A REVIEW ON GASTRO RETENTIVE FLOATING UNFOLDING FILM: A NOVEL APPROACH IN ORAL DRUG DELIVERY TECHNOLOGY

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ABSTRACT

Gastro retentive floating unfolding film systems offer an innovative approach for controlled drug delivery, designed to prolong the duration that drugs stay in the stomach and improve the bioavailability of orally administered medications. This review provides a comprehensive analysis of the formulation methods, mechanisms of floating and unfolding, and polymers commonly employed in the development of these systems. The advantages of unfolded films are emphasized, including their compact size during administration and expanded surface area in the stomach, which contribute to extended gastric retention and sustained drug release. This review also discusses challenges, such as mechanical strength, unfolding kinetics, and patient compliance. Future research should focus on optimizing material selection and exploring new drug candidates to enhance therapeutic efficacy. This review provides detailed insights into the potential of gastro-retentive floating unfolding films as a promising platform for targeted and controlled oral drug delivery. [1][2][3]

Keywords: Gastro retentive, Floating, Controlled drug delivery, Unfolding, Polymers, Bioavailability, Oral drug delivery

INTRODUCTION

Gastro retentive drug delivery systems (GRDDS) extends gastric residence time has attracted a lot of interest because it improves the bioavailability and therapeutic efficacy of medications that are mostly absorbed in the stomach and upper small intestine or have limited absorption windows. GRDDS can be developed using various methods, including floating, mucoadhesive, high-density, magnetic, and expandable systems, and occasionally a combination of these methods is employed. Floating unfolding film systems have emerged as a promising platform among various gastroretentive techniques. In particular, unfolding systems are designed to float for extended periods of time in gastrointestinal contents. [4][5]

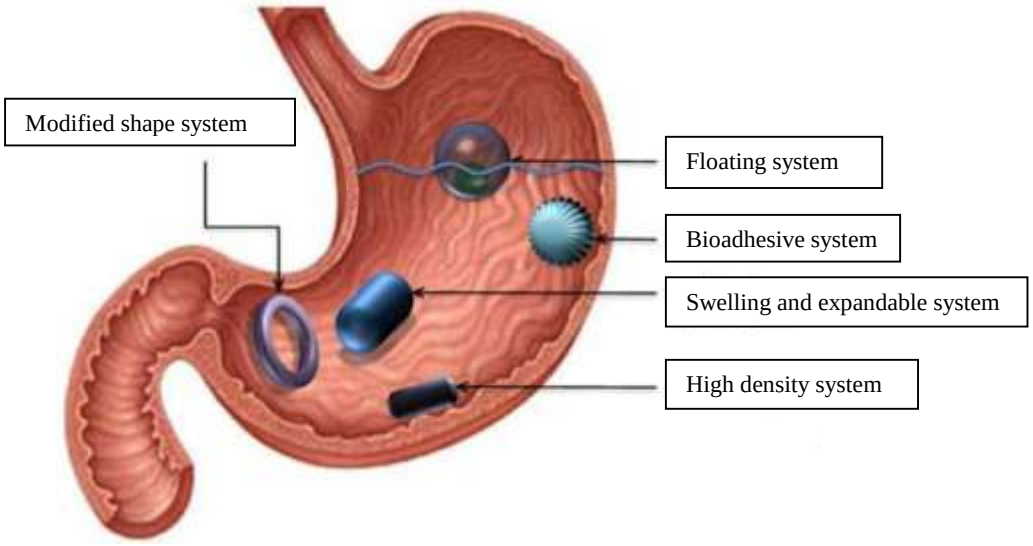

Fig.1 Approaches for developing gastroretentive systems [1]

They overcome the drawbacks of traditional dosage forms, such as rapid gastric emptying and inadequate site-specific drug release, by combining the mechanisms of expansion and flotation to remain attached to the gastrointestinal environment. [6] This allows for a steady and controlled drug release over time. The compact form of floating unfolding films is intended to unfold when they come into contact with stomach juices, greatly expanding their surface area and delaying their passage through the pylorus. [7] By facilitating simple swallowing and reducing dosage frequency, this dual mechanism not only promotes sustained medication release but also enhances patient compliance with the treatment. To balance the mechanical strength, swelling capacity, and controlled drug release kinetics, these systems must be carefully formulated using polymers and excipients. Floating unfolding film systems have the benefit of prolonged gastric retention, which makes them especially useful for medications that need to work locally in the stomach or upper gastrointestinal tract or that are unstable or poorly soluble in alkaline environments but stable at gastric pH. To maintain consistent medication delivery performance, these devices are designed to accommodate physiological fluctuations within the gastrointestinal environment. [8]

ADVANTAGES OF GASTRORETENTIVE FLOATING UNFOLDING FILM [9][10][11][12]

1. Extended Gastric Retention Time (GRT):
The film is larger than the pyloric sphincter (≈12–18 mm) after it unfolds. When combined with a low density, it floats in the stomach for 6–12 h. This benefits medications such as levodopa, acarbose, and tizanidine, which have limited absorption windows.

