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Research Article

Development and Evaluation of Polyherbal Antidiabetic Capsules Containing *Gymnema Sylvestre* and Fenugreek Extracts

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ABSTRACT

This study focused on the formulation and assessment of polyherbal antidiabetic capsules incorporating extracts of Gymnema sylvestre and Trigonella foenum-graecum. Diabetes mellitus is a persistent metabolic condition marked by increased blood glucose levels and related consequences. Herbal medicines are extensively utilized in diabetes care owing to their safety, efficacy, and less adverse effects relative to synthetic pharmaceuticals. The herbal substances were gathered, verified, desiccated, pulverized, and processed through hydroalcoholic extraction via the maceration technique. Initial phytochemical analysis verified the existence of significant phytoconstituents, including alkaloids, flavonoids, tannins, glycosides, saponins, and carbohydrates. Five formulation batches of polyherbal capsules were created utilizing varying amounts of herbal extracts in conjunction with appropriate excipients, including lactose, talc, and magnesium stearate. The formulated preparations were assessed for multiple pharmaceutical parameters, including angle of repose, bulk density, tapped density, weight fluctuation, disintegration time, drug content homogeneity, and stability investigations. The findings achieved were within acceptable parameters for all formulation batches. Among all formulations, batch F3 exhibited superior pharmaceutical features, including optimal flow qualities, minimal disintegration time, adequate drug content, and an enhanced stability profile. The research determined that the formulated polyherbal antidiabetic capsules exhibit adequate pharmacological characteristics and may represent a suitable herbal solution for the management of diabetes mellitus. The combination antidiabetic actions of Gymnema sylvestre and Fenugreek may enhance patient adherence and minimize adverse effects.

INTRODUCTION

Diabetes Mellitus

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Diabetes mellitus is a prevalent chronic metabolic condition impacting millions globally. It is marked by increased blood glucose levels due to impairments in insulin secretion, insulin action, or both. Chronic hyperglycemia can result in serious consequences including cardiovascular disorders, kidney, neuropathy, retinopathy, and impaired wound healing[1]. The prevalence of diabetes has increased rapidly due to sedentary lifestyle, obesity, stress, unhealthy dietary habits, and genetic predisposition. According to global health reports, Type 2 diabetes mellitus accounts for nearly 90–95% of all diabetic cases and has become a major public health concern[2].

Diabetes management necessitates prolonged treatment that includes oral hypoglycemic medications, insulin therapy, nutritional control, and lifestyle changes. Synthetic antidiabetic medications, while effective, may lead to side effects with continuous usage, including hypoglycemia, gastrointestinal problems, hepatic dysfunction, and weight gain[3] Therefore, there is growing interest in herbal medicines due to their safety, affordability, effectiveness, and minimal side effects.

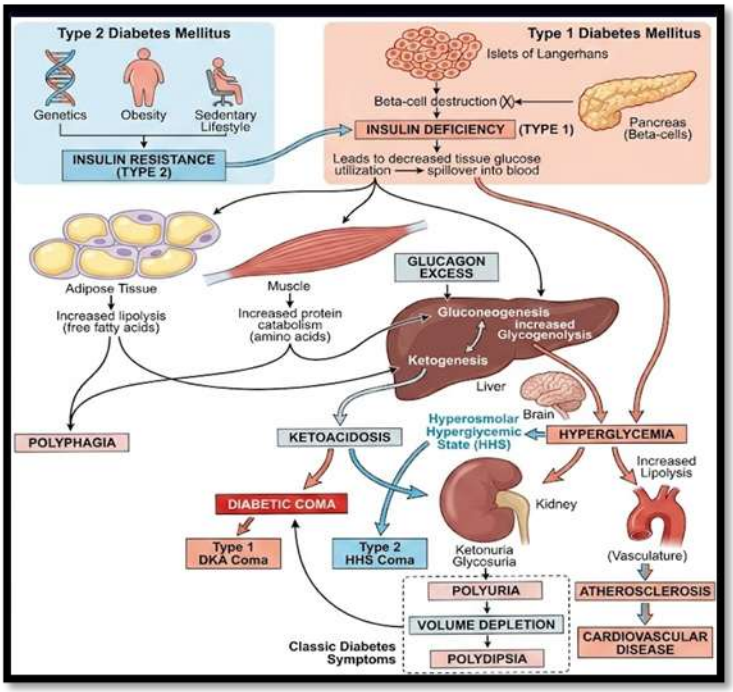


Figure 1: Pathophysiology of Diabetes Mellitus[1]

Herbal Medicine in Diabetes Management

Medicinal plants have been used traditionally for the treatment of diabetes since ancient times. Herbal drugs contain phytoconstituents such as alkaloids, flavonoids, glycosides, tannins, saponins, and terpenoids which possess significant antidiabetic activity[4]. These bioactive compounds help in reducing blood glucose levels through various mechanisms including stimulation of insulin secretion, regeneration of pancreatic β-cells, inhibition of glucose absorption, and enhancement of peripheral glucose utilization.

