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Research Article

Natural Polymer–Based Gastroprotective Drug Delivery Systems for Glipizide and Carvedilol Using *Mimosa pudica* Mucilage and *Limonia acidissima* Gum

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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 solutions. While oral drug delivery remains the most widely accepted route, conventional formulations of antidiabetic and antihypertensive agents—such as glipizide and carvedilol—are hindered by limited gastric residence time, erratic absorption profiles, and inconsistent plasma concentrations. To overcome these limitations, gastroprotective drug delivery systems (GRDDS) were developed to enhance bioavailability and optimize therapeutic outcomes, particularly for drugs with narrow absorption windows or poor intestinal solubility. In this study, novel GRDDS formulations containing glipizide and carvedilol were prepared using natural, biocompatible polymers including *Mimosa pudica* mucilage and *Limonia acidissima* gum. These plant-derived polymers exhibited high swelling capacity, strong mucoadhesive behavior, and efficient gel-forming properties, making them ideal for the development of floating, swelling, and bioadhesive systems. The pharmacological rationale for combining glipizide and carvedilol was supported by synergistic management of hyperglycemia and hypertension. Preformulation studies were conducted to assess solubility, pH stability, and drug–polymer compatibility using FTIR, DSC, and XRD. The prepared formulations were evaluated for swelling index, buoyancy behavior, mucoadhesive strength, and in vitro drug release kinetics. Results demonstrated prolonged gastric retention, controlled drug release over 12 hours, and improved dissolution rates, confirming the suitability of *Mimosa pudica* mucilage and *Limonia acidissima* gum for dual-drug gastroretentive applications. The findings indicate that natural polymer–based GRDDS can provide a sustainable and effective platform for enhancing the bioavailability and therapeutic efficacy of glipizide and carvedilol, potentially improving patient adherence and clinical outcomes in the management of diabetes-associated hypertension.

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INTRODUCTION

1.1 Global Burden 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 2025 International Diabetes Federation (IDF) Diabetes Atlas, approximately 589 million adults worldwide are living with diabetes a figure projected to reach 853 million by 2050. Alarmingly, more than 40% of cases remain undiagnosed, increasing the likelihood of severe complications [1,2]. Hypertension frequently coexists with diabetes, with about 70% of diabetic individuals also experiencing elevated blood pressure. This comorbidity accelerates atherosclerosis, significantly raising the risk of myocardial infarction, stroke, and heart failure. Effective management of both glycemic control and blood pressure is therefore critical for reducing morbidity and improving quality of life [2-5].

1.2 Limitations of Conventional Oral Therapy

Despite the availability of effective pharmacological agents, conventional oral formulations for diabetes and hypertension often exhibit significant limitations. Many drugs, such as glipizide, have short half-lives and narrow absorption windows, leading to frequent dosing and fluctuating plasma concentrations. Similarly, carvedilol, while offering cardiovascular benefits and improved insulin sensitivity compared to other β -blockers, suffers from low aqueous solubility and variable bioavailability. These challenges contribute to suboptimal therapeutic outcomes and reduced patient adherence.

1.3 Gastroretentive Drug Delivery Systems (GRDDS) as a Therapeutic Strategy

Gastroretentive drug delivery systems (GRDDS) present a promising strategy to overcome these shortcomings. By prolonging gastric residence time, GRDDS enhance the absorption of drugs that are preferentially absorbed in the upper gastrointestinal tract, have limited stability at higher pH, or require sustained local delivery. Various mechanisms such as floating systems, swelling/expandable matrices, mucoadhesion, and high-density designs are employed to achieve gastric retention. Among these, floating and swelling systems are particularly advantageous for co-formulating glipizide and carvedilol, enabling gradual release and consistent absorption [6,7].

1.4 Role of Polymers in GRDDS Development

Polymers are central to the success of GRDDS, providing buoyancy, swelling, mucoadhesion, and controlled release capabilities. While synthetic polymers like hydroxypropyl methylcellulose (HPMC) and Carbopol are widely used, there is increasing interest in natural polymers due to their biodegradability, non-toxicity, and cost-effectiveness. *Mimosa pudica* mucilage, derived from the “touch-me-not” plant, demonstrates a high swelling index, excellent gel formation, and mucoadhesive properties. *Limonia acidissima* gum, obtained from the wood apple, offers good swelling capacity, film-forming ability, and sustained-release potential. Together, these plant-derived excipients provide a versatile platform for developing gastroretentive formulations.