2. Enhanced Bioavailability:
Drugs that are mostly absorbed in the stomach or upper small intestine exhibit higher absorption because they remain at the absorption site for a longer duration, prevents early intestinal evacuation.

3. Sustained and Regulated Drug Release:
Long-term medication release can be achieved by designing a film matrix. Maintains constant plasma levels, thereby minimizing adverse effects.

4. Lowering the Frequency of Doses:
The dosage may be lowered to once daily because of prolonged retention and extended-release. Increases patient adherence, particularly to long-term treatments.

5. Reduces Dose Dumping:
The unfolding mechanism prevents abrupt entry into the gut. Floating prevents sinking and rapid emptying. This dual retention decreases the likelihood of rapid drug release.

6. Simple to Consume:
Films are easier to swallow when folded or rolled in capsule because they are thin, flexible, and compact. Both young and elderly populations can benefit from this.

7. Suitable for Substances with Stability Problems:
Longer gastric residence times are beneficial for drugs that are stable in the acidic stomach but unstable in the alkaline intestine.

8. Diminished Local Discomfort:
Slow and regulated drug release avoids high local concentrations in the gastric mucosa. This is beneficial for medications such as muscle relaxants and NSAIDs.

9. Adaptable Structure System:
Includes hydrophilic polymers (PVA, HPMC), naturally degrading polymers, NaHCO3-based effervescent agents, and lipophilic polymers for bilayer films.

DISADVANTAGES OF GASTRORETENTIVE FLOATING UNFOLDING FILM [13][14]

1. Not appropriate for all medications:
High-dose medications, medications requiring quick action, and medications that are unstable at acidic pH cannot be utilized.

2. Formulation complexity:
Complexity increases the likelihood of failure because it requires unique polymers, accurate manufacturing, and folding patterns.

3. Floating may be delayed:
Floating may be delayed if there is little stomach fluid or slow effervescence.

4. Moisture-sensitive:
When films are exposed to dampness, they may lose their mechanical strength or folding ability.

5. Limited drug loading:
The use of thin films for high-dose molecules is limited because they can only carry small amounts of medicine.

MECHANISM OF ACTION [15][16]

