IJFANS INTERNATIONAL JOURNAL OF FOOD AND NUTRITIONAL SCIENCES
ISSN PRINT 2319 1775 Online 2320 7876
Research Paper , UGC CARE Listed (Group -I) Journal Volume 11, Iss 11, 2022

Costus Igneus Oro-Herbal Films: Innovative and Cost-Effective Therapy

Praveen Babu Choppala[1*]
[1*]Department of E.C.E, Andhra University Visakhapatnam, 530003, India
praveenchoppala@andhrauniversity.edu.in

Vijaya Nirmala Gera[2]
[2]Department of E.C.E., AU-TDR-HUB, Andhra University, Vishakapatnam, 530003, India
vijayanirmala.au@gmail.com

Ravi Kumar Inakoti[3]
[3]Department of CS&SE, Andhra University, Visakhapatnam, 530003, India
ravirk1228@gmail.com

G. Malakondaiah[4]
[4]Department of E.C.E., RGUKT Ongole Campus, Ongole, 523001, India
malakondaiah.ece17@gmail.com

***Corresponding Author: -** Praveen Babu Choppala
[*]Department of E.C.E, Andhra University Vishakapatnam, 530003, India
praveenchoppala@andhrauniversity.edu.in

Abstract:

The escalating prevalence of diabetes, affecting 1 in 10 individuals across all age groups, necessitates innovative therapeutic solutions. This study introduces a novel approach to diabetes treatment through the development of oral films containing Costus Igneus extract. These films, fabricated using HPMC E5, maltodextrin, sodium alginate, PVA, propylene glycol, SSG, and honey, exhibited promising attributes. Notably, formulations F3 and F5 showcased rapid disintegration times of 11 and 12 seconds, with F3 achieving an impressive 83.57% drug release within 4 minutes. Stability assessments confirmed the reliability of formulations F3 and F4. This research underscores the potential of Costus Igneus leaf extract-based oral films to enhance bioavailability and patient adherence, offering a compelling avenue for diabetes management.

Keywords: Diabetes, Costus Igneus, Oral films, Bioavailability, Patient compliance.

I. INTRODUCTION

Humanity has a long history of relying on plants for medicinal purposes, and the World Health Organization (WHO) reports that a significant 80% of the global population, or 5.86 billion people, continues to embrace traditional medicine as their primary healthcare approach. Plants harbor a diverse array of chemical compounds, such as alkaloids, flavonoids, tannins, and phenolic compounds, which hold the potential to address both chronic and infectious diseases. The utilization of plants in traditional medicine remains of paramount importance, particularly in developing countries where these resources are integral for sustenance, shelter, and healthcare [1, 2]. Traditional herbal remedies are widely practiced in rural areas of these nations, catering to low-income individuals, farmers, residents of isolated villages, and indigenous communities, who attest to the cost-effectiveness and lower side effects of folk medicine compared to synthetic alternatives.

Diabetes mellitus, a chronic condition characterized by elevated blood glucose levels due to insulin deficiency or impaired insulin activity, is a pressing global health concern [3, 4]. In the United States, it ranks as the fourth leading cause of death, primarily due to its detrimental impact on the cardiovascular system. Insulin, essential for glucose transportation into body cells, is often lacking in individuals with diabetes, resulting in increased blood glucose levels and glucosuria (glucose excretion in urine). Costus Igneus, commonly referred to as the "Insulin plant," is a perennial herb introduced to India from South and Central America, now widespread worldwide. It is known by other names such as Spiral flag and fiery Costus. In Ayurvedic diabetes treatment, physicians recommend chewing the leaves of the Insulin plant for a month. Allopathic doctors also endorse its effectiveness in regulating blood sugar levels. Traditional medicine employs this plant to enhance longevity, address skin conditions, alleviate asthma, reduce fever, and combat intestinal worms [5, 6].

Fast dissolving films represent an advanced solid dosage form valued for their flexibility and swift onset of action, as the drug dissolves in the oral cavity with minimal saliva, compared to mouth-dissolving tablets. These films can be formulated using various hydrophilic polymers, enabling rapid dissolution or disintegration within minutes. The primary objective of the current research is to design and create Oro-herbal fast-dissolving films incorporating Costus Igneus extract and hydrophilic polymers. These films aim to swiftly lower blood glucose levels and demonstrate antidiabetic properties [7, 8].

