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Next-Generation Herbal Supplements: Review on the Development and Efficacy of Ayurvedic Antidiabetic Gummies

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Abstract: The rising global incidence of type 2 diabetes has increased the demand for safe, effective, patient-compliant alternatives to traditional antidiabetic medications. This study presents the development and evaluation of Ayurvedic antidiabetic gummies as a next-generation herbal supplementation. A comprehensive polyherbal gummy was developed using standardized extracts of Gymnema sylvestre, Momordica charantia, Trigonella foenum-graecum, Syzygium cumini, Curcuma longa, and Ocimum sanctum with careful selection of gelling agents and natural sweeteners for palatable, effective tasting gummies. The gummie was then phytochemically profiled utilizing HPTLC and LC-MS for accurate analysis of components. In vitro antidiabetic assays (α-amylase and α-glucosidase inhibition) were performed as well as DPPH scavenging for antioxidant activity in conjunction with the in viv antidiabetic potential in streptozotocin-induced diabetic rats over 21 days with continued safety studies, organ histopathology and analysis of preliminary human trial data for changes in fasting blood glucose, and HbA1c. The formulated gummies showed excellent physicochemical stability, palatability, and compliance. Phytochemical analysis confirmed the retention of key bioactives post-processing. The in vitro assays demonstrated significant enzyme inhibition and antioxidant activity. In vivo, the gummies reduced fasting glucose levels, improved insulin sensitivity, and showed no hepatic or renal toxicity. Human participants showed a reduction in fasting glucose and HbA1c over 60 days with no reported adverse effects.

Keywords: *Ayurvedic Formulation, Antidiabetic Gummies, Herbal Supplements, Polyherbal Synergy, Nutraceuticals, Type 2 Diabetes, Phytochemical Analysis, in Vitro Enzyme Inhibition, in Vivo Efficacy , Functional Foods.*

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I. INTRODUCTION

➢ *Managing the Global Costs of Diabetes*

Diabetes mellitus has become one of the greatest public health issues in the 21st century, specifically type 2 diabetes (T2DM). By the IDF, it is estimated that over 537 million adults had diabetes in 2021 and expect the number of diabetes to reach 643 million adults by 2030. The majorities of these are lifestyle-based as the result of poor eating habits, physical inactivity, and more recently stress-induced overall health. Beyond hyperglycemia, diabetes-related illness(es) typically include long-term complications (e.g., cardiovascular disease, nephropathy, neuropathy, retinopathy). The economic and social costs associated with diabetes are more acute in low- and middle-income countries. In these countries, lack of access to consistent treatment plans and education results in the inability to reverse or recover from the effects of T2DM. In light of this expanding epidemic, safe, culturally relevant, acceptable, and affordable therapeutic alternatives are urged.

➢ *Shortcomings of Conventional Treatments*

While oral hypoglycemic agents (e.g., metformin, sulfonylureas, DPP-4 inhibitors) and insulin therapy facilitate blood glucose control, the limitations of synthetic drugs are extensive. Adverse effects -sustained use of synthetic drugs can lead to serious adverse effects such as gastrointestinal distress, weight gain, hypoglycemia, or even drug resistance! Some patients take medications but still cannot correct glucose levels because they forget to take the medication, they cannot tolerate the gastrointestinal distress, they are instructed to diet (food), and lastly, compliance with medication continues to be poor (e.g., decision fatigue, etc.) already commenting that compliance with regards to medication is low in elderly patients and pediatric populations when patients have decent knowledge of prescribing and its effects that it can get even worst at when patients are challenged with pill-taking (adults) or parents to provide therapy for children with medication.

➢ *The Emergence of Herbal Nutraceuticals*

The use of herbal treatments and nutraceuticals has gained momentum over the past few years as supportive

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treatments for chronic diseases such as diabetes. These substances, which are derived from plants with medicinal properties, are perceived as safer and more natural medicine by a sizable proportion of the population. The WHO has recognized the place of traditional medicinal into healthcare and encourages countries to form a national health policy on traditional medicine. Herbal nutraceuticals have hypoglycemic effects and significant antioxidant, anti-inflammatory, and organ protective activity (e.g., liver, kidney, etc). In India, which has a cultural history of Ayurveda, there are many medicinal plants with antidiabetic activity, such as Gymnema sylvestre, Momordica charantia, Trigonella foenum-graecum, and Syzygium cumini that have demonstrated antidiabetic effects through research. Furthermore, it is assumed that these plants have a much greater effect together than individually because they atleast have a laboratory demonstrated and synergistic effect that act on multiple pathways for diabetes pathophysiology.

➢ *Rationale for Juju Ayurvedic Antidiabetic Gummies*

Although the use of herbal powders, capsules, and decoction is common, there is oftentimes poor taste and dosing forms are not consistent, and not potent enough to get prescribed by patients. Additionally, factors such as palatability and patients who will not comply with dosing as directed are serious issues when patients are willing to take your advice with the herbs, and it creates inconsistency between experience and literature. A new dosage form, such as herbal gummies, could be a bridge from traditional wisdom and modern application. There would be no palatability issues, they are easy to administer, and there is likely to be better compliance from patients, primarily youths and older patients. You can create a specific dose of polyherbal extract into a standardized and consistently accurate way, while also capturing any pharmacological effect of the Ayurvedic experience. Placing Ayurvedic herbs and extracts into a gummy also protects their pharmacological ability, and responds to trends towards functional foods and personalized nutrition. This research will help evaluate the manufacture, standardization, and therapeutic viability of Ayurvedic antidiabetic gummies as a clinical option and use an evidence informed way of planning health in diabetes.

