

POLYHERBAL INNOVATION: TABLET FORMULATION TARGETING DIABETES MELLITUS MANAGEMENT

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ABSTRACT

Background: Diabetes mellitus is a chronic metabolic disorder characterized by hyperglycemia. Traditional herbal medicines offer promising antidiabetic alternatives, leveraging natural phytoconstituents with minimal side effects. This study evaluates the antidiabetic potential of a polyherbal tablet formulation containing extracts from *Syzygium cumini* (Jamun), *Trigonella foenum-graecum* (Fenugreek), *Piper nigrum* (Pepper), and *Asphaltum punjabianum* (Shilajit).

Materials and Methods: The plant materials were shade-dried, ground to a coarse powder, and passed through an 80-mesh sieve. The extracts were formulated into tablets using microcrystalline cellulose (MCC), polyvinylpyrrolidone (PVP), croscopovidone, aerosil, and magnesium stearate as excipients. The formulation was evaluated for precompression parameters to ensure optimal flow properties. The tablets underwent standard evaluations for weight variation, hardness, friability, disintegration, and stability.

Results: Preliminary phytochemical screening confirmed the presence of alkaloids, flavonoids, phenols, tannins, saponins, glycosides, terpenoids, and other secondary metabolites in the plant extracts. Precompression studies demonstrated satisfactory flow characteristics, with an angle of repose ranging from 40.02° to 40.06°. The formulated tablets exhibited uniform weight (average 0.63 g), adequate hardness (average 3.06 kg/cm²), low friability (0.9%), and a rapid disintegration time of 1 minute and 10 seconds.

Antidiabetic Activity: The in vitro antidiabetic activity was assessed using α -amylase and α -glucosidase inhibition assays. The polyherbal tablet (PHT) demonstrated notable inhibitory activity against α -amylase with an IC₅₀ value of 31.39 μ g/mL, compared to the reference standard acarbose (IC₅₀ 3.99 μ g/mL). Similarly, in the α -glucosidase inhibition assay, the polyherbal tablet (PHT) exhibited an IC₅₀ value of 37.93 μ g/mL, while the standard drug voglibose showed a significantly lower IC₅₀ value of 5.3 μ g/mL.

Conclusion: The developed polyherbal tablet formulation exhibited promising antidiabetic activity through significant inhibition of α -amylase and α -glucosidase enzymes, highlighting its potential as an effective natural treatment for diabetes mellitus. The standardized formulation demonstrated excellent physicochemical properties and stability, supporting its suitability for further clinical investigations.

KEY WORDS: *DIABETES MELLITUS, SYZYGIUM CUMINI, TRIGONELLA FOENUM-GRAECUM PIPER NIGRUM, ASPHALTUM PUNJABIANUM.*

INTRODUCTION

Ayurveda emphasizes prevention of disease and maintenance of long, healthy life through natural means such as herbs, minerals, diet, and lifestyle practices. Unlike synthetic pharmaceuticals, which provide targeted symptomatic relief but are often costly and associated with adverse effects, herbal medicines aim to restore balance and address the root cause of disease [1]. Herbal medicines have been used worldwide since prehistoric times, with Ayurveda incorporating them as powerful therapeutic agents. Despite the 19th-century shift to synthetic drugs through chemical isolation and modification, increasing concerns about drug resistance and toxicity have led to a global resurgence of interest in plant-based remedies [2]. According to the World Health Organization, nearly 80% of the global population relies on traditional medicine as their primary source of healthcare [3]. Ayurvedic medicines are broadly classified as herbal, mineral, or animal-derived, with herbal formulations being the most widely used. Herbal drugs may involve single herbs or polyherbal formulations (PHFs). The latter combine multiple plant extracts to produce synergistic effects that enhance therapeutic efficacy compared to individual components [4]. Advances in phytochemical isolation, purification, and nanoparticle-based delivery systems have improved the bioavailability and therapeutic potential of herbal compounds [5, 6].

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia and the absence of a definitive cure, imposing a significant economic burden on healthcare systems, particularly in low- and middle-income countries. [7]. Conventional antidiabetic agents—including sulfonylureas, biguanides, thiazolidinediones, α -

glucosidase inhibitors, and secretagogues—provide glycemic control but are limited by reduced long-term efficacy, resistance, and adverse effects [8–10]. Consequently, Phytocompounds such as quercetin, curcumin, berberine, gymnemic acids, and bitter melon seed oil have garnered considerable interest due to their diverse mechanisms of action, including promoting stimulating insulin secretion, promoting pancreatic β -cell regeneration, reducing glucose absorption, improving insulin sensitivity, and increasing glycogen storage. [11–13].

