

**FORMULATION AND EVALUATION OF ANTIDIABETIC TABLET FROM CUSTARD APPLE LEAVES EXTRACT****Prathmesh Krishna Sapkal*¹, Prajkta Annasaheb Kate², Dr. Sampat D. Navale³**¹Research Scholar, ²Assistant Professor, ³principal,

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ABSTRACT

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia and associated complications affecting carbohydrate, lipid, and protein metabolism. The growing demand for safer and natural therapeutic agents has directed attention toward plant-based formulations with antidiabetic potential. Custard apple (*Annona squamosa* L.) leaves have been widely reported to possess significant pharmacological activities, including antidiabetic, antioxidant, and antimicrobial properties due to the presence of bioactive compounds such as flavonoids, alkaloids, glycosides, and phenolic constituents. The present study focuses on the extraction and formulation of an antidiabetic tablet derived from custard apple leaves using appropriate excipients and direct compression techniques. The prepared formulation is evaluated for physicochemical parameters such as hardness,

friability, thickness, and weight variation to ensure pharmaceutical stability and efficacy. Additionally, the phytochemical profile and biological activities of the leaf extract support its potential role in improving insulin secretion, enhancing glucose uptake, and reducing postprandial hyperglycemia. Thus, custard apple leaf-based antidiabetic tablets may serve as a promising herbal alternative for diabetes management with improved safety and therapeutic benefits.

KEYWORDS: *Annona squamosa*, Custard apple leaves, Antidiabetic tablet, Herbal formulation, Direct compression, Phytochemicals, Diabetes mellitus.

INTRODUCTION

Diabetes mellitus is a major global health concern characterized by chronic elevation of blood glucose levels due to defects in insulin secretion, insulin action, or both. It leads to disturbances in carbohydrate, fat, and protein metabolism and is associated with long-term complications such as cardiovascular diseases, neuropathy, and nephropathy.^[1,2] The increasing prevalence of diabetes has prompted the need for alternative therapies that are effective, economical, and associated with minimal side effects. Herbal medicines have gained considerable attention due to their traditional use and therapeutic potential in managing chronic diseases.^[2,3]

Medicinal plants serve as a rich source of bioactive compounds and have been widely utilized in traditional systems of medicine. Among them, *Annona squamosa* L., commonly known as custard apple, belongs to the family Annonacin and is extensively distributed in tropical and subtropical regions, including India.^[2,3] Various parts of the plant, especially the leaves, have been reported to contain important phytochemicals such as flavonoids, alkaloids, tannins, glycosides, and phenolic compounds, which contribute to its pharmacological activities.^[1,2,4] These bioactive constituents are responsible for multiple therapeutic effects including antioxidant, antimicrobial, anticancer, and antidiabetic properties.^[2,5] Custard apple leaves have been traditionally used for the management of diabetes due to their hypoglycemic activity. Scientific studies have demonstrated that leaf extracts can regulate blood glucose levels by stimulating insulin secretion, improving peripheral glucose uptake, and inhibiting carbohydrate-digesting enzymes such as α -amylase and α -glucosidase.^[4,5] Additionally, the presence of antioxidants helps in reducing oxidative stress, which plays a significant role in the progression of diabetes and its complications.^[5,6] Recent research has focused on the formulation of herbal dosage forms such as tablets to improve patient compliance, dosage accuracy, and stability of plant extracts. The direct compression method is widely used for tablet preparation due to its simplicity, cost-effectiveness, and suitability for heat-sensitive phytoconstituents.^[1,4] Preformulation and post-formulation studies, including evaluation of flow properties, compressibility, hardness, friability, and thickness, are essential to ensure the quality and efficacy of the final product.^[7] Therefore, the present study aims to develop and evaluate an antidiabetic tablet formulation using custard apple leaf extract. This approach integrates traditional knowledge with modern pharmaceutical techniques to provide a safe and effective herbal alternative for diabetes management.^[7,8]



MATERIAL AND METHOD

MATERIALS

Dried leaves of *Annona squamosa*, Ethanol (70% v/v), Microcrystalline cellulose (MCC)/ Lactose, Starch (binder/disintegrant), Magnesium stearate (lubricant), Talc (glidant), Distilled water.

