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Formulation and Evaluation of Polyherbal Antidiabetic Powder

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Abstract: *Objective: Diabetes Mellitus (DM) is the major crippling disease, leading to huge economic loss in the developing country, India. Thus, the utilization of the nature's pharmacy is the pivotal forum of research in the treatment of DM and its complications. The main objective of the study was to prepare the Polyherbal Powder (PHP) extract for DM and its complications and evaluate it on the basis of organoleptic characteristics, and physico-phytochemical analysis. Materials & Methods: The PHP extracts were prepared by Drying, grinding, mixing and evaluations were done for organoleptic properties, flow property of powder, and physico-phytochemical properties by standard procedures. Results: Organoleptic characters of the PHP are greenish in color, characteristic odor, astringent and bitter taste with moderately fine texture. Phytochemical qualitative analysis displayed presence of flavonoids,tannins, steroids, carbohydrates, and glycosides. The physicochemical analysis displayed longer stability results with and excellent flow property of the PHP. Conclusion: PHP beholds felicitous and potent role in treatment of DM and its complications.*

Keywords: Diabetes Mellitus

I. INTRODUCTION

Diabetes mellitus (DM), Commonly known as diabetes, is a group of metabolic disorder characterized by a high blood sugar level over a prolonged period of time. Symptoms are often include frequent urination, increased Thirst and increased appetite. If left untreated, diabetes can cause many complications. Acute complication can include diabetic Ketoacidosis, hyperglycemia. Long term complications include cardiovascular disease, stroke, chronic kidney diseases, foot ulcers, damage to the nerves, damage to the eyes and congnitive impairment.

Diabetes is either due to pancreas not producing enough insulin, or the cells of the body not responding properly to the insulin produced. There are two main types of Diabetes mellitus.

Specialty	**Endocrinology**
Symptoms	Frequent urination, increased Thirst, Increased Hunger
Complications	Diabetic Ketoacidosis, hyperglycemia, heart disease, stroke, chronic kidney failure, foot ulcers, congnitive impairment.
Risk factors	**Type I:** Family history **Type Ii:** Obesity**,** lack of exercise **,** genetics
Diagnostic method	High blood sugar level
Treatment	Healthy Diet, physical Exercise
Medication	Insulin, Anti diabetic medication like metformin
Frequency	463 million (8.8%)
Deaths	4.2 million (2019)

Table 1. Diabetes Overview

TYPES OF DIABETES

Type I diabetes results from the pancreas failure to produce enough insulin due to loss of beta cells. This form was previously referred to as "Insulin dependent Diabetes mellitus"(IDDM) or "Juvenile diabetes". The loss of beta cells is caused by an autoimmune response. The cause of this autoimmune response is unknown.

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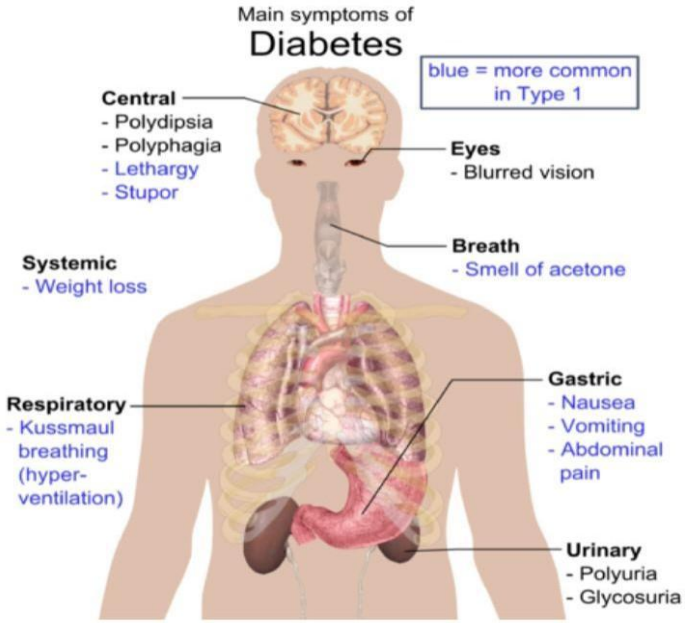
Type II diabetes begins with insulin resistance, a condition in which cells fails to respond to insulin properly. As the disease progresses, a lack of insulin may also develop. This form was previously referred to as "Non insulin – dependent diabetes mellitus "(NIDDM) or " Adult onset diabetes", The most common cause is a combination of excessive body weight and insufficient exercise.

