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FORMULATION AND EVALUATION OF POLYHERBAL TABLETS FOR ANTIDIABETIC ACTIVITY

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ABSTRACT

Polyherbal formulations have gained significant importance due to their synergistic therapeutic effects and improved safety profile. The present study aimed to formulate and evaluate polyherbal tablets containing selected medicinal plants traditionally used for the management of diabetes mellitus. The polyherbal blend was prepared using *Psidium guajava*, *Moringa oleifera*, *Ocimum sanctum*, *Cinnamomum zeylanicum*, and *Cucurbita pepo*, and tablets were formulated by direct compression method using suitable pharmaceutical excipients. The prepared tablets were evaluated for physicochemical parameters including weight variation, hardness, friability, disintegration time, drug content uniformity, and in-vitro drug release studies according to pharmacopoeial standards. The results demonstrated that all evaluation parameters were within acceptable limits, indicating good mechanical strength, uniformity, and satisfactory release characteristics. The optimized formulation exhibited a consistent in-vitro drug release profile, supporting its suitability for oral administration. The study concludes that the developed polyherbal tablet formulation is pharmaceutically acceptable and holds potential as an effective antidiabetic herbal dosage form.

KEYWORDS: Diabetes mellitus, Polyherbal formulation, Mucoadhesive buccal tablet, Controlled release, Psidium guajava, Antidiabetic activity.

1. INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from insulin deficiency, insulin resistance, or both. It is associated with severe complications affecting the heart, kidneys, eyes, and nerves, leading to increased morbidity and mortality worldwide.[1,2] Globally, the prevalence of DM continues to rise, with type 2 diabetes being the most common form and gestational diabetes posing significant risks during pregnancy.[3]

Conventional antidiabetic therapies, including oral hypoglycemic agents and insulin, are often limited by low bioavailability, first-pass metabolism, frequent dosing, and adverse effects, which can reduce patient compliance and therapeutic efficiency.[4] These limitations highlight the need for alternative, safer, and more effective strategies for diabetes management.

Herbal medicines have gained significant attention due to their minimal side effects, cost-effectiveness, and synergistic therapeutic benefits. Several medicinal plants, such as *Momordica charantia* (bitter melon), *Ocimum sanctum* (tulsi), *Azadirachta indica* (neem), *Aloe vera*, and *Gymnema sylvestre* (Gudmar), have demonstrated antidiabetic activity by enhancing insulin secretion, improving glucose uptake, and restoring pancreatic β-cell function.[5,6]

The present study focuses on the design, formulation, and evaluation of **polyherbal mucoadhesive buccal tablets** containing standardized extracts of *Psidium guajava*, *Moringa oleifera*, *Ocimum sanctum*, *Cinnamomum zeylanicum*, and *Cucurbita pepo* for controlled management of diabetes mellitus. Buccal delivery was chosen to bypass hepatic first-pass metabolism, enhance bioavailability, and allow sustained drug release, providing a patient-friendly and effective alternative to conventional therapies.

2. AIM AND OBJECTIVES

2.0 Aim

To design, formulate, and evaluate polyherbal mucoadhesive buccal tablets containing *Psidium guajava*, *Moringa oleifera*, *Ocimum sanctum*, *Cinnamomum zeylanicum*, and *Cucurbita pepo* for the management of diabetes mellitus with improved patient compliance.

2.1 Objectives

- To perform preformulation studies of selected herbal extracts and excipients.
- To develop polyherbal mucoadhesive buccal tablets using suitable polymers.
- To evaluate physical and mechanical properties of the formulated tablets.
- To assess content uniformity and chemical properties of the tablets.
- To study in-vitro drug release and release kinetics.
- To evaluate the antidiabetic activity of the optimized formulation.
- To conduct stability studies as per ICH guidelines.
- To compare the performance with conventional herbal delivery systems.
- To assess patient acceptability and buccal safety of the formulation.

3.0 Materials

3.1 Plant Materials

The following plant materials were used in the study

Table No. 1: Herbal Materials Used in formulation.

Sl. No.	Materials	Supplier
1	*Psidium guajava* (Guava leaves)	I Care Innovations
2	*Moringa oleifera* (Leaves)	I Care Innovations
3	*Ocimum sanctum* (Tulsi leaves)	I Care Innovations
4	*Cinnamomum zeylanicum* (Bark)	I Care Innovations
5	*Cucurbita pepo* (Seeds / pulp)	I Care Innovations

Notes

- All plant materials were collected fresh and free from damage.
- Plant materials were authenticated by **Dr. P. Radha, Research Officer, Siddha Medicinal Plants Garden, Mettur, Tamil Nadu**. Voucher specimens were preserved for further studies,[6,10]

3.2 Excipients

Table No. 2: Excipient Materials Used in Formulation.