II. REVIEW OF AYURVEDIC ANTIDIABETIC HERBS

➢ *Gymnema Sylvestre (Gurmar)*

Gymnema sylvestre, commonly known as "Gurmar" or "sugar destroyer," is one of the most renowned herbs in Ayurvedic medicine for managing diabetes. Its primary bioactive constituents are gymnemic acids, which have been shown to suppress the sweetness perception on the tongue and delay intestinal glucose absorption. These triterpenoid saponins also stimulate insulin secretion, regenerate pancreatic β-cells, and improve glucose uptake in peripheral tissues. Clinical studies have demonstrated significant reductions in blood glucose and HbA1c levels with standardized *Gymnema* extracts. Additionally, the herb exhibits lipid-lowering and antioxidant effects, making it beneficial in addressing comorbidities like dyslipidemia and oxidative stress in diabetic patients. Its safety profile and synergism with other antidiabetic agents make it a cornerstone of polyherbal formulations.

A B

Fig 1 A Represents the Fresh *Gymnema sylvestre* (Gurmar) Plant, while Fig B Represents the Dried Powder form of *Gymnema sylvestre* used for Formulation.

➢ *Momordica Charantia (Bitter Gourd)*

Momordica charantia (or bitter gourd) has long been used in traditional medicine as a powerful hypoglycemic agent. This herb has at least 3 bioactive compounds, charantin (a steroidal saponin), polypeptide-p (plant insulin) and vicine, which all have different mechanisms of action, but work synergistically to (1) enhance glucose uptake by skeletal muscle, (2) inhibit hepatocyte gluconeogenesis or

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glycogenolysis, and (3) enhance the regeneration of pancreatic β-cells. Bitter gourd has considerable antioxidant and anti-inflammatory effects to mitigate cell breakdown from diabetes as well. While bitter gourd itself is very bitter, individuals can use a gummy-based system to enable consumers to get their daily dose of bitter gourd without the bitter taste but achieve the same hoped-for therapeutic effect. The effect of bitter gourd on fasting blood glucose and glucose tolerance is also supported by animal models and studies in humans.

A B

Fig 2 A represents the Raw *Momordica Charantia* (Bitter Gourd) Fruit, while Fig B Represents its Dried Powdered form used in the Gummy Preparation.

➢ *Trigonella Foenum-Graecum (Fenugreek)*

Trigonella foenum-graecum (Fenugreek) or "Methi" is widely used as a culinary or medicinal herb throughout Asia. The majority of the antidiabetic effects are associated with 4-hydroxyisoleucine, trigonelline and galactomannan fibers. The action for 4-hydroxyisoleucine is primarily through stimulating the secretion of insulin without causing hypoglycaemia, which is glucose dependent. Mucilaginous fibers retain the digested carbohydrates and delay absorption or metabolism, which results in a more sustained post-prandial blood glucose level. Fenugreek helps with the sensitivity of insulin receptors and helps improve glycemic control over time. In addition to glucose, estab-lishing a good gel form in the gastrointestinal tract also benefits lipid profiles and has hepatoprotective impacts. It takes advantage of the mild flavor of fenugreek and compatibility with other herbs and can readily and easily be prepared, consumed and appreciated in gummy palatable forms, with added therapeutic and nutritional benefits.

A B

Fig 3 A Represents the Fresh Green Leaves of *Trigonella foenum-graecum* (Fenugreek), whereas Fig B Represents the Dried Fenugreek Seeds.

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➢ *Jamun (Syzygium cumini)*

Jamun (Syzygium cumini) is a tropical fruit-producing plant found to have anti-diabetic properties. The seeds, pulp and leaves of Jamun contain alkaloids, jamboline, ellagic acid and flavonoids which can modulate carbohydrate metabolism. The seeds were found to produce reductions in fasting blood glucose and improvements to pancreatic function. The seeds act by inhibiting α-amylase and α-glucosidase, which are required for reducing glucose absorption in the intestine. Jamun also modifies the insulin response, as well as reduces levels of glycosylated hemoglobin in diabetics. Additionally, Jamun is an effective antioxidant, reducing oxidative stress damage on pancreatic β-cells. Jamun is naturally sweet, and are high in antioxidants, therefore for inclusion in gummy form for glycemic management but also to improve patient adherence to treatment.

A B

Fig 4 A Represents the Dried Raw Powder of *Syzygium cumini* (Jamun), and Fig B Represents its Ripe Fruit used in Traditional Herbal Medicines.

➢ *Tulsi (Ocimum Sanctum)*

Ocimum sanctum (Holy Basil or Tulsi) has been used primarily in Ayurveda for it's purported adaptogenic, anti-diabetic, and immunomodulatory properties. Key bioactive compounds eugenol, ursolic acid, and rosmarinic acid are mainly responsible for many of the common pharmacological effects of Tulsi. Tulsi assists with the secretion of insulin, increases sensitivity to insulin, and protects against glucose increases due to cortisol effects, along with relevant anti-inflammatory/cytoprotective/antioxidant properties.

A B

Fig 5 A Represents the Powdered form of *Ocimum sanctum* (Tulsi), while Fig B Represents the Fresh Green Tulsi Plant used for Medicinal Purposes.

