencing gastric retention times. A special focus is placed on the application of floating systems, particularly the innovative approach of floating film drug delivery systems. The primary purpose of this review is to provide a thorough understanding of the advantages and disadvantages of GRFFDDS, emphasizing their potential impact on targeted drug delivery, extended residence time in the stomach, improved bioavailability, and enhanced therapeutic efficacy. The paper explores the mechanism, preparation methods, and evaluation parameters of gastroretentive floating films, offering valuable insights into their design and performance.The review provides a thorough analysis of polymers in floating film formulations and explores drug release kinetics, enhancing our scientific understanding of Gastroretentive Floating Film Drug Delivery Systems (GRFFDDS). Emphasizing the potential of GRFFDDS, the study highlights their capacity to overcome drug delivery challenges, improve patient compliance, and achieve targeted therapeutic outcomes. The conclusion underscores the promising future of GRFFDDS in advancing drug delivery technologies. This review serves as a valuable resource for researchers, pharmaceutical scientists, and practitioners, consolidating current knowledge and emerging trends in the field. The findings underscore the significance of GRFFDDS in shaping the future of drug delivery and enhancing therapeutic outcomes.

KEYWORDS: Gastroretentive drug delivery system(GRDDS); Floating Film; Solvent Casting Method; Mechanism; Controlled Release.

I. INTRODUCTION

The objective of every delivery system is to promptly achieve and sustain the desired drug concentration by delivering a therapeutic dose to the appropriate location in the body [1]. Though various drug delivery systems aim to enhance the therapeutic index and minimize drug side effects, the oral route remains the preferred, dependable, and effective pathway for administering therapeutic agents[2]. Upon ingestion, drugs are absorbed from the stomach and enter the bloodstream. However, some drugs are rapidly absorbed and eliminated, necessitating frequent dosing to maintain therapeutic levels. To overcome this limitation, Controlled release drug delivery systems offer several advantages when administered orally. They provide a consistent and prolonged release of medication, reducing the need for frequent dosing. This can improve patient compliance and reduce fluctuations in drug levels, leading to more effective treatment outcomes[3]. Gastroretentive drug delivery systems (GRDDS) are designed to stay in the stomach for an extended period, ensuring controlled release of the active ingredient. This approach has evolved over the past two decades to improve gastrointestinal retention and enhance patient-friendly drug delivery, addressing issues with conventional sustained-release oral forms [4].

This review paper specifically emphasizes the floating film drug delivery system among the various approaches within the gastroretentive drug delivery system. The importance of floating film

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drug delivery systems lies in their innovative approach to pharmaceuticals, specifically in enhancing drug bioavailability and therapeutic efficacy. By developing thin films that can float on gastric fluid, these systems ensure a controlled and sustained release of drugs in the stomach. While other floating dosage forms have been extensively researched, there's a notable research gap in floating films. Their buoyancy, attributed to CO_2 microbubble generation, sets them apart within the effervescent category, offering a unique mechanism for drug delivery [5].

1.1 Need of Gastric Retention

1) Drugs that are absorbed from the upper part of the gastrointestinal tract (GIT).
2) Drugs with lower solubility in the GIT or those prone to degradation by the basic pH when administered in the lower (distal) part of the GIT.
3) Drugs that are absorbed during variable gastric emptying times. These are often used to address specific conditions requiring local or sustained drug delivery to the stomach and small intestine [6].

1.2 Importance of Gastroretentive Drug Delivery System.

Immediate release oral delivery methods are commonly used due to their targeted absorption. However, their drawbacks have led to the development of gastroretentive drug delivery systems. These systems enhance drug retention in specific gastrointestinal sites for extended periods, ensuring controlled release at precise locations such as the stomach. This strategy offers improved drug efficacy and patient benefits [7].

1.3 Gastrointestinal Tract Anatomy and Physiology

To successfully modulate the gastrointestinal (GI) transit time of a dosage form through Gastroretentive Drug Delivery Systems (GRDDS) for drug absorption in the GIT and site-specific delivery, a comprehensive understanding of the human GIT is essential. Presently, the design of Oral Drug Delivery Systems (ODDS) relies on an empirical comprehension of GIT an atomy and physiology [8].