II. Materials and Method:

Fresh leaves of Costus Igneus were meticulously harvested from the natural surroundings in the Guntur region. To ensure the accurate identification of the plant species, a plant specimen was thoughtfully dispatched to the Department of Botany at JMJ Degree College for Women, located in Tenali, Andhra Pradesh. Upon examination, the specimen was confirmed to be Costus Igneus, a member of the Costaceae family. To prepare the plant material for extraction, the healthy leaves were subjected to a systematic process [9]. They were diligently shade-dried to preserve their integrity, following which they were meticulously pulverized into a coarse powder using an electric blender. This powder served as the foundation for the subsequent phytoconstituent extraction. The extraction process was carried out using the Soxhlet method, a trusted technique for obtaining plant constituents. Methanol was employed as the menstruum to draw out the valuable phytochemicals from the leaves. The resulting extract was then carefully collected and subjected to a process of concentration and drying, yielding a concentrated and dried extract rich in phytoconstituents. The study procured several essential materials and reagents from reputable sources [10]. Specifically, HPMC E5, sodium alginate, and PVA were sourced from Loba Chemi in Mumbai, ensuring the highest quality. Propylene glycol, SSG (sodium starch glycolate), and maltodextrin were acquired from Merck Labs, a respected name in the pharmaceutical and laboratory supply industry. Additionally, Dabur honey, a well-known brand, was thoughtfully chosen for the study from the local market [11].

Furthermore, to maintain the highest standards of research, all other ingredients employed in the study were of analytical-grade purity, assuring the integrity of the experimentation and the reliability of the results. The study encompassed a multifaceted analysis, beginning with a thorough examination of both the microscopic and physicochemical attributes of Costus Igneus leaves. This was followed by a comprehensive assessment of their phytochemical content, antibacterial and

ISSN PRINT 2319 1775 Online 2320 7876
Research Paper , UGC CARE Listed (Group -I) Journal Volume 11, Iss 11, 2022

antioxidant properties [12]. The study also involved the development of Oro-herbal films using a solvent-casting method. Here's a more refined description of each aspect:

A. Microscopic and Physicochemical Analysis

The research began with a meticulous investigation of the microscopic characteristics of Costus Igneus leaves. These observations included the cross-sectional view and the stomatal index, as illustrated in Figure 1. Various physicochemical properties of Costus Igneus leaves, such as sulphated ash, total ash, moisture content, and the presence of foreign matter, were quantitatively determined. The findings are presented in Table 1.

Phytochemical Screening:

The study then delved into the exploration of the phytochemical composition of Costus Igneus leaves. Specifically, the presence of key chemical constituents, including flavonoids, glycosides, steroids, alkaloids, tannins, phenolic compounds, diterpenes, triterpenes, and saponins, was investigated [13]. The results are summarized in Table 2 and visually represented in Figure 2.

Antibacterial Evaluation:

The research also sought to ascertain the antibacterial properties of Costus Igneus extract. To this end, the extract was subjected to rigorous testing against a range of bacterial strains, including Bacillus subtilis, Staphylococcus aureus, Pseudomonas aeruginosa, and Escherichia coli. This evaluation was carried out using both the disc plate and agar diffusion methods [14].

Antioxidant Assessment:

The antioxidant potential of the extract was methodically examined through two distinct approaches: the P-Nitroso dimethyl aniline radical scavenging assay (p-NDA) and the Reducing power method (potassium ferricyanide). As a point of reference, ascorbic acid was employed as the standard. These investigations followed the established procedure [15].

B. Preparation of Oro-Herbal Films

A noteworthy facet of this research involved the formulation and development of Oro-herbal films containing Costus Igneus extract. This innovative process was accomplished using the solvent-casting method [16]. The composition of the formulation is thoughtfully detailed in Table 2.

The formulation process entailed creating an aqueous solution that combined the essential polymer components (HPMC, PVA, Maltodextrin, Sodium alginate) and the critical plasticizer, propylene glycol. This polymer solution was stirred and deaerated to ensure proper consistency.

In parallel, another aqueous solution was thoughtfully prepared, incorporating the valuable plant extract (flavonoid), sodium starch glycolate, and honey. This solution was then meticulously blended with the polymeric dispersion.

The resulting dispersion was carefully aerated and cast onto a film former, which was maintained at a controlled temperature range of 30-50ºC. Once formed, the film was collected, precisely cut into 3x3 cm^2 pieces, and securely stored in airtight containers, ready for subsequent evaluation across a spectrum of critical parameters.

