

FORMULATION AND EVALUATION OF CASSIA AURICULATA HERBAL ORAL DISSOLVING FILM FOR EFFECTIVE MANAGEMENT OF DIABETES MELLITUS

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❖ ABSTRACT

Diabetes mellitus is a metabolic disease with a condition where an individual has high levels of sugar content in his/her blood because of a lack of insulin production. There are many traditional medicines that are available for the treatment of diabetes mellitus, but most of them have problems such as low patient compliance, gastrointestinal disorders, and difficulty in swallowing solid dosage forms. There are many studies that show that herbal medicines are very useful for treating chronic diseases, and one such medicinal herb is *Cassia auriculata*, which is very effective for antidiabetic, antioxidant, and hepatoprotective effects. This study focuses on the preparation and evaluation of oral dissolving films (ODFs) loaded with *Cassia auriculata* extract by the solvent casting technique. The films produced are evaluated based on their physiochemical properties, dissolution, and disintegration rate. **Conclusion:** The results show that *Cassia auriculata*-loaded oral dissolving films are promising alternatives for treating diabetes mellitus.

❖ **KEYWORDS:** *Cassia auriculata*, diabetes mellitus, oral dissolving films, herbal drug delivery and antidiabetic activity.

1. INTRODUCTION

Diabetes mellitus (DM), popularly known as diabetes, is a dangerous and chronic metabolic disorder, along with abnormally high blood glucose levels, because of either a deficiency of insulin secretion, an inability to utilize insulin, or a combination of both. Diabetes is a major global health concern and is among the leading causes of morbidity and mortality worldwide, affecting individuals of all age groups, genders, and regions. Insulin is very important for the regulation of blood glucose levels because it enables the entry of glucose into muscles, the liver, and the fat tissues, as well as the storage of glucose as glycogen. However, certain cells, like nerve cells and red blood cells, can use glucose even without insulin.^[1]

Diabetes mellitus represents the most common endocrine disorder, affecting more than 100 million patients worldwide, approximately 6% of the global population. This disease occurs because of inadequate insulin release or insulin resistance, leading to an imbalance in blood glucose concentrations. Insulin has a role in glucose

homeostasis, an action mediated by the stimulation of glucose storage and cellular uptake.^[2]

Diabetes is known as a chronic or long-term metabolic disease that affects the body's metabolism of carbohydrates, lipids, and proteins. The fundamental cause of diabetes has always been the inability either to produce or respond to insulin, known as insulin resistance. This, in most cases, results in the constant elevated levels of glucose in the body. Diabetes is commonly known as the "sugar disease." It is the most prevalent hormone-related disorder.^[3]

1.1 Global Impact Of Diabetes

Global Prevalence: A large percentage of people living with diabetes are not aware of the fact. Almost half the number of people living with diabetes are not aware of the reality. Approximately 240 million people worldwide have undiagnosed diabetes. At present, there are 537 million people aged 20-79 living with diabetes, which translates to 10.5% of the entire population.^[4]

Type 2 diabetes contributes to about 96% of total diabetes cases. In nearly all global regions, more than 90% of diabetes prevalence by age-standardized rates is due to type 2 diabetes. With the exception of a few global regions, such as Australasia and Western Europe, slightly lower proportions are observed. In a total of 204 countries and territories, type 2 diabetes contributes to over 80% of total diabetes cases, and there is no significant gender difference.^[5]

1.2 Types Of Diabetes

1) Type 1 Diabetes Mellitus (T1DM)

Type 1 diabetes is identifiable years before the onset of clinical symptoms, with a gradual loss of β -cell resistance to glucose, even before the onset of the condition. When the condition is diagnosed, there is a progressive decrease in insulin secretion, eventually leading to no insulin production by the body.^[6]

Type 1 diabetes occurs due to an autoimmune condition where the body's immune system attacks and destroys the β -cells in the pancreas. These β -cells produce insulin. They don't produce insulin or produce very little insulin. This condition affects people at any age but is very common among children. Insulin needs to be taken lifelong by people with type 1 diabetes to survive.^[7]

2) Type 2 Diabetes Mellitus (T2DM)

Impaired secretion of the hormone is a major underlying factor in type 2 diabetes. The secretion and sensitivity

levels can be measured by the index value that is calculated based on the relationship between the two.^[7]