Gestational diabetes is the third main form, and occurs when pregnant women without a previous history of diabetes develop high blood sugar levels.

Table 2. Comparison of type I And Type II Diabetes

Feature	Type I Diabetes	Type II Diabetes
Onset	Sudden	Gradual
Age of onset	Mostly in children	Mostly in adults
Body size	Thin or normal	Often obese
Ketoacidosis	Common	Rare
Autoantibodies	Usually present	Absent
Endogenous insulin	Low or absent	Normal, Decreased or increased
Concordance in identical twins	50%	90%
Prevalence	-10%	~90%

Fig. 01 MAIN SYMPTOMS OF DIABETES



Signs And Symptoms

Diagnosis

Table 3 :WHO DIABETES DIAGNOSTIC CRITERIA

Condition	2-hour glucose	Fasting glucose	Hba1c
Unit	Mg/dL	Mg/dL	DCCT%
Normal	<140	<110	<6.0
Impaired fasting glucemia	<140	110--125	6.0-6.4
Impaired glucose tolerance	>140	<126	6.0-6.4
Diabetes mellitus	>200	>126	>6.5

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Blood Glucose Chart			
Mg/DL	Fasting	After Eating	2-3 Hours After Eating
Normal	80-100	170-200	120-140
Impaired Glucose	101-125	190-230	140-160
Diabetic	126+	220-300	200+

. Fig.2 Blood Glucose chart

TREATMENT

Controlling blood sugar level or diabetes through diet, oral medication, insulin, Regular screening for complication is required.

Insulin: Insulin was discovered in 1921 by Banting and Best who demonstrated the Hypoglycemic action of an extract of pancreas prepared after degeneration of the exocrine part due to ligation of pancreatic duct. It was first obtained in pure crystalline form in 1926 and the chemical structure was fully worked out in 1956 by Sanger. Insulin is a two chain polypeptide having 51 amino acids. There are minor differences between human, pork and beef insulins; Thus, pork insulin is more homologous to human insulin than in beef insulin.

ORAL HYPOGLYCEMIC DRUGS

Oral Hypoglycemic agents are a group of drugs used to help to reduce the amount of sugar present in the blood. They are not insulin, but they stimulate the pancreas to produce insulin. Oral Hypoglycemic agents are usually used in treatment of adults onset of Diabetes. These drugs lower blood glucose levels in diabetics and are effective orally. Oral Hypoglycemic Drugs are useful in type 2 diabetes as adjuncts to continued dietary restraint. They fall into four groups:

