

FORMULATION AND EVALUATION OF HERBAL ANTIDIABETIC TABLET CONTAINING WITHANIA COAGULANS

Kunal Ghodake, * Yogesh B. Raut, Sanjay K. Bais

Fabtech College of Pharmacy, Sangola

Tal-Sangola, Dist.-Solapur

Maharashtra -413307

ABSTRACT

The condition known as diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia, which can lead to serious complications if not treated. The rising prevalence of diabetes necessitates the development of safe, effective, and affordable treatments. This study focuses on the development and testing of a novel herbal antidiabetic tablet containing Withania coagulans, also known as Indian cheese maker, which is well-known in traditional medicine for its anti-diabetes properties.

The study entails the systematic formulation of a botanical tablet employing Withania coagulans extracts, followed by a thorough evaluation of its physical and chemical properties. The formulation process involved selecting appropriate excipients and optimizing the tablet's hardness, friability, disintegration time, and dissolution profile to ensure consistency and efficacy. These substances are analysis of Withania coagulans extract revealed the existence of bioactive elements such as withanolides, which are responsible for its antidiabetic properties.

The herbal antidiabetic tablet containing Withania coagulans showed promising results in diabetes management, suggesting a herbal alternative to conventional antidiabetic medications. This study highlights the significance of incorporating ancient medicinal plants into modern pharmaceutical practices in order to create creative and efficient therapeutic agents for diabetes management.

Keywords: *Anti diabetic, withania coagulans, excipients, medicinal plants, herbal tablet*

*Corresponding Author Email: - kunalghodake2711@gmail.com

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INTRODUCTION

Diabetes Mellitus (DM)

Diabetes mellitus is a complex metabolic condition that causes chronic hyperglycemia caused by imperfections in the production of insulin, its action, or both. This condition is associated with high morbidity and mortality due to complications such as coronary artery disease, nerve damage, nephropathy, and retinopathy. According to the Worldwide Diabetes Federation, the worldwide prevalence of diabetes is rising at an alarming pace, with a calculated 537 million adults influenced as of 2021, and forecasts suggest that figure will rise with 783 million by 2045.^[1]

Type 2 diabetic mellitus (T2DM), which is the most typical type, accounts for roughly 90-95% of all diabetes cases. It is primarily linked to obesity, sedentary behavior, and genetic predisposition. T2DM causes resistance to insulin in peripheral organs along with pancreatic β -cell dysfunction, resulting in impaired glucose uptake and high blood glucose levels.^[2]

Current diabetes management strategies include lifestyle changes, oral hypoglycemic agents, and insulin therapy. Despite the availability of these treatments, many patients still struggle to achieve optimal glycemic control due to side effects, high costs, and the disease's progressive nature. As a result, there is a growing interest in researching alternative therapies, particularly those derived from natural sources, in order to develop more secure and efficient antidiabetic medications.^[3]

Herbal medicine has long been used in traditional systems to treat diabetes. *Withania coagulans*, additionally referred to as Indian cheese maker or Paneer dodi, is a plant that has received attention for its potential anti-diabetes properties. This medicinal plant, which belongs from the Solanaceae family, has traditionally been used in Ayurvedic medicine to treat a variety of ailments, including diabetes. Preliminary research indicates that *Withania coagulans* has significant hypoglycemic activity, which is assigned to its bioactive components such as withanolides.

In this study, we want to create and test a botanical diabetic medications tablet that includes *Withania coagulans*. The formulation process includes extraction in order and standardizing of the active substances from *Withania coagulans*, followed by the development of a tablet using suitable excipients to ensure stability, bioavailability, and patient compliance.