In type 2 diabetes, the cells' ability to respond to the insulin produced by the pancreas becomes inefficient, making the cells resistant to insulin. Despite this resistance, the production of insulin becomes lower to keep the sugar levels in the blood within the required standards. Type 2 diabetes accounts for the highest prevalence of diabetes.^[8]

This condition affects the use of glucose for energy production and, if unattended, can result in complications in the nerves, blood vessels, and organs. However, type 2 diabetes can mostly be prevented by proper lifestyle management. This involves taking appropriate measures to maintain normal body weights, physical activity, and healthy food choices.^[9-10]

1.3 Mechanisms Of Type 1 And Type 2 Diabetes

1) Type 1 Diabetes Mellitus (T1DM)

Pathophysiology: In type 1 diabetes, immune-mediated destruction of pancreatic β -cells occurs due to the action of immune cells such as T lymphocytes, macrophages, and inflammatory cytokines. This autoimmune response leads to absolute insulin deficiency and subsequent hyperglycemia.^[11]

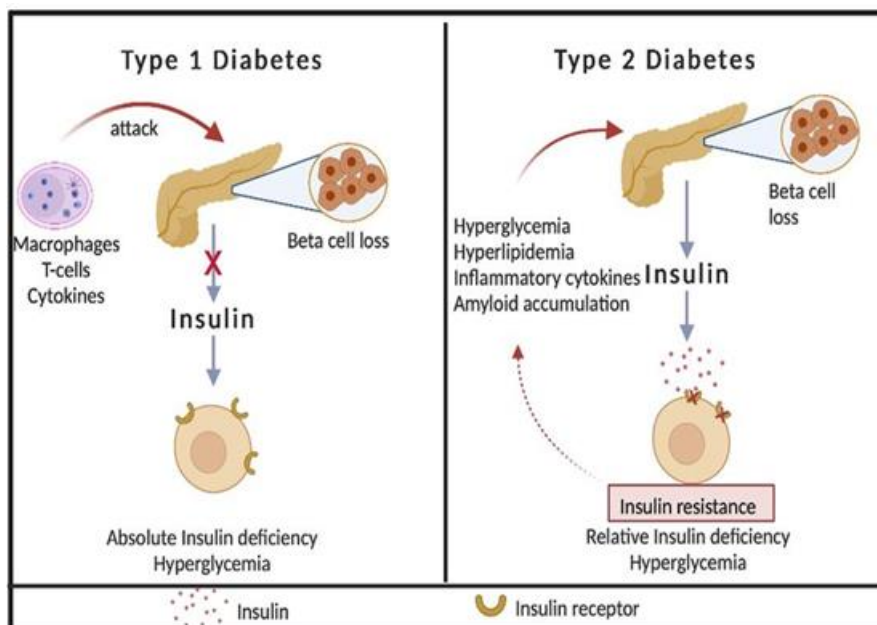


Figure 01: Mechanisms of Type I and Type II Diabetes.^[11]

T1DM involves autoimmune damage to the insulin-producing cells in the pancreas, making people completely insulin-dependent. Genetic, environmental, and autoimmune factors play an important role in the development of this condition.^[12]

2) Type 2 Diabetes Mellitus (T2DM)

In type 2 diabetes, the pancreas gets affected by the constant exposure to hyperglycemia, lipotoxicity from elevated fatty acids, the effects of inflammation, and the build-up of amyloid. The pancreas is able to secrete insulin, but this is not adequate to combat the effects of

insulin resistance. Therefore, the levels of glucose remain elevated.^[12] Type 2 diabetes is known by the coexistence of insulin resistance and progressive β -cell failure. The risk conditions for type 2 diabetes are genetic predisposition, obesity, lack of exercise, and inappropriate eating behaviors.^[11-12]

1.4 Herbal Approach In Diabetes Management

Diabetes mellitus is a metabolic disease that is typified by high glucose concentrations in the blood resulting from insufficient production of insulin or resistance to it. While insulin, metformin, and sulfonylurea have proven successful as antidiabetic drugs, they usually cause hypoglycemia, obesity, and stomach upset.^[13-14]