This comprehensive study provides a deep understanding of Costus Igneus leaves, encompassing not only their microscopic and chemical characteristics but also their potential antibacterial and antioxidant properties. Additionally, the innovative development of Oro-herbal films adds practical and innovative applications to this valuable research endeavor.

ISSN PRINT 2319 1775 Online 2320 7876
Research Paper , UGC CARE Listed (Group -I) Journal Volume 11, Iss 11, 2022

III. Evaluation tests

A. Calibration Curve for Costus Igneus Leaves Extract

For the calibration curve, a precisely weighed 10 mg of dried methanolic extract of flavonoids was dissolved in methanol within a 10 ml volumetric flask.

The solution was subjected to 10 minutes of sonication and then filtered through Whatman paper.

It was further adjusted with methanol to reach a concentration of 1 mg/ml to create a stock solution.

To establish the calibration curve, a series of solutions ranging from 20-100µg/ml was generated by extracting aliquots of 0.2 ml from the stock solution [17].

These solutions were subjected to analysis using a UV spectrophotometer. The scan spectrum results can be seen in Figure 3.

The entire process was conducted in triplicate, and the absorption maxima were observed at 250nm. The calibration curve exhibited linearity, with a correlation coefficient of 0.9985.

B. Characteristics of Oro-Herbal Films

Visual Inspection of Films: The Oro-herbal fast-dissolving oral films underwent a visual assessment to evaluate various visual parameters, especially when different polymeric matrices were employed. This included the observation of film nature, color, appearance, and texture [18].

Film Thickness Measurement: To determine the uniformity of the films, a screw gauge was used to measure their thickness. This measurement was taken at five strategically chosen locations, with four at the corners and one at the center of each film. Uniform thickness is crucial for ensuring accurate dosing [19].

Folding Endurance: The folding endurance test provides valuable insights into the flexibility and physical stability of the films. In this test, the films were repeatedly folded at the midpoint until they cracked, and the number of folds required to reach this point was recorded [20].

Tensile Strength: Tensile strength measurement was performed by taking films with dimensions of 5cm in width and 10cm in length from each formulation. The force required to break these films was measured. This process was carried out in triplicate to ensure accurate and reliable results. Tensile strength is a critical parameter, as it assesses the physical integrity and durability of the films [21].

$$\textbf{Tensile strength} = \frac{\textit{breaking force}}{\textit{Area of cross section}}$$

Percentage elongation: The mechanical stability of the films was represented in this way, the change in dimensions due to it stretches i.e. strain was measured by following way [22];

$$\%\ \textbf{elongation} = \frac{\textit{final length} - \textit{initial length}}{\textit{initial length}} * 100$$

Where, L=final length, L_0 =initial length

Percentage moisture loss: To study the film stability, moisture loss studies need to be performed. The films of size 3×3 cm^2 were placed in a desiccator containing calcium chloride and measured the weight after three days. The moisture loss was measured by using [23],

$$\%\ \text{moisture loss} = \frac{initial\ weight - final\ weight}{initial\ weight} * 100$$

Percentage moisture uptake: The weighed films were exposed to 84% RH using saturated solution of potassium chloride in desiccator until a constant weight was achieved. The % moisture uptake was calculated by using the formula

$$\%\text{moisture uptake} = \frac{final\ weight - initial\ weight}{final\ weight} * 100$$

pH of film surface: The pH of the film was measured by placing in a dish and moistened with 1ml of water and kept aside for 1min, the pH was measured by pH in triplicate [24].

Degree of swelling: It was measured by immersing 1×1 cm^2 piece of film in phosphate buffer pH 7.4 at 37^oC, the samples were taken out at predetermined time intervals from the solution, an absorbent paper was used to remove the excess dipping water and the sample was weighed. The swelling ratio was calculated by using the formulae;

$$Degree\ of\ swelling = \frac{final\ weight - initial\ weight}{initial\ weight} * 100$$

***In vitro* release studies:**

The release rate of extract from Oro-herbal film of *Costus* was determined by utilizing type II USP dissolution apparatus at 50 rpm in 900ml phosphate buffer pH 6.8, at 37 ±5ºC. Aliquot of sample was collected and maintained the sink conditions by replacing fresh medium at every 30 sec. The sample was filtered through the whatman filter paper and absorbance was measured at 250 nm. The amount of release of extract was measured by using calibration curve data and was carried out in triplicate [25].