The use of herbal formulations in diabetes management has gained importance because they provide synergistic therapeutic effects. Polyherbal formulations combine two or more medicinal plants to improve efficacy and reduce toxicity.

Such formulations are widely accepted due to their compatibility with the human body and better patient compliance[5]. Herbal antidiabetic preparations are considered promising alternatives to synthetic drugs because they can target multiple pathways involved in glucose metabolism.

Importance of Polyherbal Formulations

Polyherbal therapy is based on the principle that the combined effect of multiple herbs is superior to the effect of a single herb. The therapeutic activity of polyherbal formulations results from synergistic interactions among different phytochemicals present in the herbs[6]. In traditional systems of medicine such as Ayurveda, polyherbal preparations have been extensively used for the management of chronic diseases including diabetes mellitus.

Polyherbal capsules offer several advantages such as accurate dosage, improved stability, easy administration, enhanced patient compliance, and convenient handling. Encapsulation of herbal powders or extracts also masks unpleasant taste and odor while protecting active constituents from environmental degradation. The development of polyherbal capsules therefore represents an important approach in modern herbal drug delivery systems.

Role of Gymnema sylvestre in Diabetes

Gymnema sylvestre, commonly known as "Gudmar," is a well-known medicinal plant belonging to the family Asclepiadaceae. It has been widely used in Ayurvedic medicine for the treatment of diabetes mellitus[7]. The plant contains active constituents such as gymnemic acids, flavonoids, saponins, and triterpenoids which exhibit potent antidiabetic activity. Gymnemic acid suppresses the taste sensation for sweetness and helps reduce sugar cravings.

The antidiabetic action of Gymnema sylvestre is mainly attributed to its ability to stimulate insulin secretion, regenerate pancreatic β-cells, and improve glucose uptake by body tissues. Studies have shown that the herb significantly reduces fasting blood glucose levels and improves lipid profile in diabetic patients. In addition, it possesses antioxidant and anti-inflammatory properties which help prevent diabetic complications[8]. Due to these pharmacological activities, Gymnema sylvestre is considered an important herb for antidiabetic formulations.



Figure 2: Leaves of Gymnema sylvestre and Fenugreek Seeds[7]

Role of Trigonella foenum-graecum in Diabetes

Fenugreek, scientifically known as Trigonella foenum-graecum, belongs to the family Fabaceae and is commonly used as a medicinal as well as culinary herb. Fenugreek seeds contain bioactive compounds including trigonelline, diosgenin, alkaloids, flavonoids, and soluble dietary fibers such as galactomannan[9]. These constituents play a significant role in controlling blood glucose levels.

Fenugreek exhibits hypoglycemic activity by delaying gastric emptying, reducing intestinal glucose absorption, and improving insulin sensitivity. The high fiber content present in fenugreek helps regulate carbohydrate metabolism

and lowers postprandial blood glucose levels. Research studies have demonstrated that regular consumption of fenugreek improves glucose tolerance and reduces serum cholesterol levels[10]. Due to its multiple pharmacological benefits, fenugreek is extensively used in herbal antidiabetic preparations.

MATERIALS AND METHODS

Materials

The present research work was carried out using Gymnema sylvestre leaves and Trigonella foenum-graecum seeds because both herbs are well known for their antidiabetic activity[11]. The herbal drugs were collected from a local herbal store and identified properly before use[12]. Different excipients like lactose, talc, and magnesium stearate were used for preparation of capsules[13]. Ethanol and distilled water were used during extraction of herbal drugs[14]. All chemicals and reagents used in the research work were of analytical grade[15].

The selected herbs contain important phytoconstituents such as flavonoids, alkaloids, tannins, saponins, and glycosides which help in controlling blood glucose levels[16]. Gymnema sylvestre is traditionally known as "Gudmar" because it reduces sugar taste sensation, while Fenugreek seeds are rich in dietary fibers and compounds that improve glucose metabolism[17].