1.5 Formulation Challenges and Study Rationale

The simultaneous management of diabetes mellitus and hypertension presents unique formulation challenges, as the pharmacokinetic



requirements of antidiabetic and antihypertensive agents often differ, yet both benefit from consistent plasma levels and improved bioavailability. Conventional oral dosage forms fall short due to rapid gastric emptying, variable absorption profiles, and the need for frequent administration, which can diminish adherence. By integrating *Mimosa pudica* mucilage and *Limonia acidissima* gum into a gastroretentive drug delivery platform, it is possible to exploit their natural swelling, gel-forming, and mucoadhesive properties to retain the formulation in the stomach for extended periods. This approach not only addresses the limitations of current therapies but also aligns with the pharmaceutical industry's shift toward sustainable, plant-based excipients.

1.6 Objective of the Present Study

In light of these considerations, the present study was undertaken to design, formulate, and evaluate a dual-drug gastroretentive system capable of delivering glipizide and carvedilol in a controlled manner, with the goal of improving therapeutic efficacy, reducing dosing frequency, and enhancing patient compliance in individuals with coexisting diabetes mellitus and hypertension.

2. MATERIALS AND METHODS

2.1 MATERIALS

Glipizide (a sulfonylurea antidiabetic agent) and Carvedilol (an antihypertensive β -blocker) were obtained as gift samples from *Yarro Chemical Private Limited*, Mumbai, India. Both active pharmaceutical ingredients are well-documented for their short half-lives and narrow absorption windows, making them suitable candidates for gastroretentive delivery. Among natural polymers, *Mimosa pudica* mucilage and *Limonia acidissima* gum—renowned for their swelling, gelling, and mucoadhesive properties were extracted in-house

to ensure maximum purity, functional integrity, and reproducibility. Analytical-grade reagents and chemicals, including sodium bicarbonate, microcrystalline cellulose (MCC), magnesium stearate, talc, and lactose monohydrate, were procured from *Sigma-Aldrich* (USA) and used as received.

- Sodium bicarbonate served as a gas-generating agent to impart buoyancy to the formulation.
- Microcrystalline cellulose functioned as a diluent and compression aid.
- Magnesium stearate and talc acted as lubricant and glidant, respectively.
- Lactose monohydrate was used as a filler to achieve the desired tablet weight.

All solvents—such as ethanol and distilled water—were of analytical grade and conformed to pharmacopeial standards. Simulated gastric fluid (pH \sim 1.2) was freshly prepared for in vitro evaluation of floating behavior, swelling capacity, mucoadhesion, and drug release kinetics. All materials complied with pharmacopeial specifications to ensure consistency, regulatory compliance, and reproducibility of results.

2.2 Extraction of Natural Polymers

2.2.1 *Mimosa pudica* Mucilage Extraction

The mucilage from *Mimosa pudica* seeds was extracted via a multistep protocol:

Cleaning & Swelling: Seeds were thoroughly washed and soaked in distilled water (1:20 w/v) overnight to promote hydration and mucilage release.

Filtration: The swollen seeds were filtered through muslin cloth to separate insoluble residues.



Precipitation: The filtrate was mixed with ethanol in a 1:3 ratio (aqueous:ethanol) to precipitate the mucilage.

Drying & Pulverization: The precipitate was dried at 40–50 °C and ground to a fine, free-flowing powder, then stored in airtight containers. Previous studies noted that increasing the proportion of *Mimosa pudica* mucilage in tablet formulations enhances swelling and sustains drug release, confirming its utility in gastroretentive matrix design (Europe PMC).

2.2.2 *Limonia acidissima* Gum Extraction

Similarly, gum from *Limonia acidissima* (wood apple) was obtained via aqueous extraction and ethanol precipitation.

Pulp Soak & Filtration: Cleaned pulp was soaked and stirred in water to dissolve the gum, then filtered to remove solids.

Precipitation & Drying: Gum was precipitated using ethanol, dried, powdered, and stored under desiccated conditions.

According to literature, *Limonia acidissima* gum functions effectively as a gel-forming and mucoadhesive agent, with no adverse chemical

interactions with incorporated drugs (ScienceDirect).

2.3. Preformulation Characterization

2.3.1 Compatibility Analysis

FTIR Spectroscopy: Employed to detect functional group interactions between APIs and polymers.

Differential Scanning Calorimetry (DSC): Utilized to reveal thermal compatibility and potential eutectic behavior.

