

“Development and Evaluation of a Novel Malvaceae-Based Polyherbal Tablet for Antioxidant and Antidiabetic Potential”

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ABSTRACT

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycaemia resulting from impaired insulin secretion, insulin resistance, or both. Prolonged hyperglycaemia induces oxidative stress and inflammation, leading to progressive tissue damage and severe diabetic complications. Although synthetic antidiabetic drugs are widely used, their long-term administration is often associated with adverse effects and limited antioxidant protection. Therefore, medicinal plants rich in bioactive phytochemicals have gained considerable attention as safer alternatives for diabetes management. The present study aimed to develop and evaluate a Polyherbal tablet containing selected Malvaceae plants, namely *Abutilon indicum*, *Hibiscus rosa-sinensis*, and *Gossypium herbaceum*, for antioxidant activity and pharmaceutical stability. Aqueous, ethanolic, and chloroform extracts of the selected plants were prepared and formulated into Polyherbal tablets. Antioxidant activity was assessed using the DPPH free radical scavenging assay with ascorbic acid as the reference standard. The optimized formulations were subjected to accelerated stability testing under ICH conditions ($40 \pm 2^\circ\text{C}/75 \pm 5\%$ RH) for six months, during which physical appearance, hardness, friability, weight variation, disintegration time, dissolution profile, and microbial quality were evaluated. Among the tested extracts, the ethanolic extract of *Hibiscus rosa-sinensis* exhibited the highest antioxidant activity (70.18%), followed by chloroform *Hibiscus* (69.60%) and aqueous *Abutilon indicum* (69.07%), approaching the activity of ascorbic acid (74.23%). The optimized Polyherbal tablet maintained acceptable physicochemical and microbiological stability throughout the study. These findings suggest that the developed formulation possesses promising antioxidant potential and may serve as a stable herbal adjunct for diabetes management.

Keywords: Diabetes mellitus; Malvaceae; Polyherbal tablet; *Abutilon indicum*; *Hibiscus rosa-sinensis*; *Gossypium herbaceum*; Antioxidant activity; DPPH assay; Accelerated stability study; Herbal formulation etc..

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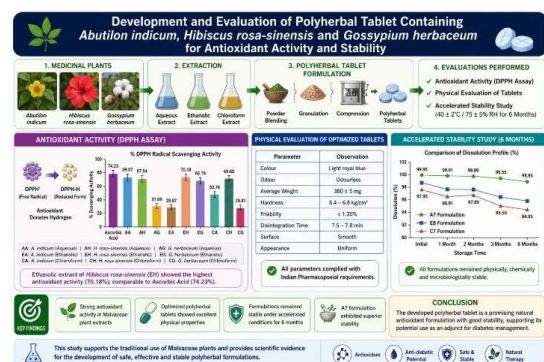


Figure 1: Graphical abstract of Novel Malvaceae-Based Polyherbal Tablet for the Antioxidant and Antidiabetic Potential.

INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by persistent hyperglycaemia resulting from impaired insulin secretion, insulin action, or both. According to the International Diabetes Federation (IDF), the global burden of diabetes continues to rise at an alarming rate, affecting hundreds of millions of individuals worldwide. Type 2 diabetes mellitus (T2DM) accounts for nearly 90–95% of all diagnosed cases and represents one of the leading causes of cardiovascular disease, nephropathy, neuropathy, retinopathy, and premature mortality. The pathogenesis of diabetes is multifactorial and involves genetic predisposition, obesity, sedentary lifestyle, chronic inflammation, insulin resistance, pancreatic β -cell dysfunction, and oxidative stress.

Oxidative stress has emerged as a critical contributor to the development and progression of diabetic complications.