Table 1: Materials Used in Formulation

Sr. No.	Material	Category	Purpose
1	Gymnema sylvestre	Herbal drug	Antidiabetic activity
2	Fenugreek	Herbal drug	Blood glucose control
3	Lactose	Diluent	Increases bulk
4	Talc	Glidant	Improves flow
5	Magnesium stearate	Lubricant	Reduces sticking
6	Ethanol	Solvent	Extraction
7	Hard gelatin capsules	Capsule shell	Filling of powder

Collection and Preparation of Herbal Drugs

Fresh Gymnema sylvestre leaves and Fenugreek seeds were collected and washed carefully using distilled water to remove dust and impurities[18]. Washing of herbal materials is important because contamination may affect the quality of formulation[19].

The herbs were dried under shade at room temperature for several days[20]. Shade drying was selected because exposure to direct sunlight may destroy important phytoconstituents present in medicinal plants[21]. Proper drying also prevents microbial growth and moisture-related spoilage[22].

After drying, the herbal materials were crushed separately using a mechanical grinder to obtain coarse powder[23]. The powdered drugs were passed through sieve no. 40 to obtain uniform particle size[24]. Uniform powder size helps improve extraction efficiency and mixing during formulation preparation[25]. The powders were stored in airtight containers until further use[26].

Extraction of Herbal Drugs

Extraction is the process of separating medicinally active compounds from herbal materials using suitable solvents[27]. In the present study, hydroalcoholic extraction was carried out using ethanol and distilled water because this solvent system extracts both water-soluble and alcohol-soluble phytoconstituents effectively[28].

The extraction process was performed by the maceration method[29]. About 100 g of powdered Gymnema sylvestre leaves was transferred into a glass container and mixed with hydroalcoholic

solvent. Similarly, Fenugreek seed powder was extracted separately using the same method[30].

The mixtures were kept undisturbed for 72 hours with occasional stirring[31]. Stirring improves contact between powder and solvent and helps increase extraction efficiency[32]. During this period, active phytoconstituents dissolved into the solvent system[33].

After completion of extraction, the mixtures were filtered through muslin cloth followed by Whatman filter paper to remove insoluble particles[34]. The filtrates obtained were concentrated by evaporation at controlled temperature to remove excess solvent[35]. The concentrated extracts were dried and stored in airtight containers under refrigerated conditions for further study[36].



Figure 3: Maceration Extraction Process

Phytochemical Screening

Phytochemical screening was carried out to identify important chemical constituents present in the herbal extracts[37]. Different qualitative tests were performed for alkaloids, flavonoids, tannins, saponins, glycosides, and carbohydrates[38].

The presence of alkaloids was confirmed by Mayer's test in which cream-colored precipitate was formed. Flavonoids were detected by Shinoda test which produced pink coloration. Ferric chloride test was used for tannins and formation of dark color confirmed their presence[39].

Foam test was carried out for saponins, while Molisch's test was used for carbohydrates. These phytoconstituents are responsible for the therapeutic activity of medicinal plants and contribute to antidiabetic action of the formulation[40].

Formulation of Polyherbal Capsules

Five different batches of polyherbal capsules were prepared using different concentrations of herbal extracts. The extracts of Gymnema sylvestre and Trigonella foenum-graecum were weighed accurately and mixed uniformly by geometric dilution method[41].

Lactose was added as diluent to improve bulk properties of powder blend[42]. Talc was incorporated to improve powder flow, while magnesium stearate was used as lubricant to prevent sticking during filling process[43].

The prepared powder blend was mixed thoroughly to achieve uniformity and proper distribution of herbal extracts[44]. The final blend was filled manually into hard gelatin capsules of suitable size[45]. The filled capsules were stored in airtight containers at cool and dry place to protect them from moisture and environmental contamination[46].

Table 2: Formulation Batches of Polyherbal Capsules

Ingredients	F1	F2	F3	F4	F5
Gymnema sylvestre extract (mg)	200	225	250	275	300
Fenugreek extract (mg)	200	225	250	275	300
Lactose (mg)	90	65	40	15	10
Talc (%)	2	2	2	2	2
Magnesium stearate (%)	1	1	1	1	1



Figure 4: Prepared Polyherbal Antidiabetic Capsules

Evaluation of Polyherbal Capsules

The prepared polyherbal capsules were evaluated for different pharmaceutical parameters to determine quality, uniformity, and suitability of the formulation[47].