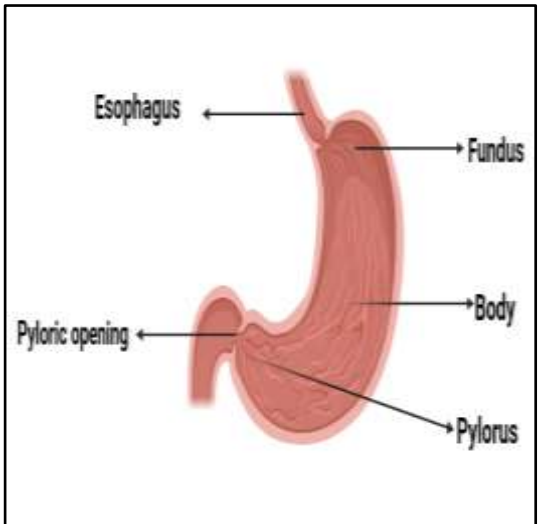

Figure 1:- Anatomy of Stomach.

The stomach is divided into three distinct regions: the fundus, body, and pylorus.
Fundus: The rounded, gas-filled area situated superior and to the left of the cardia.
Body: The large central portion of the stomach located below the fundus.
Pylorus: Positioned between the abdomen and small intestine, the pylorus is divided into the pyloric antrum, pyloric canal, and pyloric sphincter.

In a fasting state, the average pH in the fundus for a healthy individual is approximately 1.1 ± 0.15. After food intake, the pH may increase to levels between 3.0 to 4.0 due to the buffering capacity of protein. It's worth noting that gastric secretion in women is slightly lower than that in men during the fasted state[9][10].

The fundus and body act as reservoirs for undigested material, while the pylorus facilitates mixing and subsequently pumps materials for gastric emptying. Gastric emptying occurs in both fasting and fed states, each exhibiting unique characteristics.

During fasting, a person experiences a regular series of electrical events known as the migrating myoelectric cycle (MMC) or inter-digestion myoelectric cycle (IDMC). This cycle occurs approximately every two to three hours, traversing through the stomach and intestines. The MMC comprises four phases. These electrical events play a crucial role in facilitating the movement and mixing of stomach and intestinal contents, even in the absence of recent food intake [11].

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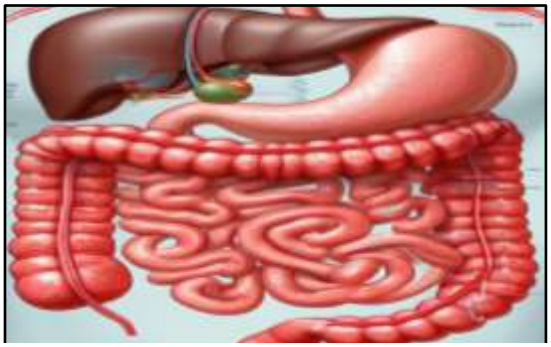

Figure 2:-Gastrointestinal Tract.

However, when an individual consumes a mixed meal, the contraction and movement pattern in the stomach and intestines undergoes a shift from the fasting state. The motility pattern associated with digestion changes, as the body now engages in the processing and digestion of the recently consumed food. This cyclic phenomenon is known as the Migrating Myoelectric Cycle (MMC)[12][13].

The Migrating myoelectric complex further classified in four phases which are explained by Sir Washington and Wilson- [14] [15]

- Phase 1- (Basic phase) last from 30-60 minutes with rare contractions.
- Phase 2- (Preburst phase) last for 20-40 minutes with intermittent action potential and contractions.
- Phase 3- (Burst phase) last for 10-20 minutes which includes intense and regular contractions for short period.
- Phase 4- last for 0-5 minutes and occurs between phase 2 and 1 of 2 consecutive cycle.

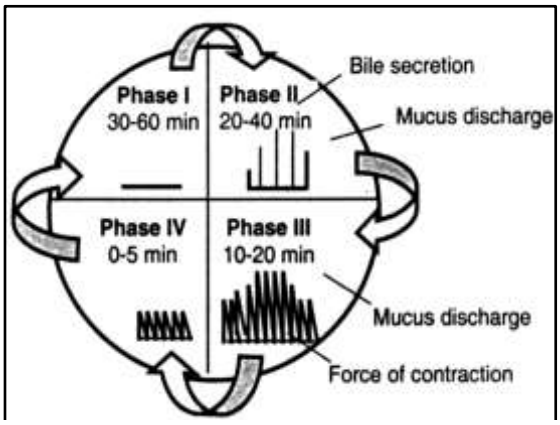

Figure 3:- Phases of Migrating Myoelectric Cycle [16]

The Migrating Myoelectric Cycle (MMC) regulates gastric motility with cyclical electrical events, crucial for continuous movement in the gastrointestinal tract. Understanding MMC is key for designing Gastroretentive Drug Delivery Systems (GRDDS) to synchronize drug release with optimal digestive phases and enhance drug retention in the stomach.