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➢ *Curcuma Longa (Turmeric)*

Curcuma longa (turmeric) has long been recognized for its principal curcuminoid curcumin, which has an impressive antioxidant, anti-inflammatory, and anti-diabetic character to it. Research has shown curcumin to improve insulin receptor activity, inhibit hepatic gluconeogenesis, stimulate glucose uptake through AMPK activation, and inhibit the advanced glycation end-products (AGEs) responsible for criteria diabetes complications like nephropathy and retinopathy. Curcumin by itself has low bioavailability; however, formulation strategies (e.g., encapsulation of curcumin or co-administration of piperine) can help it elicit effects. Curcumin can be formulated in a stabilized bioavailable form in gummy products for prolonged release and targeted delivered. Turmeric's attractive colour and history of other medicinal uses add to the mystique of the compound in our antidiabetic formulations.

A B

Fig 6 A Represents the Raw Rhizome of *Curcuma longa* (Turmeric), whereas Fig B Represents the Turmeric Powder Utilized for its Curcumin Content.

Table 1 Ayurvedic Antidiabetic Herbs and their Pharmacological Profile

S No.	Botanical Name	Common Name	Family	Part Used	Key Phytochemicals	Antidiabetic Mechanism
1	*Gymnema sylvestre*	Gurmar	Apocynaceae	Leaves	Gymnemic acids, Gurmarin, Saponins	Suppresses sweet taste receptors, stimulates insulin secretion, regenerates β-cells
2	*Momordica charantia*	Bitter Gourd	Cucurbitaceae	Fruit, seeds, leaves	Charantin, Polypeptide-p, Vicine, Momordicin	Mimics insulin, enhances glucose uptake, inhibits gluconeogenesis
3	*Trigonella foenum-graecum*	Fenugreek (Methi)	Fabaceae	Seeds, leaves	4-Hydroxyisoleucine, Trigonelline, Galactomannan	Stimulates insulin release, slows carbohydrate absorption, improves insulin sensitivity
4	*Syzygium cumini*	Jamun	Myrtaceae	Seeds, pulp, leaves	Jamboline, Ellagic acid, Flavonoids, Anthocyanins	Inhibits α-amylase and α-glucosidase, enhances pancreatic function
5	*Ocimum sanctum*	Tulsi (Holy Basil)	Lamiaceae	Leaves	Eugenol, Ursolic acid, Rosmarinic acid, Apigenin	Modulates insulin secretion, reduces cortisol-induced hyperglycemia, antioxidant
6	*Curcuma longa*	Turmeric	Zingiberaceae	Rhizome	Curcumin, Demethoxycurcumin, Bisdemethoxycurcumin	Enhances insulin receptor activity, reduces inflammation, suppresses hepatic glucose output

This table summarizes the key Ayurvedic plants incorporated in the gummy formulation. For each herb, it lists the botanical and common names, plant family, part used, major bioactive phytochemicals, and their proposed antidiabetic mechanisms of action. It emphasizes how each plant contributes to lowering blood glucose by mechanisms such as insulin secretion, inhibition of carbohydrate-digesting enzymes, enhanced glucose uptake, or β-cell regeneration.

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➢ *Synergism in Polyherbal Combinations*

Ayurveda recognizes the use of polyherbal formulations since it is more therapeutic in a holistic and synergistic manner. When the above herb is combined, these herbs can act at multiple pathophysiological targets in diabetes' pathology. They can improve insulin secretion, improve glucose uptake from the periphery, modify gut enzymes, and repair damage to pancreatic tissue caused by oxidative stress. The synergistic combination allows for reduced amounts of the maximum dose of the individual herb, reducing the adverse effect profile and promoting patient compliance. For instance employing Gymnema and Bitter gourd will enhance the secretion of insulin, and to mimic the action of insulin while Tulsi and Turmeric will provide benefit to relieve stress and alleviate inflammation. We can make antidiabetic gummy supplements based on polyherbal combinations, allowing for a complementary scheme to lead to an enhanced level of pharmacological effect based on the collaborative efforts of the herbs selected. This will allow better patient acceptability, and efficacy based on multi-targeted approach to the management of diabetes.

III. FORMULATION DEVELOPMENT

➢ *Selection of Active Ingredients*

The first and foremost stage of the formulation process is the selection of active herbal ingredients for functional antidiabetic gummies. Following traditional Ayurvedic texts as well as contemporary pharmacological evidence, six herbs were selected to provide complementary and synergistic antidiabetic actions: Gymnema sylvestre (leaves), Momordica charantia (fruit), Trigonella foenum-graecum (seeds), Syzygium cumini (seeds), Ocimum sanctum (leaves), and Curcuma longa (rhizome). In order to provide a assurance of consistency and reproducibility of the therapeutic effects, standardized or regulated extracts, for example, standardized to a known concentration of compounds eg Gymnemic acid, charantin, 4-hydroxyisoleucine, curcumin, etc., were preferred. The final polyherbal combination was designed using synergism in mechanism of action with greater than one pathway being targeted in terms of insulin secretion, insulin sensitivity, and inhibition of intestinal absorption of glucose.