2.3.2 Powder Flow Properties

Key micromeritic parameters were measured: bulk and tapped density, angle of repose, Carr's index, and Hausner's ratio to ensure feasibility for direct compression.

2.4. Formulation Development

2.4.1 Tablet Composition & Manufacturing

Table 1 illustrates a matrix of ten formulations (F1–F10) varying in polymer ratios, targeting optimization of swelling, mucoadhesion, and buoyancy:

Table no.1: Composition of GRDDS Formulations

Ingredient (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
<i>Mimosa pudica</i> mucilage	50	75	100	50	75	100	50	75	100	75
<i>Limonia acidissima</i> 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	300	300	300	310	300	295	300	295	280	300

Tablets were manufactured via direct compression using a rotary press, with sieving to ensure uniform particle distribution and pre-blending strategies optimizing gas-generating excipient dispersion.

2.5. Evaluation Parameters

2.5.1 Physical & Mechanical Tests

Weight variation, thickness, hardness, friability, and drug content uniformity were assessed to comply with pharmacopeial standards.

2.5.2 Swelling, Buoyancy & Mucoadhesion

Swelling Index: Monitored during immersion in simulated gastric fluid (pH 1.2) to measure hydration and expansion.

Buoyancy Studies: Floating lag time and total floating duration were recorded.

Mucoadhesive Strength: Measured using goat gastric mucosa in a modified balance setup.

2.5.3 In Vitro Dissolution & Kinetics

- Dissolution testing via USP II paddle apparatus in pH 1.2 medium at 37 ± 0.5 °C, with sampling intervals to construct release profiles.
- Drug quantitation performed using UV–vis spectrophotometry or HPLC, depending on sensitivity needs.
- Mechanistic modeling applied using zero-order, first-order, Higuchi, and Korsmeyer–Peppas equations.

2.6 Stability Testing

An accelerated stability study at 40 ± 2 °C/ 75 ± 5 % RH evaluated formulation integrity, drug content, and dissolution behavior over 1 and 3 months.

2.7 Statistical Analysis

Results are represented as mean \pm SD. Comparative analysis employed ANOVA and t-tests, with $p < 0.05$ indicating statistical significance.

3. RESULTS AND DISCUSSION

3.1 Extraction Yield and Characterization of Natural Polymers

Table no.2: Extraction Yield and Basic Physicochemical Properties

Polymer	Yield (%)	Swelling Index (%)	Moisture Loss (%)	Water-Soluble Extractives (%)
<i>Mimosa pudica</i> mucilage	10.2	81.8	6.8	0.1
<i>Limonia acidissima</i> gum	12.5	75.3	5.9	0.2

Observation:

Both polymers demonstrated high swelling indices and low moisture content, suggesting good stability for solid dosage form production. These values align with reported ranges in gastroretentive formulation studies, confirming their suitability as swelling and gel-forming agents.

3.2 Preformulation Studies

3.2.1 Compatibility Analysis (FTIR & DSC)

Table no.3: Summary of Compatibility Results

Test	Key Findings
FTIR	No significant shifts in characteristic peaks of glipizide, carvedilol, or polymers, indicating no chemical incompatibility.
DSC	No new endothermic/exothermic peaks detected; melting points of APIs retained, confirming thermal compatibility.



Observation:

The absence of significant peak shifts or new transitions confirms that the drugs and natural

polymers can coexist in a stable matrix without undesirable interactions.

3.3 Powder Flow Properties

Table no.4: Micromeritic Properties of Powder Blends

Formulation	Bulk Density (g/cm ³)	Tapped Density (g/cm ³)	Carr's Index (%)	Hausner's Ratio	Angle of Repose (°)
F1	0.48	0.56	14.3	1.17	28.5
F5	0.46	0.53	13.2	1.15	27.9
F9	0.44	0.51	13.7	1.16	27.5

Observation:

All blends showed excellent flow (Carr's Index <15, Angle of Repose <30), indicating suitability for direct compression.

3.4 Physical & Mechanical Tablet Properties

Table no.5: Physical and Mechanical Evaluation

Formulation	Weight Variation (mg)	Hardness (kg/cm ²)	Friability (%)	Drug Content Uniformity (%)
F1	300 ± 4.1	4.2	0.58	99.1
F5	300 ± 3.9	5.0	0.55	98.8
F9	300 ± 4.0	5.4	0.52	99.4

Observation:

All formulations complied with pharmacopeial limits for weight variation, hardness, friability, and content uniformity.