Persistent hyperglycaemia promotes excessive production of reactive oxygen species (ROS), resulting in lipid peroxidation, DNA damage, mitochondrial dysfunction, protein oxidation, endothelial injury, and inflammatory responses. These events further aggravate insulin resistance and impair pancreatic β -cell function, thereby accelerating disease progression. Consequently, therapeutic strategies possessing both antihyperglycemic and antioxidant activities are increasingly considered advantageous in comprehensive diabetes management. Although several classes of oral hypoglycemic agents, including biguanides, sulfonylureas, thiazolidinediones, DPP-4 inhibitors, SGLT-2 inhibitors, and GLP-1 receptor agonists, are available for clinical use, prolonged therapy is frequently associated with adverse effects such as gastrointestinal disturbances, hypoglycemia, weight gain, cardiovascular concerns, hepatic dysfunction, and high treatment costs. These limitations have stimulated considerable interest in medicinal plants as complementary or alternative therapeutic options due to their multi-target pharmacological activities, improved safety profile, lower toxicity, and affordability.

Medicinal plants belonging to the family *Malvaceae* occupy an important position in traditional systems of medicine. Species such as *Abutilon indicum*, *Hibiscus rosa-sinensis*, and *Gossypium herbaceum* are widely distributed throughout tropical and subtropical regions and have historically been employed for the treatment of diabetes, inflammation, wounds, fever, gastrointestinal disorders, liver diseases, and various metabolic conditions. Phytochemical investigations have demonstrated that these plants are rich sources of flavonoids, phenolic acids, anthocyanins, tannins, alkaloids, glycosides, terpenoids, and other secondary metabolites possessing significant antioxidant and antidiabetic properties.

Abutilon indicum has been reported to exhibit antihyperglycemic, Hepato protective, anti-inflammatory, antioxidant, and Nephro protective activities attributable to its abundant flavonoid and phenolic constituents. *Hibiscus rosa-sinensis* contains anthocyanins, quercetin derivatives, cyanidin glycosides, and polyphenolic compounds capable of scavenging free radicals and reducing oxidative damage. Similarly, *Gossypium herbaceum* contains bioactive flavonoids and phenolic compounds that have demonstrated antioxidant, antimicrobial, anti-inflammatory, and glucose-lowering properties in experimental studies. The combination of these medicinal plants into a single Polyherbal formulation may therefore provide synergistic pharmacological effects by targeting multiple biochemical pathways involved in diabetes progression.

Polyherbal formulations have gained increasing scientific attention because multiple phytoconstituents can interact synergistically to improve therapeutic efficacy while minimizing adverse effects. Compared with single-herb preparations, Polyherbal formulations often exhibit enhanced antioxidant capacity, improved bioavailability, broader pharmacological activity, and better patient acceptability. Standardized herbal tablets also offer several pharmaceutical advantages, including accurate dosing, ease

of administration, improved stability, portability, and enhanced patient compliance.

Evaluation of antioxidant activity represents an important component of herbal drug development because oxidative stress plays a central role in diabetic complications. Among the available analytical methods, the 2, 2-diphenyl-1-picrylhydrazyl (DPPH) free radical scavenging assay is widely accepted owing to its simplicity, reproducibility, sensitivity, and rapid assessment of hydrogen-donating ability. The reduction of the stable purple DPPH radical into its yellow non-radical form provides a quantitative measure of antioxidant potential, enabling comparative evaluation of different plant extracts.

Equally important is the assessment of pharmaceutical stability, which ensures that herbal formulations retain their quality, safety, efficacy, and microbiological integrity throughout storage. Accelerated stability studies performed according to the International Council for Harmonisation (ICH) Q1A (R2) guidelines provide valuable information regarding formulation robustness under elevated temperature and humidity conditions and assist in predicting product shelf life.

Based on these scientific considerations, the present study was designed to develop a standardized Polyherbal tablet formulation containing extracts of *Abutilon indicum*, *Hibiscus rosa-sinensis*, and *Gossypium herbaceum*. The study aimed to compare the antioxidant activity of different solvent extracts using the DPPH assay, formulate a stable herbal tablet, and evaluate its accelerated stability under ICH-recommended storage conditions. The outcomes are expected to provide scientific evidence supporting the development of standardized Malvaceae-based herbal formulations as potential adjuncts for the management of diabetes mellitus and oxidative stress-related complications.