➢ *Excipients and Gelling Agents (Pectin, Gelatin, etc.)*

To deliver the active herbal blend in a way that is easy to consume, excipients and gelling agents were employed. Pectin, which is a natural polysaccharide obtained from plant matter and forms gels that are stable at increased temperature so compatible with the other herbal components, was selected as it is vegetarian based and allows for better compatibility/ processing of herbal components and gels. Specified batches contained gelatin, which is also a gelling agent with preferred textural attributes, and is the most widely used gelling agent used for nutraceutical gummies (which are usually supplements). Excipients included citric acid (for pH adjustment and shelf-stability) and sodium citrate.

➢ *Sweeteners and Flavor Masking*

Herbal gummy formulations are challenging in part because the taste (and sometimes bitterness or astringency) of plant extracts can provide significant hurdles, especially when the extracts are from the plants Momordica charantia or Gymnema sylvestre. In order to make the product more palatable to take daily (or more often), several natural sweeteners (e.g. stevia (Steviol glycosides), fructooligosaccharides (FOS), and honey) were added to the formulation. These sweeteners can benefit diabetics and not cause glucose spikes to blood sugar levels postprandially. Natural fruit flavors (e.g., mixed berry, mango, or lemon) were added to also mask the undesired herbal notes, serve as aroma notes as well as improving the sensory matrix. Ultimately, multiple taste tests and sensory evaluation panels helped us find solutions for acceptable flavor-sweetener combinations across a wide age demographic of diabetic sufferers.

➢ *Processing and Manufacturing Workflow*

Manufacturing workflows were designed to ensure that the sensitive herbal compounds would not be compromised due to heat, light or airflow. The workflows would start with forming a homogeneous herbal extract blend, while gelling agents could be dissolved in heated aqueous media. All the extracts were then added, followed by the sweeteners, citric acid (i.e. acidifier), and the flavors were incorporated. The mixture was then heated to ~70–80°C (depending on the gelling agent) followed by deaerated. The gel mass was cast into sterilized silicone molds and allowed to cool.

➢ *Quality Control Parameters*

To ensure safety, efficacy, and batch-to-batch consistency, the finished gummies underwent a battery of quality control tests. Physicochemical tests included moisture content, pH, weight variation, hardness, and disintegration time. Phytochemical analysis was performed using HPTLC or LC-MS to quantify active markers like gymnemic acid, curcumin, and 4-hydroxyisoleucine. Microbial load testing confirmed the absence of harmful pathogens such as *E. coli*, *Salmonella*, and *Staphylococcus aureus*. Stability studies were conducted under accelerated conditions to evaluate the shelf life and retention of active compounds over time. Additionally, sensory evaluations were conducted periodically to ensure consumer acceptability. All parameters were maintained in compliance with FSSAI, AYUSH, and WHO guidelines for herbal nutraceutical products.

IV. PHYTOCHEMICAL CHARACTERIZATION

➢ *Extraction and Standardization*

The herbal extracts in the formulation were extracted using no standard extraction processes, but all extraction processes were standardized to provide maximum yield and bioactive compound reproducibility. The plant materials were shade-dried, powdered, and extracted in solvent using hydroalcoholic mixtures (typically 70 % ethanol or methanol) via reflux or maceration, filtered, concentrated via rotary evaporation under reduced pressure, and then lyophilized to yield dry powder. All extracts were standardized to known phytochemical markers - i.e., gymnemic acid from Gymnema sylvestre, charantin from Momordica charantia, and curcumin from Curcuma longa (all used in the formulation). The standardization was carried out using AYUSH and WHO standards for herbal products.

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➢ *Perform HPTLC/GC-MS/LC-MS Profiling*

A combination of chromatographic and spectrometric techniques to authenticate and chemically profile herbal extracts were performed on extracts –

- *High-Performance Thin Layer Chromatography (HPTLC):*

Widely used for routine fingerprinting and semi-quantitative analysis and show the presence of gymnemic acid, trigonelline, and flavonoids in the extracts. The samples and standards were developed with maximum separation on silica gel 60 F254 plates using suitable developing solvent systems and visualized using UV or sprayed with a derivatizing agent.

- *Gas Chromatography-Mass Spectrometry (GC-MS):*

Used primarily for the analysis of volatiles oils from Ocimum sanctum and trace levels of eugenol, caryophyllene and other volatile phytoconstituents.

- *Liquid Chromatography-Mass Spectrometry (LC-MS/MS):*

Used for the accurate identification and quantification of non-volatile actives including charantin, 4-hydroxyisoleucine, curcumin and ellagic acid. The analysis of liquid sample preparations of methanol dilutions were filtered through 0.22 µm membranes prior to injection.

The analytical methods above were used to produce unique fingerprints of all respective plant extracts and confirm was the active compounds of interest were present in the final gummy formulation.

➢ *Quantification of Bioactives (e.g. Charantin, Gymnemic Acid).*

Quantitative analysis was paramount for therapeutic efficacy and dose consistency. Table 1 summarizes representative values of key bioactives from the standardized herbal extracts used for the gummy formulation.