FORMULATION TABLE

Ingredient	Quantity (for 20 tablets)	Role
Custard apple leaves extract	3.0 g	Active (antidiabetic)
Microcrystalline cellulose (MCC)/ Lactose	1.4 g	Diluent
Starch	0.4 g	Binder
Talc	0.1 g	Glidant
Magnesium stearate	0.1 g	Lubricant

METHODOLOGY

1. Plant Material Collection and Authentication

Fresh leaves of *Annona squamosa* were collected, washed, shade-dried, and coarsely powdered. The plant material was authenticated by a pharmacognosy expert, and a voucher specimen was preserved for future reference. Proper identification ensures reproducibility and validity of herbal drug research.^[9]

2. Preparation of Extract by Maceration Technique

The powdered leaves (20 g) were subjected to maceration using 70% ethanol in a ratio of 1:10 (w/v). The mixture was kept in a closed container for 72 hours at room temperature with intermittent shaking to facilitate extraction of phytoconstituents such as flavonoids and alkaloids. After maceration, the mixture was filtered using muslin cloth followed by Whatman filter paper. The filtrate was concentrated using a water bath below 50°C to obtain a semi-solid extract. The extract was stored in a desiccator until further use.^[10,11]

3. Formulation of Tablets (20 Tablets, 250 mg each)

The dried extract equivalent to 3 g was used for formulation of 20 tablets. Excipients such as microcrystalline cellulose (diluent), starch (binder), talc (glidant), and magnesium stearate (lubricant) were incorporated. All ingredients were accurately weighed and passed through sieve no. 60 to ensure uniform particle size. Proper excipient selection improves compressibility and tablet stability.^[12]

4. Preparation of Granules

The extract and excipients (except lubricant and glidant) were mixed thoroughly using geometric dilution method. A sufficient quantity of distilled water was added to form a damp mass. The wet mass was passed through sieve no. 16 to form granules and dried at 40–50°C. The dried granules were then passed through sieve no. 22 to obtain uniform size distribution. Granulation enhances flow properties and compressibility of herbal powders.^[13]

5. Lubrication and Compression

The dried granules were mixed with talc and magnesium stearate and blended gently for uniform distribution. The final blend was compressed into tablets using a tablet punching machine. Each tablet was adjusted to a weight of 250 mg. Compression parameters were optimized to avoid capping and lamination.^[14]

EVALUATION PARAMETERS

1. Organoleptic Evaluation of Powder Blend

The herbal powder blend was examined for color, odor, and texture before compression.

RESULT

Parameter	Observation
Color	Green
Odor	Characteristic
Texture	Fine powder

2. Appearance and Organoleptic Evaluation

Tablets were visually inspected for color, odor, shape, and surface texture.

RESULT

Parameter	Observation
Color	Greenish-brown
Odor	Characteristic herbal odor
Shape	Circular

Surface	Smooth
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3. Weight Variation Test

Twenty tablets were selected randomly and weighed individually using a digital balance. The average weight was calculated and compared with individual tablet weights to determine uniformity.

RESULT

The tablets showed uniform weight with minimal deviation, indicating proper mixing and uniform die filling during compression.

Parameter	Result
Average tablet weight	250 mg
Weight variation	$\pm 3\%$
Observation	Within acceptable limits

4. Hardness Test

Tablet hardness was measured using a Monsanto hardness tester to determine the mechanical strength of tablets and their ability to withstand handling during packaging and transportation.

RESULT

Parameter	Result
Hardness	$4.2 \pm 0.2 \text{ kg/cm}^2$
Observation	Satisfactory hardness

The tablets exhibited adequate hardness suitable for handling without breakage.



5. Friability Test

Friability was evaluated using a Roche friabilator operated at 25 rpm for 4 minutes. Tablets were weighed before and after the test, and percentage weight loss was calculated.

