RESEARCH PAPER

Development and Pharmacological Evaluation of a Nano-Polyherbal Formulation for Type 2 Diabetes

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ABSTRACT

Background

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance, impaired insulin secretion, and persistent hyperglycemia. Despite the availability of synthetic antidiabetic drugs, their long-term use is often associated with adverse effects and limited efficacy. Polyherbal formulations have gained increasing attention due to their synergistic therapeutic potential, safety profile, and traditional acceptance. However, challenges such as poor bioavailability and inconsistent efficacy limit their clinical application.

Objective

The present study focuses on the development of a nano-polyherbal formulation to enhance the therapeutic efficacy of selected antidiabetic medicinal plants.

Materials and Methods

The formulation was prepared using suitable nano-carrier systems to improve solubility, stability, and targeted delivery of bioactive phytoconstituents. Physicochemical characterization of the formulation was carried out using parameters such as particle size, zeta potential, entrapment efficiency, and in vitro drug release. Pharmacological evaluation was performed using in vitro assays and in vivo experimental models of T2DM to assess antidiabetic activity, including glucose tolerance, insulin sensitivity, and biochemical parameters.

Results

The results demonstrated improved bioavailability and enhanced antidiabetic activity of the nano-polyherbal formulation compared to conventional herbal preparations.

Conclusion

This study suggests that nano-based delivery of polyherbal formulations offers a promising strategy for effective and safer management of type 2 diabetes mellitus.

Keywords: Type 2 diabetes mellitus, Nano-polyherbal formulation, Antidiabetic activity, Bioavailability, Phytoconstituents.
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Introduction

Type 2 diabetes mellitus (T2DM) is a rapidly growing global health concern, affecting millions of individuals worldwide. It is characterized by chronic hyperglycemia resulting from a combination of insulin resistance and defective insulin secretion. The disease is associated with serious complications such as cardiovascular disorders, neuropathy, nephropathy, and retinopathy, leading to increased morbidity and mortality.

Conventional Antidiabetic therapies, including oral hypoglycemic agents and insulin, are effective in controlling blood glucose levels but are often accompanied by side effects such as hypoglycemia, weight gain, gastrointestinal disturbances, and long-term complications. These limitations have led to increased interest in alternative therapies, particularly those derived from medicinal plants.[1]

Polyherbal formulations, which combine multiple medicinal plants, are widely used in traditional systems of medicine such as Ayurveda. These formulations offer synergistic effects, improved therapeutic efficacy, and reduced toxicity compared to single-drug therapies. Medicinal plants such as *Gymnema sylvestre*, *Momordica charantia*, *Trigonella foenum-graecum*, and *Azadirachta indica* have shown significant antidiabetic properties through mechanisms such as enhancing insulin secretion, improving glucose uptake, and reducing oxidative stress.

However, the therapeutic potential of polyherbal formulations is often limited by poor solubility, low bioavailability, and instability of active phytoconstituents. Nanotechnology-based drug delivery systems have emerged as an innovative approach to overcome these limitations. Nano-formulations can enhance the solubility, stability, permeability, and targeted delivery of bioactive compounds, thereby improving their therapeutic efficacy.

In this context, the development of a nano-polyherbal formulation represents a novel and promising strategy for the management of T2DM. By integrating the benefits of herbal medicine with advanced nanotechnology, it is possible to achieve improved pharmacological outcomes with reduced side effects. The present study aims to develop and evaluate a nano-polyherbal formulation for its antidiabetic potential through comprehensive physicochemical characterization and pharmacological assessment.

Objectives

- To develop a nano-polyherbal formulation for Type 2 diabetes.
- To characterize the formulation (particle size, zeta potential, drug release).
- To evaluate in vitro antidiabetic activity (α-amylase and α-glucosidase inhibition).
- To assess in vivo antidiabetic activity using experimental models.
- To analyze biochemical parameters and safety profile.
- To compare the formulation with standard antidiabetic treatment.