Table 2 Quantified Bioactive Markers in Standardized Extracts

Herbal Source	Bioactive Marker	Method Used	Concentration (mg/g extract)
Gymnema sylvestre (leaves)	Gymnemic acid	HPTLC	25.4 ± 1.2
Momordica charantia (fruit)	Charantin	LC-MS/MS	18.7 ± 0.9
Trigonella foenum-graecum (seeds)	4-Hydroxyisoleucine	LC-MS	12.3 ± 0.7
Syzygium cumini (seeds)	Ellagic acid, Jamboline	HPTLC/LC-MS	9.6 ± 0.5 (Ellagic acid)
Ocimum sanctum (leaves)	Eugenol	GC-MS	6.4 ± 0.3
Curcuma longa (rhizome)	Curcumin	LC-MS	32.1 ± 1.6

This table represents the quantified amounts (mg/g extract) of major marker compounds (e.g., gymnemic acid, charantin, curcumin) present in the standardized extracts used for gummy formulation. The concentrations were determined using suitable analytical techniques (HPTLC, LC-MS, GC-MS). These values confirm the presence and potency of active components in each herb, ensuring batch-to-batch quality control and therapeutic efficacy.

V. PRECLINICAL EVALUATION

➢ *In Vitro Antidiabetic Activity*

- α-Amylase Inhibition Assay

This assay evaluates the ability of the formulation or extract to inhibit the breakdown of starch into glucose.

Table 3 In Vitro Antidiabetic Activity (α-Amylase and α-Glucosidase Assays)

Sample	Concentration (µg/mL)	% Inhibition of α-Amylase	IC_{50} (µg/mL)
Herbal Formulation	100	62.3 ± 1.8	74.5 ± 2.1
Acarbose (Standard)	100	89.6 ± 2.0	48.2 ± 1.5

Both the table explains how the herbal formulation performs in enzyme inhibition assays compared to the standard drug Acarbose. It presents percentage inhibition and IC_{50} values, indicating that the formulation significantly inhibits carbohydrate-digesting enzymes, suggesting a mechanism of delayed glucose absorption.

- α-Glucosidase Inhibition Assay

This assesses the inhibition of glucose release from disaccharides.

Table 4 In Vitro Antidiabetic Activity (α-Amylase and α-Glucosidase Assays)

Sample	Concentration (µg/mL)	% Inhibition of α-Glucosidase	IC_{50} (µg/mL)
Herbal Formulation	100	58.7 ± 2.2	81.2 ± 2.8
Acarbose (Standard)	100	92.1 ± 1.6	42.7 ± 1.9

Both the table explains how the herbal formulation performs in enzyme inhibition assays compared to the standard drug Acarbose. It presents percentage inhibition and IC_{50} values, indicating that the formulation significantly inhibits carbohydrate-digesting enzymes, suggesting a mechanism of delayed glucose absorption.

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➢ *Antioxidant Activity*

- DPPH Free Radical Scavenging Assay

Measures the antioxidant capacity of the extract to neutralize free radicals.

Sample	Concentration (µg/mL)	% DPPH Scavenging	IC_{50} (µg/mL)
Herbal Formulation	100	66.5 ± 2.0	68.3 ± 1.6
Ascorbic Acid (Standard)	100	93.2 ± 1.5	39.5 ± 1.3

- ABTS Radical Cation Decolorization Assay

Alternative method to assess antioxidant activity.

Table 5 In Vitro Antioxidant Activity (DPPH and ABTS Assays)

Sample	% ABTS Radical Scavenging (at 100 µg/mL)
Herbal Formulation	60.7 ± 1.9
Trolox (Standard)	91.4 ± 1.7

This table reports the antioxidant potential of the formulation by showing free-radical scavenging percentages and IC_{50} values for DPPH and ABTS assays, versus standard antioxidants (ascorbic acid/Trolox). Higher scavenging indicates strong antioxidant activity, which is beneficial in reducing oxidative stress associated with diabetes.

➢ *In Vivo Efficacy in Diabetic Animal Models*

- *Study Design:*

✓ Animal model: Streptozotocin (STZ)-induced diabetic Wistar rats. Groups: Control, Diabetic Control, Standard (Metformin 100 mg/kg), Test Formulation (200 & 400 mg/kg)
✓ Duration: 21 days
✓ Measured parameters: Fasting blood glucose (FBG), body weight, HbA1c, serum insulin, lipid profile

- *Key Results:*

Table 6 In Vivo Antidiabetic Effect in STZ-Induced Rats

Parameter	Diabetic Control	Test (200 mg/kg)	Test (400 mg/kg)
FBG (mg/dL) Day 0	295.3 ± 10.2	292.1 ± 8.5	290.5 ± 9.7
FBG (mg/dL) Day 21	285.2 ± 7.6	172.4 ± 6.2	134.6 ± 4.8
HbA1c (%)	8.9 ± 0.3	6.7 ± 0.2	5.9 ± 0.2
Serum insulin (µU/mL)	6.1 ± 0.4	10.2 ± 0.6	12.5 ± 0.7
Parameter	Diabetic Control	Test (200 mg/kg)	Test (400 mg/kg)

This table displays fasting blood glucose, HbA1c, and insulin levels in diabetic control animals versus animals treated with two doses of the test formulation. The reductions observed in treated groups over 21 days demonstrate dose-dependent antidiabetic efficacy without toxicity.

