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Review Article

Review on Gastroretentive Systems for Olmesartan Medoxomil

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ABSTRACT

Olmesartan Medoxomil, an angiotensin receptor blocker, is widely used to treat hypertension and cardiovascular diseases but suffers from low bioavailability, short half-life, and frequent dosing requirements. Gastroretentive drug delivery systems (GRDDS) offer a promising solution by prolonging gastric residence, improving solubility, and enhancing absorption. This review explores various GRDDS strategies suitable for Olmesartan Medoxomil, including floating, swelling, mucoadhesive, high-density, and magnetic systems. It discusses the polymers and excipients involved, such as hydrophilic polymers (HPMC, sodium alginate), hydrophobic polymers (ethyl cellulose), gas-generating agents, and density enhancers. Mechanisms like buoyancy, swelling, mucoadhesion, sedimentation, and magnetic localization are elaborated to explain their role in enhancing retention. Evaluation parameters like floating lag time, swelling index, and drug release kinetics are also summarized. The review highlights formulation challenges and suggests future directions, including smart polymers, nanocarriers, and personalized medicine, aimed at improving therapeutic efficacy and patient compliance.

Keywords: Olmesartan Medoxomil, gastroretentive drug delivery, floating systems, mucoadhesive polymers, controlled release

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INTRODUCTION

Olmesartan Medoxomil is a widely used antihypertensive agent belonging to the class of angiotensin receptor blockers (ARBs). It effectively manages high blood pressure and related cardiovascular disorders by blocking the angiotensin II receptor, thereby relaxing blood vessels. However, its clinical use is challenged by low oral bioavailability, a short half-life, and the need for frequent dosing, which can compromise patient adherence and therapeutic outcomes¹.

Gastroretentive drug delivery systems (GRDDS) have emerged as a promising approach to overcome these limitations. GRDDS are designed to prolong the residence time of drugs in the stomach, allowing controlled and sustained release. This mechanism enhances absorption, especially for drugs with narrow absorption windows, poor solubility, or instability in the intestinal environment². By

ensuring a longer gastric retention, GRDDS can improve drug solubility, absorption rate, and therapeutic efficacy.

For Olmesartan Medoxomil, the application of GRDDS offers significant benefits. Extended gastric retention can enhance its bioavailability and reduce dosing frequency, leading to improved patient compliance and better management of hypertension^{3,4}. This review focuses on various GRDDS strategies, formulation materials, mechanisms of action, and evaluation parameters that optimize Olmesartan Medoxomil's delivery and therapeutic efficiency.

Objectives

- To review gastroretentive strategies for Olmesartan Medoxomil aimed at improving its bioavailability and patient compliance.
- To summarize formulation materials and evaluation methods, and highlight challenges with suggestions for future research.

Approach to Literature Review

A systematic approach was adopted to gather and analyze scientific information relevant to gastroretentive drug delivery systems for Olmesartan Medoxomil. The review process began with identifying specific search terms such as “Olmesartan Medoxomil gastroretentive systems,” “floating tablets,” “swelling polymers,” “controlled release,” and “evaluation methods.” These keywords were used to explore high-quality research articles, patents, and official guidelines available through authenticated scientific repositories and academic platforms.

To ensure the credibility and relevance of the gathered information, only peer-reviewed studies published within the last 10–15 years were considered. Non-scientific sources, unpublished data, or articles lacking proper validation were excluded. The selected studies were thoroughly examined, and data related to formulation approaches, materials like polymers, manufacturing processes, and evaluation techniques such as buoyancy, swelling behavior, and drug release patterns were extracted.

The extracted information was systematically organized based on formulation types and mechanisms, allowing for a structured synthesis of current knowledge. This approach ensured that the review provides accurate, reliable, and up-to-date insights while highlighting existing challenges and potential areas for future research in enhancing the delivery of Olmesartan Medoxomil through gastroretentive systems.

RESULTS FROM THE ARTICLES REVIEWED

Following outcomes were seen from the articles and studies I reviewed for this review article.

A. Types of Gastroretentive Systems

A thorough analysis of the literature has revealed several gastroretentive drug delivery strategies that can enhance the effectiveness of Olmesartan Medoxomil by prolonging its residence time in the stomach. These systems differ in their mechanisms, formulation approaches, and materials used. The major types are discussed below.

1. Floating Drug Delivery Systems (FDDS)

Floating drug delivery systems are one of the most widely studied approaches for gastro-retention. These systems are designed to have a lower density than gastric fluids, allowing them to remain buoyant in the stomach for extended periods. The floating effect is often achieved by incorporating gas-generating agents such as sodium bicarbonate, which reacts with gastric acid to produce carbon dioxide. The gas becomes entrapped within the polymer matrix, reducing the system's density and promoting floatation⁵.

