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Formulation and Evaluation of Antidiabetic Tablet From Custard Apple Leaves

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Abstract: *Diabetes mellitus is a chronic disease affecting carbohydrate metabolism, requiring effective long-term management. This research focuses on utilizing custard apple leaves, traditionally recognized for their antidiabetic potential, to formulate tablets using the direct compression method. The formulation included sodium starch glycolate, starch, acacia, and MCC as excipients. Comprehensive pre- and post- formulation evaluations confirmed acceptable pharmatechnical properties. These findings suggest that custard apple leaf-based tablets could offer a natural and effective alternative for managing blood glucose levels.*

The present study focuses on the formulation and evaluation of an antidiabetic tablet derived from custard apple (Annona squamosa) leaves, known for their traditional medicinal use in controlling blood sugar levels. The leaves were collected, dried, powdered, and used as the active pharmaceutical ingredient (API) in a tablet formulation created using the direct compression method. The formulation included excipients like sodium starch glycolate, acacia, starch, and microcrystalline cellulose.

Keywords: Diabetes

I. INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder, resulting from insulin deficiency, characterized by abnormal increase in the blood sugar level, altered metabolism of carbohydrates, proteins and lipids, and an increased risk of vascular complications. According to the World Health Organization, diabetes mellitus is a chronic metabolic disorder marked by persistent hyperglycemia and disturbances in the metabolism of carbohydrates, fats, and proteins. This involves the autoimmune destruction of pancreatic beta cells, leading to insulin deficiency, along with abnormalities that cause resistance to insulin action Diabetes affects individuals of all ages. All types of diabetes can be managed with medication and lifestyle modifications, with most cases requiring long-term (lifelong) care.

Primary source of glucose, sugar is found in carbs in food and beverages. It is the main energy source for your body, supplying glucose to all of your cells through the bloodstream to be used as fuel.

1.1 CLASSIFICATION

Type 1

Type 1 diabetes commonly develops in children and is referred to as juvenile-onset diabetes mellitus or insulin-dependent diabetes mellitus. In this type, the pancreas produces insufficient insulin, requiring individuals to take insulin injections for life.

Type 2

Type 2 diabetes, which is more prevalent, typically occurs in individuals over 40 and is known as adult-onset diabetes mellitus. It is also referred to as non-insulin-dependent diabetes mellitus. In type 2 diabetes, the pancreas produces insulin, but the body does not utilize it effectively. High blood sugar levels can often be managed through diet and/or medication, although some patients may require insulin.

Type 2 diabetes mellitus is characterized by insulin resistance, which may be accompanied by relatively decreased insulin secretion. The impaired responsiveness of body tissues to insulin is thought to involve the insulin receptor, although the exact defects remain unidentified. Cases of diabetes mellitus resulting from known defects are classified separately.

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1.2 List Of Antidiabetic Medicinal Plants:

- Aloe Vera
- Cinnamon
- Green tea
- Custard apple leaves
- Momordica Charantia
- Garlic
- Fenugreek
- Ginger
- Annona squamosa
- Medicago sativa

1.3 SYMPTOMS

Diabetes symptoms vary depending on how much your blood sugar is elevated. Some people, especially those with prediabetes or type 2 diabetes, may not experience symptoms initially. In type 1 diabetes, symptoms tend to come on quickly and be more severe.

The following are the symptoms of diabetes mellitus

- Frequent urination
- Ketonuria (high ketone levels in urine)
- Fluctuations in mood
- Blurred vision
- Weight loss
- Weakness
- Excessive thirst
- Slower rate in healing of sores
- Increased Fatigue
- Numbness And Tingling Especially In Your Feet And Hands
- Slow Healing Sores
- Red, Swollen ,Tender Gums
- Skin Itchy Irritability

1.4 CAUSES

Genetics play a role in increasing the likelihood of developing diabetes, and it often runs in families.