PHFs have shown promising antidiabetic, wound-healing, and anti-inflammatory activities through synergistic interactions among bioactive constituents [14–16]. However, challenges such as chemical incompatibility, instability, and weak regulatory oversight limit their wider adoption [17, 18]. Most Ayurvedic formulations are manufactured under the Drugs and Cosmetics Act, yet requirements for toxicity and clinical studies remain less stringent than for synthetic drugs [19, 20]. Despite these limitations, evidence from pharmacological and clinical studies indicates that PHFs may offer effective, safe, and affordable alternatives or adjuncts to conventional diabetes therapy [21–23]. Numerous studies have demonstrated the significant antidiabetic activity of polyherbal formulations (PHFs) in preclinical models. However, most reports remain limited to in vivo evaluations, and comprehensive toxicity, pharmacokinetic, and pharmacodynamic studies are scarce. To ensure safety and therapeutic reliability, molecular-level investigations of mechanisms are required, along with systematic toxicity profiling. Well-designed clinical trials are also essential to validate efficacy, establish standardized formulations, and strengthen regulatory acceptance. Such progress would facilitate patenting and commercialization of novel PHFs, providing affordable and safer alternatives to synthetic antidiabetic drugs currently burdened with adverse effects. The therapeutic activity of PHFs is attributed to a wide array of phytochemicals, including alkaloids, flavonoids, glycosides, phenolic acids, saponins, polysaccharides, stilbenes, and tannins. Variations in extraction methods, plant part used, and growing or storage conditions influence phytochemical profiles and may account for inconsistencies in reported efficacy [24,25]. Despite these challenges, the holistic, multi-target approach of PHFs offers an advantage over single-drug therapies. Advances in nanotechnology and green synthesis methods further hold promise for enhancing bioavailability and stability of phytoconstituents. Future research should focus on:

1. **Rigorous safety and efficacy validation** through toxicity studies and controlled clinical trials.
2. **Standardization and quality control** of herbal raw materials and formulations.
3. **Mechanistic studies at molecular and cellular levels** to identify active principles.
4. **Development of functional foods and nutraceuticals** with antidiabetic potential.

Several plants widely used in traditional medicine—including *Wattakaka volubilis*, *Tinospora cordifolia* [26], *Azadirachta indica* [27], *Abrus precatorius* [28], *Trigonella foenum-graecum* [29], *Aloe barbadensis* [29,30], *Mangifera indica* [30], *Acacia arabica* [30], *Allium cepa* [30], *Momordica charantia* [31], *Syzygium cumini* [32,33], and *Camellia sinensis* [34,35]—have shown antihyperglycemic or hypoglycemic activities, often through α -amylase/ α -glucosidase inhibition, insulin stimulation, antioxidant effects, and improved lipid metabolism. These plants, either individually or as components of synergistic polyherbal formulations, represent promising candidates for the development of next-generation antidiabetic therapies. In conclusion, although PHFs are traditionally used and pharmacologically promising, their global acceptance depends on stronger scientific validation, standardization, and clinical translation. With rational use and scientific backing, PHFs could evolve into safer, effective, and affordable options for diabetes management.

MATERIALS AND METHODS

Extraction of Plant Materials

Plant materials of *Syzygium cumini*, *Trigonella foenum-graecum*, and *Piper nigrum* were sliced, shade-dried, pulverized into a coarse powder, and sieved through an 80-mesh screen. The resulting powders were dried using various methods and subsequently subjected to preliminary phytochemical screening for further analysis.

Formulation Development

Dried extracts of *S. cumini*, *T. foenum-graecum*, *P. nigrum*, and Shilajit were used in tablet preparation. Microcrystalline cellulose (MCC) was used as a diluent, polyvinylpyrrolidone (PVP) as a binder, croscopovidone as a disintegrant, and magnesium stearate and colloidal silicon dioxide (Aerosil) as glidants. The weighed active ingredients were blended with MCC and excipients, homogenized for 30 minutes, and compressed into tablets by direct compression.