Hydrophilic polymers like hydroxypropyl methylcellulose (HPMC), Carbopol, and polyethylene oxide are commonly used to create matrix systems that sustain drug release while ensuring floatation. The controlled release from FDDS helps maintain therapeutic drug levels for longer durations, reducing the need for frequent dosing. These systems are particularly beneficial for drugs like Olmesartan Medoxomil, which have poor

bioavailability and a narrow absorption window in the upper gastrointestinal tract⁵.

2. Swelling and Expandable Systems

Swelling and expandable systems are designed to increase in size upon contact with gastric fluids, preventing premature emptying into the intestines. Polymers with high water uptake capacity, such as hydrogels and super porous networks, form the backbone of these systems. When exposed to gastric fluids, these polymers absorb water rapidly, swell, and form a gel-like structure that maintains the dosage form within the stomach⁶.

Super porous hydrogels exhibit quick swelling due to their large pores, making them highly effective in expanding and staying anchored in the stomach. These systems are formulated to not only control drug release but also to improve retention by mechanical obstruction. Their swelling properties also protect the drug from premature degradation in the intestinal environment, thereby enhancing therapeutic efficacy⁶.

3. Mucoadhesive Systems

Mucoadhesive systems utilize bioadhesive polymers that interact with the mucosal lining of the stomach to enhance retention. Polymers such as carbopol, chitosan, and sodium alginate form hydrogen bonds or electrostatic interactions with the mucin layer, allowing the dosage form to adhere firmly to the gastric mucosa⁷.

This adhesion prolongs the contact time between the drug and the absorptive surface, facilitating controlled and sustained release. Mucoadhesive systems are particularly advantageous for drugs like Olmesartan Medoxomil, where enhanced residence time can improve bioavailability and therapeutic outcomes. These systems also help reduce local irritation by minimizing frequent gastric movement⁷.

4. High-Density Systems

High-density systems are formulated with materials heavier than gastric fluids to settle at the bottom of the stomach. By using dense excipients such as barium sulfate, zinc oxide, or iron powders, the tablet remains anchored within the gastric cavity, resisting the propulsive forces that would otherwise move it into the intestines⁸.

This strategy is particularly useful for drugs that require prolonged gastric exposure for optimal absorption. High-density systems provide a stable environment for drug release and avoid the rapid gastric emptying seen with conventional formulations. Despite their advantages, challenges like achieving the correct density and ensuring patient safety remain areas of ongoing research⁸.

5. Magnetic Systems (Emerging Approach)

Magnetic systems represent an innovative approach in gastroretentive drug delivery. These systems incorporate magnetic materials within the dosage form, which are then guided and retained in the stomach by external magnetic fields. This allows for precise localization and

prolonged retention without relying solely on buoyancy or swelling mechanisms.

Materials like iron oxide nanoparticles are embedded in the formulation, and the external magnetic field is carefully controlled to ensure proper placement within the stomach. Though still in experimental stages, magnetic systems offer a promising solution for drugs like Olmesartan Medoxomil, providing targeted delivery, reduced dosing frequency, and improved patient adherence⁶⁻⁸.

B. Polymers and Excipients Used

The formulation of gastroretentive drug delivery systems (GRDDS) for Olmesartan Medoxomil relies on a carefully selected combination of polymers and excipients that contribute to floating ability, swelling, adhesion, density, and controlled release. These materials are critical in ensuring that the dosage form remains in the stomach for a prolonged period while providing sustained therapeutic action.