Obesity: Excess weight and abdominal fat can cause insulin resistance, which is a major trigger for type 2 diabetes.

Physical inactivity: Insufficient physical activity can increase the likelihood of developing type 2 diabetes.

High blood pressure: Elevated blood pressure is another risk factor for developing diabetes.

HIV/AIDS: Chronic inflammation from HIV and the use of HAART medications can raise the risk of developing diabetes.

Autoimmune disease: Autoimmune disorders can contribute to the development of diabetes.

Hormonal imbalances: Disruptions in hormone levels can lead to the development of diabetes.

II. CUSTARD APPLE LEAVES

Custard apple, also known as sweetsop or sugar apple, is a tropical fruit with a creamy, custard-like flesh and a sweet, slightly acidic flavor, often described as a mix of strawberry and pineapple. The custard apple! Also known as Annona retusa, this tropical fruit is native to the Americas and is a member of the Annona family. It has a sweet, creamy pulp surrounding a single seed, and its flavor is often described as a combination of strawberry, pineapple, and banana .

he custard apple is rich in vitamins A and C, potassium, and fiber, making it a nutritious addition to a healthy diet. In some parts of the world, the fruit is also used to make jam

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• Botanical Name: Annona Squamosa.
• Family: Annonaceae (custard apple family or soursop family).
• Origin : Native to the New World tropics , specifically the West Indies and South America.
• Common Name: Custard apple leaves part used: Leaves
• Chemical Constituents :-
Quercetin (0.19- 1.60 µg/g)
Gallic acid (0.49- 0.89µg/g)
Coffee acid (0.07- 2.57µg/g)
Ferulic acid (0.72-2.89µg/g)
Cinnamic acid (0.02- 0.05µg/g)

2.1 MECHANISM OF ACTION

1. Stimulation of Insulin Secretion
•Compounds in the leaves may stimulate pancreatic β-cells to release more insulin.
• This helps lower blood glucose levels by promoting glucose uptake into cells.

2. Enhancement of Peripheral Glucose Uptake
•Flavonoids and polyphenols improve insulin sensitivity in peripheral tissues.
•They upregulate GLUT4 (glucose transporter 4), enhancing glucose uptake in muscle and adipose tissue.

3. Inhibition of Carbohydrate-Digesting Enzymes
•The leaf extracts inhibit enzymes like:
•α-amylase: breaks down starch into sugars
•α-glucosidase: converts disaccharides to glucose
•This leads to delayed glucose absorption from the intestine and lower postprandial (after- meal) blood sugar spikes.

2.2 PARTS CUSTARD APPLE :

Table no. 1: Plant Description

Parts of Plant	Chemical Constituents	Pharmacological Activity
Friut	Sugar, Vitamin, Minerials & Phytochemicals like Alkaloids, Flavonoids, Phenolic compounds	Anti- Oxidant; Anti-Diabetes; Anti- Tumor; Anti- Inflammatory
Peel	Alkaloids, Tannin, Saponins, Flavonoids, Phenolic compounds	Anti- Microbial; Anti- Cancer; Anti -Oxidant
Stems	Alkaloids, Tannin, Saponins, Sterols, Fixed oil , Protien, Flavonids, Reducing sugars, Glycosides	Anti- Microbial; Anti- Cancer; Anti -Oxidant Anti- Inflammatory
Roots	Alkaloids, Flavonoids, Acetogenins	Anti- Microbial; Anti- Oxidant; Anti- Inflammatory
Leaves	Alkaloids, Flavonoids, Tannin, Glycosides	Anti- Microbial; Anti- Cancer; Anti -Oxidant; Anti-Diabetes; Hepatoprotective

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INGREDIENTS:

1. Custard apple :

Fig1 : Custard apple

Plant Material Collection:

1. Custard apple leaves

Custard apple leaves were collected from rural areas of Loha city, where these plants are commonly found on farms. The leaves were gathered during the winter season for the preparation of antidiabetic custard apple leaf tablets. After collection, the leaves were thoroughly washed with clean water, dried under morning sunlight, and then crushed into a fine powder.