Pre-compression Evaluation

Powder blends for trial batches were formulated using different excipient ratios to achieve optimal flowability and compressibility. These blends were assessed for bulk density, tapped density, Carr's index, Hausner's ratio, and angle of repose.

Composition of Herbal Tablet Formulation

The herbal tablets were formulated using four active ingredients: Piper nigrum (125 mg), Syzygium cumini (syn. Eugenia jambolana, E. cumini) (125 mg), Trigonella foenum-graecum (125 mg), and Shilajit (Asphaltum punjabianum) (125 mg), giving a total of 500 mg herbal powder. The complete composition of the trial formulation is presented in Table 1.

Table 1. Composition of herbal tablet formulation

S.No	Ingredients	Quantity (mg)
1.	Herbal powder	500
2.	Microcrystalline cellulose (MCC)	83
3.	Polyvinylpyrrolidone (PVP)	6
4.	Crospovidone	19
5.	Aerosil	6
6.	Magnesium stearate	6
7.	Total weight	620

Preliminary Phytochemical Analysis

Seed extracts of *S. cumini*, *T. foenum-graecum*, and *P. nigrum* were subjected to preliminary phytochemical screening for detection of primary and secondary metabolites as per standard procedures [36,37]. Herbal drugs are biosynthetic reservoirs of both primary metabolites (e.g., carbohydrates, proteins, lipids) and secondary metabolites (e.g., glycosides, alkaloids, flavonoids, tannins), which are of pharmacological importance.

PREFORMULATION STUDIES [38]

Angle of repose

The angle of repose was determined using the fixed-height method to evaluate the flow characteristics of the powder blends in all formulations. A funnel with a 10 mm internal diameter stem was positioned 2 cm above a flat surface. Approximately 10 g of the sample was gradually poured along the funnel wall until the tip of the powder cone touched the funnel stem. The base radius of the cone was measured by outlining a rough circle around its perimeter. The angle of repose was then calculated using the following formula based on the average radius

$$\theta = \tan^{-1} (h/r)$$

Where, θ = Angle of repose
 h = Height of the pile
 r = Average radius of the powder cone

Loose Bulk Density (LBD)

The loose bulk density of the granules was determined by carefully transferring 25 g of the sample into a 100 mL graduated cylinder using a glass funnel. The volume occupied by the sample was measured and recorded. The apparent bulk density was calculated by dividing the weight of the powder by the corresponding volume.

$LBD = \text{Weight of the powder} / \text{Volume of the packing}$

Tapped Bulk Density (TBD)

Tapped bulk density was measured by gently pouring 25 g of the sample through a glass funnel into a 100 mL graduated cylinder. The cylinder was tapped from a height of 2 inches until a constant volume was obtained. The final volume was recorded, and the tapped density was calculated. The process involved allowing the cylinder, containing a known mass of the powder blend, to drop from a height of 10 cm at 2-second intervals until no further change in volume occurred.

$TBD = \text{Weight of the powder} / \text{Volume of the tapped packing}$

Compressibility Index

The compressibility index of the powder blends was calculated using Carr's Compressibility Index to evaluate the flow properties.

$$\text{Compressibility Index (\%)} = (\text{TBD} - \text{LBD}) \times 100 / \text{TBD}$$

Hausner's Ratio

Hausner's ratio, an indicator of the frictional resistance and flow behavior of the powder, was determined using the following formula. An ideal Hausner's ratio value ranges between 1.2 and 1.5.

$$\text{Hausner's Ratio} = \text{TBD} / \text{LBD}$$

Evaluation of Polyherbal Tablets

All formulated tablets were evaluated for the following parameters:

Color and Appearance

The tablets were visually inspected to assess their color, surface texture, and overall appearance.

Weight Variation Test

Twenty tablets were randomly selected and individually weighed to determine the average tablet weight. Each tablet's deviation from the mean was calculated, ensuring that not more than two tablets deviated beyond the specified percentage limit and none exceeded twice that range.

Hardness and Friability Test

Tablet hardness was measured using a calibrated Monsanto hardness tester, while friability was assessed with a Roche friabilator operated for 4 minutes at 25 rpm.

Disintegration Test

The disintegration time was determined using a standard disintegration apparatus. Each tube (80–100 mm in length, 28 mm internal diameter, and 30–31 mm external diameter) was fitted with a rust-resistant wire gauge at the bottom. Six tablets were placed in the tubes, which were moved up and down 28–32 times per minute. Complete disintegration was confirmed when no residue remained on the mesh (10-mesh screen).