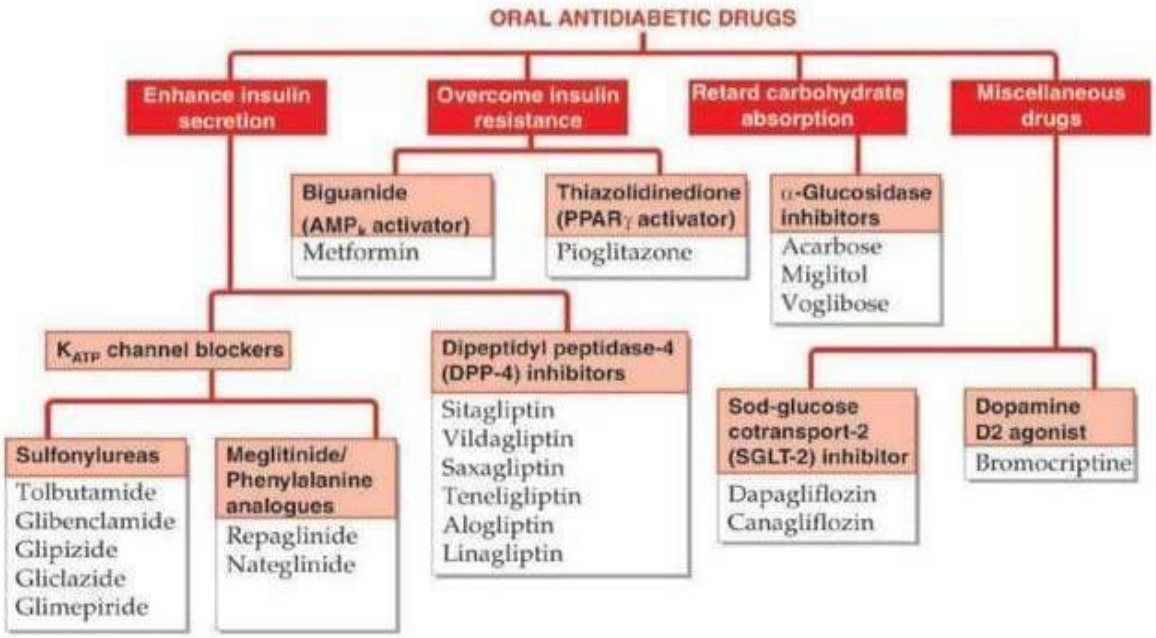

FIG. 3 CLASSIFICATION OF ORAL HYPOGLYCEMIC AGENTS

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MAJOR SIDE EFFECTS OF ORAL HYPOGLYCEMIC AGENTS

- Gastrointestinal issues: Diarrhea, constipation, bloating, gas, upset stomach, and nausea.
- Hypoglycemia: Low blood sugar that can occur after exercise, a missed meal, or if the drug dose is too high.
- Weight gain: A possible side effect of OHAs.
- Fluid retention: A possible side effect of OHAs.
- Tingling sensation: A possible side effect of OHAs in the hands and feet.
- Drowsiness: A possible side effect of OHAs.
- Skin reactions: A possible side effect of OHAs.
- Anaemia: Metformin can block vitamin B12 absorption and cause anaemia, especially after long-term use.
- Literature review

1. Suryakant Verma et al 2024 :

The most prevalent endocrine disorder diabetes mellitus affect around 100 million people globally. The use of herbal medicine to treat problems of type I and type Ii diabetes mellitus is widely acknowledged. Several plants have been used as separately or in combination because this formulations are safe and non-toxic

2. Subharaman Parasuraman et al 2014 :

The study finding demonstrate the Anti diabetic effect of polyherbal formulation at those level 250 and 500 mg per kg the Anti diabetic potential of polyherbal formulation is comparable with glibenclaimide.

3. Rashmi Saxena et al 2019 :

The physical and phytochemical characteristics of the Powder helps to determine the Powder stability and its performance.

4. Abhijeet Sahu and Deepali Naik et al 2024 :

The Anti diabetic polyherbal powder has ability to modulate cellular composition and regenerating pancreatic beta cells leading to sufficient insulin secretion.

5. Bharti D. R. and yahayalam Allhamhoom et al 2023 :

The Biguanide class of drug has been linked to a variety of side effects including metallic taste, nausea, vomiting, diarrhea, anoxia and lactic acidosis. As a search a current study shows poly herbal formulations are safe and effective meditations in treatment of diabetes mellitus.

6. Aakash Kale et al 2018 :

The physical chemical parameter such as bulb density tapped density cars index house PH and organoleptic characteristics can be efficiently used for standard digestion of herbal Anti diabetic drugs in a polyherbal formulations.

7. Akshay A. et al 2023 :

The formulation made from polyherbal plant source it is less likely to cause adverse effect than marketed type 2 diabetes drugs.

8. Kuntal manna et al 2024 :

The nutraceutical Powder have significant Anti diabetic activity. This may minimize various malnourished diseases in children and pregnant women. In future research of stability study of the product will be performed.

9. Gurugude Harshada and gaikar Mayuri et al 2024 :

The standard of the formulated churna is confirmed by the analysed a parameters. The enzymatic activity investigation conducted in vitro using the mentioned technique receives that the churna formulation has the ability to lower blood glucose levels in the body.

10. H.S. Chandel and M. Tellang et al 2011 :

The polyherbal Anti diabetic properties shows the its use in Anti diabetic therapy in the that house prepared formulation possess comparable activity when compared to that of the market formulations.

PLAN OF WORK

1 Literature review

2. Ingredient selection

a. Source

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b. Collection
3. Powder preparation
a. Plant material preparation
I. Wash, Dry, mix
4. Mixing method
5. Formulation
6. Storage
7. Evaluation of physical properties
a. Colour
b. Taste
c. Flavour d.Texture
8. Evaluation of physiochemical Properties
a. Angle of repose
b. Bulk density
c. Tapped density
d. Carr's compressibility index
e. Hausner's Ratio
9. Evaluation of phytochemical properties
a. Test for glycosides
b. Test for tannins
c. Test for flavonoids
10. Compilation of data
11. Submission and report

Hence Herbal Formulations Plays Important Role In Treatment Of Diabetes With Very Less Or No Side Effects.

INDIAN HERBAL DRUGS WITH ANTI DIABETIC PROPERTIES

1. Trigonella foenum graecum Synonyms: Fenugreek, Methi

Biological source: It is obtained from dried seeds of plant Trigonella foenum graceum belonging to family Fabaceae.