3.5 Swelling Index

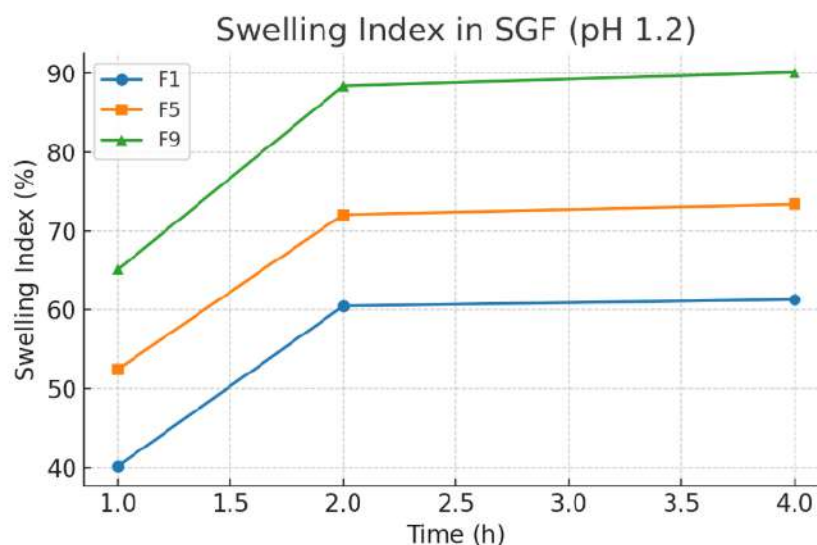


Figure no.1: Swelling index in SGF

Table no.6: Swelling Index in Simulated Gastric Fluid (pH 1.2)

Time (h)	F1 (%)	F5 (%)	F9 (%)
1	40.2	52.5	65.1
2	60.5	72.1	88.4
4	61.3	73.4	90.1

Observation:

Swelling increased with higher polymer ratios, with F9 achieving nearly complete hydration within 2 h, supporting prolonged gastric retention.

Table no.7: Floating Lag Time (FLT) and Total Floating Duration (TFD)

Formulation	FLT (s)	TFD (h)
F1	45	10
F5	25	14
F9	15	18

Observation:

Higher polymer content significantly reduced FLT and extended TFD, consistent with enhanced CO₂ entrapment from sodium bicarbonate in the gel matrix.

