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Review Article

Innovative Gastroprotective Systems Utilizing Natural Polymers for Glipizide and Carvedilol: A Review on Mimosa pudica and Limonia Acidissima

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ABSTRACT

The co-existence of diabetes mellitus and cardiovascular diseases presents a significant clinical challenge that demands innovative, patient-centric therapeutic approaches. While oral drug delivery remains the most widely accepted administration route, conventional formulations of antidiabetic and antihypertensive agents—such as glipizide and carvedilol—are often hindered by limited gastric residence time, erratic absorption profiles, and inconsistent plasma concentrations. To address these limitations, gastroprotective drug delivery systems (GRDDS) have emerged as a promising strategy to enhance bioavailability and optimize therapeutic outcomes, especially for drugs characterized by narrow absorption windows or poor solubility in intestinal environments. This review provides a comprehensive overview of the formulation and evaluation of novel GRDDS incorporating glipizide and carvedilol in combination with natural, biocompatible polymers including Mimosa pudica mucilage and Limonia acidissima gum. These plant-derived polymers demonstrate favorable characteristics such as high swelling capacity, pronounced mucoadhesive behavior, and efficient gel-forming properties, rendering them particularly suitable for the development of floating, swelling, and bio adhesive systems. The article discusses the pharmacological rationale for combining glipizide and carvedilol, the therapeutic advantages conferred by gastroprotective delivery in diabetic and hypertensive management, and recent advances in the use of natural polymer-based platforms. A critical analysis is presented covering preformulation studies, formulation methodologies, and in vitro evaluation techniques, including assessments of swelling index, buoyancy behavior, mucoadhesive strength, and sustained drug release kinetics. The integration of Mimosa pudica mucilage and Limonia acidissima gum not only facilitates prolonged gastric retention and controlled release but also aligns with the growing emphasis on sustainable, plant-based pharmaceutical excipients. This review

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aims to provide a scientific foundation to inform and inspire further experimental research into dual-drug, polymer-based gastroprotective systems as a promising avenue for improving adherence and clinical outcomes in chronic disease management.

INTRODUCTION

1.1 Overview of Diabetes Mellitus and Hypertension

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both. According to the International Diabetes Federation (IDF), over 537 million adults worldwide are currently living with diabetes, and this number is projected to rise dramatically in the coming decades. Chronic hyperglycemia contributes to microvascular and macrovascular complications including neuropathy, nephropathy, retinopathy, and cardiovascular diseases [1,2].

Hypertension frequently coexists with diabetes mellitus, creating a synergistic impact on cardiovascular morbidity and mortality. Approximately 70% of diabetic patients develop hypertension, and the combination accelerates atherosclerosis, increasing the risk of myocardial infarction, stroke, and heart failure. Therefore, effective management of both glycemic control and blood pressure is crucial in diabetic patients to reduce long-term complications and improve quality of life [3,4].

1.2 Limitations of Conventional Oral Therapy

Conventional oral formulations of antidiabetic and antihypertensive agents often present several challenges:

- **Variable Bioavailability:** Many drugs exhibit poor or variable absorption due to their physicochemical properties and short gastric residence time.

- **Frequent Dosing:** Short half-life drugs like glipizide require multiple daily dosing, leading to patient non-compliance.
- **Fluctuating Plasma Levels:** Conventional dosing often results in peaks and troughs, increasing the risk of hypoglycemia or therapeutic failure.
- **Gastrointestinal Side Effects:** High doses can irritate the gastrointestinal mucosa, leading to discomfort and discontinuation of therapy [5-7].

Addressing these limitations necessitates the development of innovative drug delivery approaches that can improve therapeutic efficacy, patient adherence, and safety profiles.

1.3 Rationale for Combining Glipizide and Carvedilol

Glipizide is a second-generation sulfonylurea that lowers blood glucose by stimulating pancreatic β -cells to secrete insulin. It has a relatively short half-life (~2–4 hours) and is primarily absorbed in the upper gastrointestinal tract. Therefore, prolonging its gastric residence can significantly improve bioavailability and glycemic control.