1.3.1 Factors Affecting Gastric Retention Time of the Dosage Form:

Factors influencing gastric retention time include gastric emptying rate, density, and buoyancy of the drug delivery system. Size, shape, swelling, and erosion of the system also play roles. Viscosity, gastric pH, and food interactions affect retention, while gastrointestinal motility and enzyme interactions impact drug release. Patient variability, disease states, and formulation techniques, like matrix or floating systems, contribute to the complexity. Drug properties, including solubility and stability, influence the design of gastroretentive drug delivery systems (GRDDS) [17].

1.4 There Are Various Method for Increasing Gastric Residence Time of Drug in Stomach Such as -

- Floating Systems: These systems use low-density components, including gas-generating systems, to enable the dosage form to float in gastric fluid.
- SwellingSystems: They expand or swell when in contact with gastric fluid. Their size increases significantly than that of pyloric sphincter and thus, after swelling, remain logged in the stomach.
- Bio-adhesive Systems: These systems involve the dosage form adhering to the mucosal surface, with various theories to ensure adhesion for prolonged retention.
- High-Density Systems: Dosage forms with a higher density than gastric fluid tend to remain in the distal section of the stomach.
- Super Porous Hydrogel Systems: The dosage form swells due to water uptake through porous structures using capillary wetting mechanisms.
- Raft-Forming Systems: These systems contain polymers that swell and form an in situ gel layer, floating above the gastric fluid.

These methods aim to optimize drug release and absorption within the stomach [18] [19]

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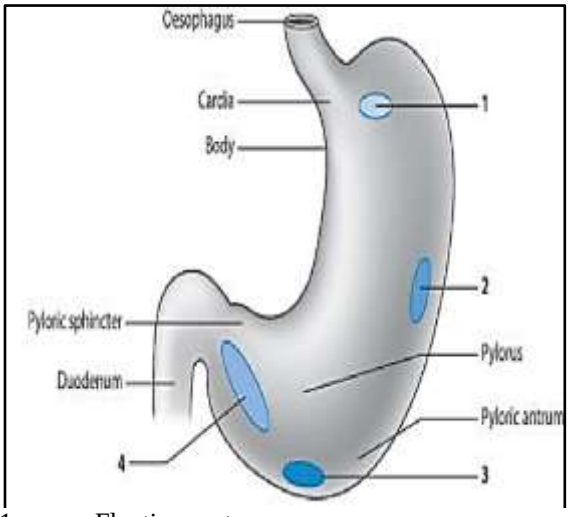

1. Floating system
2. Bio-adhesive system
3. High-density system
4. Swellable system

Figure4:- Various Approaches For Gastroretentive Drug Delivery System.

II. FLOATING DRUG DELIVERY SYSTEM

Conventional formulations aren't ideal for drugs absorbed in the upper GIT, unable to withstand gastric emptying. This limits drug release in the desired colon area, resulting in partial release and reduced dosage efficiency[20]. To overcome this limitation, floating systems are being used, Floating systems are a part of sustained-release systems that are thought to be extremely promising when the drug has an unexpected stomach emptying time and a short gastric residency period. Floating systems are especially effective when the medicine has a limited bioavailability and solubility [21].A floating drug delivery system is method that prolongs drug residence in the upper gastrointestinal tract, improving drug absorption and efficacy, either locally or systemically. It maximizes drug availability for absorption in solution [22].

Floating systems possess a density lower than that of gastric content, enabling them to persist in the stomach for an extended period without disturbing its contents. Such systems are commonly recognized as floating drug delivery systems or low-density systems [23].

Floating system contribute to increased Gastric Retention Time (GRT) and reduced fluctuations in plasma drug concentration. These systems release drugs slowly at the desired rate. Once the drug is released, the remaining system is expelled from the stomach. However, in addition to the essential gastric content required for the proper implementation of the buoyancy retention principle, a minimal level of floating force (F) is also necessary to ensure the dosage form remains consistently buoyant on the surface of the meal [24].

Among various drug delivery techniques, floating drug delivery systems are widely employed for gastro retention. Floating systems, in particular, have undergone extensive research due to their non-interference with GI tract motility. Additionally, they can be categorized as effervescent and non-effervescent systems [25].