2.0 Materials and Methods:

2.1 Chemicals and Reagents: analytical grade chemicals and reagents were used throughout the study. 2,2-diphenyl-1-picrylhydrazyl (DPPH), ascorbic acid, ethanol, methanol, chloroform, distilled water, and all solvents used for extraction and analytical studies were of analytical reagent (AR) grade. Excipients used for tablet formulation, including microcrystalline cellulose, lactose monohydrate, starch, talc, magnesium stearate, and polyvinylpyrrolidone (pvp k-30), complied with the specifications of the Indian pharmacopoeia (IP).

2.2 Plant Materials:

Fresh leaves of *Abutilon indicum* (L.), *Hibiscus rosa-sinensis* Linn. And *Gossypium herbaceum* Linn. Belonging to the family *Malvaceae* were collected from different regions of Dhule district, Maharashtra, India. The plant materials were authenticated by a qualified taxonomist, and voucher specimens were deposited in the departmental herbarium for future reference.

The collected plant materials were washed thoroughly with distilled water to remove adhering dust and foreign matter and shade-dried at ambient temperature (25–30°C) for approximately 10–15 days. The dried materials were

pulverized using a mechanical grinder and sieved through a 60-mesh sieve to obtain a uniform powder. The powdered samples were stored in airtight containers protected from moisture and light until further use.

2.3 Preparation of Plant Extracts:

Powdered plant materials of each species were extracted separately using three different solvents according to their polarity.

2.3.1 Aqueous Extraction: Approximately 100 g of powdered plant material was macerated with distilled water (1:10 w/v) for 48 hours with intermittent shaking. The extract was filtered through Whatman No.1 filter paper and concentrated using a rotary evaporator under reduced pressure at temperatures below 45°C. The concentrated extract was further dried in a hot air oven and stored in airtight containers.

2.3.2 Ethanolic Extraction: For ethanolic extraction, 100 g of powdered material was extracted with 95% ethanol using Soxhlet extraction for 8–10 hours. The extract was filtered and concentrated under reduced pressure using a rotary vacuum evaporator. The concentrated extract was dried and preserved in desiccators until use.

2.3.3 Chloroform Extraction: The powdered material was extracted with chloroform using Soxhlet extraction for approximately 8 hours. The extract was filtered, concentrated under reduced pressure, and stored at 4°C in amber-coloured containers.

2.4 Preparation of Polyherbal Tablet Formulation

The optimized Polyherbal tablet formulation was prepared by combining standardized extracts of *Abutilon indicum*, *Hibiscus rosa-sinensis*, and *Gossypium herbaceum*.

The dried extracts were blended with suitable pharmaceutical excipients including microcrystalline cellulose, lactose, starch, talc, and magnesium stearate. Polyvinylpyrrolidone (PVP K-30) was employed as a binder during granulation.

Wet granulation was carried out by preparing a uniform damp mass using the binder solution. The wet mass was passed through sieve No.16 to produce granules, followed by drying at 45–50°C until the moisture content reached acceptable limits. The dried granules were received through sieve No.22 and lubricated with talc and magnesium stearate before compression.

Tablets weighing approximately 380 ± 5 mg were compressed using a rotary tablet compression machine fitted with standard flat-faced punches.

2.5 Evaluation of Tablet Formulation: The prepared tablets were evaluated according to Indian Pharmacopoeia specifications.

2.5.1 Appearance: The tablets were visually examined for colour, shape, surface smoothness, cracking, capping and uniformity.

2.5.2 Weight Variation: Twenty tablets were individually weighed using an electronic analytical balance. The average weight and percentage deviation were calculated according to Indian Pharmacopoeia limits.