Over the past few years, herbal medicine has received great attention owing to its low toxicity and multitargeting mechanisms. Flavonoids, alkaloids, and saponins present in herbal drugs display their antidiabetic activity by blocking glucosidase enzyme activity, promoting insulin release, and decreasing glucose uptake in intestines.^[13-14]

1.5 Oral Dissolving Films

Oral dissolving films (ODF) are thin films that disintegrate within the oral cavity rapidly without requiring any additional solvent like water. They can be regarded as an enhanced mode of drug delivery that facilitates greater compliance in pediatric and geriatric patients along with dysphagia.^[15]

❖ Advantages Of Odf

- Immediate disintegration and fast onset of action
- High patient compliance
- Does not require the use of water during administration
- Does not undergo first-pass effect
- Good taste-masking ability.^[15-16]

❖ Disadvantages Of Odf

- Limited drug load capacity
- Moisture-sensitive nature and stability problems
- Difficulties in masking bitter-tasting drugs
- Physical vulnerability
- Formulation-dependent.^[15-16]

1.6 Properties Of A Suitable Drug For Odf

The medication chosen to be formulated into an ODF must have certain characteristics in order to produce an effective product. The medication should ideally taste excellent and have a tiny molecular size and low molecular weight. When it comes into contact with water or saliva, it should be highly stable and soluble. To facilitate efficient absorption, the medication must be somewhat ionized at oral pH. The medication should also be permeable through the oral mucosa and stable under various circumstances. Additionally, in order for the medication to be evenly dispersed across the film, the dosage should not be higher than 40 mg.^[17]

1.7 Rationale of Study

Diabetes mellitus is one of the fastest-growing metabolic disorders all around the globe, mainly defined by high levels of blood glucose caused by inadequate insulin secretion and resistance to insulin.^[17,18] While treatments including insulin administration and oral anti-diabetics are highly efficient in diabetes mellitus management, they may cause such side effects as hypoglycemia, gastrointestinal problems, and poor patient compliance.^[17-18]

The increasing popularity of herbal remedies is caused by their safety as well as therapeutic benefits. Active constituents of plants, such as flavonoids, alkaloids, and phenols, possess antidiabetic properties by facilitating insulin secretion, reducing glucose absorption, and altering carbohydrate metabolism. *Cassia auriculata* is a medicinal herb widely used due to its powerful antihyperglycemic and antioxidant effects.^[17-18]

Still, herbal medications have poor patient compliance along with a lack of dosing homogeneity, which is why innovative techniques, including the development of oral dissolving films, have been introduced, as they do not require water to be consumed orally and can dissolve within seconds.

Thus, the goal of the current study was the design and assessment of oral dissolving films containing *Cassia auriculata* extracts.

2. PLANT PROFILE

- **Botanical Name:** *Cassia auriculata* Linn.
- **Family:** Fabaceae (Leguminosae)
- **Common Names:** Tanner's Cassia, Avaram Senna, Tarwar, Awal, Tarwad.
- **Plant Form:** Shrub

2.1 Macroscopic Description

- **Height:** 1.5–3 meters
- **Leaves:** Pinnate, light green, alternate
- **Flowers:** Bright yellow, large, showy
- **Part Used:** Flowers, leaves, seeds, and roots (flowers and leaves are most commonly used for medicinal purposes).



Figure 2: Tanner's cassia.^[19]

2.2 Geographical Source: *Cassia auriculata* is a tropical shrub widely distributed throughout India, Sri Lanka, and other South Asian countries. It thrives in dry, warm climates, especially in the Tamil Nadu, Maharashtra, and Karnataka regions.^[19]

2.3 Traditional Uses

- Used in Ayurveda, Siddha, and folk medicine for treating diabetes, skin diseases, fever, and urinary disorders.
- Decoction of flowers is traditionally used to regulate blood sugar levels.^[19]

2.4 Phytochemical Constituents:

- Flavonoids (kaempferol, quercetin)
- Tannins
- Phenolic compounds
- Saponins
- Alkaloids
- Glycosides^[19-20]

2.5 Pharmacological Activities

- Antidiabetic
- Antioxidant
- Hepatoprotective
- Antimicrobial
- Anti-inflammatory^[19-20]

3. AIM AND OBJECTIVES

❖ Aim

To formulate and evaluate oral dissolving films containing *Cassia auriculata* extract for the effective management of diabetes mellitus.