Effervescent systems or gas-generating systems achieve floatability through the generation of gas bubbles. To achieve flotation of a medication delivery system in the stomach, a floating chamber filled with vacuum, air, or an inert gas is used. The gas can enter the chamber by volatilization of an organic solvent (such as ether or cyclopentane) or CO2 produced by an effervescent reaction between organic acids and carbonate-bicarbonate salts. The matrices are structured in such a way that when they reach the stomach, the acidity of the gastric contents releases carbon dioxide, which is trapped in the jellified hydrocolloid. This causes the dose form to rise, maintaining its buoyancy. A reduction in specific gravity permits the dose form to float on the chime[26][27].

Non-effervescent systems operate by inducing irregular expansion upon swallowing, absorbing gastric fluid and impeding its exit from the stomach. These systems, often termed plug-type systems, exhibit a tendency to remain close to the pyloric sphincter. One approach to producing such dosage forms involves blending the drug with a gel. Post oral administration, this mixture is exposed to gastric fluid, preserving the size and maintaining a bulk density less than that of the external gelatinous barrier. The trapped air within the swollen polymer contributes to the buoyancy of these dosage forms [28].

III. FLOATING FILM DRUG DELIVERY SYSTEM.

Floating film drug delivery systems are an innovative approach in the field of pharmaceuticals. These systems involve the development of thin films that can float on the surface of the gastric fluid in the stomach for an extended period. The primary goal of this technology is to enhance the bioavailability and therapeutic efficacy of drugs by ensuring a controlled and sustained release [5].

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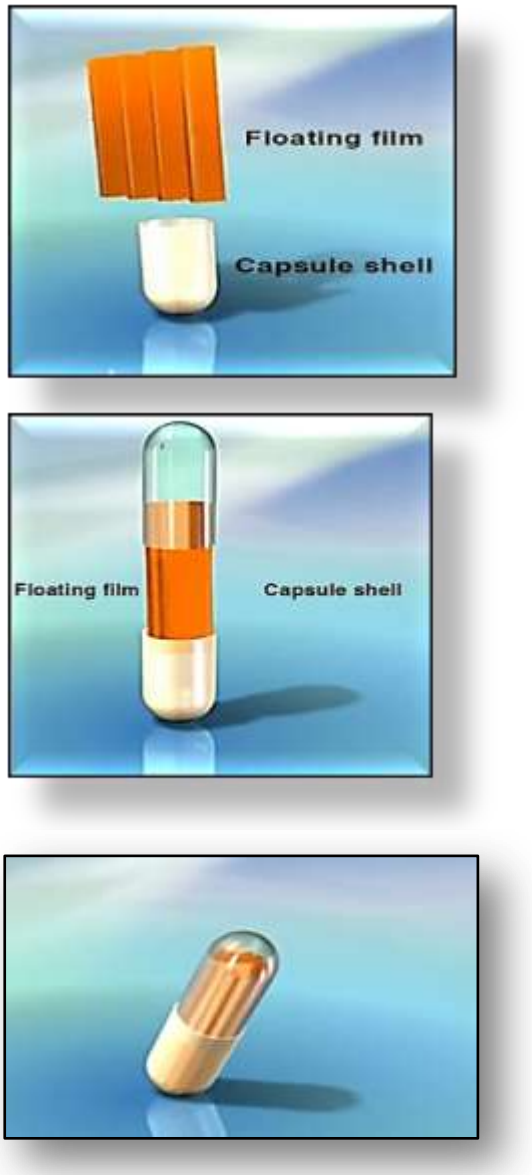

Figure 5:- Floating Film Enclosed In Capsule Shell.

Numerous researchers have extensively explored floating oral dosage forms, including tablets, capsules, microspheres, and beads. However, a gap in research on floating films has been noted. Floating dosage forms are broadly classified into two main categories: effervescent and non-effervescent, as discussed earlier. Now, focusing on floating films, they fall within the effervescent category. The buoyancy of these films is intricately linked to the generation of CO_2 micro bubbles within the film matrix. This unique mechanism distinguishes floating films from their counterparts in the realm of floating dosage forms[29].

Floating film drug delivery systems offer a contemporary alternative to conventional dosage forms like tablets, capsules, and liquid orals. An oral delivery method frequently employed involves embedding a drug-loaded thin film strip inside a capsule. The perks of opting for floating films are numerous: the preparation process is straightforward, it saves time, proves cost-effective, and carries a reduced risk of cross-contamination. Moreover, these films are easier to handle compared to microspheres, adding a layer of convenience to the drug delivery process[30].