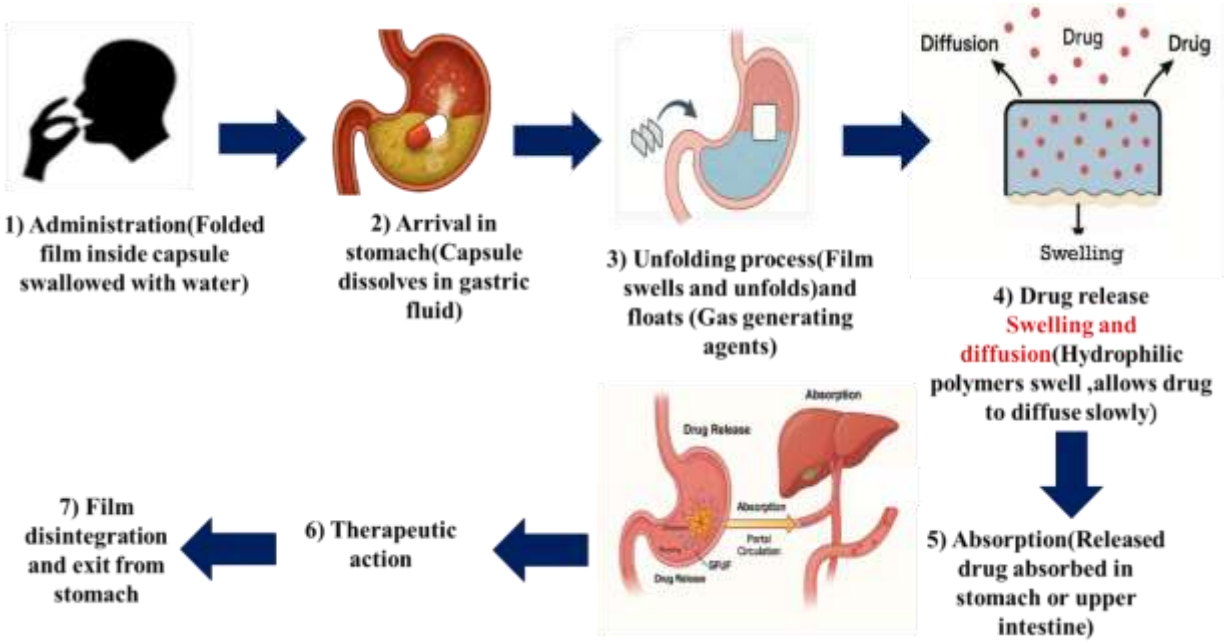

Fig.2 Mechanism of gastroretentive floating unfolding film

The operation of the floating film drug delivery system is based on the use of hard gelatin capsules with an unfolding formulation. This specific composition is first transported by a hard gelatin capsule. The capsule dissolves when it comes into contact with the gastric acid of the stomach, allowing the unfolding-type formulation to be released. A film was developed using this formulation, resulting in an enlarged structure. Importantly, the carrier is designed to maintain these unfolded characteristics over an extended period. The system swells and creates a colloidal gel barrier upon contact with the gastric media. This gel barrier, created by the swelling polymer of the formulation, absorbs air and lowers the density of the system. This change in density provides dose form buoyancy, allowing it to float on gastric juice. Following consumption, these formulations remain localized in the gastrointestinal tract, allowing the medicine to be released gradually and consistently. This design ensures continuous medication delivery to the upper gastrointestinal tract, contributing to better therapeutic results.

POLYMERS AND OTHER COMPONENTS USED IN GASTRORETENTIVE FLOATING UNFOLDING FILM

The choice of polymer is critical for achieving the necessary mechanical strength, flexibility, buoyancy, and controlled drug release in these systems.

1. Main Polymers Utilized

1.1 Cellulose Derivatives:

Hydroxypropyl methylcellulose (HPMC) (E5, E15, E50, K4M, K15M, K100M) and ethyl cellulose (EC) are widely used for their film-forming ability, swelling properties, and control over drug release. HPMC provides hydration and diffusion, whereas EC adds mechanical strength and modulates the release rate. Sodium Carboxymethyl Cellulose was used to moderately slow the release through swelling. Hydroxyethyl cellulose and methyl cellulose were used to support sustained release. [17][18][19][20][21][22][23]

1.2 Acrylic Polymers:
Eudragit variants (RS100, RLPO, RSPO, and NE) are popular for their flexibility, permeability, and ability to sustain drug release. They are often combined with plasticizers like PEG 400 or dibutyl phthalate to enhance film properties. [21][24][25]

1.3 Natural Polymers:
Sodium alginate, pectin, chitosan, guar gum and xanthan gum are valued for their biocompatibility, mucoadhesive properties, and ability to form gels or dense matrices, supporting both floating and unfolding mechanisms. [23][26][27][28]

1.4 Other Polymers:
Polyvinylpyrrolidone (PVP K90), carbopol, and polyethylene oxide, polyvinyl acetate, sodium polyacrylates are also used to adjust film flexibility, swelling. [8][24][26][27]

2. Other components utilized in formulating Gastroretentive floating unfolding film

2.1 Plasticizers:
PEG 400 or 600, Dibutyl phthalate, Glycerol. Plasticizers are essential for film flexibility and durability, especially in bilayer or unfolding systems. [18][24]

2.2 Gas-generating agents:
Sodium bicarbonate, citric acid, and tartaric acid are critical for rapid buoyancy and unfolding and are often used in combination for effervescence. [18][29][32][33]

2.3 Anti-adhesive agents:
MCC, Starch, Talc, Magnesium stearate, sodium bicarbonate, and citric acid prevent the film from sticking to itself, ensuring proper unfolding in the gastric environment. [29]

2.4 Solvent:
The choice of solvent affects the polymer dissolution, film uniformity, drug distribution, and final mechanical properties of the film. Ethanol is the most frequently used solvent for dissolving a wide range of polymers, especially in solvent casting and evaporation methods for unfolding films. Chloroform, methanol, and DCM are preferred for hydrophobic polymers such as ethyl cellulose and Eudragit, often used in combination to optimize solubility and film properties. Water is essential for hydrophilic polymers and is sometimes mixed with alcohol to enhance dissolution and film uniformity. [30][31]

METHODS OF PREPARATION

1. Solvent Casting Method:
Typically used for unfolding films and bilayer systems. Polymers (e.g., HPMC, ethyl cellulose, Eudragit, sodium alginate) and drugs are dissolved in an appropriate solvent, cast into molds, and dried to form films. Plasticizers, such as PEG 400 or DBP, are used to improve flexibility and fold endurance. Films are frequently folded and enclosed in hard gelatin capsules for oral administration, which unfold upon exposure to gastrointestinal juices. [18][19][20][24][30][34]

2. Solid dispersion method:
Drugs and polymers are co-dissolved or dispersed, and then cast and dried to form films with improved drug dispersion and release properties. [20]