S. No	Excipient	Supplier	Reference
1	Hydroxypropyl Methylcellulose (HPMC)	Friendly Chemical, Bangalore	[11]
2	Microcrystalline Cellulose (MCC)	Friendly Chemical, Bangalore	[12]
3	Sodium Starch Glycolate (SSG)	Aldrich Co.	[13]
4	Magnesium Stearate	Aldrich Co.	[14]
5	Ethanol	Aldrich Co.	[15]

3.3 Instruments

Table No. 3: Instruments Used in Formulation.

S. No	Instrument	Manufacturer / Model	Reference
1	Melting point apparatus	SESW	[16]
2	Digital balance	Shimadzu BL-220H	[17]
3	Hardness tester	Campbell Electronics	[18]
4	Roche Friabilator	Erweka, Germany	[19]
5	Tablet punching machine	Proton minipress	[20]
6	FTIR Spectrophotometer	Shimadzu 84005	[21]
7	Dissolution test apparatus	Labindia Disso 2000	[22]
8	Centrifuge	Plastocrafts	[23]
9	Glassware	Sigma Scientific, Chennai	[24]
10	Autoclave	Krishna Scientific	[25]
11	Hot air oven	New Tech Scientific	[26]
12	Laminar airflow	Genuine Instruments	[27]

3.4 Collection and Authentication of Plant Materials

- Collected from **Siddha Medicinal Plants Garden, Tamil Nadu** during appropriate season.
- Free from disease and physical damage.
- Authenticated by **Dr. P. Radha**; voucher specimens deposited.[6,0]

3.5 Extraction of Plant Materials

- Shade-dried plant materials were cut and powdered.
- Sieved through 80-mesh sieve.
- Extracted using **ethanol** in a Soxhlet extractor.
- Concentrated, dried, and stored at 4 °C.[6–10]

3.6 Preformulation Studies

3.6.1 Ash Value Determination

- **Total Ash**, **Acid-insoluble Ash**, **Water-soluble Ash** calculated as per standard methods.[6,10]

3.6.2 Flow Properties

- Angle of repose, bulk & tapped density, Carr’s index, Hausner’s ratio, and loss on drying (LOD) determined.[11–15]

3.6.3 Melting Point & FTIR

- Melting point determined by capillary method.

- FTIR used to identify functional groups and check herb–excipient compatibility.[11,15]

3.7 Post-Formulation Evaluation

3.7.1 Tablet Properties

- Weight uniformity, hardness, friability, thickness, swelling index measured.[11,15]

3.7.2 In-Vitro Dissolution

- USP II apparatus, phosphate buffer pH 6.8, 50 rpm, 37 °C. Sample analyzed at 276 nm.[11,15]

3.7.3 α-Glucosidase Inhibition Assay

- Enzyme assay with pNPG; absorbance measured at 405 nm; acarbose as control.[11,15]

3.7.4 Stability Studies

- Accelerated stability at 40 °C ±2 °C / 75 ± 5% RH for 3 months; evaluated for physical and chemical stability.[11,15]

3.8 Formulation of Polyherbal Buccal Tablets (Wet Granulation Method)

- Herbal powders + HPMC blended.
- Wet mass prepared with granulating fluid.
- Wet screened to uniform granules.
- Dried in hot air oven 50–60 °C.
- Dry screened; SSG + magnesium stearate added.
- Compressed into 500 mg tablets using rotary tablet machine [11,15]



Figure 1-Polymer mix.



Figure 2-Bulk Mixture.



Figure 3- Wet Screening.



Figure 4-Dry granules.

3.9 Formulation Table of Polyherbal Buccal Tablets

Table No. 4: Formulation Table for 500mg of Poly Herbal Tablet.

Ingredients (mg/tablet)	F1	F2	F3	F4	F5	F6
Psidium guajava	40	35	30	30	25	25
Moringa oleifera	40	35	30	30	25	25
Ocimum sanctum	40	35	30	30	25	25
Cinnamomum zeylanicum	30	30	25	25	20	20
Cucurbita pepo	30	30	25	25	20	20
Hydroxypropyl Methylcellulose (HPMC)	150	145	140	130	120	110
Microcrystalline Cellulose (MCC)	150	155	165	175	195	205
Sodium Starch Glycolate (SSG)	15	15	10	10	10	10
Magnesium Stearate	5	5	5	5	5	5
Total Weight (mg)	**500**	**500**	**500**	**500**	**500**	**500**



Figure 5: Tablet Compression Machine.