Thickness

Tablet thickness was measured using a digital Vernier caliper to ensure uniformity.

Stability Studies

Stability testing of the formulated tablets was conducted in a stability chamber maintained at 40 °C and 75% relative humidity for one month.

In Vitro Antidiabetic Activity

- **α -Amylase Inhibition Assay:**

The α -amylase inhibitory potential was assessed. Test samples (10–320 $\mu\text{g/mL}$) were incubated with α -amylase (0.1 mg/mL) and a starch substrate. Absorbance was recorded at 565 nm, and the percentage inhibition was calculated. Acarbose was used as the reference standard.

- **α -Glucosidase Inhibition Assay:**

Test samples (10–320 $\mu\text{g/mL}$) were incubated with α -glucosidase enzyme and *p*-nitrophenylglucopyranoside (pNPG) substrate in phosphate buffer (pH 6.8). The reaction was terminated using sodium bicarbonate, and absorbance of the released *p*-nitro phenol was measured at 405 nm. Voglibose served as the standard reference.

RESULT AND DISCUSSIONS**Preliminary Phytochemical Screening**

The polyherbal formulation containing *Trigonella foenum-graecum* (T.foenum), *Piper nigrum* (P.nigrum), and *Syzygium cumini* (S.cumini) was tested for major phytoconstituents. The polyherbal formulation comprising *Trigonella foenum-graecum*, *Piper nigrum*, and *Syzygium cumini* was subjected to qualitative phytochemical analysis to detect the presence of major secondary metabolites. The results revealed that all three plants were rich in alkaloids, flavonoids, glycosides, phenols, tannins, saponins, and terpenoids. Carbohydrates and proteins were detected in *T. foenum-graecum* and *P. nigrum* but absent in *S. cumini*. Sterols were observed in *P. nigrum* and *S. cumini* but absent in *T. foenum-graecum*, whereas resins were present in *T. foenum-graecum* and *S. cumini* but absent in *P. nigrum*. The overall phytochemical profile indicates a broad spectrum of bioactive compounds across the three plants, suggesting synergistic potential in the polyherbal formulation, particularly due to the abundance of alkaloids, flavonoids, and saponins, which are known to contribute to antidiabetic and antioxidant activities.

Table 2: Preformulation Parameters of Powder Blend

	Parameters	Trial 1	Trial 2	Trial 3	Average
1.	Angle of repose (°)	40.02	40.03	40.06	40.03
2.	Loose bulk density (g/ml)	0.36	0.39	0.42	0.39
3.	Tapped bulk density (g/ml)	0.50	0.53	0.56	0.53
4.	Compressibility index (%)	26.75	26.4	23.63	25.29
5.	Hausner's ratio	1.38	1.35	1.33	1.36

The polyherbal formulation was assessed for its flow and compressibility properties. The angle of repose averaged 40.03°, indicating acceptable flow behavior. The loose bulk density and tapped bulk density were measured at 0.39 g/mL and 0.53 g/mL, respectively. The compressibility index (25.29%) and Hausner's ratio (1.36) reflected fair flow characteristics with moderate compressibility, confirming the blend's suitability for tablet compression. All evaluated parameters were within pharmacopoeial limits, demonstrating good flow and compressibility of the powder blend.

Table 3: Evaluation Parameters of Polyherbal Tablets

S.No	Parameter	Observation / Range	Limit / Standard
1.	Average Weight (mg)	630 ± 0.026	±5% of average
2.	Hardness (kg/cm ²)	3.0–3.2	3–6
3.	Thickness (mm)	12.87–12.92	–
4.	Friability (%)	0.9	≤1
5.	Disintegration Time (min:sec)	1:10	≤15
6.	Appearance	Light brown, round	–
7.	Odor	Characteristic	–
8.	Taste	Slightly bitter	–

All formulations exhibited an average tablet weight ranging from 610.5 to 630.5 mg, with thickness values between 12.7 and 12.9 mm. The mean hardness of the tablets varied from 3.0 to 3.6 kg/cm². Friability values were found to be between 0.59% and 0.92%, confirming good mechanical strength. The tablet thickness was influenced by the punch size (12 mm) and tablet weight (approximately 630 mg). Adequate friability is essential for ensuring the tablets can withstand mechanical stress during handling and compression, and all formulated polyherbal tablets showed friability values within the acceptable pharmacopoeial limit (not more than 1%). The formulations also demonstrated uniform and satisfactory drug content, complying with standard specifications.