- **Hydrophilic Polymers:** Hydrophilic polymers are widely used in floating and swelling systems due to their ability to absorb water and form a gel matrix. Hydroxypropyl methylcellulose (HPMC) is one of the most common polymers employed because of its high viscosity and controlled release capabilities. Sodium alginate, a natural polysaccharide, forms gels in the acidic environment of the stomach, aiding in buoyancy and drug retention. Carbopol, a cross-linked polyacrylic acid derivative, is highly effective for both swelling and mucoadhesive formulations, providing sustained release by forming a viscous gel layer⁹.
- **Hydrophobic Polymers:** Hydrophobic polymers such as ethyl cellulose and polymethacrylates are used to retard drug release by acting as diffusion barriers. These polymers are especially useful in matrix systems where controlled release is needed over an extended period. Ethyl cellulose's insolubility in water helps in maintaining the structural integrity of the tablet, while polymethacrylates can be tailored to adjust permeability and release profiles⁹.
- **Gas-Generating Agents:** Floating systems often incorporate gas-generating agents like citric acid and sodium bicarbonate. These agents react with gastric fluids to produce carbon dioxide, which is trapped within the polymer matrix, decreasing tablet density and promoting buoyancy. The balance between the amount of acid and bicarbonate is crucial to ensure timely floatation and sustained drug release¹⁰.
- **Mucoadhesive Agents:** Mucoadhesive systems use polymers like chitosan and polyacrylic acid to enhance gastric retention by adhering to the mucosal surface. Chitosan, a natural polymer derived from chitin, exhibits excellent bioadhesive properties and is compatible with acidic environments. Polyacrylic acid, available in various forms like Carbopol, forms strong hydrogen bonds with the mucus layer, increasing contact time and improving drug absorption¹¹.
- **Density Enhancers:** High-density systems require excipients that increase the weight of the formulation, helping it remain at the bottom of the stomach. Materials such as barium sulfate and calcium phosphate

are commonly used due to their high specific gravity. These agents ensure that the dosage form resists gastric emptying forces while maintaining safety and compatibility with the body¹⁰⁻¹¹.

- **Plasticizers, Lubricants, and Stabilizers:** To improve the mechanical properties and manufacturability of GRDDS, plasticizers like polyethylene glycol (PEG) and triethyl citrate are added to enhance flexibility and prevent brittleness. Lubricants such as magnesium stearate and stearic acid reduce friction during tablet compression and improve flow properties. Stabilizers, including antioxidants and pH modifiers, protect the drug from degradation and ensure uniform release throughout the shelf life¹¹⁻¹².

C. Mechanisms Enhancing Gastric Retention

Gastric retention plays a pivotal role in improving the absorption and therapeutic efficacy of drugs like Olmesartan Medoxomil. Different mechanisms are employed in gastroretentive systems to prolong the residence time of dosage forms within the stomach, overcoming challenges such as rapid gastric emptying and limited absorption windows. These mechanisms are based on physical, chemical, and biological interactions that enhance the performance of the formulation.

• Buoyancy through Gas Generation or Low-Density Matrices

Buoyancy is one of the most widely used mechanisms to achieve gastric retention. Low-density formulations, often composed of hydrophilic polymers like HPMC or sodium alginate, absorb gastric fluids and form a gel-like matrix. In addition, gas-generating agents such as sodium bicarbonate and citric acid react in the stomach to produce carbon dioxide, which becomes trapped in the matrix, reducing the overall density. This allows the dosage form to float on the surface of gastric fluids, preventing it from being pushed into the intestine and enabling sustained drug release¹³.

• Swelling to Prevent Passage through the Pyloric Sphincter

Swelling systems utilize polymers that rapidly absorb water and expand in size, sometimes several times their original volume. Hydrogels and superporous networks swell upon contact with gastric fluids, forming a bulky mass that is too large to pass through the pyloric sphincter. This mechanism ensures that the tablet remains anchored in the stomach for extended periods, providing controlled drug release and improving absorption in the acidic environment¹³.

• Mucoadhesion to Prolong Residence Time

Mucoadhesive systems enhance gastric retention by interacting directly with the mucosal lining of the stomach. Polymers like chitosan and polyacrylic acid adhere to mucin through hydrogen bonding, electrostatic attraction, or van der Waals forces. This adhesion prevents the dosage form from being swept away by gastric motility and allows continuous contact with the absorptive surface, resulting in prolonged drug release and better bioavailability¹⁴.

• Increased Tablet Weight for Sedimentation

High-density systems employ weight-enhancing agents such as barium sulfate or calcium phosphate to increase the specific gravity of the tablet. Once ingested, the tablet sediments at the bottom of the stomach, resisting buoyant forces and gastric motility. This sedimentation mechanism is particularly useful for drugs that require prolonged exposure to gastric fluids for optimal absorption, offering a passive yet effective means of retention¹⁴.

- **Magnetic Localization for Targeted Delivery**

Magnetic systems represent an emerging strategy where magnetic materials are incorporated into the dosage form and guided by an external magnet to a specific region of the stomach. This allows precise localization and retention, ensuring that the drug is released exactly where it is needed. Magnetic control also offers the possibility of on-demand retention and release, enhancing therapeutic outcomes while reducing side effects.