This study is significant because it combines traditional wisdom with current pharmaceutical practices, potentially resulting in a natural and effective alternative to diabetes management.^[4]

Withania coagulans (Paneer ke Phool)



Figure No. 1: *Withania Coagulans*

Commonly referred to as "Paneer ka Phool" or "Indian cheese maker," *Withania coagulans* is a member of the Solanaceae family of medicinal plants. It has been widely used to treat a variety of illnesses, including diabetes mellitus, in traditional medical systems, especially in Ayurveda.^[5] The plant is native to Iran, Afghanistan, Pakistan, and India, and modern science is beginning to acknowledge its medicinal potential.^[6]

The main benefit of paneer ka phool is that it has anti-diabetic qualities. It has been demonstrated that the bioactive components of *Withania coagulans*, particularly withanolides, have strong hypoglycemic effects. These substances function through multiple mechanisms, including upregulating insulin secretion, boosting insulin sensitivity, and blocking enzymes that break down carbohydrates, such as α -amylase and α -glucosidase. By taking these steps, blood glucose levels can be effectively managed overall and postprandial.^[7]

Withania coagulans has anti-inflammatory, antioxidant, and immunomodulatory qualities along with its hypoglycemic action. These qualities are helpful in the treatment of diabetes and its aftereffects. Antioxidant characteristics aid in reducing stress caused by oxidative damage, a common problem among diabetics that speeds up the development of complications like nephropathy and neuropathy.^[8]

Benefits of Indian Rennet

Hypoglycemic effect

The hypoglycemic effect of Indian rennet is its main anti-diabetic benefit. Withanolides, one of the bioactive compounds found in the plant, has been demonstrated to dramatically lower levels of glucose in the blood. These substances raise the responsiveness of peripheral organs to insulin and increase the amount of insulin secreted by pancreatic β -cells. Better glycemic control is maintained by this dual action. Research has indicated that *Withania coagulans* extracts possess the ability to impede the activity of two key enzymes involved in the metabolism of carbohydrates: α -amylase and α -glucosidase. The plant lowers postprandial blood glucose levels by reducing the decomposition of carbohydrates into glucose by inhibiting these enzymes.^[9]

Antioxidant effects

Oxidative stress is frequently associated with diabetes and can result in a number of complications, including retinopathy, nephropathy, and neuropathy. Strong antioxidant qualities found in Indian rennet aid in scavenging free radicals and mitigating oxidative stress. Flavonoids and phenolic compounds, among other antioxidants found in *Withania coagulans*, are essential for shielding the cells of the pancreas from oxidative damage, maintaining their functionality, and improving insulin secretion.^[10]

Anti-inflammatory effect

Insulin resistance and its complications progress at a rate that is significantly influenced by chronic inflammation. *Withania coagulans* have potent anti-inflammatory properties that may help ease this problem. Withanolides, which prevent the synthesis of pro-inflammatory cytokines, are mainly responsible for the anti-inflammatory qualities. Better insulin sensitivity and general metabolic health can result from this reduction in inflammation, which can help with diabetes management.^[11]

Lipid profile improvement

Dyslipidemia, a disorder marked through abnormal lipid levels that raises the possibility of cardiovascular diseases, is a common problem among patients with diabetes. It has been discovered that *withania coagulans* improve lipid profiles by raising levels of high-density lipoprotein (HDL) and decreasing levels of triglycerides, total cholesterol, and low-density lipoprotein (LDL).

Patients with diabetes benefit from this lipid-modulating effect because it lowers their risk of developing cardiovascular problems linked to their condition.^[12]

Immunomodulatory effect

Indian rennet's potential as an antidiabetic is further enhanced by its immunomodulatory qualities. *Withania coagulans* aid in preserving the equilibrium of immune functions, that's frequently upset in diabetic patients, by regulating the immune response. This balanced immune response helps diabetics stay healthier overall by reducing their risk of infection and other immune-related complications.^[13]

Other benefits of Indian Rennet help in the treatment of asthma, the berries of this plant cleanse the blood that removes acne easily, chewing on the branches helps to clean the tooth, paste Paneer Dodi, when applied on wounds, speeds up the healing process, relieves stress, promote a sense of well-being, reduces body aches and improves physical stamina.^[14]

Taxonomical Classification

Kingdom: Plantae, Plants.