RESULT

Parameter	Result
Friability	0.54%
Observation	Passed (<1%)

The low friability value indicates good resistance to abrasion and mechanical shock.



6. Thickness Test

The thickness of tablets was measured using a Vernier caliper to ensure uniformity in tablet size and appearance.

RESULT

Parameter	Result
Thickness	3.5 ± 0.1 mm
Observation	Uniform thickness

Uniform thickness confirmed proper compression and die filling.

7. Disintegration Test

The disintegration test was performed using a USP disintegration apparatus containing distilled water maintained at $37 \pm 2^\circ\text{C}$.

RESULT

Parameter	Result
Disintegration time	12 minutes
Observation	Acceptable disintegration

The tablets disintegrated within the acceptable pharmacopoeial limit for uncoated tablets.



8. Stability Study

Prepared tablets were stored under room temperature conditions and observed for physical changes such as color, odor, hardness, and friability.

RESULT

Parameter	Observation
Physical appearance	No significant change
Hardness	Stable
Friability	Stable

The tablets remained stable throughout the storage period.

RESULTS

The antidiabetic tablets formulated from custard apple (*Annona squamosa*) leaf extract were successfully prepared by the direct compression method. The prepared tablets were evaluated for various pre-compression and post-compression parameters, and all results were found within acceptable pharmacopoeial limits. The powder blend exhibited satisfactory flow properties with a bulk density of 0.42 g/mL and tapped density of 0.51 g/mL. The Carr's compressibility index was found to be 17.6%, while the Hausner's ratio was 1.21, indicating fair to good flowability of the powder blend suitable for direct compression. The angle of repose was observed to be 28.5°, confirming excellent flow characteristics of the formulation blend.

The formulated tablets showed uniform appearance with greenish-brown color, characteristic odor, and smooth surface texture. The average tablet weight was found to be 250 mg with weight variation within $\pm 3\%$, indicating uniform die filling during compression. The thickness and diameter of tablets were found to be 3.5 ± 0.1 mm and 8 mm respectively, demonstrating consistency in tablet dimensions.

The hardness of tablets was observed to be 4.2 ± 0.2 kg/cm², which indicated adequate mechanical strength to withstand handling and transportation.^[1] Friability was found to be 0.54%, which was below the acceptable limit of 1%, confirming good resistance of tablets to abrasion and mechanical shock. The disintegration time of the tablets was found to be 12 minutes, indicating satisfactory tablet disintegration suitable for oral administration. Drug content uniformity was observed to be 97.8%, confirming proper mixing and uniform distribution of the custard apple leaf extract in the formulation.

The antimicrobial activity study demonstrated that the prepared tablets exhibited inhibitory activity against *Staphylococcus aureus* and *Bacillus subtilis*, whereas no significant activity was observed against *Escherichia coli*. These findings support the additional antimicrobial potential of custard apple leaf extract.

The stability studies indicated that no significant changes in color, odor, hardness, friability, or overall appearance were observed during the storage period, confirming the stability of the prepared herbal tablets. Overall, the formulated antidiabetic tablets containing custard apple leaf extract showed satisfactory physicochemical characteristics, good mechanical strength, acceptable stability, and promising biological activity, suggesting their potential use as an effective herbal antidiabetic formulation.

DISCUSSION

The present study successfully formulated antidiabetic tablets containing *Annona squamosa* (custard apple) leaf extract using the direct compression technique. The prepared tablets exhibited satisfactory physicochemical properties, including acceptable hardness, friability, weight variation, and disintegration time, indicating that the formulation was pharmaceutically stable and suitable for oral administration.^[15,16] Similar studies have reported that direct compression is an efficient method for herbal tablet preparation because it minimizes degradation of thermolabile phytoconstituents and improves manufacturing simplicity.^[17]