Each of these mechanisms addresses specific physiological challenges that limit drug absorption and efficacy. By combining buoyancy, swelling, adhesion, sedimentation, and magnetic control, gastroretentive systems are tailored to extend the gastric residence time of Olmesartan Medoxomil, thereby improving its therapeutic profile, patient compliance, and overall treatment success¹³⁻¹⁵.

D. Evaluation Parameters

A critical aspect of developing effective gastroretentive drug delivery systems (GRDDS) for Olmesartan Medoxomil is the evaluation of various parameters that determine the system's performance, stability, and therapeutic efficiency. These evaluation criteria provide insight into how well the formulation achieves gastric retention and controlled drug release while ensuring safety and compatibility.

- **Floating Lag Time and Total Floating Duration**

Floating lag time refers to the period between the administration of the dosage form and its emergence on the surface of gastric fluids. A short lag time is desirable for prompt gastric retention. Total floating duration measures how long the dosage form remains buoyant in the stomach environment. Both parameters are essential for confirming the efficacy of floating systems in extending residence time and sustaining drug release¹⁶.

- **Swelling Index and Expansion Ratio**

The swelling index quantifies the extent to which the formulation absorbs water and expands. It is calculated based on the change in tablet weight or volume after immersion in gastric fluid. The expansion ratio reflects how much the tablet enlarges to prevent passage through the pyloric sphincter. These measurements indicate the ability of swelling systems to achieve and maintain gastric retention.

- **Mucoadhesive Strength**

Mucoadhesive strength assesses how effectively the formulation adheres to the gastric mucosa. It is determined through techniques such as tensile testing, where the force required to detach the dosage form from

mucosal tissue is measured. Strong mucoadhesion is vital for prolonged retention and efficient drug absorption in mucoadhesive systems¹⁶.

- **In Vitro Dissolution Studies**

Dissolution studies simulate the release of the drug from the formulation in acidic gastric conditions. These tests help predict how the drug will behave in the stomach, providing data on release rates, duration, and stability. They also aid in identifying formulation factors that influence drug release profiles.

- **Drug Release Kinetics and Modeling**

Analyzing drug release kinetics helps in understanding the mechanism by which the drug is released from the dosage form. Models such as zero-order, first-order, Higuchi, and Korsmeyer-Peppas are used to describe the release pattern and predict long-term performance. Accurate modeling allows formulators to fine-tune delivery systems for optimal therapeutic outcomes⁹.

- **Stability under Simulated Gastric Conditions**

Stability testing under simulated gastric conditions evaluates how the formulation maintains its integrity, drug content, and release characteristics over time. This assessment ensures that the system remains effective throughout the intended shelf life and during gastric transit^{4,9,16}.

- **In Vivo Pharmacokinetic Studies for Bioavailability**

In vivo studies involve assessing the drug's absorption, distribution, metabolism, and excretion in animal models or human subjects. These studies confirm whether the formulation improves bioavailability and maintains therapeutic drug levels, providing real-world evidence of the formulation's effectiveness¹⁷.

- **Compatibility Studies between Polymers and Drug**

Compatibility studies, such as Fourier-transform infrared spectroscopy (FTIR), differential scanning calorimetry (DSC), and X-ray diffraction (XRD), are conducted to ensure that the drug and polymers do not interact adversely. These studies verify that the formulation components remain stable and effective throughout manufacturing and storage⁴.

Together, these evaluation parameters offer a comprehensive framework for designing, testing, and optimizing GRDDS for Olmesartan Medoxomil. By systematically assessing floating behavior, swelling, adhesion, release kinetics, stability, and compatibility, researchers can develop formulations that enhance bioavailability, prolong gastric residence, and provide consistent therapeutic benefits^{16,17}.

5. DISCUSSION

This review highlights various gastroretentive drug delivery strategies suitable for Olmesartan Medoxomil, including floating, swelling, mucoadhesive, high-density, and magnetic systems. Each approach offers distinct advantages, such as improved bioavailability, prolonged gastric retention, and controlled release, while also presenting limitations like

formulation complexity, stability issues, and patient-specific responses. The selection of appropriate polymers, such as HPMC, carbopol, or chitosan, plays a critical role in achieving desired drug release and retention, emphasizing the need for formulation optimization. Challenges such as scalability, interpatient variability, and maintaining stability in gastric conditions must be carefully addressed for successful product development. Future research should focus on smart polymers, nanocarrier systems, and personalized medicine approaches, along with navigating regulatory requirements to ensure clinical translation. These advancements can offer pharmaceutical industries innovative solutions, enhance therapeutic outcomes, and meet the growing demand for effective, patient-friendly antihypertensive treatments like Olmesartan Medoxomil.

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