A floating film serves as a carrier for medication, prepared from a blend of active pharmaceutical ingredients, polymers, a film-forming agent, plasticizer, and a solvent. The manufacturing process involves the solvent casting method. In this method, the drug and polymer are mixed with an appropriate amount of solvent, additional ingredients are introduced as needed, the mixture is then poured into a petri plate, and the drying process follows to produce a thin, smooth film layer. This method ensures the effective delivery of drugs [31].

Combining the concept of floating with the ability to expand by unfolding and swelling using a blend of biodegradable polymers (both hydrophilic and hydrophobic) offers a unique strategy to prolong the time a drug stays in the stomach. This involves a capsule that dissolves after ingestion, releasing a film which is folded and placed inside a capsule. The film then unfolds and swells, typically through the osmotic absorption of gastric fluid [32].

The key advantage of this approach lies in the convenience of using hard gelatin capsules. However, there are challenges in designing the polymeric film to control drug release. Selecting the right polymer with the desired unfolding and expanding capabilities in the stomach poses a challenge, as does the complexity of formulating a drug-loaded polymeric film. Addressing these issues is crucial for the successful development of this type of dosage form [33].

3.1 Need of Gastroretentive Floating Film Drug Delivery System [34] [35]

- Floating films enable site-specific drug release, crucial for drugs with specific gastrointestinal absorption sites.
- Floating films prevent degradation in the stomach, optimizing absorption for acid-sensitive drugs.

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- Easy-to-swallow floating films enhance patient comfort and adherence.
- Floating films address gastric emptying variability, ensuring consistent drug absorption in diverse populations.
- Prolonged residence time aids absorption of high molecular weight drugs with slower uptake.
- Floating films protect drugs in the gastrointestinal tract, preserving stability until controlled release.
- Controlled release minimizes variability in drug concentrations among patients and within individuals.
- Floating films allow incorporation of multiple drugs, streamlining complex treatment regimens.
- Floating films address limitations of non-site specificity in traditional oral drug delivery.
- Pharmaceutical emphasis on site-specific drugs drives the need for customizable floating film formulations.
- Easy swallowing and reduced discomfort make floating films an attractive option for patients.
- Localized drug action ensures consistent therapeutic effects where needed in the gastrointestinal tract.
- Tailored release for drugs at specific sites enhances absorption and therapeutic efficacy.
- Prolonged drug release reduces dosing frequency, improving patient compliance and convenience.
- Floating films enable precise drug action at targeted sites.
- Floating films release drugs where absorption is most effective, optimizing therapeutic outcomes.

3.2 Advantages of Gastroretentive Floating Film Drug Delivery System[36] [37]

- Targeted Drug Delivery:

Floating films enable precise drug delivery to the small intestine, ideal for drugs with a narrow absorption window in this region.

- Extended Residence Time in the Stomach:

Floating films are designed to float on gastric fluid, ensuring prolonged contact with the stomach lining, leading to sustained therapeutic effects. Extended stomach residence time is advantageous for drugs requiring local action in the upper part of the small intestine.

- Improved Bioavailability:

Floating films enhance bioavailability by prolonging the drug's presence in the stomach, leading to improved therapeutic outcomes.

- Improved Patient Compliance:

Simplified dosing regimens and reduced frequency of dosing in floating film systems contribute to improved patient compliance.

- Improved Therapeutic Efficacy:

Enhanced bioavailability and controlled drug release result in improved therapeutic efficacy for drugs delivered through floating films.

- Reduces Frequency of Dosing:

Prolonged drug release allows for less frequent dosing, enhancing patient convenience and adherence to the prescribed therapy.

- Targeted Therapy for Upper GI Tract:

Floating films can be designed to release drugs specifically in the stomach, allowing targeted therapy for local action in the upper gastrointestinal tract.

- Reduced Side Effects:

Controlled and sustained drug release minimizes fluctuations in drug plasma levels, reducing side effects associated with abrupt peaks and troughs in concentration.

- Minimized Fluctuations in Plasma Drug Concentration:

Controlled drug release minimizes fluctuations in plasma concentration, reducing concentration-dependent adverse effects, crucial for drugs with narrow therapeutic indices.

- Complete Absorption of Drugs:

Floating film drug delivery systems ensure complete drug absorption from the dosage form.

- Site-independent Efficacy:

The sustained release principles of floating formulations provide consistent efficacy regardless of the specific site of action of the drug.

3.3 Disadvantages of Gastroretentive Floating Film Drug Delivery System.[38] [39]

- Inadequate fluid volume can hinder proper floating, affecting drug release.
- Not suitable for drugs causing stomach irritation or having solubility issues.
- Timing is crucial; administering before bedtime may lead to premature drug release.
- Floating systems may not be suitable for drugs with bioavailability concerns, especially those undergoing first-pass metabolism.