Subkingdom: Tracheobionta, Vascular plants.

Super division: Spermatophyta, Seeds plants.

Division: Angiosperma;

Class: Dicotyledons.

Order: Tubiflorae;

Family: Solanaceae.

Genus: *Withania*;

Species: *coagulans*

Botanical Name: *Withania coagulans* (Stocks) Dunal,

Synonyms: *Puneeria coagulans* Stocks.

Regional Name: Telugu: Penneru-gadda, Pennerugadda,

Kannada: Amakiregadday, Asvagandhi,

Malayalam: Amukkuram,

Marathi: Ashwagandha

Punjabi: Khamjira.

Parts used: Fruits

Description

Native to dry areas of India, Pakistan, Sri Lanka, and portions of Africa (including Congo, South Africa, Egypt, and Morocco), *Withania somnifera* is a plant. It thrives in full sun, good drainage, and sandy and loamy soils. It is a plant that grows well in dry, disturbed soils, wastelands, and along field edges. It is resistant to drought.

Withania somnifera grows to a height of approximately 35–75 cm (14–30 inches) as a small, perennial shrub. In ideal circumstances, it can reach a height of 170 centimeters (5.6 feet).^[15]

Withania somnifera is a plant with simple, ovate, alternating leaves. Usually, they measure 2.5–5 cm in width and 5–10 cm in length. The leaves have a surface that is slightly tomentose, or hairy, and a dull green color.

The stems are erect, branching, and covered in fine grayish-white tomentose hairs. The vegetation produces small, inconspicuous greenish-yellow flowers.

The flowers are arranged in axillary clusters. Each flower is approximately 5-10 mm in diameter and has five lobes that form a tiny bell-shaped corolla.^[16]

Withania somnifera produces small, round berries that turn bright red-orange when ripe. Each berry measures approximately 5-8 mm in diameter and contains numerous yellow, kidney-shaped seeds.

Withania somnifera has a well-developed root system that includes a robust, fleshy and tuberous main root that is frequently utilized in herbal medicine.^[17]

Phytoconstituents:

Withania somnifera's phytoconstituents, which include flavonoids, steroidal lactones, alkaloids, saponins, withanolides, and tannins, are responsible for a variety of the plant's therapeutic benefits. Due to these compounds' adaptogenic, anti-inflammatory, antioxidant, immunomodulatory, and neuroprotective properties, ashwagandha is a highly valued herb in both conventional and alternative medicine.^[18]

Phytochemistry:

Ashwagandha, or *Withania somnifera*, is a plant whose phytochemistry is characterized by a wide range of bioactive compounds that are mostly found in its leaves and roots.^[19] The most important phytoconstituents found in ashwagandha are called withanolides, which are a class of steroidal lactones that are found in nature. Among these are well-known substances with pharmacological properties such as anti-inflammatory, anti-tumor, immunomodulatory, and neuroprotective effects: withaferin A, withanolide A, and withanolides. Ashwagandha has sedative and anxiolytic qualities due to the presence of alkaloids like withanine, somniferine, and cuscohygrine in addition to withanolides.^[20] Anti-stress and immunomodulatory properties are exhibited by saponins such as sitoindosides and saponin A/B. Quercetin and kaempferol are two examples of flavonoids that have anti-inflammatory and antioxidant properties. A portion of ashwagandha's tannins is responsible for its antimicrobial and wound-healing qualities.^[21]



Figure No. 2: Withania Somnifera Plant

Ayurvedic Properties

Rasa (Taste): Bitter (Tikta) and Astringent (Kashaya)

Guna (Qualities): Light (Laghu) and Unctuous (Snigdha)

Virya (Potency): Heating (Ushna)

Vipaka (post-digestive effect): Sweet (Madhura)

Ayurvedic Applications

Pachana, Depana, Raktadosha, Sotha, Antrasula.