❖ Objectives

- 1) To obtain bioactive components from *Cassia auriculata* by using the Soxhlet extraction technique.
- 2) To conduct phytochemical screening on the extracted compound.
- 3) To prepare oral dissolving films from *Cassia auriculata* through the use of appropriate film-forming agents and plasticizers.
- 4) To assess the prepared films in terms of various physiochemical parameters like thickness, weight variation, folding endurance, and surface pH.
- 5) To conduct stability testing of the optimized formulation according to ICH guidelines.

4. MATERIALS AND METHODS

Materials: Fresh leaves of *Cassia auriculata* Linn. were collected, authenticated by a botanist, shade-dried at room temperature ($25 \pm 2^\circ\text{C}$), and powdered to a coarse consistency. *Cassia auriculata* is a rich source of bioactive antidiabetic compounds, particularly flavonoids and phenolics.^[21]

❖ Methods

1. Preparation of *Cassia auriculata* Extract

The Soxhlet extraction was carried out for 6–8 hours using 250 mL of 95% ethanol with 25 g of shade-dried *Cassia auriculata* leaf powder packed in a thimble.

The extract was concentrated using a rotary evaporator under reduced pressure to obtain a viscous residue. The concentrated extract was then stored in a cool and dry place for further use.^[21]



Figure 3: Soxhlet extraction apparatus.

2. Phytochemical Screening

Preliminary phytochemical analysis of the ethanolic extract of *Cassia auriculata* was carried out using

qualitative chemical assays. It was revealed that glycosides, saponins, flavonoids, tannins, and phenolics were present in the plant extract, but not the alkaloids.

Table 1: Phytochemical screening of extract.

Sr. No.	Test for phytoconstituents	Result
1.	Alkaloid	-
2.	Glycoside	+
3.	Saponin	+
4.	Flavonoid	+
5.	Tannins	+

3. Oral Film Formulation Components: The oral dissolving films were formulated using the following components with typical concentration ranges.^[22]

- Active Pharmaceutical Ingredient (API): 1–30% w/w
- Film-forming polymers: 40–60% w/w
- Plasticizers: 0–20% w/w
- Sweetening agents: 0–10% w/w
- Saliva stimulating agents: 2–6% w/w
- Flavouring agents: Q.S.
- Surfactants: Q.S. (as required for solubility enhancement)

Table 2: Formulation of Cassia auriculata Oral Dissolving Film.^[22]

Sr. No.	Ingredients	F1	F2	F3
1.	<i>Cassia auriculata</i>	160mg	160mg	160mg
2.	MC (Methyl cellulose)	1g	1.2g	1.1g
3.	PVA (Polyvinyl alcohol)	0.5g	0.3g	0.4g
4.	Glycerin	0.5ml	0.6ml	0.55ml
5.	Sucrose	0.5g	0.5g	0.5g
6.	SLS (Sodium Lauryl Sulfate)	0.05g	0.03g	0.04g
7.	Citric acid	0.25g	0.20g	0.22g
8.	Menthol	0.25g	0.20g	0.22g
9.	Sodium Benzoate	50mg	50mg	50mg
10.	Ethanol 95%	5ml	5ml	5ml
11.	Distilled water	q. s to 50ml	q. s to 50ml	q. s to 50ml

Table 3: Excipients and Their Role.^[23]

Excipients	Role
MC (Methyl Cellulose)	Film-Forming Polymer
Polyvinyl Alcohol	Copolymer for Strength
Glycerin	Plasticizer
Sucrose	Sweetener
Menthol	flavoring agent
Citric acid	Saliva-Stimulating agent
SLS (Sodium lauryl Sulfates)	Surfactant
Sodium Benzoate	Preservative
Ethanol	Solvent for extract
Distilled water	Solvent for polymer and make up Volume

4. Preparation of Oral Dissolving Films (Odfs)

❖ Solvent casting Method

This is one of the easiest and most popular methods employed in the development of ODFs. In this process, a solution comprising water-soluble polymers together with the drug substance as well as other excipients was made through dissolving them in distilled water. Mixing was accomplished using high-speed mechanical stirrers to attain an even solution. When the solution attained evenness and transparency, it was carefully poured on the leveled glass or Petri dishes in order to attain evenness. The solution was left under room temperature or mild heat to allow evaporation of the solvent, resulting in the formation of a film. The selection of suitable polymers and solvents plays an important role in determining the quality and performance of the prepared film.^[24, 25]