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- The need for a sufficient fluid volume may require specific administration conditions, such as taking the dosage form with a glass of water or using bioadhesive coatings.
- Issues with fluid stability and solubility can result in inadequate drug release and compromised therapeutic outcomes.

3.4 Application of Gastroretentive Floating Film Drug Delivery System. [40]

- Enhanced Bioavailability: Floating film drug delivery systems optimize drug absorption, particularly beneficial for medications with low bioavailability.
- Sustained Drug Delivery: These systems ensure prolonged release, maintaining steady therapeutic levels and reducing the need for frequent dosing.
- Site-Specific Drug Delivery: Tailored for drugs absorbed in the stomach or proximal small intestine, minimizing systemic exposure and potential side effects.
- Absorption Enhancement: Addressing poor bioavailability by precisely targeting specific absorption sites in the upper gastrointestinal tract.
- Decreased Adverse Activity at the Colon: By preventing drug exposure in the colon, these systems minimize adverse effects and the risk of resistance development.
- Reduced Fluctuations of Drug Concentration: Minimizing concentration fluctuations ensures a consistent blood level, crucial for drugs with a narrow therapeutic index.
- Future Perspective of GRFDDS: Ongoing research explores combined mechanisms for further optimization, especially focusing on drugs absorbed in the upper gastrointestinal tract.

IV. POLYMERS USED IN FLOATING FILM DRUG DELIVERY SYSTEM [41] [42]

In floating film drug delivery systems, various polymers are commonly used. Some examples include:-

- Cellulose Ethers:
- Hydroxypropyl methylcellulose (HPMC)
- Hydroxypropyl cellulose (HPC)
- Hydroxyethyl cellulose (HEC)
- Methylcellulose (MC)
- Methylhydroxyethylcellulose
- Ethylcellulose
- Sodium carboxymethylcellulose (sodium cmc)
- Vinyl Derivatives:
- Polyvinyl pyrrolidone (PVP)
- Polyvinyl alcohol (PVA)
- Glycols:
- Polyvinyl alcohol-polyethylene glycol copolymers
- Polyethylene glycols
- Acrylic Polymers:
- Methacrylate aminoester copolymer
- Ethylacrylate-methylmethacrylate copolymer

V. METHOD OF PREPARATIONOF FLOATING FILM.[43][44]

Gastroretentive floating films can be produced using diverse methods, including solvent casting, rolling, hot-melt extrusion, semisolid casting, and solid dispersion extrusion. Solvent casting method is most preferred method among these methods for the preparation of gastroretentive floating film.

Preparation of floating film by using solvent casting method

1. Ingredients Preparation:
- Weigh the desired amounts of the drug (active ingredient) and polymer.
- Select suitable solvents for dissolving the drug and polymer.
2. Drug Solution Preparation:
- Dissolve the active ingredient (drug) in a suitable solvent to create a homogeneous drug solution.
3. Polymer Solution Preparation:
- Dissolve a polymer in a chosen solvent to create a polymer solution. Adjust polymer concentration based on desired film properties.