Weight Variation Test

Twenty capsules from each batch were selected randomly and weighed individually using an electronic balance[48]. The average weight of capsules was calculated and compared with individual capsule weights[49].

This test was performed to ensure uniform filling of powder blend inside capsules and proper dose uniformity[50]. Less variation in capsule weight indicates accurate filling process and good formulation quality[51].

Disintegration Test

Disintegration test was carried out using USP disintegration apparatus containing distilled water maintained at 37 ± 2°C[52]. Capsules were placed in the basket assembly and the apparatus was operated under standard conditions[53].

The time required for complete breakdown of capsules was recorded[54]. This test helps determine how quickly the capsule shell breaks and releases the herbal contents after administration[55].

Drug Content Uniformity

The capsules were opened carefully and powder equivalent to one dose was dissolved in suitable solvent[56]. The solution was filtered and analyzed using UV spectrophotometer after suitable dilution[57].

This study was performed to ensure equal distribution of herbal extracts in all capsules and to confirm uniformity of formulation[58].

Stability Study

The prepared capsules were stored in airtight containers at room temperature and accelerated conditions for a specified period[59]. Capsules were observed periodically for changes in color, odor, appearance, and physical stability[60].

Stability studies are important because herbal formulations may undergo degradation due to heat, moisture, and environmental conditions[61]. Stable formulations ensure better shelf life and therapeutic effectiveness[62].

RESULTS & DISCUSSION

The present study was carried out for formulation and evaluation of polyherbal antidiabetic capsules containing extracts of Gymnema sylvestre and Trigonella foenum-graecum. Five formulation batches were prepared and evaluated for various pharmaceutical parameters including percentage yield, phytochemical screening, preformulation studies, capsule evaluation, and stability studies.

The obtained results indicated satisfactory pharmaceutical characteristics of all prepared formulations. The herbal extracts showed presence of important phytoconstituents responsible for

antidiabetic activity. All batches exhibited acceptable flow properties, uniform capsule weight, satisfactory disintegration time, and good drug content uniformity.

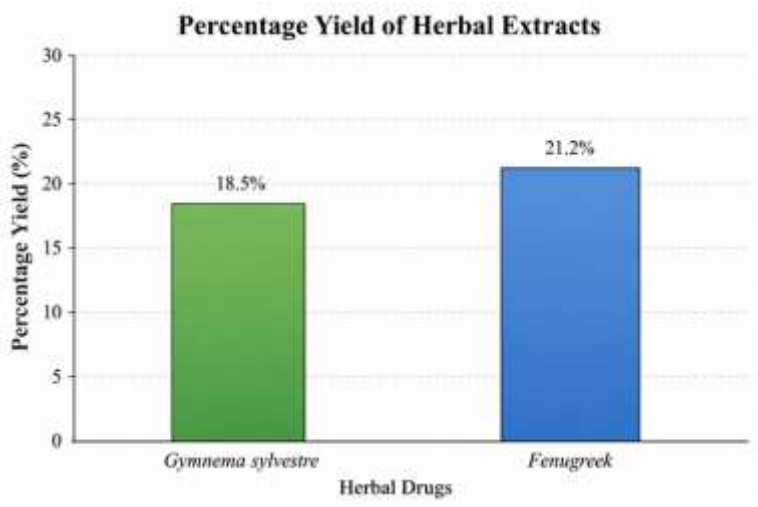
Percentage Yield of Herbal Extracts

The percentage yield of herbal extracts was calculated after completion of hydroalcoholic extraction process. Both herbal drugs showed satisfactory extraction yield due to efficient extraction of phytoconstituents by hydroalcoholic solvent system.

Fenugreek extract showed slightly higher percentage yield compared to Gymnema sylvestre because Fenugreek contains higher amount of soluble fibers, carbohydrates, and mucilage components. Proper extraction yield is important because it directly influences therapeutic efficacy of herbal formulations.

Table 3: Percentage Yield of Herbal Extracts

Herbal Drug	Quantity Taken (g)	Extract Obtained (g)	Percentage Yield (%)
Gymnema sylvestre	100	18.5	18.5
Fenugreek	100	21.2	21.2



Graph 1: Percentage Yield of Herbal Extracts

The obtained results confirmed that hydroalcoholic extraction was suitable for extraction of active phytoconstituents from both medicinal plants. The extracts obtained were dark brown in color with characteristic odor and semisolid consistency. The extracts were stored in airtight containers under refrigerated conditions to preserve phytochemical stability.