2.5.3 Hardness: Tablet hardness was measured using a Monsanto hardness tester. Six tablets were analysed and the mean hardness was expressed in kg/cm².

2.5.4 Friability: Friability testing was performed using a Roche friabilator operated at 25 rpm for 4 minutes (100 revolutions).

2.5.5 Disintegration Time: Disintegration testing was performed using the USP disintegration apparatus containing distilled water maintained at $37 \pm 0.5^\circ\text{C}$. Six tablets were tested and the average disintegration time was recorded.

2.5.6 In-Vitro Dissolution Study: Drug release studies were carried out using USP Type-II (Paddle) dissolution apparatus containing 900 mL phosphate buffer (pH 6.8) maintained at $37 \pm 0.5^\circ\text{C}$ with paddle rotation at 50 rpm. Aliquots of dissolution medium were withdrawn at predetermined intervals and analysed spectrophotometrically. Equal volumes of fresh dissolution medium were replaced after each sampling to maintain sink conditions.

2.6 Determination of Antioxidant Activity by DPPH Radical Scavenging Assay: The antioxidant activity of aqueous, ethanolic and chloroform extracts was determined using the DPPH free radical scavenging assay according to a modified microplate method.

A freshly prepared DPPH solution (0.1 mM) was prepared in methanol. Various concentrations of plant extracts (100 µg/mL) were mixed with DPPH solution in a 96-well microplate. The reaction mixtures were incubated in the dark for 30 minutes at room temperature. The absorbance was measured at 517 nm using a microplate reader.

Ascorbic acid served as the reference antioxidant. The percentage inhibition was calculated using the following equation:

$$\% \text{ Inhibition} = \frac{A_{\text{control}} - A_{\text{sample}}}{A_{\text{control}}} \times 100$$

Where, A_{control} = Absorbance of control, A_{sample} = Absorbance of test sample.

All experiments were carried out in triplicate ($n = 3$), and the results were expressed as mean $\pm$ standard deviation.

Accelerated Stability Study: The optimized herbal tablet formulations (A7, E8 and C7) were subjected to accelerated stability studies according to ICH Guideline Q1A(R2). The tablets were packed in HDPE containers and stored in a stability chamber maintained at Temperature $40 \pm 2^\circ\text{C}$, Relative Humidity $75 \pm 5\%$ for a period of six months. Samples were withdrawn at, Initial, One month, Two months, Three months and Six months.

The following parameters were evaluated at each interval: Physical appearance, Colour, Odour, Weight variation, Hardness, Friability, Disintegration time, Dissolution profile and Microbial load etc.

2.8 Microbial Load Determination: Microbial quality of the optimized tablet formulations was evaluated according to Indian Pharmacopoeial guidelines. Total aerobic microbial count and fungal count were determined using nutrient agar and Sabouraud dextrose agar media. Plates were incubated under suitable conditions and examined for microbial growth. The absence of visible microbial colonies indicated microbiological stability of the formulations during storage.

2.9 Statistical Analysis: All experimental observations were performed in triplicate and expressed as Mean $\pm$ Standard Deviation (Mean $\pm$ SD). Statistical analysis was performed using GraphPad Prism version 9.0 (GraphPad Software, USA). Differences among experimental groups were analysed by one-way analysis of variance (ANOVA) followed by Tukey's multiple comparison test. A value of $p < 0.05$ was considered statistically significant.

3. Results:

3.1 Antioxidant Activity of Malvaceae Plant Extracts by DPPH Radical Scavenging Assay: The antioxidant potential of aqueous, ethanolic, and chloroform extracts of *Abutilon indicum* (A), *Hibiscus rosa-sinensis* (H), and *Gossypium herbaceum* (G) was evaluated using the DPPH free radical scavenging assay. Ascorbic acid was used as the reference antioxidant.