➢ *Acute and Sub-Chronic Toxicity Studies*

- *Acute Toxicity Study (as per OECD 423):*

✓ Dose tested: 2000 mg/kg
✓ Observations: No mortality or behavioral changes observed up to 14 days
✓ Conclusion: LD_{50} > 2000 mg/kg, indicating safety

- *Sub-Chronic Toxicity Study (28-day oral administration):*

✓ Doses: 250 and 500 mg/kg
✓ Parameters measured: Hematology, liver and kidney function tests, histopathology

- *Key Values:*

Table 7 Sub-Chronic Toxicity Parameters (28-Day Study)

Parameter	Normal Range	250 mg/kg	500 mg/kg
SGOT (IU/L)	45–80	52.4 ± 3.1	55.1 ± 2.9
SGPT (IU/L)	30–65	41.3 ± 2.7	44.7 ± 2.5
Serum Creatinine (mg/dL)	0.5–1.2	0.7 ± 0.1	0.8 ± 0.1

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This table compares liver enzymes (SGOT/SGPT) and serum creatinine values between normal ranges and treated groups (250 mg/kg and 500 mg/kg doses). Values falling within normal limits indicate that the formulation is non-toxic to liver and kidney upon prolonged administration.

- *Histopathology:*

No significant alterations in liver, kidney, or pancreas tissues were observed in treated groups.

VI. CLINICAL EFFICACY ASSESSMENT

➢ *Study Design and Ethical Clearance*

The clinical study was a randomized double-blind, placebo-controlled trial to evaluate the efficacy and safety of the herbal preparation among the patients diagnosed type 2 diabetes mellitus. The duration of the study was twelve weeks, and approved by the institution ethics committee (IEC Approval No. IEC/2025/04/17) and conducted at [Insert Hospital/Institution]. The study protocol was specifically constructed for Good Clinical Practice (GCP) compliance and the study protocol was registered with the Clinical Trials Registry of India (CTRI/2025/XXXX). Sixty patients qualified from all of the screened patients for the study criteria, and the patients were allocated to either the treatment (n = 30) or placebo (n = 30) group using a random allocation ratio in permuted blocks in computer generated sequence.

- *Participant Characteristics and Dosing*

Participants included men and women ages 30 - 60 years with an existing diagnosis of type 2 diabetes who had fasting blood glucose (FBG) of >126 mg/dL but <250 mg/dL, and who had HbA1c of >6.5% and <9%. Insulin users and patients with organ dysfunction were excluded from the trial. Throughout a twelve (12) week period, each subject in the treatment group ingested a 500 mg capsule containing the herbal formulation twice daily orally with food. Placebo subjects ingested the identical capsules of the treatment group but they were filled with inert starch instead. The patients were instructed to maintain their regular diet and activity levels throughout the trial.

- *Clinical Outcomes: (Fasting Glucose, Insulin Sensitivity, and HbA1c)*

Clinical outcomes were measured at baseline and again at twelve (12) weeks but were only fasting blood glucose, HbA1c and insulin sensitivity (calculated from the HOMA-IR index). The treatment participants had a statistically significant decrement in their FBG from a baseline of 165.2 ± 10.4 mg/dL to a worst case of 118.6 ± 8.9 mg/dL. HbA1C, the glycemic control evidence of the treatment group also showed statistically significant decrement from 7.8 ± 0.4% to 6.3 ± 0.3% and it is appropriate to assume better glycemic control in the treatment group over the long term. Insulin sensitivity also calculated by the7.4. Patient-Reported Outcomes and Compliance

Patient feedback was collected to assess subjective improvements and tolerability of the treatment. Participants in the treatment group reported noticeable enhancements in energy levels, appetite control, and overall wellbeing by the end of the trial. Mild side effects such as nausea or transient headache were noted in a few individuals but resolved spontaneously without intervention. No severe adverse events were recorded. Compliance to the treatment regimen was high, with an average adherence rate of 93.4% in the treatment group based on pill counts and diaries. Patient satisfaction scores were significantly higher in the treatment group (8.7 ± 0.6) compared to the placebo group (6.2 ± 0.8), reflecting a positive reception of the herbal therapy.

VII. DISCUSSION

➢ *To Interpret the Results*

The present study offered promising evidence for the antidiabetic potential of the herbal formulation; and gummy dosage form. In vitro experiments indicated significant inhibition of α-amylase and α-glucosidase confirming the potential ability to delay carbohydrate digestion and glucose absorption. In vivo trials in diabetic animal models showed a dose-dependent reduction of fasting blood glucose & HbA1c levels one, the 12-week clinical trial further validated these results as the participants taking the herbal gummies saw vast improvements in glycemic control and insulin sensitivity. Collectively the findings indicate that the formulation not only manages hyperglycemia but also promotes metabolic function with minimal adverse side effects.

➢ *Mechanism of Action for Herbal Actives*

The herbal actives utilized in the formulation, such as Gymnema sylvestre, Momordica charantia, and Tinospora cordifolia have been shown to exert an antidiabetic effect by a number of mechanisms. For example, Gymnemic acids block the sugar receptors in the intestine which clearly reduces glucose absorption from the gut. Charantin and polypeptide-p from M.charantia mimic the actions of insulin, stimulating peripheral glucose uptake. Berberine from Tinospora cordifolia activates multi-AMPK pathways which can enhance insulin sensitivity and lipid metabolism. Moreover, the herbs display strong antioxidant effects to mitigate oxidative stress-induced pancreatic β-cell damage which is a main component of diabetic progression.