Carvedilol is a non-selective beta-adrenergic blocker with additional α -1 blocking properties, used for managing hypertension and heart failure. In diabetic patients, controlling blood pressure with carvedilol not only reduces cardiovascular risks but also demonstrates less adverse impact on glucose metabolism compared to other beta-blockers [8,10]. Combining these two agents in a single formulation can offer synergistic benefits for diabetic patients with coexisting hypertension. However, both drugs face challenges with oral administration:

- **Glipizide:** limited absorption window, short half-life.
- **Carvedilol:** low aqueous solubility, variable bioavailability (~25–35%).



A gastroprotective system can mitigate these issues by ensuring sustained, localized release in the stomach.

1.4 Gastroprotective Drug Delivery Systems (GRDDS)

Gastroprotective drug delivery systems (GRDDS) are designed to prolong the residence time of dosage forms in the stomach. By maintaining the formulation in the gastric environment, GRDDS can enhance the absorption of drugs with:

- Narrow absorption windows in the upper small intestine.
- Poor solubility at higher pH.
- Stability issues in the intestinal environment.

1.4.1 Advantages of GRDDS

- Enhanced Bioavailability: Prolonged contact with absorption sites.
- Controlled Release: Sustained therapeutic levels with fewer fluctuations.
- Reduced Dosing Frequency: Improved patient compliance.
- Targeted Delivery: Localized drug action in the stomach.

1.4.2 Mechanisms of Gastric Retention

Multiple approaches can be utilized to retain dosage forms in the stomach:

Floating Systems: Low-density formulations float on gastric fluids.

- Swelling/Expandable Systems: The formulation swells to prevent passage through the pylorus.
- Mucoadhesive Systems: Adhere to the gastric mucosa.
- High-Density Systems: Sink to the bottom of the stomach.

Among these, floating and swelling systems are particularly attractive for combining glipizide and carvedilol, ensuring gradual release and consistent absorption [11-15].

1.5 Role of Natural Polymers in GRDDS

Polymers play a pivotal role in GRDDS by providing:

- Buoyancy (through gel formation and gas entrapment).
- Swelling (to prevent early gastric emptying).
- Mucoadhesion (to adhere to the gastric lining).
- Controlled matrix erosion for sustained release.

Synthetic polymers (HPMC, Carbopol) are widely used, but there is growing interest in natural polymers due to their biodegradability, biocompatibility, non-toxicity, and cost-effectiveness.

1.5.1 *Mimosa pudica* Mucilage

Mimosa pudica, commonly known as “Touch-me-not,” produces mucilage with:

- High swelling index.
- Excellent gel-forming ability.
- Mucoadhesive properties.

Studies demonstrate its capability to sustain drug release and promote floating in gastric fluid, making it suitable for swelling and floating GRDDS [16,17].

1.5.2 *Limonia acidissima* Gum

Limonia acidissima, or wood apple, yields a natural gum with:

- Good swelling capacity.
- Film-forming and matrix-sustaining characteristics.



- Mucoadhesive behavior [17,18].

1.6 Justification for the Present Review

Developing a dual-drug gastroprotective formulation of glipizide and carvedilol using *Mimosa pudica* and *Limonia acidissima* is a novel approach that aligns with current trends in:

- Personalized and combination therapy.
- Use of plant-derived excipients.
- Targeted delivery systems for chronic diseases.

1.7 Objectives of the Review

1. To explore the pharmacological rationale for combining glipizide and carvedilol in diabetic patients with hypertension.
2. To discuss the challenges of conventional oral delivery and the benefits of GRDDS.
3. To review physicochemical and functional properties of *Mimosa pudica* mucilage and *Limonia acidissima* gum in drug delivery.
4. To outline formulation strategies, evaluation techniques, and kinetic modeling of GRDDS.
5. To encourage further research on natural polymer-based combination therapies in chronic disease management.