The assay demonstrated considerable variation in antioxidant activity among the different solvent extracts. Among all tested samples, the ethanolic extract of *Hibiscus rosa-sinensis* (EH) exhibited the highest antioxidant activity (70.18%), followed closely by chloroform extract of *Hibiscus rosa-sinensis* (CH, 69.60%), aqueous extract of *Abutilon indicum* (AA, 69.07%), and aqueous extract of *Hibiscus rosa-sinensis* (AH, 67.54%). These values approached the antioxidant activity of the standard ascorbic acid (74.23%), indicating strong free radical scavenging potential. In contrast, aqueous and chloroform extracts of *Gossypium herbaceum* demonstrated comparatively lower antioxidant activity (29.81–31.69%), suggesting that solvent selection significantly influences the extraction of antioxidant phytoconstituents.

Table 3.1 antioxidant activity of different plant extracts by DPPH assay:

Sample	Mean Absorbance (OD)	% DPPH Radical Scavenging
Control	1.704	—
Ascorbic Acid	0.439	74.23
AA	0.527	69.07
AH	0.553	67.54
AG	1.164	31.69
EA	1.195	29.87
EH	0.508	70.18
EG	0.576	66.19
CA	0.839	50.76
CH	0.518	69.60
CG	1.196	29.81

Values are expressed as Mean (n = 3).

Figure 3.1

Comparative antioxidant activity of aqueous, ethanol and chloroform extracts using DPPH radical scavenging assay.

3.2 Comparative Evaluation of Antioxidant Activity: Comparison of all extracts revealed that *Hibiscus rosa-sinensis* possessed the greatest antioxidant capacity irrespective of extraction solvent. Ethanolic extraction provided the highest recovery of antioxidant

photochemical, indicating that phenolic compounds and flavonoids responsible for free radical scavenging are more efficiently extracted in ethanol. Among the three plant species investigated, *Gossypium herbaceum* showed relatively lower antioxidant activity in aqueous and chloroform extracts, whereas the ethanolic extract demonstrated moderate antioxidant potential.

3.3 Physical Evaluation of Optimized Polyherbal Tablet

Formulation: The optimized polyherbal tablets prepared by wet granulation exhibited satisfactory physical appearance with smooth surfaces, uniform colour, and absence of visual defects such as capping, lamination, or cracking. The tablets complied with Indian Pharmacopoeial specifications for weight variation, hardness, friability, and disintegration time.

Table 3.2 Physical Evaluation of Optimized Polyherbal Tablets:

Parameter	Observation
Colour	Light royal blue
Odour	Odourless
Average Weight	380 $\pm$ 5 mg
Hardness	6.4–6.8 kg/cm ²
Friability	$\leq$ 1.20%
Disintegration Time	7.5–7.8 min
Surface	Smooth
Appearance	Uniform

The optimized formulations exhibited excellent mechanical strength while maintaining rapid disintegration, indicating suitability for oral administration.

3.4 Accelerated Stability Study: Accelerated stability testing was conducted according to ICH Q1A(R2) guidelines at 40 $\pm$ 2°C/75 $\pm$ 5% RH for six months. Throughout the study period, no significant changes were observed in tablet appearance, colour, odour, or consistency. The formulations remained physically intact with no evidence of swelling, cracking, or discoloration.

3.4.1 Stability Evaluation of A7 Formulation: The A7 formulation demonstrated outstanding stability during storage. Tablet hardness varied only slightly between 6.1 and 6.5 kg/cm² throughout six months. Friability remained constant at approximately 1.20%, indicating excellent mechanical integrity. Disintegration time remained nearly unchanged, varying between 7.46 and 7.57 minutes. Dissolution efficiency decreased only marginally from 99.95% initially to 98.95% after six months. No microbial contamination was detected throughout the study.