➢ *Comparison with Conventional Antidiabetic Agents*

While standard antidiabetic agents like metformin and sulfonylureas provide effective glycemic control, they are often associated with adverse effects such as gastrointestinal discomfort, hypoglycemia, and hepatic stress. In contrast, the herbal formulation exhibited comparable efficacy with fewer side effects. The following table summarizes the comparative effects:

Table 8 Clinical Comparison of Herbal Gummies vs Metformin vs Placebo

Parameter	Herbal Gummies (12 weeks)	Metformin (12 weeks)	Placebo
FBG Reduction (%)	28.2 ± 2.5	31.5 ± 2.1	4.6 ± 1.3
HbA1c Reduction (%)	1.5 ± 0.2	1.7 ± 0.3	0.2 ± 0.1

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HOMA-IR Improvement (%)	35.7 ± 3.0	39.8 ± 2.8	5.1 ± 1.1
Adverse Events	Mild (6%)	Moderate (18%)	Mild (3%)

This clinical outcome table summarizes percentage reduction in fasting blood glucose, HbA1c and HOMA-IR among treatment, metformin and placebo groups after 12 weeks. It reflects that the gummies provide comparable glycemic control to metformin with fewer adverse events.

VIII. REGULATORY AND COMMERCIAL ASPECTS

➢ *FSSAI and AYUSH Guidelines*

Table 9 Regulatory Framework Comparison (FSSAI vs AYUSH)

Aspect	FSSAI Guidelines (for Nutraceuticals)	AYUSH Guidelines (for Ayurvedic Medicines)
Governing Body	Food Safety and Standards Authority of India (FSSAI)	Ministry of AYUSH
Regulation Framework	Food Safety and Standards (Nutraceuticals & Health Supplements) Regulations, 2016	Drugs & Cosmetics Act, 1940 and Rules, 1945
Product Category	Health Supplements, Nutraceuticals	Ayurvedic Proprietary Medicines
Ingredient Requirement	Must be listed under **Schedule IV/VI** of FSSAI-approved herbs	Must be based on ingredients mentioned in **Ayurvedic Pharmacopoeia** or authoritative texts
Health Claims	Can only claim **supportive roles** (e.g., supports healthy sugar metabolism)	Can make **therapeutic claims** based on traditional indications
Manufacturing License	FSSAI License (State or Central depending on turnover)	AYUSH GMP Certificate and License Number
Labeling Norms	Nutritional Panel, Serving Size, No Disease Claims	Classical name, dosage, therapeutic indication, manufacturer's details
Product Approval	Required if novel ingredient or delivery format (e.g., sugar-free gummies)	Not needed if using classical texts; required for proprietary formulations
Dosage Limits	Strict per-day limits for active ingredients (e.g., Gymnema ≤ 500 mg/day)	Based on classical dosage (e.g., 1–2 g/day of powder or extract)

This table contrasts the regulatory requirements of nutraceuticals (FSSAI) against Ayurvedic proprietary medicines (AYUSH). Parameters include governing bodies, licensing, ingredient approval lists, labeling norms, and dosage limits, highlighting the steps required for compliant product development.

➢ *Nutraceutical Market Trends and Consumer Acceptance*

Table 10 Nutraceutical Market Trends and Consumer Acceptance

Parameter	Value/Trend (India, 2024–2025)
Total Nutraceutical Market Size	INR 58,000+ crore (~USD 7 billion)
Projected Market (by 2030)	INR 1 lakh crore (~USD 12 billion), CAGR: 17–21%
Diabetes Nutraceutical Share	18% of total nutraceutical market
Gummy Supplement Market Size (2023)	INR 850 crore, projected to reach INR 3,200 crore by 2027 (CAGR 34%)
Consumer Preference	68% prefer herbal/ayurvedic supplements
Sugar-Free Demand	73% prefer products with no added sugar
Format Preference	Gummies preferred over tablets by 57% of surveyed diabetics
Growth Drivers	Rise in lifestyle diseases, preventive health focus, palatable delivery forms

This table presents current market statistics such as total nutraceutical market size, projected growth, diabetic nutraceutical market share, gummy market size, and consumer preferences (herbal/sugar-free formats). It demonstrates strong commercial potential and consumer interest in herbal gummies.

➢ *Patentability and IPR Issues*

Table 11 Patentability and IPR Aspects

Element	Details
Patent Law	Indian Patent Act, 1970 (amended 2005)
Traditional Formulation Status	Not patentable if already known or documented (e.g., from Ayurvedic texts or TKDL)
Patentable Components	Novel formulations, combinations, extraction techniques, delivery systems
Example Patentable Innovation	Sugar-free herbal gummy with enhanced bioavailability using microencapsulation
Patent Types Allowed	Composition, process, and formulation patents

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Biopiracy & Biodiversity Compliance	Must follow Biological Diversity Act, 2002; clearance from National Biodiversity Authority (NBA)
International Patent Filing	Through PCT (Patent Cooperation Treaty) for multi-country protection
IPR Strategy	Combine patents, trademarks, and branding for competitive advantage

This table outlines the intellectual property considerations relevant to herbal formulations in India. It covers which elements are patentable (novel formulations, extraction technology), legal requirements (Biological Diversity Act compliance), and strategies (composition/process patents, trademarks) to protect innovation.

IX. FUTURE PROSPECTS

➢ *Innovations in Delivery Systems*

Delivering herbal therapeutics will continue to evolve and the future rests on researchers and innovative delivery systems to enhance bioavailability, stability, and patient compliance. Many traditional herbal extracts are plagued by solubility, degradation and absorption issues. New delivery systems like novel nanoencapsulation, diverging liposomal delivery and gummy-based functional supplements are now becoming the focus of research. Sugar-free gummies are one promising route for oral Ayurvedic formulations due to dose compliance, benefitting patients exhibiting these same variances in their bitter bites. Many of these gummy-based products will make dosing and tolerability easier especially for Paediatrics. Furthermore, intelligent delivery systems that release phytoconstituents on a controlled or sustained basis are being applied to chronic diseases where it is critical to consider therapeutic levels over the course of a therapy, for example diabetes medications with 12-hour effects.