Stability studies:

The optimized formulation was carried for stability studies by placing the formulation at 40^{0}C, 75 %RH for 3 months. After the specified period, the samples were analyzed for various evaluation parameters [26, 27].

IV. RESULTS AND DISCUSSIONS

Costus Igneus, commonly referred to as the insulin plant, has been the subject of a literature survey that has revealed its potential applications in treating various conditions. These applications include diabetes, bronchitis, asthma, promoting longevity, reducing fever, eliminating worms, and even enhancing sexual attractiveness in cosmetics. In the current research project, the focus is on utilizing the methanolic extract from the leaves of Costus Igneus to create Oro-herbal films specifically designed for treating diabetes. The process began with the collection of fresh leaves from locations near Guntur, followed by their careful drying through an air-drying process. A microscopic examination of the leaves provided valuable insights into the plant's anatomy. Notable findings included the presence of epidermis, trichomes, vascular bundles, palisade parenchyma, xylem, paracytic stomata, and phloem, highlighting the complex structure of the leaves. By employing a soxhlation process, the dried powder of Costus Igneus was subjected to extraction using methanol as the solvent. The resulting extract was subsequently dried, and a series of tests were conducted to ascertain the presence of various phytochemical constituents. In Figure 1, the stomatal index was determined to be 33%, with the upper and lower epidermis exhibiting stomatal numbers of 15 and

18, respectively. These findings provided valuable insights into the leaf's structure. The results of the study, presented in Figure 2 and Table 1, highlighted the presence of several phytochemical constituents, including carbohydrates, cardiac glycosides, alkaloids, flavonoids, total phenolics, and tannins, shedding light on the leaf's chemical composition. To assess the antibacterial properties of the extract, the agar well diffusion method was employed. It was used to study the effects on both gram-positive bacteria, specifically S. aureus and B. subtilis, and gram-negative bacteria, including E. coli and P. aeruginosa. These bacterial strains are known to be responsible for a range of human infections. The results, as shown in Figure 3, indicated that the extract exhibited good antibacterial activity against E. coli and a moderate effect against S. aureus.

Figure 1: Microscopic data of *Costus Igneus* leaf

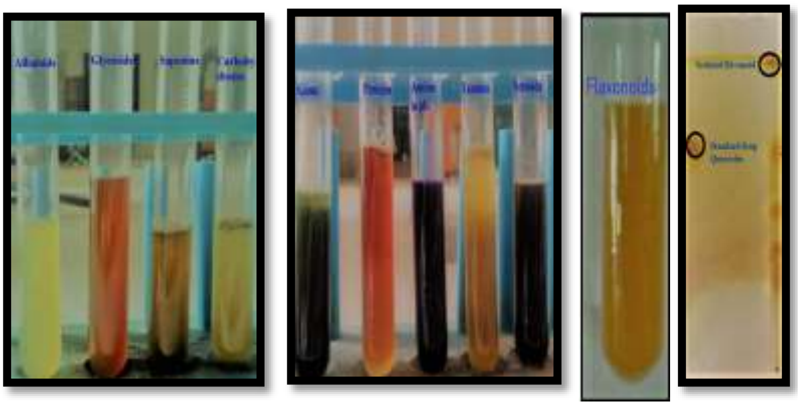


Figure 2: Phytoconstituent profile of *Costus Igneus* leaf extract

Table 1: Physicochemical parameters of leaves of *Costus Igneus*

Physico-chemical Parameter	Data
Moisture content	13.28±0.043
Foreign matter	0.06±0.080
Total ash	14.98±0.09
Acid insoluble ash	2.84±0.072
Water soluble ash	10.7±0.124
Sulphated ash	12.4±0.025

Table 2: Phytochemical constituent’s data of *Costus igneus extract*

Name of the Test	Methanolic Extract
Carbohydrates	+
Proteins	+

IJFANS INTERNATIONAL JOURNAL OF FOOD AND NUTRITIONAL SCIENCES
ISSN PRINT 2319 1775 Online 2320 7876
Research Paper UGC CARE Listed (Group -I) Journal Volume 11, Iss 11, 2022

Amino acids	+
Steroids	+
Cardiac glycosides	+
Flavonoids	+++
Alkaloids	++
Tannins & phenolic compounds	+