3. Hot-melt extrusion:
A solvent-free technique. The drug and polymer are heated and combined in an extruder. The extrudate is flattened and formed into a film. Folding memory and flexibility are engineered during formulation. [22]

4. Semisolid casting:
This method is used when the polymer is heat-sensitive. A solvent is used to combine the polymer and drug, which are then heated until they become semisolid. Then formed semisolid solution is spread onto a casting plate. Drying produced a homogeneous film. Cut, fold, and fill the capsules. [35]

5. Rolling method:
The drug and polymer are mixed with the solvent and plasticizer to form a viscous solution. The mixture is spread evenly on a moving belt using a roller or blade. The film is dried to remove the solvent and solidify. The film is then cut, folded, and filled into capsules. This method ensures uniform thickness and good mechanical strength and is suitable for large-scale production. [35]

EVALUATION [30][36][37][38][39]

The evaluation of gastroretentive floating unfolding films (GFUF) is essential to ensure their quality, efficacy, safety, and desired gastroretentive behavior. The evaluation involves a series of physicochemical, mechanical, in vitro, and in vivo tests.

1. Physical Appearance:
Visual inspection of color, uniformity, and surface defects. Ensures visual quality, absence of cracks, and air bubbles.

2. Thickness:
The measurement is performed using a micrometer screw gauge. This confirms the uniformity of the film thickness.

3. Weight Variation:
Weighing individual film units using a digital balance. It checks the consistency of the film mass and dosage.

4. Drug Content Uniformity:
The film is crushed and placed in a solvent, and the solution is shaken for 24 h. The solution is then filtered, and the samples were analyzed for drug content using a UV spectrophotometer. This ensures accurate and uniform drug distribution.

5. Folding Endurance:
Assessed manually by repeated folding at one point until break. It tests the mechanical strength and flexibility.

6. In Vitro Buoyancy Test:
Film is placed in Simulated Gastric Fluid (SGF, pH 1.2), and the lag time and duration of floating are observed. This verifies the gastric flotation property.

7. Unfolding Behavior:
In the SGF using a dissolution apparatus, the time for the film to unfold from the folded state is measured. This ensures that the film unfolds to prevent premature gastric exit.

8. Swelling Index:

The film swelling behavior can be examined using gravimetric analysis. It indicates matrix hydration and drug release control.The weight of the sample to be tested in the dry form (W1) and sample immersed in buffer removed at various time intervals and its weight recorded as (W2). The following equation for calculation,

$$Swelling\ index(\%)=(W2-W1)/W1\times100$$

9. Tensile Strength and percent elongation at break:
Measured using a tensile testing machine (texture analyzer). It evaluates the film's resistance to stress. Tensile strength and % elongation values can be calculated using the following equations,

Tensile strength=force at break/cross sectional area of the sample

%Elongation at break=Increase in length/Original length×100

10. In Vitro Drug Release:
An in vitro drug release study is carried out using the USP dissolution apparatus in the SGF over time. It assesses sustained or controlled drug release.

11. Kinetic release study:
The data obtained from the drug release investigation are subjected to various kinetic drug models for analysis using different software.

12. In Vivo Retention Study:
Animal studies are conducted to confirm gastric retention and film behavior in vivo.

13. Surface Morphology:
Scanning Electron Microscopy(SEM) is used to assess the film smoothness, porosity, and structural integrity.

14. Stability Studies:
ICH-guided testing is performed under varied temperatures and humidities. Determines shelf life and storage requirements.

APPLICATIONS

1. Chronic Disease Management:
Provides controlled release and improved bioavailability for drugs, including metformin (diabetes), gliclazide (diabetes), and carvedilol(hypertension). [40][41]

2. Drugs with Narrow Absorption Windows:
Itopride hydrochloride, riboflavin, cinnarizine, and baclofen all benefit from longer plasma levels and enhanced absorption. [19][24][30][41]

3. Obesity Therapy:
Films containing hydroxycitric acid obtained from Garcinia extract have shown efficiency in decreasing lipid accumulation and delivering long-lasting anti-obesity benefits. [31]

4. Gastrointestinal Disorders:
Treatment of H. pylori infection using antibiotics like amoxicillin and clarithromycin, as well as anti-ulcer drugs like lafutidine. [18][40]

5. Neurological Disorders:
Long-term stomach retention boosts the effectiveness of gabapentin for neuropathic pain and pramipexole for Parkinson's disease. [40][42]

6. Advanced and Personalized Therapies:
3D Printing Applications - Customizable floating unfolding films can be manufactured for patient-specific dose and release profiles, thereby expanding their utility in personalized medicine. [8][43][44]

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