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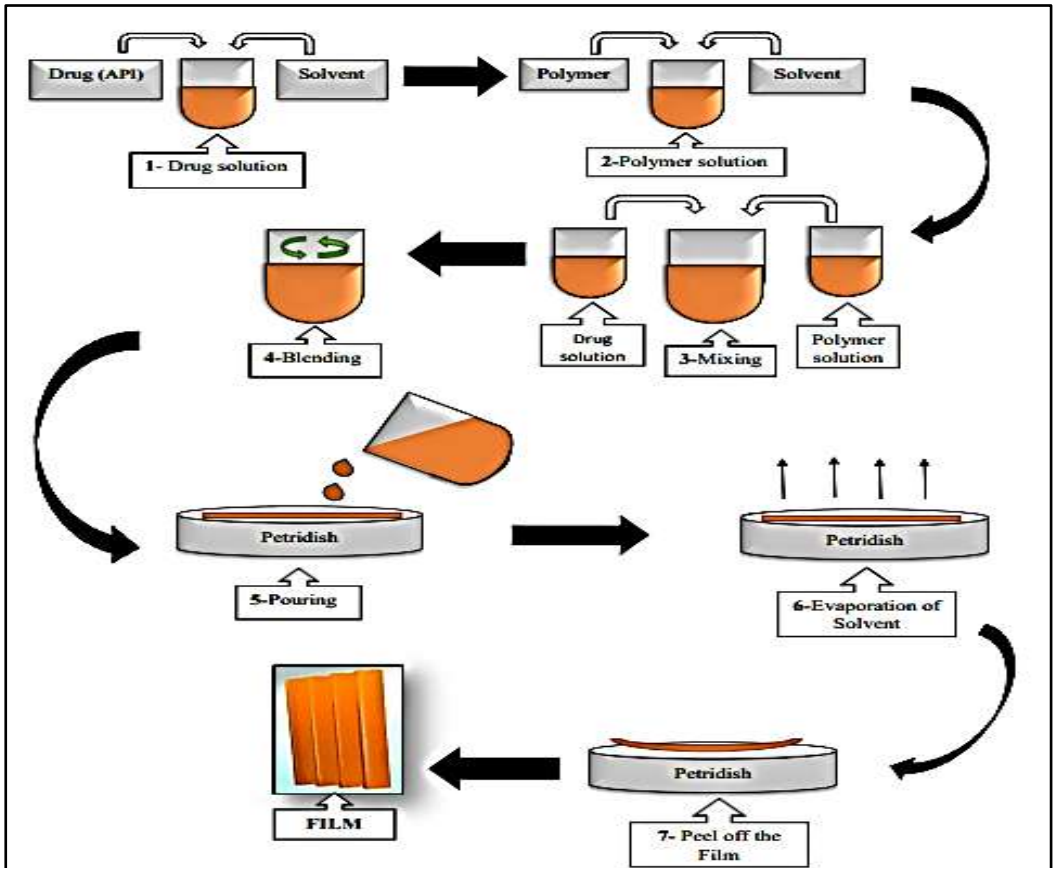

Figure 6:- Method of Preparation

4. Blend Drug Solution with Polymer Solution:
- Combine the drug solution with the polymer solution, ensuring thorough mixing for a uniform drug-polymer mixture.
5. Casting:
- Spread the combined drug-polymer solution onto a substrate or mold.
- Pour the mixture into a clean petri dish, maintaining a controlled environment for consistency.
6. Solvent Evaporation:
- Allow the solvent from both the drug and polymer solutions to evaporate.
- Control the drying process to achieve a uniform film thickness.
7. Film Formation:
- As the solvent evaporates, polymer chains and drug molecules arrange to form a solid film on the substrate.
- Film properties are influenced by factors such as drug concentration, polymer type, and casting conditions.
8. Film Removal
- After drying, carefully remove the films from the petri dish using a sharp blade.

VI. MECHANISM OF GATRORETENTIVE FLOATING FILM DRUG DELIVERY SYSTEM [45] [46]

The working principle of the floating film drug delivery system hinges on the utilization of hard gelatin capsules containing an unfolding type formulation. Initially, the hard gelatin capsule serves as a carrier for this specialized formulation. When the capsule comes into contact with gastric acid in the stomach, it dissolves, facilitating the release of the unfolding type formulation. Within this formulation, a film unfolds, achieving an expanded configuration. Crucially, the carrier is designed to maintain these unfolded properties for an extended duration. As the system interacts with gastric media, it undergoes swelling and forms a colloidal gel barrier. This gel barrier, formed by the swollen polymer within the formulation, absorbs air, thereby reducing the density of the system. This reduction in density imparts buoyancy to the

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dosage form, causing it to float on the gastric fluid. Following ingestion, these formulations remain localized in the gastric region, releasing the drug in a sustained and prolonged manner. This design ensures a continuous drug supply to the upper gastrointestinal tract absorption site, contributing to enhanced therapeutic outcomes.

VII. EVALUATION OF GATRORETENTIVE FLOATING FILM DRUG DELIVERY SYSTEM. [47-54]

1. Fourier transform infrared spectroscopic study (FTIR):

To investigate the interaction between the drug and polymers, Fourier transform infrared spectroscopy (FTIR) was employed. IR spectra of Furosemide, a physical mixture of Furosemide with polymers, and the film were obtained using the KBr disk method. The spectra were scanned in the range of 400 to 4000 cm-1 with a resolution of 1 cm-1. This analytical approach allowed for the examination of molecular interactions and structural changes in the components, shedding light on the compatibility of the drug with the polymers in the film.