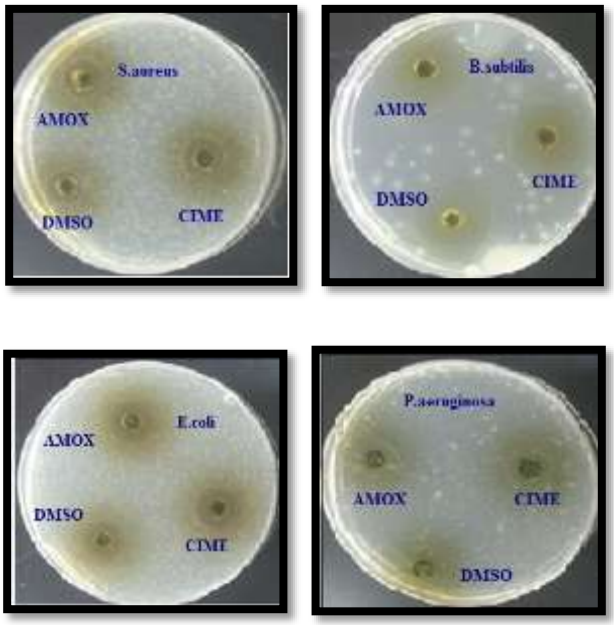


Figure 3: Antibacterial activity profile of *Costus Igneus* leaf extract

In addition to its antibacterial properties, the antioxidant potential of the methanolic extract from Costus Igneus was also investigated. This assessment involved varying concentrations of the extract and employed two methods: the p-nitroso dimethyl aniline radical scavenging assay and the reducing power method. The data, provided in Table 3, revealed a notable increase in free radical scavenging activity with rising extract concentration.
Furthermore, the spectral analysis of the pure extract, as depicted in Figure 4, showed an absorption maximum at 250nm. This information is valuable for characterizing the extract's chemical properties.

The compatibility of the extract with the excipients used in the film formulation was evaluated using IR spectroscopy. As illustrated in Figure 5, the spectra indicated that there was no evidence of interaction between the extract and the excipients, as there were no discernible changes in peak properties. This suggests that the extract is suitable for integration into the film formulation without any adverse effects.

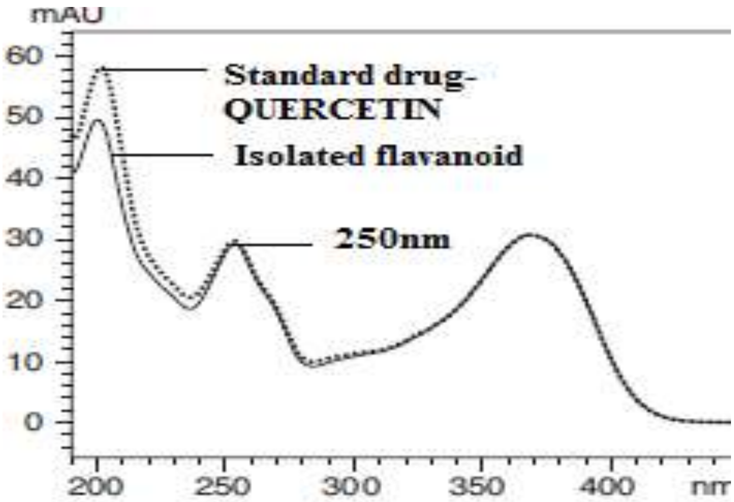
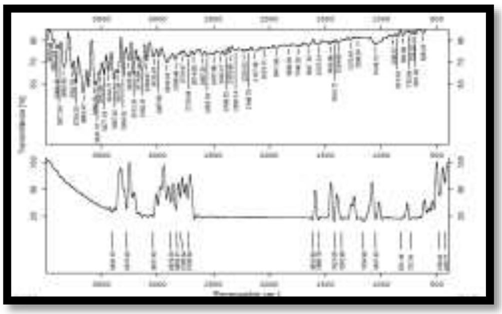
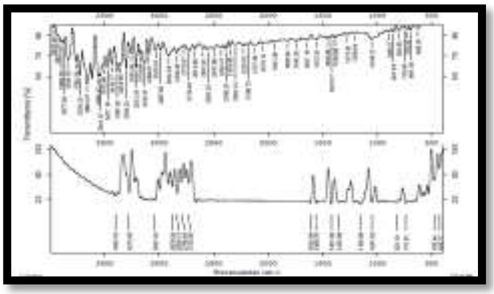