Step 1: Preparation of Polymer Solution

A polymer solution of MC was prepared using a 2% w/v concentration by dissolving MC in 50 mL of distilled water. It was stirred for 1 hour continuously on a magnetic stirrer at 500 rpm at 25±2°C.^[25-26]

Step 2: Adding Extract

An extract of *Cassia auriculata* was added into the polymer solution in sufficient quantity to provide 5 mg of active ingredients for a 1.5 × 1.5 cm² film.

Step 3: Addition of Excipients

Glycerin in 1% w/v and propylene glycol in 1% w/v concentrations were used as plasticizers.

For the purpose of masking a taste to the formulation, sucrose in 1% w/v concentration and menthol in 0.5% w/v concentration were added as a sweetener and flavor, respectively.

Sodium benzoate (0.1% w/v) was incorporated into the solution as a preservative, and the mixture was further stirred for 30 minutes to ensure uniform mixing.

Step 4: Film Casting

Film solution was cast on a leveled glass surface, like a glass petri dish (surface area $\approx 63.58 \text{ cm}^2$). Drying was done for 24-48 hours at $25 \pm 2^\circ\text{C}$ at room temperature.^[25-26]

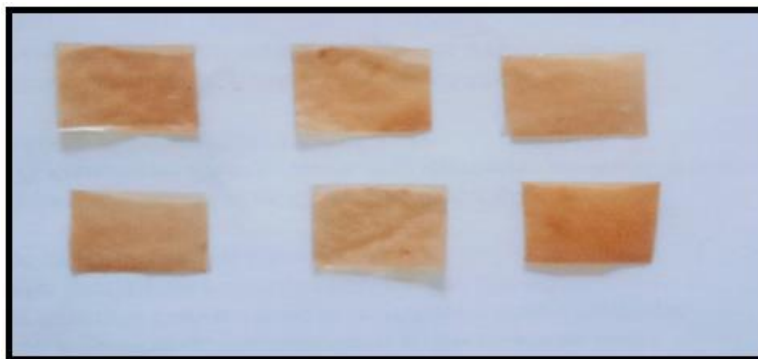


Figure 4: Cassia auriculata Odf.

5. EVALUATION PARAMETERS OF ORAL DISSOLVING FILMS

1. Appearance

The films prepared were examined by eyesight and found to be uniform, smooth, and transparent in appearance and had a light brownish (amber) color. No air bubbles or any defects were seen on the film's surface.

Texture

The texture of films was found to be soft and foldable without breaking.

Odor and Taste

There was a mild Characteristic odor from the films of the herbal extract, and they were acceptable in taste.

2. Thickness

The thickness of films was measured by digital vernier calipers at three different points of each film, and an average was obtained. Films had a uniform thickness.

Table 4: Thickness of Prepare herbal films.

Film No.	Thickness mm
1.	0.19
2.	0.21
3.	0.20

The average thickness of the film was found to be $0.20 \pm 0.02 \text{ mm}$.

3. Weight Variation

Each film sample was weighed by an analytical balance. The weights of various films were noted down, and their average value was calculated. There was slight variation in weight, which confirmed uniform distribution of the drug and its excipients within films.

Step 5: Film Cutting and Storage

The films were removed from their dried form and cut into $2 \times 2 \text{ cm}^2$ squares using sterile scissors. Each square weighed about 5 mg of extract. The films were then packed in airtight aluminum foil that had been placed with a desiccant.

Table 5: Weight Variation of Prepared Herbal Films.

Batch	Average Weight
F1	0.05 ± 0.007
F2	0.06 ± 0.005
F3	0.05 ± 0.006

Result: The prepared herbal film showed minimal weight variation, indicating uniform distribution of drug and excipient in all formulations.

4. Surface pH

The surface pH of the prepared oral dissolving film was determined by placing the film in small quantity of distilled water for few minutes. The pH was then measured using pH meter.^[27]

Result

Among the prepared formulations, F2 showed a lower surface pH (5.0), indicating a more acidic nature which may cause slight irritation in the oral cavity. F1 exhibited acceptable pH, while F3 showed a near neutral surface pH of 6.5, making it more suitable and comfortable for oral administration. Hence, F3 was considered the optimized formulation.