Chemical Constituents: Triogonelline, Nicotinic acid, and trigocaumarin are alkaloids found in plant. 4-hydroxyisoleucine is key Amino acid. Vitamins include Ascorbic acid, pyridoxine, retinol and Niacin.

Antidiabetic Action : 4-Hydroxyisoleucine (4-HIL): This amino acid stimulates insulin secretion, improves glucose tolerance, and enhances insulin sensitivity, leading to better blood sugar control. Saponins: Saponins may help reduce blood sugar levels and lower cholesterol Trigonelline: Trigonelline is a major bioactive compound with potential antidiabetic

effects. Galactomannan: Galactomannan, a type of soluble fiber, may help regulate blood sugar levels by slowing down glucose absorption and increasing gastric emptying time.

Fig.4 Trigonella foenum graecum seeds

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2. Annona Squamosal
Synonyms: Custard apple, Sugar apple
Biological source: A dried leaves of plant Annona Squamosa belonging to family Annonaceae.
Chemical constituents : Alkaloids like anonaine, phenolic compounds like eugenol, geraniol. Antidiabetic action : Flavonoids : Kaempferol, rutin, quercetin, and others are potent antioxidants and can contribute to various antidiabetic effects.β-caryophyllene: This compound, a type of sesquiterpene, has shown to have antidiabetic and antioxidant properties.

Fig. 5 Annona Squamosa leaves

3. Aegle marmelos
Synonym : bael, bel, golden apple
Biological source: It is obtained from unripe or half unripe fruit and leaves of plant aegle marmelos belonging to family Rutaceae.
Chemical constituents: Aegeline, fragrine, rutin, kaempferol-3-o rutinoside, gallic acid, p- coumaric acid, oxalic acid, mineral and vitamins.
Antidiabetic Action : Inhibiting Digestive Enzymes Aegle marmelos extracts have been shown to inhibit alpha-amylase and alpha-glucosidase, enzymes that break down carbohydrates
.This inhibition slows down the absorption of glucose into the bloodstream, leading to lower blood sugar levels after meals. One study found that the alcohol extract of bael leaves inhibited alpha-amylase activity by 60.2%, comparable to the standard drug acarbose, which is used to treat diabetes. Improving Insulin Sensitivity:Some studies suggest that Aegle marmelos can improve insulin sensitivity, allowing cells to better utilize glucose. For example, oleic acid and p-cymene, identified in bael, have been shown to improve insulin sensitivity and promote the survival of beta cells, which produce insulin.

Fig. 6 Aegle marmelos leaves

4. Murraya koenigii
Synonyms : Karipatta, curry leaves, Sweet Neem

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Biological source: The leaves of plant murraya koenigii tree belonging to family Rutaceae.
Chemical constituents: carbazole alkaloids like mahanine, murrayanine and mahanimbine.
Antidiabetic Action: Mahanimbine: This alkaloid has been shown to decrease blood glucose levels by enhancing insulin effects, increasing peripheral glucose uptake, and stimulating beta- cell function in the pancreas.Other Carbazole Alkaloids: Research suggests that carbazole alkaloids, in general, possess alpha-glucosidase inhibitory activity, which can help reduce the absorption of carbohydrates in the gut, thereby lowering blood sugar levels. Impact on Beta- Cell Regeneration:Some studies indicate that these alkaloids may also play a role in the regeneration of beta cells in the pancreas, which are responsible for insulin production.

Fig.7 Murraya koenigii leaves

5. Mentha Spicata
Synonyms: Spearmint, mint, mentha
Biological source: It is obtained from the entire plant of mentha Spicata belonging to family lamiaceae.
Chemical constituents : It includes carvone, limonene, 1,8 cineole, menthol polyphenols and essential oils.
Anti Diabetic action: Carvone: This is a major component of spearmint essential oil. Studies suggest carvone can improve insulin sensitivity, reduce blood glucose levels, and act as an antioxidant

Fig. 8 Mentha Spicata leaves

Herbal medicines have played a vital role in the therapeutics when safe and efficient therapy is required. Herbs had been used by all cultures throughout history but India has one of the oldest, richest and most diverse cultural living traditions associated with the use of medicinal plants. Presently the need for herbal drugs is growing because of the fact that these are biosafe with no side effects. Many analysis-based studies regarding pharmacological research in India, have been conducted in the past. Pharmaceutical research across the world shows that, natural products are potential sources of novel molecules for drug development.