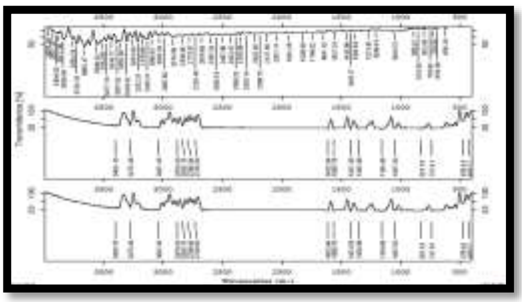
Figure 4: Scan spectrum of standard pure drug quercetin and isolated flavonoid



(a)



(b)



(c)

Figure 5: Comparative IR spectra of a) F3 b) F4 c) F6 formulations

Table 3: Antioxidant activity of methanolic leaf extract of *C.igneus*

S.No	Name of the Drug	CONCENTRATION (μg/ml)	ABSORBANCE (nm)

Reducing power			
1.	Ascorbic acid	100	0.245
		200	1.075
2.	CI Methanolic Extract	100	0.234
		200	0.330
p-Nitroso Dimethyl Aniline radical scavenging method			
1.	Ascorbic acid	200	1.163
		400	1.322
2.	CI Methanolic extract	200	0.089
		400	0.237

The leaf extract of Costus Igneus was utilized to formulate Oro-herbal fast dissolving films. This was accomplished through the solvent casting method, following the formulation specified in Table 4.

Table 4: Formulae of oro-herbal film of *Costus igneus extract*

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
CI Plant extract (flavanoid) (mg)	100	100	100	100	100	100	100	100	100	100
HPMC E5 (%)	4	-	-	-	2	-	2	2	-	-
Maltodextrin (%)	-	4	-	-	-	2	2	-	2	-
Sodium alginate (%)	-	-	4	-	-	2	-	2	-	2
PVA (%)	-	-	-	4	2	-	-	-	2	2
PG(ml)	2	2	2	-		2	2	2	-	-
SSG(mg)	3	3	3	3	3	3	3	3	3	3
Honey(ml)	2	2	2	2	2	2	2	2	2	2
Water(ml)	10	10	10	10	10	10	10	10	10	10

Figure 6 depicts the resulting films. These prepared films underwent a comprehensive evaluation, covering various morphological parameters.

Figure 6: Oro-herbal film of *Costus Igneus*

The collected data revealed that the films displayed homogeneity, transparency, and uniformity, as documented in Table 5. However, it's worth noting that certain films, specifically F2, F8, and F9, exhibited a tacky nature. In addition to morphological assessments, the formulations were subjected to rigorous testing to determine their physicochemical and physico-mechanical properties. The detailed findings from these evaluations are provided in Table 6 and Table 7, shedding light on the

ISSN PRINT 2319 1775 Online 2320 7876
Research Paper , UGC CARE Listed (Group -I) Journal Volume 11, Iss 11, 2022

various characteristics of the films, including thickness, elongation, surface pH, stability under humidity conditions, tensile strength, folding endurance, disintegration time, drug content, and drug release profiles.

Table 5: Morphological properties of Oro-herbal film of *Costus Igneus extract*

S. NO	Formulation	Visual appearance	Surface	Film forming capacity	Tackiness
1	F1	Homogenous, transparent	Smooth	Very good	Non tacky
2	F2	Homogenous, transparent	Smooth	Average	Tacky
3	F3	Homogenous, transparent	Smooth	Very Good	Non tacky
4	F4	Homogenous, transparent	Smooth	Very good	Non tacky
5	F5	Homogenous, transparent	Smooth	Best	Non tacky
6	F6	Homogenous, transparent	Smooth	Average	Non tacky
7	F7	Homogenous, transparent	Smooth	Very good	Non tacky
8	F8	Homogenous, transparent	Smooth	Best	Tacky
9	F9	Homogenous, transparent	Smooth	Best	Non tacky
10	F10	Homogenous, transparent	Smooth	Average	Tacky