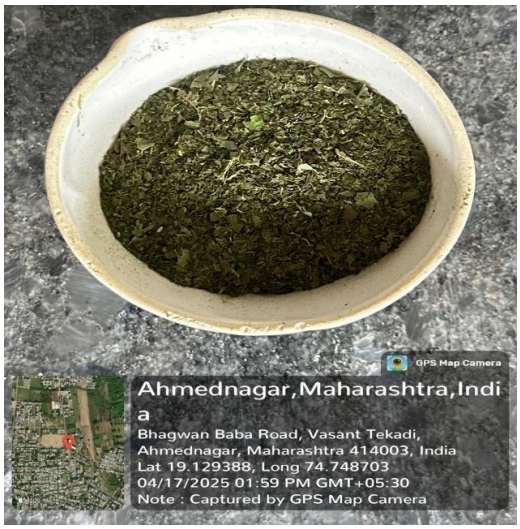

Fig 2 : Dried powder of custard appl

2. Sodium Starch Glycolate:

Sodium starch glycolate is a superdisintegrant used to promote the rapid disintegration and dissolution of immediate-release (IR) solid dosage forms. It is the sodium salt of carboxymethyl ether of starch. Superdisintegrants are substances that facilitate faster disintegration in smaller quantities compared to conventional disintegrants. Sodium starch glycolate is a naturally derived material that can be used in tablet and capsule formulations as a disintegrant, binder, and diluent. It rapidly absorbs water, causing the particles to swell, which leads to quick disintegration of tablets and granules.

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3. Starch:

Synonym: Amylum.

Biological Source: Starch consists of polysaccharide granules obtained from the grains of maize (Zea mays Linn); rice (Orzya sativa Linn); or wheat (Triticum aestivum Linn); belonging to family Gramineae or from the tubers of potato (Solanum tuberosum Linn.). Family: Solanaceae.

Chemical Constituents:

Starch contains chemically two different polysaccharides, such as amylose (β- amylose) and amylopectin (α- amylose), in the proportion of 1:2.

Binder: Starch can act as a binder to hold the active pharmaceutical ingredients and other excipients together. This is crucial for sublingual tablet, as they need to dissolve or disintegrate rapidly in the saliva under tongue.

4. Acacia

Synonym : Gum acacia, gum Arabic, acacia

Biological source: Indian gum is the dried gummy exudation obtained from the stem and branches of Acacia Arabica belonging to family Leguminosae.

Family- Leguminosae

Thickening Agent: Acacia gum can contribute to the viscosity of the tablet. Formulation, providing a suitable consistency for processing and ensuring uniform distribution of the API and other excipients.

5. Microcrystalline cellulose (MCC):

Microcrystalline cellulose (MCC) adds bulk to tablet formulations without significantly increasing overall weight, making it ideal for producing tablets of suitable size and shape for sublingual administration. Additionally, MCC enhances the flow properties of the tablet blend during manufacturing, ensuring uniform ingredient distribution and consistent tablet weight.

III. METHODS & MATERIALS

Custard apple leaves were initially gathered after which they were simply leaves and dried. The leaves were cleaned with filtered water, thoroughly rinsed and allowed to air dry approximately 10 min room temperature . Custard apple leaves was gentally cut off, and they drie d in room temperature. The material was dried and grind tu fine powder with the aid of sieves number 44,60,80 & 85 .

METHOD OF PREPARATION:

Direct compression method

FORMULA:

Sr.No.	EXCIPIENT	QUANTITY TAKEN	USES
1.	Custard apple leaves	10 gm	API
2.	Sodium starch glucolate	0.6 gm	Super disintigrant
3.	Starch paste	q.s.	Binder
4.	Acacia	0.8 gm	Thickening agent
5.	Microcrystalline cellulose (MCC)	0.8 gm	Diluent

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Fig 3 : Ingredients

.PROCEDURE :

Accurately weighed quantity of API (custard apple leaves)and all excipient(sodium starch glycolate , microcrysalline cellulose) and mix with mortar and pestle as per formula.