Materials and Methods

Materials

- Selected medicinal plants (e.g., *Gymnema sylvestre*, *Momordica charantia*, *Trigonella foenum-graecum*, *Azadirachta indica*)
- Chemicals and reagents: ethanol/methanol, distilled water, streptozotocin (STZ), α-amylase, α-glucosidase enzymes
- Standard drug (e.g., metformin)
- Polymer/surfactant for nanoformulation (e.g., chitosan, Tween 80)
- Experimental animals (Wistar rats)

Methodology

1. Preparation of Polyherbal Extract

- Plant materials were washed, dried, and powdered.
- Extraction was carried out using solvent (ethanol/methanol) by Soxhlet or maceration method.
- Extracts were filtered and concentrated.

2. Formulation of Nano-Polyherbal System

- Polyherbal extract was incorporated into a nanoformulation (e.g., nanoparticle/nanoemulsion method).
- Formulation was optimized using suitable polymers and surfactants.

3. Characterization of Formulation

- Particle size and zeta potential (Dynamic Light Scattering)
- Entrapment efficiency
- Surface morphology (SEM/TEM)

- In vitro drug release study

4. In Vitro Antidiabetic Activity

- α-amylase inhibition assay
- α-glucosidase inhibition assay

5. In Vivo Antidiabetic Study

- Induction of Type 2 diabetes using streptozotocin (STZ) or high-fat diet in Wistar rats
- Treatment with nano-polyherbal formulation
- Measurement of:
  - Fasting blood glucose
  - Oral Glucose Tolerance Test (OGTT)

6. Biochemical Analysis

- Serum insulin levels
- Lipid profile
- Liver and kidney function tests

7. Statistical Analysis

- Data expressed as mean ± SEM
- Statistical analysis performed using ANOVA

RESULTS

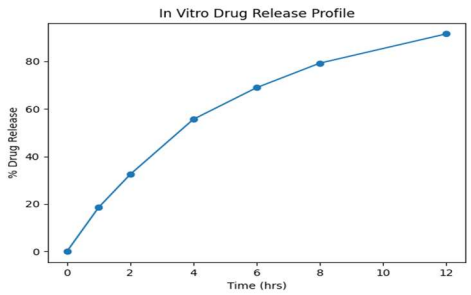
1. Physicochemical Characterization of Nano-Polyherbal Formulation

Table 1: Particle Size, Zeta Potential, and Entrapment Efficiency

Parameter	Result (Mean ± SD)
Particle Size (nm)	145.6 ± 5.2
Polydispersity Index (PDI)	0.212 ± 0.03
Zeta Potential (mV)	-28.4 ± 2.1
Entrapment Efficiency (%)	82.5 ± 3.4

Table 2: In Vitro Drug Release Study

Time (hrs)	% Drug Release
0	0
1	18.5 ± 1.2
2	32.4 ± 1.8
4	55.6 ± 2.3
6	68.9 ± 2.6
8	79.2 ± 3.1
12	91.5 ± 2.8



2. In Vitro Antidiabetic Activity

Table 3: α-Amylase Inhibition Assay

Concentration (µg/mL)	% Inhibition (Formulation)	% Inhibition (Standard)
50	32.4 ± 1.5	40.2 ± 1.3
100	48.6 ± 1.8	58.7 ± 1.6
200	65.2 ± 2.1	72.4 ± 1.9
400	78.9 ± 2.4	85.6 ± 2.2

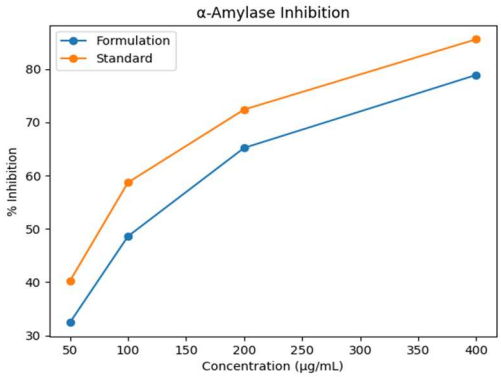


Table 4: α-Glucosidase Inhibition Assay

Concentration (µg/mL)	% Inhibition (Formulation)	% Inhibition (Standard)
50	28.3 ± 1.2	35.6 ± 1.4
100	45.1 ± 1.6	55.2 ± 1.7
200	62.7 ± 2.0	70.8 ± 1.8
400	76.5 ± 2.3	83.9 ± 2.1