Medicinal Uses

Adaptogenic Properties

By regulating the stress response, ashwagandha functions as an adaptogen, assisting the body in managing and adapting to stress. It keeps cortisol levels in check and promotes adrenal function.^[22]

Enhancement of Cognitive Function

The herb has been shown to enhance mental clarity, memory, and attention. It is applied to counteract cognitive decline and promote cognitive health.^[23]

Anti-Anxiety and Antidepressant Effects

Research has demonstrated that this herb can lessen anxiety and depression symptoms. It improves mood and lowers stress, which supports emotional well-being.^[24]

Handling Diabetes

Ashwagandha is good for people with type diabetes because it increases insulin sensitivity and helps control blood sugar levels.^[25]

Potential to Prevent Cancer

Studies suggest that ashwagandha may prevent cancer by preventing the growth of cancer cells and triggering their death.^[26]

What is paneer ka phool?

A common medicinal plant in traditional Ayurvedic medicine is paneer ka phool, also called *Withania coagulans* or Indian rennet. The plant is indigenous to Afghanistan, Pakistan, and India and is a member of the Solanaceae family.^[27] Its berries are known as "Indian cheese maker" because they have the ability to coagulate milk, which is why cheese is made with them. Paneer ka phool is well known for its medicinal properties, especially in the treatment of diabetes. Because of its hypoglycemic action, blood sugar levels can be lowered.^[28] It also has hepatoprotective, antioxidant, and anti-inflammatory qualities, which help to protect the liver from oxidative stress and reduce inflammation.^[29]

How does paneer ka phool help in management of diabetes

Withania coagulans, also known as paneer ke phool, is primarily used to treat diabetes because of its hypoglycemic and insulin-sensitizing qualities. Withanolides, one of the bioactive compounds found in the plant, is essential for controlling blood sugar levels.

Withania coagulans extracts have been demonstrated in studies to dramatically lower blood glucose levels in diabetic models. The increased glucose absorption by peripheral tissues and the stimulation of insulin secretion from pancreatic beta cells are responsible for this effect. The plant increases insulin sensitivity, which aids in the body's cells using glucose more effectively. This is especially helpful in the management of Type 2 diabetes, since the main issue here is insulin resistance.^[30]

Withania coagulans contain steroidal lactones called withanolides, which have been shown to have the ability to increase insulin sensitivity and stimulate the release of insulin from pancreatic cells. Higher insulin sensitivity lowers blood sugar levels by facilitating cells' better use of glucose.^[31]

Materials and methods

Plant Collection: Obtain *Withania coagulans* fruits from a reputable herbal garden or supplier.

Extraction of Active Constituents Preparation: Clean and dry the fruits in the shade.

Powdering: Grind the dried fruits into a fine powder using a mechanical grinder.

Extraction: Use ethanol or another appropriate solvent in a Soxhlet extraction. After 8 to 10 hours of extraction, the solvent should turn clear. Utilize a rotary evaporator to filter and concentrate the extract.

To create a dry powder, dry the extract in a vacuum oven set at 40°C.

Experimental Work

Formulation of antidiabetic tablet

The formulation process involves the following steps:

Blending

Combine the dried extract with the excipients in a geometric ratio.

Granulation

Employ the wet granulation method with starch paste as a binder.

Drying

Dry the wet granules at 50°C.

Sizing

Sieve the dried granules to achieve a uniform size;

Lubrication

Combine the granules with talc and magnesium stearate.

Compression

Press the granules into tablets using a rotary tablet press.^[32]

Evaluation of Tablets

Tablet Thickness

Use a Vernier caliper to measure the thickness.

Hardness

Use a Monsanto hardness tester to ascertain the hardness.

Friability

Check the tablet's resistance to abrasion by using a friabilator.

Weight Variation

Determine the average weight by weighing each of the twenty tablets separately.