↓

In the above mixture a solution of binder (starch paste) was added to make a lump mass.

↓

This lump mass was screened using sieve with the suitable equipment and forms granules.

↓

Then these granules ware dried in hot air oven at 60 .

↓

After drying the granules ware screened through a sieve to get uniform sized granules

↓

These granules mixed with lubricant in and also preservative .

↓

Compresed this into a punching machine to gate proper shape and size of the tablet .

Fig: Compress Tablet

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IV. EVALUATION PARAMETER

4.1. PRE -FORMULATION :

Bulk Density:-

Weighed quantity of tablet blend was transferred into 100ml measuring cylinder without tapping during transfer. The volume occupied by drug was measured. Bulk density was calculated and found 0.44 gm/ml

Bulk Density = weight of granules/bulk volume of granules

= 22/50 = 0.44 gm/ml

Fig 5: bulk density

Tapped Density:-

Weighed accurate quantity of powder sample was into a graduated cylinder. Volume occupied by the drug was noted down. Then cylinder was subjected to 100, 200 & 300 taps in tap density apparatus. The experiment was performed in triplicate and tapped density was calculated and was found 0.51 kg/m3

$$\text{Tapped Density} = \frac{Weight\ of\ gra}{Volume\ of\ granules\ a}$$

=22/43 =0.51gm/ml

Fig 6: tapped density

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Carr's Index:-

The compressibility index and Hauser"s ratio was measured and found within the range of 15-20 %

Carr"s Index = $\frac{Tapped\ density - Bulk}{Tapped\ densit}$

= 0.51 − 0.44/0.51 × 100 = 13%

Hausners Ratio:- Hausners Ratio was calculated and was within the specified limit and found within the range of 1.10-1.18

Hausner"s Ratio= $\frac{Tapped\ densi}{Bluk\ density}$

= 0.51/0.44 = 1.15

Angle of Repose

Weighed quantity of the powder sample was passed through a funnel kept at a height 2cm from the base. The powder was passed till it forms a heap and touches the tip of the funnel. The angle of repose was calculated and found within the range and having good flow property

Angle of repose= $\tan\theta = h/r$

D1=8.9cm, D2=8.8cm, D3=9cm, D4=9cm

Radius= $diametr/2$

R1 = $D1/2$ = 8.9/2 = 4.45cm

R2= $D2/2$ = 8.8/2 = 4.4cm

R3= $D2/3$ = 9/3= 4.5 cm

R4 = $D2/2$=9/2= 4.5cm

Average of radius = $R1+R2+R3+R4$ = = $4.45+4.4+4.5+4.5$ = 4.46 cm

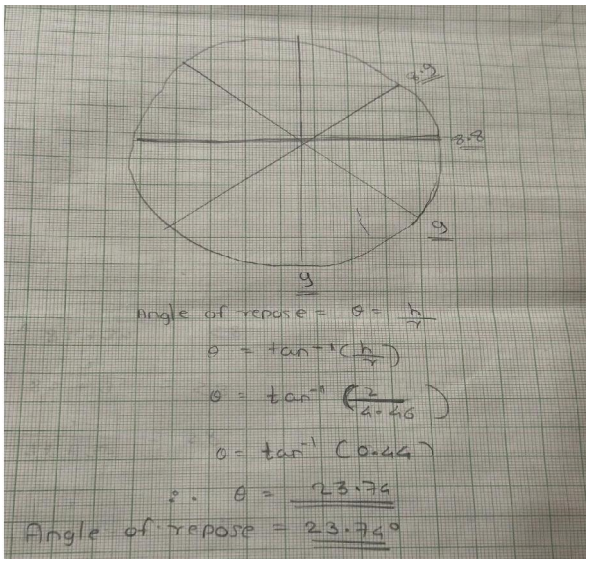

Fig 7 : angle of repose

Angle of repose is 23.74°

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4.2 .Post-formulation studies- Hardness Test:-

Tablets require certain amount of strength or hardness, to with stand mechanical shocks of handling in manufacture, packaging and shipping. The most widely used apparatus to measure tablets hardness (strength) is the pifzer hardness tester.