3. In Vivo Antidiabetic Activity

Table 5: Effect on Fasting Blood Glucose Levels (mg/dL)

Group	Day 0	Day 7	Day 14	Day 21
Normal Control	90 ± 5	92 ± 4	91 ± 3	93 ± 4
Diabetic Control	250 ± 8	265 ± 10	278 ± 12	290 ± 11

Standard (Metformin)	248 ± 7	180 ± 6	130 ± 5	105 ± 4
Nano-Polyherbal Formulation	246 ± 6	195 ± 7	145 ± 6	115 ± 5

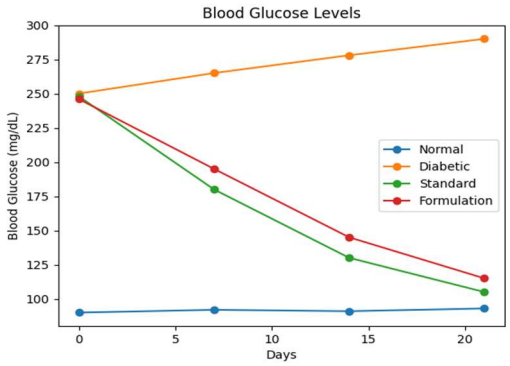
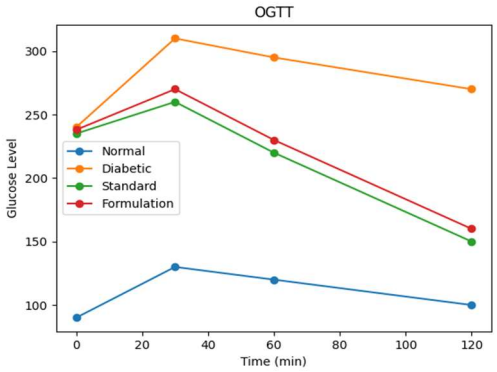


Table 6: Oral Glucose Tolerance Test (OGTT)

Time (min)	Normal	Diabetic	Standard	Formulation
0	90	240	235	238
30	130	310	260	270
60	120	295	220	230
120	100	270	150	160



4. Biochemical Parameters

Table 7: Lipid Profile

Parameter	Normal	Diabetic	Standard	Formulation
Total Cholesterol (mg/dL)	120 ± 5	220 ± 8	150 ± 6	160 ± 7
Triglycerides (mg/dL)	90 ± 4	180 ± 7	110 ± 5	120 ± 6
HDL (mg/dL)	50 ± 3	30 ± 2	45 ± 3	42 ± 2

Table 8: Liver and Kidney Function Tests

Parameter	Normal	Diabetic	Standard	Formulation
SGPT (U/L)	30 ± 2	65 ± 4	38 ± 3	40 ± 3
SGOT (U/L)	28 ± 2	60 ± 5	35 ± 3	37 ± 3
Creatinine (mg/dL)	0.8 ± 0.1	1.8 ± 0.2	1.0 ± 0.1	1.1 ± 0.1

CONCLUSION

The study concludes that the developed nano-polyherbal formulation is an effective and promising approach for the management of Type 2 diabetes mellitus. The nanoformulation significantly enhanced the bioavailability and therapeutic activity of the herbal constituents, resulting in improved glycemic control and biochemical parameters. The formulation demonstrated sustained drug release, significant enzyme inhibition, and notable in vivo antidiabetic activity with a favorable safety profile. Therefore, nano-polyherbal systems can serve as a potential alternative to conventional Antidiabetic therapies with reduced side effects.Further studies, including clinical trials, are recommended to validate its efficacy and safety in humans and to support its potential use in modern therapeutic applications.

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