Phytochemical Screening of Herbal Extracts

Preliminary phytochemical screening confirmed the presence of several important phytoconstituents such as alkaloids, flavonoids, tannins, glycosides, saponins, and carbohydrates in both herbal extracts. These phytoconstituents are responsible for antidiabetic and antioxidant activities of the formulation.

Gymnema sylvestre extract showed presence of gymnemic acids, flavonoids, and glycosides which help reduce intestinal glucose absorption and improve insulin secretion. Fenugreek extract contained trigonelline, fibers, and saponins which contribute to glucose lowering activity.

Table 4: Phytochemical Screening of Herbal Extracts

Phytoconstituent	Gymnema sylvestre	Fenugreek
Alkaloids	Present	Present
Flavonoids	Present	Present
Tannins	Present	Present
Glycosides	Present	Present
Saponins	Present	Present
Carbohydrates	Present	Present

The presence of flavonoids and tannins indicates antioxidant potential of the herbal extracts. Oxidative stress plays an important role in diabetes mellitus; therefore antioxidant activity may help reduce diabetic complications. Saponins and glycosides present in the extracts may improve insulin activity and glucose utilization.

The phytochemical screening results confirmed that both medicinal plants possess important bioactive constituents suitable for preparation of polyherbal antidiabetic formulation.

Evaluation of Powder Blend

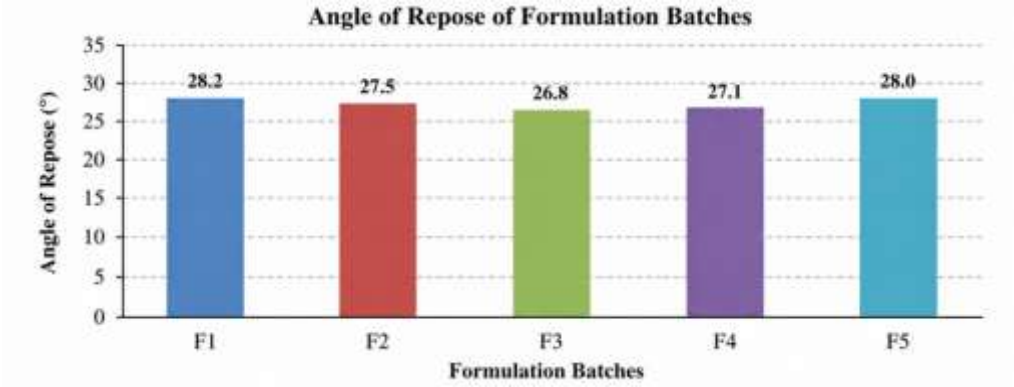
The formulated powder mixtures were assessed for angle of repose, bulk density, tapped density, Carr's index, and Hausner ratio. These criteria are crucial as they denote the flowability and compressibility characteristics of powder blends prior to capsule filling.

The angle of repose for all formulation batches was determined to be below 30°, signifying favorable flow characteristics. Optimal flowability is crucial for effective capsule filling and dosage form homogeneity.

The bulk density and tapped density measurements were within acceptable parameters for all batches. Carr's index values under 20% signify acceptable compressibility properties of the powder blends. Hausner ratio values under 1.25 indicate favorable flow characteristics.

Table 5: Evaluation of Powder Blend

Parameters	F1	F2	F3	F4	F5
Angle of Repose (°)	28.2	27.5	26.8	27.1	28.0
Bulk Density (g/ml)	0.42	0.44	0.45	0.43	0.44
Tapped Density (g/ml)	0.51	0.52	0.53	0.51	0.52
Carr's Index (%)	17.6	15.3	15.0	15.6	15.3
Hausner Ratio	1.21	1.18	1.17	1.18	1.18



Graph 2: Angle of Repose of Formulation Batches

Among all batches, formulation F3 showed better flow characteristics due to optimum concentration of herbal extracts and excipients. Good flow properties ensure uniform filling of powder blend into capsules and minimize variation in capsule weight.

The obtained preformulation results confirmed suitability of the powder blends for capsule formulation.

Evaluation of Polyherbal Capsules

The prepared polyherbal capsules were evaluated for weight variation, disintegration time, drug content uniformity, and physical appearance. The results obtained were found within acceptable pharmacopeial limits.