The hardness test of the tablets was found to be 6 kg/cm 2 using hardness tester apparatus. The hardness was measured by using hardness tester.

Fig 8 : hardness test

Friability Test :-

Friability can be evaluated by means of Roche friability test apparatus.Friability is related to the ability of tablets to withstand both shocks and abrasion without crumbling during manufacturing, packing, transportation and consumer handling. Friability can be evaluated by means of Roche friability test apparatus. compressed tablets that loose less than 0.5% to 1.0% in weight generally considered as acceptable.

$$formula = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

$$1 \text{ tablet} = \frac{0.380 - 0.378}{0.380} \times 100$$

$$= 0.5\%$$

$$2 \text{ tablet} = \frac{0.380 - 0.379}{0.380} \times 100$$

$$= 0.2\%$$

$$3 \text{ tablet} = \frac{0.380 - 0.377}{0.380} \times 100$$

$$= 0.7\%$$

$$4 \text{ tablet} = \frac{0.380 - 3.78}{0.380} \times 100$$

$$= 0.5\%$$

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Fig 9 : friability test

Disintegration Test :- In vitro disintegration time was measured using disintegration apparatus. The tablets was dissolve excellent in disintegration time period (12min).

In vitro disintegration time was measured using USP disintegration test apparatus for DT test randomly one tablets were selected from each batch and test was performed in 900 ml distilled water 35°c to 37°c temperature .

Fig 10 :disintegration test

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Thickness Test:- To determine the uniformity and physical dimension of tablets thickness is measured by Vernier caliper for randomly selected 10 tablets from formuation.
The thikkness test of the tablets was found to be 3.3mm.

Fig 11 : thickness test

V. RESULT

Table 6- Pre formulation study –

Sr.no	Test	Observation	conclusion
1	Angle of repose	23.74°	Excellent
2	Bulk density	0.44gm/ml	
3	Tapped density	0.51gm/ml	
4	Carr"s index	13%	
5	Hausner ratio	1.15	Excellent

Table 7- Post compression study-

Sr.No	Parameter		Result
1	General Apperance	Colour - Odour - 3) Size – 4) Shape-	Greenish Characteristics Length- 1cm width- 0.5 cm Circular
2	Average weight		400 mg
3	Hardness test		4.3 kg/cm2
4	Friability test		0.5 to 1 %
5	Disintegration test		12 min
6	Thickness test		3.3mm

VI. CONCLUSION

In the present study, an attempt was made to formulate and evaluate antidiabetic tablets using custard apple (Annona squamosa) leaves. The preformulation studies revealed good flow properties with an angle of repose of 23.74°, bulk density of 0.44 gm/ml, and Hausner's ratio of 1.15, indicating excellent compressibility and flowability. Among

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different batches prepared, Batch C (sieve #80) was found most suitable based on preformulation parameters and was used to develop tablet formulations coded F1, F2, F3, and F4 with varying concentrations.

Post-compression evaluation showed that the F1 (100%) formulation passed all quality control tests, including hardness (4.3 kg/cm²), friability (0.5–1%), disintegration time (12 minutes), and thickness (3.3 mm), meeting acceptable pharmacopeial standards.

Thus, it can be concluded that custard apple leaves possess significant potential as a natural antidiabetic agent, and the formulated tablets demonstrated good mechanical strength, acceptable disintegration time, and promising antimicrobial activity. These findings support the potential development of custard apple-based herbal formulations for diabetes management.

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