2. Differential Scanning Calorimetric (DSC) study:

To explore potential interactions between Furosemide and the polymers employed in the Floating Film formulation, we conducted a Differential Scanning Calorimetric (DSC) study. This involved analyzing the thermal characteristics of the pure drug, a physical mixture of the polymers and Furosemide, and the film itself. The thermal behavior of the film was investigated using a DSC 30S instrument from Mettler Toledo India Pvt. Ltd., Switzerland, with a heating rate of 100°C/min. Measurements were carried out within a heating range of 40 to 280°C under nitrogen atmospheres. This approach allowed us to identify any thermal changes and assess the compatibility of the drug with the selected polymers in the film.

3. Thickness:

To ensure the consistency of the polymeric film thickness, a micrometer screw gauge was employed to measure thickness at various points. This step was essential in verifying the uniformity of the film thickness.

4. Weight uniformity:

To assess weight uniformity, three films were randomly chosen from each batch and individually weighed using a digital balance. The outcomes were then scrutinized for mean weight and standard deviation.

5. Folding endurance:

To evaluate folding endurance, a strip of a specific area was consistently and repeatedly folded at the same location until it reached the point of breaking. The folding endurance value is determined by the number of times the film can be folded at the same spot without breaking. This measurement provides insights into the film's toughness, with a lower folding endurance value indicating greater brittleness

6. In vitro unfolding study:

In the in vitro unfolding study, the prepared polymeric film is folded in two different ways, either in a rolling or zigzag manner, and then inserted into capsules. This is done to investigate how well the films, containing Furosemide, can stretch back or unfold when the gelatin capsule disintegrates in the stomach. To assess the unfolding properties, a USP dissolution apparatus II (paddle) is used, rotating at 50 rpm in a 900 ml 0.1 N HCl solution at 37 ± 0.5°C. The films are regularly examined for their unfolding behavior at specific intervals during this process. This study helps evaluate the film's ability to return to its original state when exposed to stomach conditions.

7. In vitro buoyancy studies:

To study how well the capsules float, we followed Rosa's approach for in vitro buoyancy studies. The capsules were placed in a beaker with 250 ml of 0.1N HCl and stirred consistently at 50 rpm. By visually observing the floating duration and expansion of the film, we recorded the behavior to understand how long the film stays afloat under these conditions.

8. Drug content:

To determine drug content, the film is cut into pieces and immersed in a 100 ml solution of 0.1N NaOH for complete drug extraction. The solution is continuously stirred using a mechanical stirrer, and a sample is withdrawn after a specific period. This sample is then diluted with 0.1N NaOH solution, and the drug content is measured spectrophotometrically at 271 nm.

9. **Swelling index:**

To determine the swelling index, start by recording the initial weight of the film as W1. Then, immerse

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the film in a 0.1N HCl solution at a temperature of 37 ± 1°C for 360 minutes and weigh it again (W2). Calculate the swelling index using the formula: Swelling index (%) = ((W2 - W1) / W1) x 100. This formula helps quantify the percentage increase in weight due to the film's swelling in the specified solution.

10. Moisture content:

To determine moisture content, the individually weighed prepared films are placed in a desiccator with calcium chloride at room temperature for 24 hours. The films are then periodically reweighed until a constant weight is achieved. Calculate the percent moisture content using the formula: % Moisture content = [(Initial weight – Final weight) / Final weight] x 100. This formula helps quantify the percentage change in weight due to moisture absorption by the films during the process.

11. In vitro drug release:

For the in vitro drug release study, we utilized the USP paddle apparatus and a double beam UV spectrophotometer (Jasco V-530, Shimadzu Corporation, Japan) at a constant temperature of 37±0.5°C and 50 rpm. The dissolution medium was 900 mL of acidic buffer (pH 1.2). Capsules containing folded films were positioned in the dissolution vessel. At predetermined intervals, 5 mL of sample solution was withdrawn, appropriately diluted, and its absorbance recorded at 274 nm using the UV spectrophotometer. To maintain consistency, an equal volume of fresh dissolution medium was promptly replenished after each sample withdrawal. The percentage of dissolved drug was calculated using PCP disso V3 software, providing insights into the in vitro release profile over time.

VIII. CONCLUSION

In summary, the exploration of floating film drug delivery systems underscores their pivotal role in revolutionizing drug administration. This comprehensive review navigates through the intricate design principles, mechanisms, and evaluations of these systems, emphasizing their potential to enhance drug bioavailability and therapeutic outcomes. By addressing challenges and highlighting advantages such as targeted delivery, extended residence time, and improved patient compliance, the paper contributes to a nuanced understanding of gastroretentive drug delivery. As pharmaceutical research evolves, floating film formulations emerge as promising contenders, offering a contemporary and patient-friendly approach to drug delivery in the upper gastrointestinal tract.

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