Table 6: Physico-mechanical properties of oro-herbal films

S.NO	Formulation	Thickness (mm±SD)	%elongation (%±SD)	Folding endurance	Weight uniformity	Tensile Strength	Surfaces PH
1	F1	0.125±0.016	1.5±0.011	>210	3.52±0.041	1.45±0.012	5.32±0.051
2	F2	0.128±0.021	2.3±0.015	>225	3.54±0.041	1.63±0.018	5.69±0.064
3	F3	0.129±0.018	1.8±0.013	>270	3.55±0.042	1.85±0.021	5.88±0.075
4	F4	0.132±0.032	4.5±0.022	>270	3.57±0.042	2.15±0.041	5.54±0.031
5	F5	0.123±0.010	1.2±0.009	>250	3.63±0.046	2.42±0.062	6.08±0.090
6	F6	0.135±0.024	3.5±0.016	>260	3.65±0.046	1.34±0.009	6.25±0.092
7	F7	0.172±0.051	5.2±0.028	>250	3.73±0.050	2.35±0.055	5.90±0.082
8	F8	0.153±0.058	5.8±0.039	>240	3.81±0.051	1.92±0.032	6.32±0.95
9	F9	0.143±0.052	3.9±0.030	>240	3.83±0.052	2.35±0.055	6.55±0.125
10	F10	0.135±0.060	2.9±0.040	>225	3.85±0.052	1.36±0.009	6.58±0.127

Table 7: Physico-chemical properties of formulated oro-herbal films

S.NO	Formulation	%Moisture Uptake	%Moisture Loss	Disintegration time (sec)	Drug Content
1	F1	2.041±0.056	1.136±0.014	61.2±0.132	89.1±0.03
2	F2	2.145±0.071	1.269±0.015	57.3±0.128	94.4±0.55
3	F3	2.052±0.074	1.146±0.018	47.3±.0140	98.3±0.01
4	F4	2.183±0.074	1.312±0.016	49.9±0.131	96.6±0.007
5	F5	2.207±0.075	1.450±0.017	82.4±0.147	92.9±0.03
6	F6	2.144±0.071	1.132±0.013	50.23±0.125	96.1±0.01
7	F7	2.166±0.073	1.045±0.010	53.3±0.125	92.4±0.06
8	F8	2.088±0.058	1.430±0.016	62.4±0.132	88.2±0.01
9	F9	2.114±0.062	1.224±0.015	67.3±0.137	90.1±0.03
10	F10	2.106±0.060	1.515±0.020	69.8±0.138	95.4±0.02

Table 8: Stability data of Oro-herbal films

S.no	Physical appearance	Tackiness	Film separation	Disintegration
F3	Very good	Non Tacky	Separates	41.32±0.22
F4	Average	Non Tacky	Separates	52.23±0.14
F6	Good	Tacky	Difficult to separates	61.85±0.13

The formulated films all exhibited consistent thickness, ranging from 0.125±0.016 to 0.172±0.051 mm. The percentage of elongation showed variability, with values ranging from 1.2±0.009 to 5.8±0.039. Importantly, the surface pH of all the formulations fell within the range of 5.32±0.051 to 6.58±0.127. These pH values closely resembled the pH of saliva, indicating that the films are safe for oral use and unlikely to cause irritation. The stability of the films was rigorously examined by assessing their moisture-related properties. The results of these tests indicated that the films remained stable under different humidity conditions, suggesting their suitability for practical use. The tensile strength and percentage elongation results revealed that the films possessed the

IJFANS INTERNATIONAL JOURNAL OF FOOD AND NUTRITIONAL SCIENCES
ISSN PRINT 2319 1775 Online 2320 7876
Research Paper UGC CARE Listed (Group -I) Journal Volume 11, Iss 11, 2022

necessary structural integrity to withstand transportation without damage. Additionally, the high folding endurance of the films indicated that they were not brittle in nature and could endure bending and folding without breaking. Regarding the disintegration time, all films displayed rapid disintegration, with values falling within the range of 47.3-82.4 seconds. This rapid disintegration is advantageous for the intended application. Initiating the study, the films underwent a drug release assessment, conducted at a speed of 50 rpm and spanning a 5-minute duration. The resulting data revealed an immediate release pattern, as visually represented in Figure 7.