IN- VITRO ANTIDIABETIC ACTIVITY OF THE POLYHERBAL TABLETS

Table: 4 In -Vitro α -Amylase Inhibition Assay

S.No	Conc (μ g/mL)	PHT (%) Inhibition	Acarbose (%) Inhibition
1.	10	20.91	50.02
2.	20	29.24	74.22
3.	40	61.20	89.38
4.	80	86.22	94.84
5.	160	92.72	96.81
6.	320	95.06	97.11

The polyherbal formulation (PHT) exhibited a dose-dependent inhibitory effect on α -amylase activity. Percentage inhibition (Table: 3) increased from 20.91% at 10 μ g/ml to 95.06% at 320 μ g/ml. In comparison, the standard drug acarbose showed higher inhibition at lower concentrations (50.02% at 10 μ g/ml) and reached a maximum of 97.11% at 320 μ g/ml. These results indicate that the formulation possesses significant α -amylase inhibitory potential, approaching that of acarbose at higher concentrations.

IC₅₀: PHT = 31.39 μ g/ml; Acarbose = 3.99 μ g/ml.

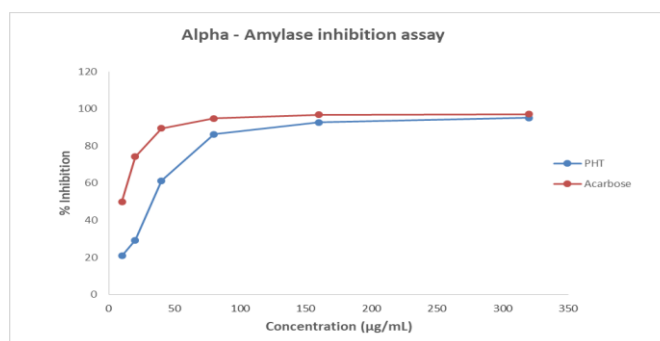


Fig1: Graphical Representation of Alpha amylase Inhibition assay using acarbose

Qualitative phytochemical screening of the polyherbal formulation confirmed the presence of alkaloids, flavonoids, glycosides, phenols, tannins, saponins, and terpenoids in all three extracts — *Trigonella foenum-graecum*, *Piper nigrum*, and *Syzygium cumini*. Carbohydrates and proteins were detected in *T. foenum-graecum* and *P. nigrum* but absent in *S. cumini*. Sterols were observed in *P. nigrum* and *S. cumini* but not in *T. foenum-graecum*, whereas resins were present in *T. foenum-graecum* and *S. cumini* but absent in *P. nigrum*. The broad spectrum of phytoconstituents, particularly alkaloids, flavonoids, and saponins, suggests potential synergistic activity contributing to the therapeutic efficacy of the formulation. The IC₅₀ value of the polyherbal test sample (PHT) was determined to be 31.39 μ g/mL, while that of the reference standard (Acarbose) was 3.99 μ g/mL.

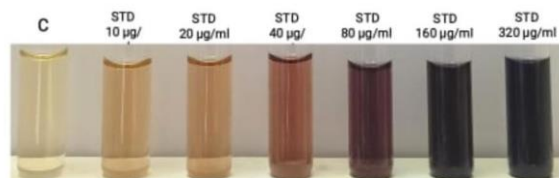


Fig 2: Diagram showing the different concentration of the standard solution of Agarbose

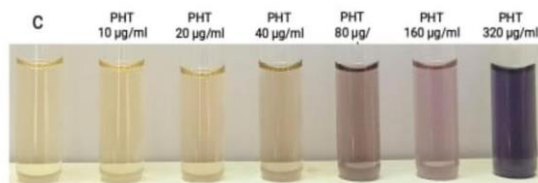


Fig 3: Diagram showing the different Concentration of the formulated Polyherbal tablets (PHT)

Table 5: In Vitro α -Glucosidase Inhibition Assay

S.No	Conc ($\mu\text{g/mL}$)	PHT Inhibition (%)	Voglibose (%) Inhibition
1.	10	11.31	41.55
2.	20	38.35	79.95
3.	40	62.13	88.05
4.	80	65.55	92.59
5.	160	82.77	96.05
6.	320	94.51	97.17

IC₅₀: PHT = 37.93 $\mu\text{g/mL}$; Voglibose = 5.39 $\mu\text{g/mL}$.