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Diabetes is the world's largest endocrine disease involving metabolic disorder of carbohydrate, fat and protein. According to the WHO projections, the prevalence of diabetes is likely to increase by 35%. Statistical projections about India suggest that the number of diabetics will rise from 15 million in 1995 to 57 million in the year of 2025 making it the country with the highest number of diabetics in the world. In this work a polyherbal formulation was developed and compared with that of a marketed formulation.

Formulation and Evaluation of Polyherbal Nutraceutical Based antidiabetic powder.

Materials and methods

Selection and Collection of Herbs

1. The annona squamosal, Trigonella foenum-graecum, Murraya koenigii, Aegle marmelos Correa, Mentha spicata were from the Beed local market, however special care was taken to ensure that the ingredients were clean and current.
2. After the collection of annona squamosal, Trigonella foenum-graecum, Murraya koenigii, Aegle marmelos Correa, Mentha spicata, it was dried in shade for 24 hrs and all ingredients powder with the help of mixer or were reduce in small size and pass through the sieve No.40.

 Methods -Preparation of powder formulation

1. Clean annona squamosal, Trigonella foenum-graecum, Murraya koenigii, Aegle marmelos Correa,
2. Mentha spicata were first cut into small pieces and dried outside for one day before being ground separately in a grinder and passing through sieve no. 40.
3. With a mortar and pestle, combine all the powder medications according to the recipe.
4. Following the mixing process, the powder was dried for one hour at 40°C in a hot air oven before being sealed in a container.

Fig.9 Curry leaves fig. Mentha seed powder fig. Pudina powder. Fig. Bael powder

Batch Formulation

Sr. No.	Herbs	Quantity Taken
1	Aomona Squamosa	20 g
2	Aegle marmelos	20 g
3	Trigonella foenum graecum	20 g
4	Murraya koenigii	20 g
5	Mentha Spicata	20 g

Table 4 : Batch Formulation

Quality Evaluation :It was crucial to determine the quality of the manufactured herbal immunity booster in order to determine its effectiveness and safety. By comparing it to the accepted parameters, evaluation of the phytochemicals and physicochemicals was done. A sensory assessment of hearing, touch, taste, smell, and sight was also done.

Sensory Evaluation

Parameters	Formulation
1. Colour	Strongly like
2. Taste	Strongly like
3. Flavour	Moderately like

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4. Texture	Strongly like
5.Overall acceptability	Strongly like

Table 5: Sensory Evaluation

Observed sensory evaluation criteria for the polyherbal anti-diabetic powder. The formulation's observed characteristics, including colour, flavour, texture, and general acceptability at room temperature, are shown in Table 5 Based on the evaluation of paired comparisons, the powder has excellent flavour, taste, and overall acceptance. Analysis was also done on changes in sensory characteristics during storage.

Physicochemical and Phytochemicals Analysis

Physicochemical and phytochemical measurements were run in order to assess the formulation's appropriateness for nutritional purposes.

Physicochemical Evaluation

Determination of Moisture content

Using the AACC technique, moisture content was measured. A two-gram sample was put into a glass Petri plate that had been heated, weighed, and dried in a hot air oven for two hours at 130

°C. till construction. After cooling in the dessicator after being weighed after drying, the glass Petri plate was reweighed. Weight loss as a percentage of moisture content was determined.

$Moisture\ content$ (%) = W1 – W2/ Weight of sample ×100

W1 = weight of sample before drying. W2 = weight of sample after drying.

Determination of Ash content

AACC approach was used to quantify and characterize the ash content. Two grams of the material were put into a pre-weighed crucible, which was then exposed to a muffle furnace's 820°C for four hours before being cooled in a dessicator and weighed.

Ash(%) = Weight of Ash / weight of sample ×100

Angle of repose : The angle of repose is measured by using the stationary funnel technique. A funnel was positioned above paper that was laid horizontal and fastened with its point at a specific height (h). The mixture was made meticulously poured through the funnel until the conical piles base touched the funnels tip. The cylindrical piles base radius was calculated. the following method was used to determine the angle of repose.

Tan Ɵ =h/r

where Ɵ = Angle of repose,

h= height of piles,

r= Radius of piles base.

Angle of repose values between 25 and 30 shows outstanding flow properties, 31 to 35 so good flow property, 36 to 40 so acceptable flow property and 41 to 45 show passable flow properties angles of repose values between 40 and 60 employee a poorly flowing substances.

Bulk Density :A dry 100 ml container was filled with a 15 gram powder mixture without being compacted. Without compacting the Powder was meticulously leveled and the uncertaint of visible volume Vo was measured.