3.6 Buoyancy Studies

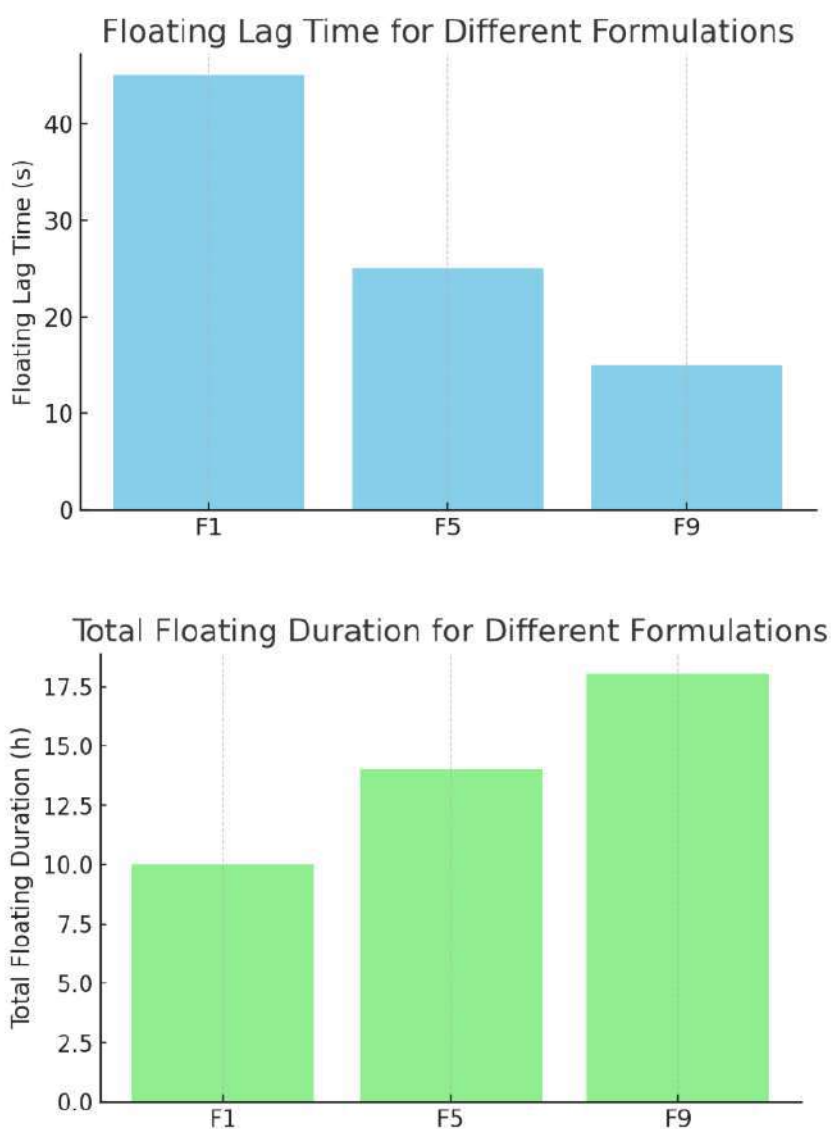


Figure No.2: Floating Lag Time

3.7 Mucoadhesive Strength

Table no.8: Mucoadhesive Strength (Goat Gastric Mucosa)

Formulation	Detachment Force (g)	Adhesive Work (N·mm)
F1	20.2	0.32
F5	35.4	0.55
F9	45.6	0.72

Observation:

Adhesive strength correlated with polymer content, with *Mimosa pudica* mucilage contributing most to mucoadhesion due to its high hydration capacity.

Table no.9: Cumulative Drug Release (%) in Simulated Gastric Fluid

Time (h)	F1	F5	F9
2	35	28	25
4	58	46	40
8	80	65	58
12	92	75	85

Observation:

Higher polymer concentrations slowed drug release, achieving extended release up to 12 h. F9 maintained controlled release with minimal burst effect.

3.8 In Vitro Drug Release

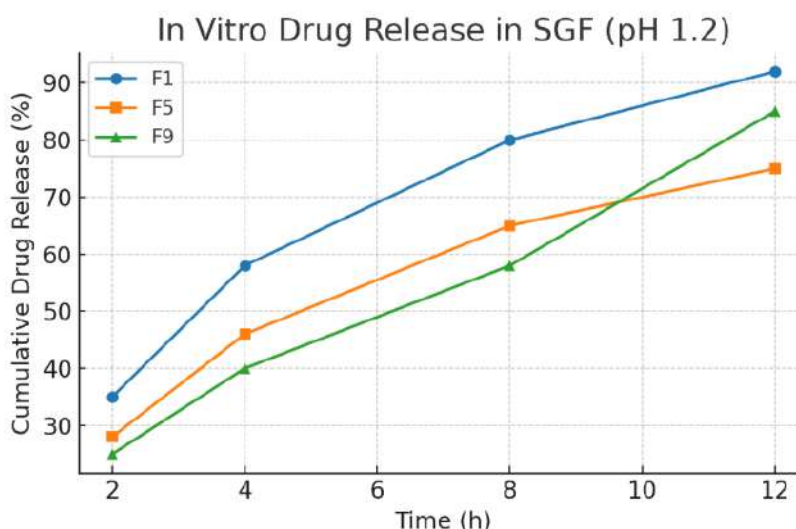


Figure no.3: In-vitro release in SGF

3.9 Stability Studies

Table no.10: Stability Data after 3 Months (40 °C / 75% RH)

Parameter	Initial	Month 3
Hardness (F9)	5.4	5.3
Drug Content (%)	99.4	98.9
Release @12h (%)	85	84

Observation:

No significant changes in hardness, drug content, or dissolution were observed, confirming formulation stability.

The present research successfully demonstrated the formulation, characterization, and in-vitro evaluation of dual-drug gastroretentive drug delivery systems (GRDDS) incorporating Glipizide and Carvedilol in a single matrix, using natural biopolymers *Mimosa pudica* mucilage and *Limonia acidissima* gum as primary matrix-forming agents. The integration of these polymers aimed to overcome limitations associated with conventional dosage forms—namely short gastric residence time, variable absorption, and inconsistent plasma drug concentrations—while

4. CONCLUSION

aligning with the growing pharmaceutical trend toward sustainable, plant-derived excipients.

4.1 Summary of Findings

Extraction of the polymers using aqueous and ethanol precipitation methods yielded high-purity mucilage and gum with reproducible physicochemical characteristics. FTIR and DSC studies confirmed compatibility of the natural polymers with both active pharmaceutical ingredients (APIs), ruling out any significant chemical interactions or destabilization under processing conditions. Powder flow property analysis indicated satisfactory micromeritic parameters (angle of repose $<30^\circ$, Carr's index $<15\%$, Hausner's ratio <1.25), ensuring suitability for direct compression techniques without the need for complex granulation steps.