Table 3.3 Stability Results of Optimized A7 Formulation:

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Parameter	Initial	1 Month	2 Months	3 Months	6 Months
Weight (mg)	380 ± 5	381 ± 5	381 ± 5	382 ± 5	381 ± 5
Hardness (kg/cm ²)	6.4	6.5	6.4	6.1	6.3
Friability (%)	1.20	1.20	1.20	1.20	1.20
Disintegration (min)	7.55	7.57	7.46	7.56	7.55
Dissolution (%)	99.95	99.91	99.89	99.55	98.95
Microbial Growth	Nil	Nil	Nil	Nil	Nil

3.4.2 Stability Evaluation of E8 Formulation: The E8 formulation also remained stable under accelerated conditions. Although a gradual reduction in dissolution profile was observed (98.95% to 95.95%), all evaluated parameters remained within pharmacopeial acceptance limits. Minor fluctuations in hardness and friability were observed but were not considered statistically significant.

Table 3.4 Stability Results of E8 Formulation:

Parameter	Initial	1 Month	2 Months	3 Months	6 Months
Weight (mg)	383 ± 5	381 ± 5	380 ± 5	382 ± 5	382 ± 5
Hardness (kg/cm ²)	6.5	6.3	6.4	6.7	6.1
Friability (%)	1.10	1.40	1.30	1.30	1.20
Disintegration (min)	7.65	7.87	7.76	7.96	7.65
Dissolution (%)	98.95	97.91	97.89	96.55	95.95
Microbial Growth	Nil	Nil	Nil	Nil	Nil

3.4.3 Stability Evaluation of C7 Formulation: The C7 formulation exhibited acceptable pharmaceutical stability throughout storage. The dissolution profile showed a gradual decline from **97.95%** to **94.95%**, while hardness, friability, and disintegration time remained within acceptable pharmacopeia limits. No microbial contamination was observed during the study.

Table 3.5 Stability Results of C7 Formulation:

Parameter	Initial	1 Month	2 Months	3 Months	6 Months
Weight (mg)	383 ± 5	380 ± 5	381 ± 5	383 ± 5	381 ± 5
Hardness (kg/cm ²)	6.8	6.2	6.9	6.1	6.3
Friability (%)	1.30	1.30	1.60	1.20	1.10
Disintegration (min)	7.75	7.67	7.96	7.96	7.65
Dissolution (%)	97.95	96.91	97.89	95.55	94.95
Microbial Growth	Nil	Nil	Nil	Nil	Nil

3.5 Comparative Stability Performance of Optimized Formulations: A comparative assessment demonstrated that the A7 formulation exhibited the highest overall stability under accelerated storage conditions. It retained superior dissolution efficiency (98.95%), consistent hardness, low friability, and excellent microbiological stability. The E8 and C7 formulations also remained stable but showed comparatively greater reductions in dissolution profile during storage.

Table 3.6 Comparative Summary of Optimized Formulations After Six Months:

Parameter	A7	E8	C7
Weight (mg)	381 ± 5	382 ± 5	381 ± 5
Hardness (kg/cm ²)	6.3	6.1	6.3
Friability (%)	1.20	1.20	1.10
Disintegration (min)	7.55	7.65	7.65
Dissolution (%)	98.95	95.95	94.95
Microbial Growth	Nil	Nil	Nil

Discussion: The present study successfully developed a standardized polyherbal tablet containing extracts of *Abutilon indicum*, *Hibiscus rosa-sinensis*, and *Gossypium herbaceum*, and evaluated its antioxidant activity and accelerated stability. The findings indicate that the selected *Malvaceae* plants possess significant antioxidant potential, supporting their traditional use in managing oxidative stress associated with diabetes mellitus.