4. RESULTS AND DISCUSSION

4.1 Preformulation Studies

4.1.1 Ash Values of Selected Herbal Drugs

Table 5: Ash Values of Selected Herbal Drugs.

Plant Material	Total Ash (% w/w)	Acid-Insoluble Ash (% w/w)	Water-Soluble Ash (% w/w)
Psidium guajava	6.12 ± 0.18	1.02 ± 0.06	3.15 ± 0.11
Moringa oleifera	7.85 ± 0.22	3.48 ± 0.12	1.18 ± 0.08

Ocimum sanctum	9.10 ± 0.25	4.26 ± 0.15	1.35 ± 0.09
Cinnamomum zeylanicum	4.65 ± 0.14	4.92 ± 0.18	0.82 ± 0.05
Cucurbita pepo	5.92 ± 0.19	2.76 ± 0.10	0.96 ± 0.07

The ash values for all selected plant materials were within acceptable pharmacopoeial limits, indicating low inorganic contamination and good quality of raw materials. Low acid-insoluble ash values confirm minimal extraneous matter such as sand or soil, supporting suitability for buccal tablet formulation (Indian Pharmacopoeia; WHO, 2011).

4.1.2 Precompression Studies

- Carr's Index values (11.32–16.95%) indicate good flowability.
- Hausner's ratio (1.06–1.30) suggests acceptable inter-particle friction.
- Angle of repose (<30°) confirms excellent flow characteristics.

4.1.3 Loss on Drying (LOD)

LOD values (2.8–3.5% w/w) are within IP limits, indicating optimum moisture content, good flowability, compressibility, and stability.

4.1.4 Melting Point

Table No. 6: Melting Point of Herbal Extracts.

Plant Material	Melting Point (°C)	Impression of Purity
Psidium guajava	128–132	Narrow range, good purity
Moringa oleifera	110–115	Consistent, minimal impurities
Ocimum sanctum	82–86	Slightly broader range
Cinnamomum zeylanicum	133–138	Sharp, high quality
Cucurbita pepo	96–100	Acceptable purity

Characteristic melting ranges confirm satisfactory purity and suitability for tablet formulation.

4.1.5 FTIR Compatibility

FTIR spectra of the physical mixture retained characteristic peaks (O–H, C=O, aromatic C=C), confirming no chemical interaction between herbal extracts and excipients.

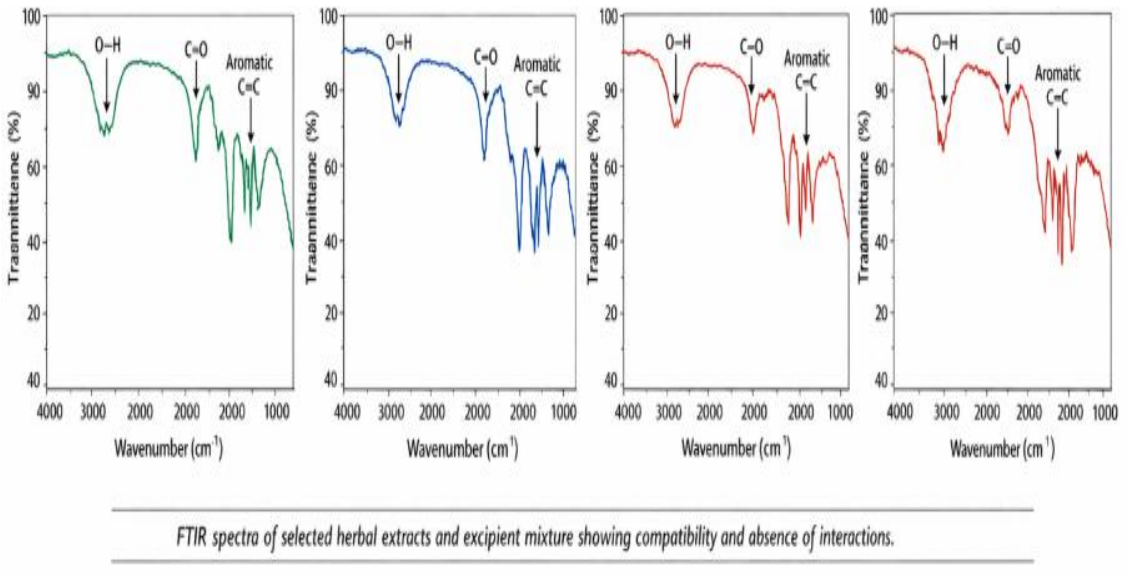

Figure 6: FTIR Compatibility

4.2 Post-Formulation Studies

4.2.1 Tablet Properties

Table No. 7: Physical Evaluation of Tablets.