The capsules appeared uniform in size, shape, and color. No visible cracks, leakage, or powder loss were observed during evaluation studies. All batches showed satisfactory filling and proper locking of capsule shells.

Table 6: Evaluation of Polyherbal Capsules

Parameters	F1	F2	F3	F4	F5
Average Weight (mg)	498	500	501	503	505
Disintegration Time (min)	12	11	9	10	11
Drug Content (%)	94.5	96.2	98.4	97.5	96.8

The weight variation test demonstrated minimal discrepancies among capsules from the same batch, signifying a consistent filling procedure and effective blending of the formulation. The uniformity of capsule weight is crucial as it guarantees precise dosage administration and medicinal efficacy.

Disintegration investigations indicated that all formulations decomposed within acceptable timeframes. Rapid disintegration is essential as it facilitates the expedited release of plant extracts following oral ingestion. Formulation F3 had the shortest disintegration time owing to the optimal content of lactose and superior powder properties.

Studies on drug content homogeneity indicated an adequate dispersion of herbal extracts within all capsules. Formulation F3 exhibited the greatest drug content value, indicating superior homogeneity and uniformity in the combination of herbal extracts with excipients.

Stability Studies

The prepared capsules were subjected to short-term stability studies under room temperature and accelerated conditions. The formulations were evaluated periodically for changes in color, odor, appearance, and physical stability.

No major changes were observed in capsule appearance during storage period. The capsules remained intact without any visible cracks, leakage, or microbial growth. Drug content values remained within acceptable limits indicating stability of herbal constituents during storage.

Table 7: Stability Study of Optimized Batch (F3)

Parameter	Initial	After Stability Study
Color	Brown	Brown
Odor	Characteristic	Characteristic
Disintegration Time	9 min	10 min
Drug Content	98.4%	97.8%

The stability findings demonstrated that the formulated capsules maintained stability under storage settings. A minor reduction in drug content following storage may result from environmental factors such humidity and temperature; nonetheless, the alterations remained within acceptable parameters.

The optimized formulation batch F3 demonstrated superior stability relative to other batches owing to a balanced concentration of herbal extracts and excipients.

The formulated preparations exhibited favorable flow qualities, acceptable assessment metrics, and appropriate stability attributes. Among all formulations, F3 exhibited superior pharmaceutical features, including enhanced flowability, expedited breakdown, elevated drug content, and an improved stability profile.

The formulation's amalgamation of flavonoids, glycosides, tannins, and saponins may confer synergistic antidiabetic effects by enhancing insulin secretion, diminishing glucose absorption, and exhibiting antioxidant properties.

SUMMARY AND CONCLUSION

This work effectively developed and assessed polyherbal antidiabetic capsules incorporating extracts of Gymnema sylvestre and Trigonella foenum-graecum. The herbal extracts included significant phytoconstituents, including flavonoids, tannins, glycosides, and saponins, which contribute to antidiabetic action. Five formulation batches were created and assessed for several pharmaceutical characteristics.

The produced capsules exhibited adequate flow characteristics, consistent weight fluctuation, acceptable disintegration time, and commendable drug content consistency. The stability investigations verified that the formulation maintained stability under storage conditions. Among all batches, formulation F3 exhibited superior pharmaceutical properties and overall efficacy.

The research suggests that the formulated polyherbal capsule may function as a safe and effective herbal alternative for managing diabetes mellitus, enhancing patient compliance while minimizing negative effects.

FUTURE SCOPE

The formulated polyherbal antidiabetic capsules exhibit significant promise for further expanded study and development. Subsequent research may be conducted to assess in-vivo antidiabetic efficacy utilizing appropriate animal models to validate the therapeutic efficiency of the formulation. Clinical trials may also be conducted to assess safety and efficacy in human participants.

Additional efforts might be undertaken to standardize herbal extracts and identify specific active phytoconstituents responsible for antidiabetic effects. Advanced analytical methodologies, including HPLC and FTIR, can be employed for comprehensive evaluation of the formulation.

The formulation may be altered into sustained release or nanoherbal dose forms to enhance bioavailability and medicinal efficacy. The extensive manufacture and marketing of the formulated product may offer an efficacious herbal treatment alternative for those with diabetes.

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62. Recent advances in herbal antidiabetic formulations and novel drug delivery systems were reviewed and incorporated in the present work for better formulation development and therapeutic effectiveness.

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