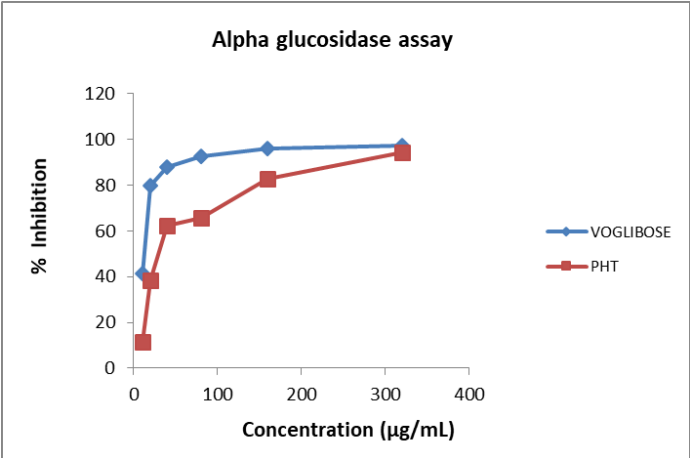


Fig 4: Graphical representation of Alpha glucosidase assay using Voglibose

The IC₅₀ value of test the polyherbal sample (PHT) was found to be 37.93µg/mL, whereas the standard drug (Voglibose) exhibited an IC₅₀ value of 5.3µg/mL.

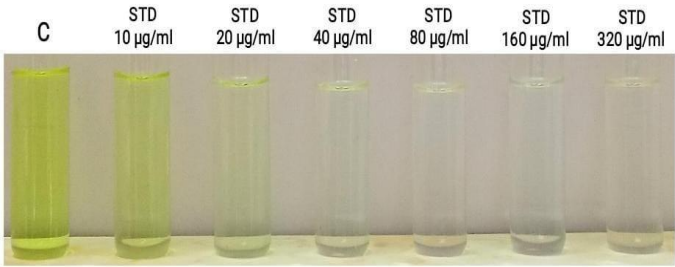


Fig 5: Diagram showing the different concentration of the standard solution of Voglibose

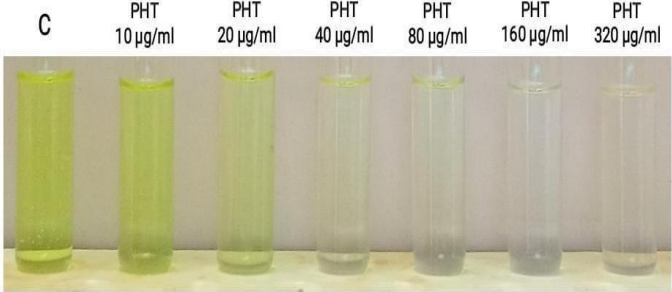


Fig 6: Diagram showing the different concentration of the formulated Polyherbal tablets (PHT)



Fig 7: Poly Herbal Tablet

Discussion

The formulated trial batches of the polyherbal tablet were optimized by adjusting excipient proportions to achieve satisfactory flow and compressibility properties. Herbal medicines remain one of the oldest forms of healthcare, and traditional practices continue to inform the prevention and management of various diseases. Based on literature review, four medicinal plants (*Syzygium cumini*, *Trigonella foenum-graecum*, *Piper nigrum*, and *Shilajit*) were selected for the formulation of the polyherbal tablet, and its antidiabetic potential was evaluated. Preliminary phytochemical analysis confirmed the presence of key bioactive constituents, including alkaloids, steroids, glycosides, flavonoids, phenols, tannins, and Terpenoids, which may contribute to the antidiabetic activity. Preformulation studies demonstrated uniformity, good flow, and compressibility within pharmacopoeial limits, indicating suitability for tablet formulation. The formulated polyherbal tablets were evaluated and standardized based on physical parameters, including appearance, weight uniformity, thickness, and hardness, friability, and disintegration time. The *in vitro* antidiabetic potential, determined through α -amylase and α -glycosidase inhibition assays using acarbose and voglibose as reference standards, revealed notable enzyme inhibitory activity. The polyherbal tablet effectively reduced glucose levels, likely due to synergistic effects of its phytoconstituents, highlighting its potential as a natural antidiabetic formulation.

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