5. Folding Resistance

The degree of resistance to folding for the produced films was tested by folding the films back and forth continuously from one point till they were broken. The total number of times the film was folded before breaking was recorded as folding endurance; this gives an idea about the mechanical strength of the films. The greater the folding endurance value, the more flexible and durable the film is.^[27-28]

6. Disintegration Time

Time required for complete disintegration of the film in either simulated saliva solution or distilled water at a temperature of $37 \pm 0.5^\circ\text{C}$. Total disintegration of the films is usually observed during the period of 30-60 seconds.

Results

Disintegration time of the ODF was measured by keeping it in distilled water maintained at $37 \pm 0.5^\circ\text{C}$ while stirring. Complete disintegration of the film was observed after 55 seconds. This value lies within the ideal range of disintegration time of ODFs, i.e., 30-60 seconds.

7. In vitro Drug Release Study

For studying the drug release from ODFs, an in vitro test was conducted using phosphate buffer pH 6.8 at $37 \pm 0.5^\circ\text{C}$ with constant stirring. Samples were withdrawn

from the dissolution medium at predetermined time intervals and subjected to analysis through UV-visible spectrophotometry.

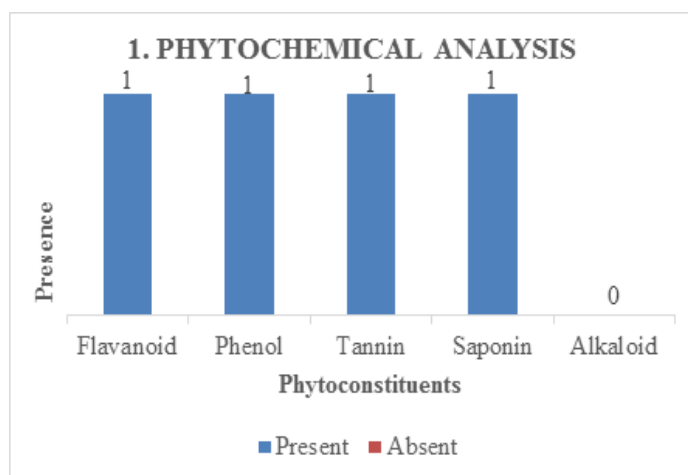
8. Stability Studies

Studies on the stability of the developed films were carried out following the ICH recommendations under both accelerated and long-term conditions.^[29-30]

6. RESULT

6.1 Phytochemical Analysis

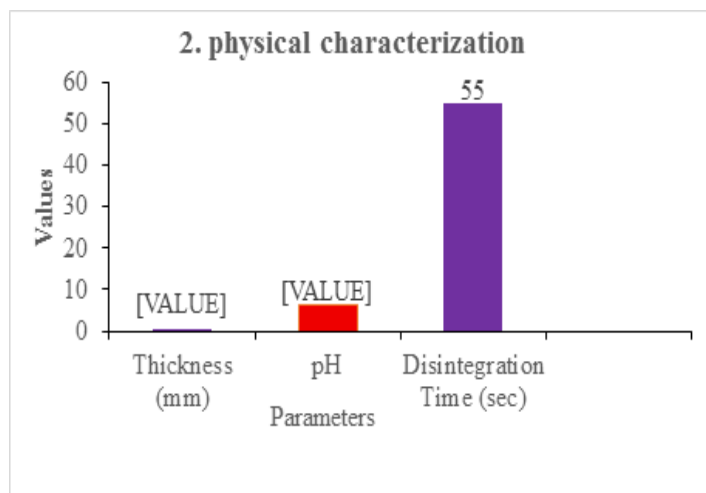
Phytochemical analysis was conducted on the ethanolic extract of *Cassia auriculata* using conventional qualitative chemical analysis methods. The findings indicated that the extract contained flavonoids, phenols, tannins, and saponins, whereas no alkaloids were detected. The biological activity of these compounds is associated with the known antioxidant and antidiabetic properties of the herb.