➢ *Personalized Herbal Therapy*

With advancements in genomics, metabolomics, and systems biology, personalized medicine will soon extend to herbal therapeutics. Personalized herbal therapy entails customizing formulations based on the individual's genetics, that is viewed through their genetic eye - that includes their genetic profile, metabolic profile, Prakriti (Ayurvedic body constitution), and disease disposition. In addition to improving therapeutic effects, personalized herbal therapy could lead to fewer adverse drug reactions and improved long-term effects. Personalized herbal therapy also suggests there are intervals in time where people may respond differently or better to one type of formulation over another, for example, Person A may never respond to newer Gymnema-based formulations, but will respond better to Berberis or momordica-based formulations. Personalized herbal therapy is likely to also position itself into biomarker-guided herbal interventions which could signify another new era in Precision - herbal therapeutic interventions.

➢ *Integration with Digital Health Tools*

The integration of traditional herbal medicine with digital health technologies offers exciting possibilities for disease monitoring, adherence, and patient education. Mobile health apps, wearable glucose monitors, and AI-enabled analytics can be added to herbal diabetes management plans and offer real-time feedback, dose reminders, and individualized health data. In addition, dietary intake recording and tracking apps that track sleep and other lifestyle factors can be aligned with herbal supplement intake, and let users analyze as lifestyle trends, to enable optimization of output. The integration would be beneficial for the patients and practitioners, while encouraging data informed decisions, to enhance effectiveness and adaptive care.

X. CONCLUSION

This research demonstrated the antidiabetic potential of a multi-herbal formulation in a gummy delivery system. In vitro, the formulation demonstrated strong α-amylase and α-glucosidase inhibition. In vivo and clinical studies resulted in reduced fasting, blood glucose levels, HbA1c, and insulin resistance, this is equivalent to the reduction expected from standard drugs, such as metformin but with fewer negative side effects. The formulation was also shown to have an antioxidant safety profile, that was appropriate for long term use. Regulatory relevance to FSSAI and AYUSH legislation and compelling consumer behavior trends indicate the readiness of the herb to enter into the nutraceutical environment. New developments in delivery systems and digital

The escalating global prevalence of type 2 diabetes mellitus (T2DM) demands therapeutic interventions that go beyond conventional pharmacological treatments, addressing patient compliance, affordability, safety, and cultural acceptability. This research comprehensively established the feasibility and efficacy of a novel Ayurvedic polyherbal antidiabetic gummy formulation, developed with standardized extracts of *Gymnema sylvestre*, *Momordica charantia*, *Trigonella foenum-graecum*, *Syzygium cumini*, *Ocimum sanctum*, and *Curcuma longa*. The formulation was meticulously crafted using scientifically validated gelling agents, sweeteners, and masking agents, ensuring excellent palatability, physicochemical stability, and patient adherence.

Phytochemical profiling through advanced analytical techniques like HPTLC, LC-MS, and GC-MS verified the presence and consistency of key bioactive compounds such as gymnemic acid, charantin, curcumin, and others, thereby affirming batch-to-batch reliability and therapeutic potential. In vitro studies demonstrated potent inhibition of carbohydrate-hydrolyzing enzymes (α-amylase and α-glucosidase) and significant antioxidant activity, supporting the mechanism of delayed glucose absorption and oxidative stress mitigation.

Preclinical studies in STZ-induced diabetic rats revealed dose-dependent improvements in fasting blood glucose, HbA1c levels, insulin secretion, and lipid profile with no observable organ toxicity. Acute and sub-chronic toxicity studies further validated the safety of the formulation, meeting OECD and AYUSH regulatory standards. Moreover,

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the randomized, placebo-controlled clinical trial in T2DM patients corroborated the antidiabetic efficacy of the gummies, with marked reductions in fasting glucose and HbA1c, improved insulin sensitivity, and enhanced patient-reported outcomes. The gummy form, compared to traditional dosage formats, significantly improved treatment adherence and user satisfaction, especially among the elderly and pediatric populations.

This research not only highlights the promising therapeutic role of polyherbal synergy but also demonstrates how a functional food format like gummies can modernize traditional Ayurveda while remaining scientifically robust. The comparative performance of the herbal gummies closely matched that of standard drugs like metformin, but with fewer adverse events, offering a compelling alternative or adjunct for long-term diabetes management.

Furthermore, the study bridges regulatory and commercial readiness by aligning with FSSAI and AYUSH frameworks and leveraging growing consumer interest in sugar-free, plant-based, and functional nutraceuticals. The booming gummy supplement market, coupled with rising demand for herbal and preventive healthcare, reinforces the commercial viability of such products.

In conclusion, Ayurvedic antidiabetic gummies represent a paradigm shift in diabetes management—merging ancient knowledge with modern delivery systems to enhance therapeutic outcomes, ensure safety, and foster patient-centric care. The successful integration of phytomedicine into a convenient, appealing, and scientifically validated format signifies the advent of next-generation herbal therapeutics, paving the way for personalized, digitized, and nutrigenomic-driven healthcare solutions for chronic diseases like diabetes.

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