The DPPH assay showed that all extracts exhibited antioxidant activity, with the ethanolic extract of *Hibiscus rosa-sinensis* demonstrating the highest free radical scavenging activity (70.18%), followed by its chloroform extract (69.60%) and the aqueous extract of *Abutilon indicum* (69.07%). The strong antioxidant effect is mainly attributed to the presence of flavonoids, phenolic compounds, anthocyanins, tannins, and other phytochemicals that neutralize reactive oxygen species and help protect pancreatic β-cells from oxidative damage. The polyherbal approach combines multiple bioactive constituents that may act synergistically to provide antioxidant, antihyperglycaemic, anti-inflammatory, and organ-protective effects. Such combinations are expected to improve therapeutic efficacy while reducing the required dose of individual plant extracts.

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The optimized tablets prepared by wet granulation exhibited acceptable pharmaceutical properties, including uniform weight, adequate hardness, low friability, and rapid disintegration, all complying with Indian Pharmacopoeial standards.

Accelerated stability studies conducted according to ICH Q1A(R2) guidelines demonstrated that the formulations remained stable for six months under $40 \pm 2^\circ\text{C}$ and $75 \pm 5\%$ RH. No significant changes were observed in physical characteristics or tablet quality parameters. Formulation A7 showed the highest dissolution (98.95%) after storage, and all formulations remained within acceptable limits without any microbial contamination.

Conclusion:

The present investigation successfully developed and evaluated a standardized Polyherbal tablet formulation containing extracts of *Abutilon indicum*, *Hibiscus rosa-sinensis*, and *Gossypium herbaceum*, three medicinal plants belonging to the family *Malvaceae*. The formulation demonstrated satisfactory pharmaceutical characteristics and exhibited significant antioxidant activity, supporting the traditional therapeutic use of these plants in the management of diabetes mellitus.

Among the evaluated extracts, the ethanolic extract of *Hibiscus rosa-sinensis* showed the highest DPPH free radical scavenging activity (70.18%), followed by the chloroform extract of *Hibiscus rosa-sinensis* (69.60%) and the aqueous extract of *Abutilon indicum* (69.07%). These findings indicate that the selected medicinal plants are rich sources of bioactive phytoconstituents capable of effectively neutralizing reactive oxygen species. The observed antioxidant activity is primarily attributed to the presence of flavonoids, phenolic compounds, anthocyanins, tannins, and other naturally occurring secondary metabolites.

The formulated Polyherbal tablets complied with Pharmacopoeial quality requirements regarding weight variation, hardness, friability, and disintegration time, appearance, and dissolution characteristics. Furthermore, accelerated stability studies conducted under ICH Q1A (R2) conditions demonstrated that the optimized formulations maintained acceptable physical, chemical, and microbiological stability throughout the six-month study period. Among the formulations investigated, A7 exhibited superior stability, showing minimal variation in pharmaceutical parameters and the highest dissolution profile after storage.

The study provides scientific evidence supporting the pharmaceutical development of standardized Malvaceae-based Polyherbal formulations as promising natural antioxidant preparations. Such formulations may contribute to reducing oxidative stress, which plays a central role in the pathogenesis and progression of diabetes mellitus. Although encouraging results were obtained, additional investigations involving phytochemical standardization, bioactive compound isolation, in vivo pharmacological studies, molecular mechanism elucidation, toxicological evaluation, pharmacokinetic assessment, and randomized

clinical trials are necessary before clinical application. Nevertheless, the present work establishes an important foundation for the development of safe, effective, and scientifically validated herbal formulations for diabetes management.

Declarations: Ethics Approval and Consent to Participate. The experimental protocol involving laboratory animals was conducted in accordance with the guidelines of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), Government of India. The study was approved by the Institutional Animal Ethics Committee (IAEC) of DCS's A.R.A. College of Pharmacy, Nagaon, Dhule, Maharashtra, India.

Consent for Publication: Not applicable.

Availability of Data and Materials: The datasets generated and analysed during the present study are available from the corresponding author upon reasonable request.

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Data Availability Statement: The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Conflict of Interest Statement: The authors declare that they have no known competing interests or personal relationships that could have influenced the work reported in this paper..

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