2. MATERIALS AND METHODS

2.1 Materials

Various studies on gastroprotective drug delivery systems (GRDDS) have employed a combination of synthetic and natural excipients to develop effective formulations. Commonly utilized *active pharmaceutical ingredients* include Glipizide, a sulfonylurea antidiabetic agent, and Carvedilol, an antihypertensive β -blocker, which have been incorporated in gastroretentive matrices to enhance gastric residence time and improve bioavailability. Both drugs are typically procured

from certified pharmaceutical suppliers or received as gift samples. Among natural polymers, *Mimosa pudica* mucilage and *Limonia acidissima* gum have been extensively investigated due to their swelling, gelling, and mucoadhesive properties. These biopolymers are commonly extracted in-house to ensure purity and functional integrity.

In addition to the active drugs and polymers, auxiliary excipients are essential for achieving desired physicochemical and functional attributes. These include:

- **Sodium bicarbonate**, which acts as a gas-generating agent facilitating buoyancy.
- **Microcrystalline cellulose**, serving as a diluent and compression aid.
- **Magnesium stearate** and **talc**, employed as lubricant and glidant respectively.
- **Lactose monohydrate**, used as a filler to adjust tablet weight.

Extraction procedures often rely on *analytical grade solvents* such as ethanol and distilled water, with simulated gastric fluid (pH ~1.2) prepared for in vitro performance assessments. All materials conform to pharmacopeial specifications to ensure reproducibility and regulatory compliance.

2.2 Extraction of Natural Polymers

2.2.1 Mimosa pudica Mucilage

Extraction of *Mimosa pudica* mucilage typically follows a sequential process comprising cleaning, swelling, filtration, precipitation, and drying. Cleaned seeds are soaked overnight in distilled water to promote mucilage hydration and swelling. The swollen mass is then filtered through muslin cloth to remove insoluble components. Ethanol precipitation (commonly in a 3:1 ratio) effectively isolates mucilage from the aqueous extract. The precipitate is subsequently dried under controlled



temperatures (40–50 °C) and pulverized into a fine powder, which is stored in airtight containers to maintain functionality.

2.2.2 Limonia Acidissima Gum

Extraction of *Limonia acidissima* gum is conducted similarly. The cleaned fruit pulp is soaked in water with intermittent stirring to facilitate gum dissolution. The viscous solution is filtered to remove particulate matter and then precipitated with ethanol. Dried gum is powdered and stored under desiccated conditions. These methods are consistently cited for yielding polymers with reliable swelling and mucoadhesive profiles.

2.3 Preformulation Studies

Preformulation characterization provides critical insights into compatibility, stability, and processability:

- **Drug–excipient compatibility** is assessed using *Fourier Transform Infrared Spectroscopy (FTIR)*, which identifies characteristic functional group interactions.
- **Differential Scanning Calorimetry (DSC)** aids in detecting potential eutectic formations or thermal events indicating incompatibility.

Micromeritic evaluations—including *bulk and tapped density*, *angle of repose*, *Carr’s index*, and *Hausner ratio*—are routinely conducted to characterize powder flow and compressibility, critical parameters in direct compression manufacturing.

2.4 Formulation Development

Direct compression has emerged as a preferred method for fabricating gastroprotective tablets, due to its simplicity and scalability. In this approach, accurately weighed quantities of APIs,

polymers (*Mimosa pudica* mucilage and *Limonia acidissima* gum), and functional excipients are passed through standardized sieves (commonly 60-mesh) to ensure uniform particle size distribution. The blending sequence typically involves pre-mixing APIs with polymers and sodium bicarbonate to enable even dispersion of the gas-generating agent, followed by incorporation of diluents, lubricants, and glidants. The final blend is compressed into tablets of defined geometry (e.g., 12 mm diameter) using a rotary tablet press. Formulation optimization studies frequently vary polymer concentrations to evaluate the influence on swelling, buoyancy, mucoadhesion, and drug release characteristics.

2.5 Evaluation Parameters

2.5.1 Physical and Mechanical Properties

Evaluations Include:

- *Weight variation*
- *Tablet thickness*
- *Hardness*
- *Friability*
- *Drug content uniformity*

These parameters are essential for ensuring consistency and compliance with pharmacopeial requirements.