Disintegration Time

To determine how long it takes for tablets to dissolve, use a disintegration test device.^[33]

Formulation Table

Sr No.	Ingredients	Quantity Sufficient for 30 tablets	Quantity Sufficient for 1 tablet
1	Withania Coagulans	27 g	0.9 g
2	Glycine max	1.5 g	0.05 g
3	Starch	1.2 g	0.04 g
4	Sodium benzoate	0.15 g	0.005 g
5	Gelatin	0.15 g	0.005 g
6	Talc	0.45 g	0.015 g
7	Magnesium stearate	0.15 g	0.005 g

Table No. 1: Formulation table

Preparation of granules by wet granulation method:

1. Making an Extract Using a suitable extraction technique (such as solvent extraction with ethanol or water), obtain the extract of *Withania coagulans*. To make a fine powder, dry the extract.
2. Blending of Basic Ingredients Calculate how much *Withania coagulans* extract, diluent, disintegrant and binder are needed. To get a consistent blend, thoroughly combine these ingredients in a dry blender or with a mortar and pestle.
3. Getting the Binder Solution Ready Making a binder solution requires dissolving the remaining binder in the appropriate solvent (ethanol or water).
4. Granulation Stirring constantly, slowly add the binder solution to the dry mix. Both manual labor and a granulator/high-shear mixer can be used for this. Keep mixing until the mixture resembles a wet mass or dough.
5. Sorting To create granules, pass the wet mass through an appropriate sieve (10–20 mesh, for example). Gather the grains onto a serving tray.
6. Mixing To guarantee even distribution, combine the sized granules with the remaining disintegrant and lubricant (such as magnesium stearate). In order to avoid sticking and guarantee correct disintegration, this step is essential.
7. Press Using a tablet press, compact the granule mixture into tablets. Depending on the required tablet specifications, set the machine's parameters (weight of tablet, compression force). Check the tablets' thickness, hardness, and weight consistency on a regular basis while they are being compressed.
8. Testing After Compression Examine the tablets for friability, dissolution, hardness, and disintegration time, among other characteristics. If the tablet quality is not up modify the formulation or process parameter.^[34]



Figure No.3: Granules Preparation



Figure No.4: Tablets of Withania coagulans

RESULT

PHYSICAL EVALUATION OF TABLETS

All the formulated tablets were subjected to following evaluation parameters.

Sr No.	Parameters	Observations
1	Colour	Brown
2	Appearance	Round
3	Weight Variation Test	1.0001%
4	Hardness	2
5	Friability	10.05%
6	Thickness	0.5cm
7	Disintegration Time	1min

Table No. 2: Physical evaluation of tablets

DISCUSSION

Withania coagulans, commonly known as Indian rennet or Paneer dodi, has shown promising antidiabetic properties due to its bioactive compounds like withanolides and flavonoids. Formulating an herbal tablet involves selecting appropriate excipients to ensure stability, bioavailability, and therapeutic efficacy of these compounds. Key formulation parameters include optimizing the concentration of Withania coagulans extract, choosing suitable binders, disintegrants, and lubricants, and assessing their compatibility. Evaluation methods include in vitro dissolution studies, content uniformity, and stability testing to ensure consistent drug release and shelf-life.

CONCLUSION

The creation and assessment of a herbal antidiabetic tablet containing Withania coagulans were effectively carried out in this study. The goal of the study was to create a natural, efficient substitute for diabetes treatment by utilizing the strong antidiabetic and antioxidant qualities of Withania coagulans. The tablets were formulated using the wet granulation method, which guarantees uniform quality and effectiveness. The prepared tablets were tested for friability, hardness, disintegration time, and dissolution profiles, among other characteristics. The findings showed that the tablets complied with the necessary pharmaceutical standards, demonstrating good mechanical strength as well as the proper rates of disintegration and solvation—all necessary for efficient glucose regulation.

CONFLICTS OF INTEREST

Nil.

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