6.2 Physical Characterization of Oral Disintegrating Films

The prepared dissolving films (F1 and F3) were observed to be smooth, homogeneous, flexible, and free from any kind of flaws like air bubbles or cracks. However, formulation F2 showed comparatively poor film-forming characteristics with reduced flexibility. The film

thickness varied between 0.19 ± 0.02 mm and 0.24 ± 0.01 mm, indicating the uniformity of film formation. Variation in weight is also limited within acceptable values, indicating uniform distribution of drug and excipients. The pH of the surface of the films was within the range of 5.0 to 6.5, showing that these values were suitable for the mouth.



6.3 Disintegration Time

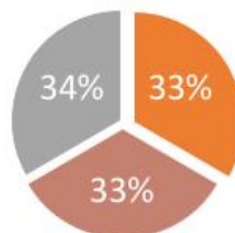
The disintegration time of the developed oral dissolving film was obtained as 55 seconds when placed in distilled

water at $37 \pm 0.5^\circ\text{C}$ with mild stirring, and it was found to be within the desired range of ODFs (30-60 seconds).

OVERALL RESULTS

Overall Results:

- Good Film properties
- Fast Disintegration
- Oral Suitability



7. DISCUSSION

This project focused on the formulation and evaluation of herbal oral dissolving films (ODFs) containing *Cassia auriculata* extract for the effective management of Diabetes Mellitus. Diabetes mellitus is a chronic metabolic disorder characterized by elevated blood glucose levels due to insufficient insulin secretion or insulin resistance. Conventional antidiabetic therapies are effective but often associated with side effects such as gastrointestinal irritation, hypoglycemia, and poor patient compliance. Therefore, the development of a safer and patient-friendly herbal formulation was considered beneficial.

In this study, *Cassia auriculata*, a medicinal plant well known for its antidiabetic, antioxidant, and hepatoprotective properties, was selected as the herbal drug candidate. The plant extract was prepared by Soxhlet extraction using ethanol as solvent, followed by phytochemical screening. The screening confirmed the presence of important bioactive constituents such as flavonoids, tannins, glycosides, saponins, and phenolic compounds, which are responsible for antidiabetic activity.

The oral dissolving films were prepared by the solvent casting method using methyl cellulose (MC) and polyvinyl alcohol (PVA) as film-forming polymers. Plasticizers, sweeteners, flavoring agents, surfactants, and preservatives were added to improve flexibility, taste, stability, and patient acceptability. The prepared films were evaluated for various physicochemical parameters including appearance, thickness, weight variation, surface pH, folding endurance, disintegration time, and drug content.

Among all formulations, formulation F3 showed the best results with acceptable surface pH, good flexibility, uniform thickness, and rapid disintegration within 55 seconds, which falls within the ideal range for ODFs. The films were smooth, transparent, and mechanically stable, indicating successful formulation development.

Overall, the study demonstrated that *Cassia auriculata* loaded oral dissolving films can serve as a promising herbal drug delivery system for diabetes management. The developed ODFs offer advantages such as fast disintegration, ease of administration without water, improved patient compliance, and potential enhancement in bioavailability. Hence, this formulation may be considered a suitable alternative to conventional oral dosage forms for antidiabetic therapy.

8. CONCLUSION

In this study, we have succeeded in developing oral dissolving films made of *Cassia auriculata* extract through the process of the solvent casting method by using MC and PVA as polymers. The produced films exhibited satisfactory properties in terms of flexibility, homogeneity, smooth surface, and satisfactory physical properties. The addition of plasticizers and flavoring agents enhanced the performance of the films.

On the whole, we conclude that the developed films possess satisfactory physicochemical properties and hence could be used as an effective herbal drug delivery system in treating diabetes mellitus.

9. FUTURE PROSPECTIVE

The area of oral dissolving films has made immense progress in the last few years, emerging as a superior drug delivery platform compared to traditional forms of medicines such as tablets and capsules. The oral thin film drugs possess various benefits, including fast disintegration, enhanced bioavailability, convenient use, and high levels of patient compliance, particularly among children and elderly individuals.

This novel method is currently under intense study for prescription and non-prescription medicines, while further investigation is also being conducted for vaccines and hormones. Considering the future developments in pharmaceutical science and regulatory policies, oral dissolving films will be a crucial aspect of upcoming drug delivery systems.^[29-30]

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