The following method was used to determine the mass density.

Pb = M/Vo

where, pb= Apparent bulk density,

M= weight of sample, V = apparent volume of powder.

Tapped Density: Following the steps outlined in the measurement of bulk density the sample containing cylinder was first tapped 500 times then 750 more times until the difference between the succeeding measurements was less than two percent the tab volume Vf was the major to the nearest graduated unit . Using the following method the tap density was determined in grams per Mili liter.

Ptap = M / Vf,

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where ptap = Tapped Density, M= weight of sample,
Vf = tapped volume of powder.

Cars index the compressibility index : Cars index is a metric for a powder tendency to be compacted it can be calculated using the mass and pierced density.substance is more flowable if it serves as a go for the relative significance of a particle inter actions there are commonly more particle contacts in poorly moving material which results in a larger dispersiency.

Compressibility index = {(ptap – pn)/ptap}/×100

where, pb = Bulk density, ptap = Tapped Density.

Hausner's Ratio: The Hausner's ratio is a proximate indicator of particle movement simplicity. The method used to determine it is follows tapped density divided by bulk density is known as Hausner's Ratio. Lower Hausner's ratio (1.25) suggest better flow properties than larger ones.

Carr's Index	Angle of Repose	Hausner Ratio	Flow Characteristics
10	25-30	1.00-1.11	EXCELLENT
11-15	31-35	1.12-1.18	GOOD
16-20	36-40	1.19-1.25	FAIR
21-25	41-45	1.26-1.34	PASSABLE
26-31	46-55	1.35-1.45	POOR
32-37	56-65	1.46-1.59	VERY POOR
>38	>66	>1.60	VERY, VERY POOR

Table. Flow properties of powder.

Phytochemical evaluation Test for glycosides :

Cardiac glycoside Keller killani test extract(0.5 g) taken with the distilled water 5 ml. To this glacial acetic acid (2 ml) containing of a few drops of ferric chloride was added followed by H2SO4 along the side of the test tube the formation of brown ring at the interface gives positive indication for cardiac glycoside and violet ring appear below the brown ring.

Test for tannins :

Extract Leaf and bark (0.5 gram each) was separately stirred with distilled water (10 ml) and then filtered a few drops of five percent ferrous chloride were then added black or blue green coloration or precipate was taken as positive result for the presence of tannins.

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Test for Flavonoids :

Stock solution 1 ml was taken in a test tube and added few drops of dilute NaOH solution and intense yellow colour was appeared in the test tube. It became colourless when on addition of a few drops of dilute acid that indicated the presence of flavonoids.

Test for Steroid (Salkowski test) :

The crude extract (about 100 mg) was separately shaken with chloroform (2 mL) followed by the addition of concentrated H2SO4 (2 mL) along the side of the test tube, a reddish-brown coloration of the interface indicates the presence of steroid.

Test for alkaloids:

Several chemical tests can be used to detect alkaloids, including Mayer's test, Dragendorff's test, Wagner's test. These tests involve adding specific reagents to plant extracts, and the formation of a precipitate or color change indicates the presence of alkaloids.

Mayer's Test:

Involves adding Mayer's reagent (potassium mercuric iodide) to the plant extract. A yellowish or white precipitate indicates a positive result.

Result And Discussion

Phytochemical analysis

Sr.No.	Constituents	Result
1	Glycosides	Present
2	Tannins	Present
3	Flavonoids	Present
4	Steroids	Present

Table 6. Phytochemical analysis

Physiochemical Evaluation

Sr.no.	Parameters	Result
1	Moisture content	0.81%
2	Ash content	4.5%
3	Angle of repose	30.6
4	Bulk density	0.5
5	Tapped Density	0.625
6	Carrs index	20
7	Hausner’s ratio	1.25

Table 7. Physiochemical Evaluation

Fig.10 Formulation

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II. CONCLUSION

The current study establishes the hypoglycemic activity of polyherbal powder. The leaves of the plant contain several chemical substances that are capable of producing different types of pharmacological activities using various mechanisms. Traditionally this plant was used to treatment of diabetes these polyherbal powder can be used as effective polyherbal antidiabetic powder formulation. People with diabetes can benefit from the mixture. Since the formulation is made from a plant source, it is less likely to cause adverse effects than marketed Type 2 diabetics drugs. All the herbs used in this preparation are easily available during any season and are not costly thus the product is economically feasible.

Conflict of interest : There are no conflicts of interest.

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