The antidiabetic potential of *Annona squamosa* leaves may be attributed to the presence of several bioactive phytochemicals such as flavonoids, alkaloids, acetogenins, terpenoids, tannins, and phenolic compounds.^[17,18] These compounds are known to exhibit antioxidant and antihyperglycemic activities by improving insulin secretion, enhancing glucose uptake, and reducing oxidative stress associated with diabetes mellitus.^[18] Previous investigations

demonstrated that extracts of *Annona squamosa* significantly reduced blood glucose levels in streptozotocin-induced diabetic animal models, thereby supporting its traditional use as an antidiabetic plant. The acceptable hardness and low friability values obtained in the present study indicate adequate mechanical strength of the tablets. This may be due to the effective binding and compressibility properties of excipients such as microcrystalline cellulose and starch used in the formulation. Earlier pharmaceutical studies have also reported that herbal formulations prepared with appropriate excipient combinations exhibit improved structural integrity and reduced tablet breakage during handling and storage.^[19]

The disintegration behavior of the prepared tablets was found to be within acceptable pharmacopoeial limits, ensuring proper release of active phytoconstituents after oral administration. Rapid disintegration and dissolution are essential for herbal formulations because they directly influence bioavailability and therapeutic efficacy. The presence of hydrophilic constituents in *Annona squamosa* leaves may further facilitate dissolution and absorption of active compounds in the gastrointestinal tract.^[19]

Several studies have highlighted the strong antioxidant properties of *Annona squamosa* leaves due to the presence of quercetin, kaempferol, rutin, chlorogenic acid, and caffeic acid. Oxidative stress plays a major role in the progression of diabetes and its associated complications; therefore, antioxidants present in the formulation may help protect pancreatic β -cells from oxidative damage and improve glycemic control. The observed therapeutic potential of the present formulation may therefore be associated with both antihyperglycemic and antioxidant mechanisms.^[20]

In addition to antidiabetic activity, *Annona squamosa* leaves have also been reported to possess antimicrobial, anti-inflammatory, hepatoprotective, and cytoprotective properties. These multiple pharmacological activities may provide additional benefits in diabetic patients who are more prone to infections and metabolic complications. The antimicrobial activity observed in the present study against Gram-positive organisms further supports previous findings regarding the therapeutic versatility of custard apple leaf extract. The stability study revealed that the tablets remained physically stable without significant changes in color, odor, hardness, or friability during storage. Stability of herbal formulations is important because environmental conditions may affect phytochemical integrity and therapeutic effectiveness. Previous reports emphasized that proper excipient selection and direct compression techniques contribute significantly to maintaining stability and shelf life of herbal

tablets.^[19,20] Overall, the findings of the present investigation support the potential application of *Annona squamosa* leaf extract as a natural antidiabetic agent in tablet dosage form. The formulation demonstrated satisfactory pharmaceutical properties and promising therapeutic potential, suggesting that custard apple leaf tablets may serve as an effective herbal alternative for diabetes management with fewer side effects compared to synthetic drugs.^[21]

CONCLUSION

The present study successfully formulated and evaluated antidiabetic tablets containing custard apple (*Annona squamosa*) leaf extract using the direct compression method. The prepared tablets exhibited satisfactory pre-compression and post-compression characteristics including acceptable flow properties, hardness, friability, weight variation, thickness, and disintegration time, indicating good pharmaceutical quality and stability. The phytochemical constituents present in custard apple leaves, such as flavonoids, alkaloids, tannins, glycosides, and phenolic compounds, may contribute significantly to the antidiabetic activity of the formulation through antioxidant and hypoglycemic mechanisms. The formulation also demonstrated additional antimicrobial potential, supporting the therapeutic versatility of *Annona squamosa* leaf extract.

The study highlights the importance of herbal drug formulations as safer and cost-effective alternatives for diabetes management. The direct compression technique proved to be a simple and effective method for preparing stable herbal tablets while preserving the biological activity of phytoconstituents. Overall, the developed antidiabetic tablet formulation showed promising pharmaceutical and therapeutic properties and may serve as a potential natural alternative for the management of diabetes mellitus. Further pharmacological and clinical investigations are recommended to establish long-term efficacy, safety, and therapeutic application in human subjects.

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