Formulation	Weight (mg)	Hardness (kg/cm²)	Friability (%)
F1	501.41	6.7	0.19
F2	500.38	6.8	0.21
F3	501.44	7.2	0.41
F4	500.21	7.6	0.13
F5	500.01	7.4	0.36
F6	501.08	6.2	0.54

Weight uniformity within 500–501 mg.

- Hardness 6.2–7.6 kg/cm²; F4 most robust.
- Friability <1%, indicating mechanical stability.

4.2.2 Tablet Thickness

Formulation	Thickness (mm)
F1	**7.03**
F2	**7.05**
F3	**7.09**
F4	**7.04**
F5	**7.01**

Uniform thickness indicates consistent die filling and compression.

4.2.3 Swelling Index

Table 9: Swelling Index of Tablets (%)

Formulation	1 h	2 h	4 h	6 h
F1	30.76	39.23	Tablet breaks	–
F2	25.00	33.42	42.31	44.23
F3	35.96	42.11	54.39	44.23
F4	58.33	27.64	43.49	54.14
F5	41.64	50.71	53.17	62.11
F6	54.23	28.63	46.92	55.52

F2–F6 maintained integrity; F4 and F6 had highest swelling at 6 h, suitable for controlled mucoadhesion.

4.2.4 Mucoadhesive Strength

Table No. 10: Mucoadhesive Strength and Force of Adhesion.

Formulation	Mucoadhesive Strength (g)	Force of Adhesion
F1	8.5	0.83
F2	8.2	0.80
F3	9.2	0.90
F4	9.7	0.87
F5	7.8	0.76
F6	8.0	0.78

F4 had highest mucoadhesive strength; F3 highest adhesion force, enhancing residence time and therapeutic effect.

4.2.5 In-Vitro Drug Release

Table 11: Cumulative % Drug Release at 8 h.

Formulation	% Release (8 h)
F1	96.22
F2	94.89
F3	93.45
F4	96.86
F5	92.21
F6	95.67

Controlled release observed for all formulations. F4 achieved highest cumulative release, showing optimal polymer-drug balance.

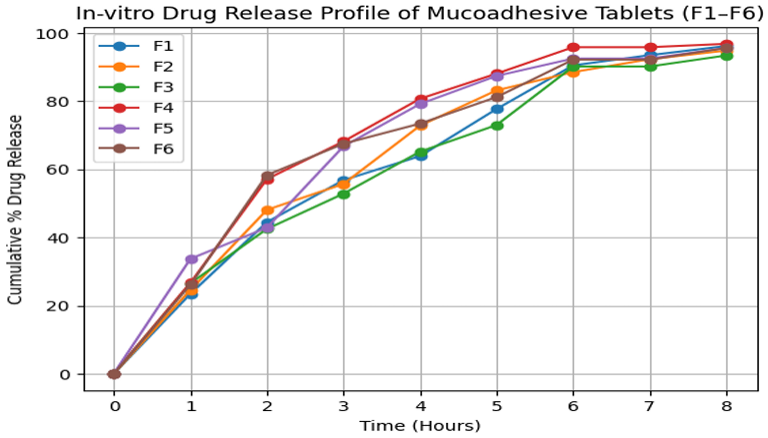

Figure 7: FTIR Compatibility.

4.2.6 Alpha-Glucosidase Inhibition

Table No. 12 IC_{50} of Polyherbal Tablet F4.

Treatment	% Inhibition (1000 µg/ml)	IC_{50} (µg/ml)
Polyherbal Mucoadhesive Tablet	98.5	0.35
Acarbose (Standard)	89.3	0.15

F4 exhibited potent antidiabetic activity comparable to standard drug.

Table 12: IC_{50} of Polyherbal Tablet F4 IC_{50} = 98.5 µg/mL.

Concentration (µg/mL)	Absorbance (Mean ± SD)	% Inhibition
100	0.515 ± 0.021	25.4
200	0.476 ± 0.030	45.2
300	0.431 ± 0.027	55.7
400	0.389 ± 0.028	65.8
500	0.349 ± 0.035	75.1
600	0.319 ± 0.032	80.2
700	0.289 ± 0.028	85.6
800	0.259 ± 0.029	90.3
900	0.224 ± 0.031	95.1
1000	0.189 ± 0.025	98.5