2.5.2 Swelling Behaviour

Swelling index assessments involve incubating tablets in simulated gastric fluid, periodically weighing them, and calculating the degree of hydration and expansion. This property is central to achieving the desired gastric retention.

2.5.3 Buoyancy and Mucoadhesion

In vitro buoyancy is determined by measuring floating lag time (time to rise to the medium’s surface) and total floating duration (time the tablet

remains buoyant). Mucoadhesive strength, assessed using modified balance techniques with biological tissues (e.g., goat stomach mucosa), provides insights into the formulation's capacity to adhere to gastric lining.

2.5.4 Drug Release Profiling

Dissolution studies employ the *USP Type II apparatus* (paddle method) in simulated gastric fluid (pH 1.2) at 37 ± 0.5 °C. Sampling at regular intervals enables construction of release profiles. Drug concentrations are quantified via UV–visible spectroscopy or HPLC, depending on assay sensitivity requirements.

2.5.5 Release Kinetics

Data are modelled to elucidate release mechanisms using:

- Zero-order and first-order kinetic equations
- Higuchi diffusion model
- Korsmeyer–Peppas model (to explore anomalous transport)

2.6 Stability Studies

Accelerated stability testing is performed under ICH-recommended conditions (40 ± 2 °C / $75 \pm 5\%$ RH) to assess formulation robustness over time. Evaluations encompass physical integrity, drug content, and dissolution performance, typically monitored over 1–3 months.

2.7 Statistical Analysis

Experimental results are reported as mean $\pm$ standard deviation. Statistical comparisons utilize ANOVA or t-tests, with significance thresholds commonly set at $p < 0.05$ to establish reliability and reproducibility of observed trends.

Table no. 1: Representative Gastroprotective Tablet Compositions

Ingredients (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Glipizide	5	5	5	5	5	5	5	5	5	5
Carvedilol	6.25	6.25	6.25	6.25	6.25	6.25	6.25	6.25	6.25	6.25
Mimosa pudica mucilage	50	75	100	50	75	100	50	75	100	75
Limonia acidissima gum	50	50	50	75	75	75	100	100	100	75
Sodium bicarbonate	40	40	40	40	40	40	40	40	40	40
Microcrystalline cellulose	80	55	30	55	30	5	30	5	—	30
Lactose monohydrate	60	60	60	60	60	60	60	60	60	60
Magnesium stearate	4	4	4	4	4	4	4	4	4	4
Talc	5	5	5	5	5	5	5	5	5	5
Total Weight (mg)	300	300	300	310	300	295	300	295	280	300

4. CONCLUSION

Gastroprotective drug delivery systems (GRDDS) have demonstrated considerable promise in improving the therapeutic efficacy of drugs with narrow absorption windows and limited solubility in the lower gastrointestinal tract. The combination of glipizide and carvedilol, targeting diabetic patients with comorbid hypertension, represents a rational therapeutic strategy benefitting from prolonged gastric residence and

controlled release. Natural polymers such as *Mimosa pudica* mucilage and *Limonia acidissima* gum have emerged as effective biocompatible matrices for developing floating and mucoadhesive dosage forms. Their swelling capacity, gel-forming ability, and bioadhesive characteristics contribute significantly to extending gastric retention time and sustaining drug release over 12 hours.



Evidence across formulation studies has consistently demonstrated:

- Satisfactory micromeritic properties enabling direct compression manufacturing.
- Robust mechanical characteristics ensuring tablet integrity.
- Efficient buoyancy and prolonged floating duration facilitated by a combination of swelling polymers and gas-generating excipients.
- Strong mucoadhesion to gastric mucosa, further enhancing retention.
- Controlled drug release profiles conforming to diffusion-driven mechanisms (commonly Higuchi kinetics).

Stability assessments under accelerated conditions confirm that optimized formulations maintain their physicochemical and functional properties over storage periods typical of commercial shelf life.

Collectively, these findings underscore the potential of combining naturally derived excipients with rational formulation design to develop patient-centric gastroretentive platforms for polytherapy in chronic metabolic disorders. Further in vivo investigations and clinical translation will be pivotal in establishing the long-term safety, efficacy, and patient compliance associated with these delivery systems.

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