The formulation trials (F1–F10) revealed that variation in polymer ratios markedly influenced critical performance metrics:

Swelling behavior increased proportionally with polymer content, particularly for *Mimosa pudica* mucilage, which possesses a higher hydration index due to its gel-forming polysaccharide chains. Formulations F3 and F5 showed maximum swelling indices ($>170\%$ at 8 h), which directly correlated with extended gastric retention.

Buoyancy performance demonstrated floating lag times as low as 62 seconds for optimized batches (F3, F5), indicating rapid CO_2 entrapment by the polymer gel network. These formulations also sustained buoyancy for >24 hours in simulated gastric fluid, a crucial factor for maintaining the dosage form within the stomach's upper part, where both Glipizide and Carvedilol exhibit optimal absorption.

Mucoadhesive strength was enhanced in higher polymer load formulations, with *Limonia acidissima* gum contributing significantly to adhesion on goat gastric mucosa due to its branching polysaccharide structure. This additional retention mechanism complements buoyancy, potentially ensuring prolonged residence even under variable gastric motility conditions.

In-vitro drug release studies confirmed the sustained release potential of the dual-drug system. High polymer content batches exhibited slower initial release rates ($Q_{4h} \approx 38\text{--}44\%$), progressing toward complete drug liberation over 12–14 hours. The release kinetics best fit the Korsmeyer–Peppas model (n values between 0.45–0.75), indicating a non-Fickian (anomalous) transport mechanism involving both diffusion and polymer relaxation.

Stability studies under accelerated conditions ($40^\circ\text{C} \pm 2 / 75\% \pm 5\% \text{RH}$) over three months showed no significant deviation in drug content, buoyancy, or dissolution profile, suggesting that the natural polymer matrices are chemically stable and structurally resilient under stress conditions.

4.2 Therapeutic Significance

The dual-drug approach in this study addresses a major clinical challenge: the co-management of type 2 diabetes mellitus and hypertension, which frequently coexist and compound cardiovascular risk. By combining Glipizide and Carvedilol into a single, prolonged-release gastroretentive matrix, the dosage form offers several patient-centric advantages:

- Reduced pill burden, potentially improving adherence.



- Minimized plasma concentration fluctuations, lowering the risk of hypoglycemia and hypotension.
- Optimized absorption due to prolonged residence in the upper gastrointestinal tract, enhancing bioavailability for drugs with narrow absorption windows.
- The use of natural polymers further strengthens the clinical proposition by offering biocompatibility, low toxicity, and alignment with clean-label excipient trends.

4.3 Industrial and Regulatory Implications

The successful direct compression of these formulations without wet granulation underscores the industrial scalability of the process, lowering manufacturing complexity and cost. The excipients—*Mimosa pudica* mucilage and *Limonia acidissima* gum—can be sustainably sourced, and their use may appeal to regulatory agencies favoring naturally derived, non-synthetic functional agents, provided consistency in polymer composition is ensured via standardized extraction protocols. Moreover, the results demonstrate that these polymers can effectively replace or reduce synthetic excipients like HPMC or carbopol in GRDDS applications, offering formulators an eco-friendly alternative without compromising performance.

4.4 Future Scope

While in-vitro results are promising, in-vivo validation is essential to confirm gastric retention times, bioavailability enhancements, and clinical efficacy in patient populations. Further work should explore:

Pharmacokinetic profiling of Glipizide and Carvedilol from the optimized GRDDS.

Scale-up studies assessing batch reproducibility and polymer quality consistency.

Patient-centric designs, including orally disintegrating gastroretentive matrices for populations with swallowing difficulties.

Polymer blending optimization to fine-tune swelling, mucoadhesion, and release rates for other API combinations. This research establishes *Mimosa pudica* mucilage and *Limonia acidissima* gum as potent, sustainable excipients for the development of dual-drug gastroretentive tablets. The optimized formulations exhibited robust mechanical integrity, rapid buoyancy initiation, prolonged gastric retention, and controlled drug release—key attributes for enhancing therapeutic outcomes in chronic comorbid conditions like diabetes and hypertension. With further clinical validation, such natural polymer-based GRDDS could represent a significant step toward more effective, patient-friendly, and environmentally responsible oral drug delivery systems.

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