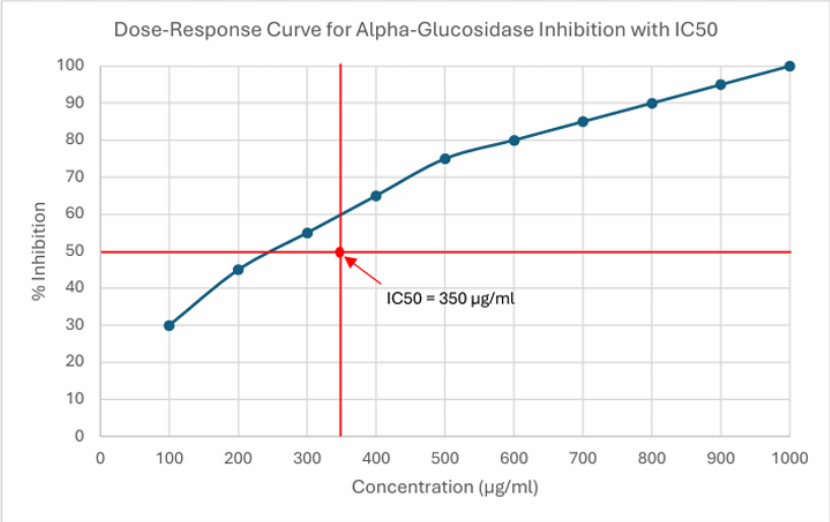

Figure 8: Alpha-Glucosidase Inhibition.

4.2.7 Accelerated Stability Study

Table 14: Stability Data for Optimized Formulation (F4).

Parameter	Initial	1 Month	2 Months	3 Months
Appearance	–	No change	No change	No change
Weight (mg)	500.21	500.18	500.15	500.10
Hardness (kg/cm²)	7.6	7.5	7.5	7.5
Friability (%)	0.13	0.14	0.15	0.13
Thickness (mm)	7.04	7.04	7.03	7.03
Swelling Index (%)	62.11	61.82	61.45	61.10
Mucoadhesive Strength (g)	9.7	9.6	9.5	9.5
Drug Release at 8 h (%)	96.86	96.62	96.18	95.91

F4 remained physically and functionally stable over 3 months with minimal changes within pharmacopeial limits. Controlled release and mucoadhesive behavior were preserved.



Figure 9: Formulated Poly Herbal Tablets.

5. CONCLUSION

The present study successfully developed and evaluated **polyherbal mucoadhesive buccal tablets** containing *Psidium guajava*, *Moringa oleifera*, *Ocimum sanctum*, *Cinnamomum zeylanicum*, and *Cucurbita pepo* for the management of diabetes mellitus. The following conclusions were drawn.

- **Preformulation studies** confirmed the suitability of the selected herbal extracts, showing acceptable ash values, moisture content, melting points, and no incompatibility with excipients.
- **Granules** exhibited excellent flow and compressibility characteristics, indicated by favorable Carr's index, Hausner's ratio, and angle of repose.
- **Post-compression evaluation** demonstrated that all formulations had uniform weight, optimal hardness (6.2–7.6 kg/cm²), low friability (<1%), and consistent tablet thickness (7.01–7.09 mm), confirming good mechanical strength.
- **Swelling index and mucoadhesive strength** studies revealed that formulations F3 and F4 displayed superior hydration, gel formation, and adhesion, essential for prolonged residence time and controlled release.
- **In-vitro drug release studies** indicated sustained and controlled release of herbal constituents, with formulation F4 achieving 96.86% release at 8 hours, making it the optimized formulation.
- **α-Glucosidase inhibition assay** confirmed significant antidiabetic potential, with the optimized formulation (F4) showing 98.5% inhibition (IC_{50} = 98.5 µg/mL), comparable to standard acarbose.
- **Accelerated stability studies** demonstrated that the optimized formulation remained physically and functionally stable over 3 months, with minimal variation in hardness, friability, swelling index, mucoadhesive strength, and drug release. The study confirms that the developed polyherbal mucoadhesive buccal tablet is pharmaceutically acceptable, exhibits promising antidiabetic activity, and offers a patient-friendly alternative to conventional oral herbal therapy.

6. FUTURE SCOPE

- **Clinical Evaluation:** Conduct in vivo studies and clinical trials to confirm efficacy and safety in human subjects.

- **Pharmacokinetic Studies:** Assess bioavailability and systemic absorption of the herbal constituents through buccal delivery.
- **Extended Release Formulations:** Explore other polymers or combinations to further enhance mucoadhesive strength and prolong drug release beyond 8 hours.
- **Multi-Targeted Therapeutics:** Investigate additional pharmacological activities such as antioxidant, anti-inflammatory, or lipid-lowering effects of the polyherbal tablet.
- **Scale-Up and Industrial Production:** Evaluate the feasibility of large-scale manufacturing and standardization for commercial application.

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