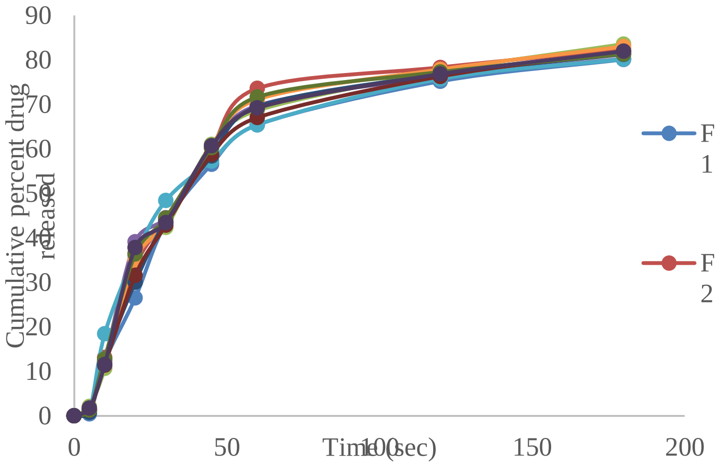


Figure 7: *In vitro* release profile of Oro-herbal film of *Costus Igneus*

Upon comprehensive evaluation, formulations F3, F4, and F6 displayed not only favorable drug release characteristics but also exhibited desirable physicochemical properties. Recognizing the potential of these formulations, they were selected for further investigation in stability studies. These stability studies encompassed subjecting the chosen formulations—F3, F4, and F6—to controlled environmental conditions. The formulations were placed in an environment maintained at a temperature of 40±2°C and a relative humidity (RH) of 75±5% for an extended duration of 3 months. Throughout the course of these studies, a range of parameters was meticulously monitored to gauge the formulations' stability over time. The culmination of these studies presented a compelling outcome: formulation F3 remained exceptionally stable throughout the entire 3-month duration. For a detailed breakdown of the findings from these stability studies, including information on performance and consistency over time, please refer to Table 8. This table encapsulates the essential data that substantiates the favorable attributes of formulation F3 in the context of stability, offering a robust foundation for further considerations in this research endeavor.

V. CONCLUSION

To enhance convenience for diabetic geriatric patients, we formulated an Oro-herbal fast dissolving film using the extract of the Costus Igneus plant, known for its good antidiabetic properties. This oral film provides ease of administration and is suitable for use during travel. The study involved a literature review and a patent survey of the Costus Igneus plant to justify our choice of ingredient. We evaluated the prepared Oro-herbal film for various physical properties and drug release parameters, with the F3 formulation proving to be the most effective based on comparative studies. In conclusion, our results suggest that the leaves of the Costus Igneus plant can be effectively delivered in the form of oral films, potentially improving patient compliance among diabetic geriatric patients.

REFERENCES

ISSN PRINT 2319 1775 Online 2320 7876
Research Paper , UGC CARE Listed (Group -I) Journal Volume 11, Iss 11, 2022

1. Dubey NK. Global promotion of herbal medicine: India's opportunities. Asia Pacific trade Med. 2017; 13(2): 4-5.
2. Patwardhan B, Vaidya ADB, Chorghade M. Ayurdea and natural products drug discovery. Curr Sci. 2004; 86: 789-799.
3. Yu Shi, Chao Zhang, Xiaodong Li. Traditional medicine in India. Journal of Traditional Chinese Medical Sciences. 2021; 8(1): S51-S55.
4. Ashok D, Vaidya B, Thomas P, Devasagayam A. Current Status of Herbal Drugs in India: An Overview. Journal of Clinical Biochemistry and Nutrition 2007; 41(1): 1-11.
5. Sandhu DS, Heinrich M. The use of health foods, spices and other botanicals in the Sikh community in London. Phytotherapy Res., 2005; 19: 633-42.
6. Lemonnier N, Shou G, Prasher B, Mukerji M, Chen Z, Brahmachari SK, Noble D, Auffray C, Sagner M. Traditional knowledge based medicine: A review of history, principles and relevance in the present context of P4 system medicine. Progress in Preventive medicine. 2017; 2(7): e0011.
7. Manukumar HM, Shiva Kumar J, Chandrashekar B, Raghava S and Umesha S: Evidences for diabetes and insulin mimetic activity of medicinal plants: Present status and prospects. Critical Reviews in Food Science and Nutrition 2016; 57(12): 2712-29.
8. Modak M, Dixit P, Londhe J, Ghaskadbi S, Devasagayam TP. Indian herbs and herbal drugs used for the treatment of diabetes. J Clin Biochem Nutr. 2007; 40(3): 163-73.
9. Hegde PK, Rao HA, Rao PN. A review on Insulin plant (Costus igneus Nak). *Pharmacogn Rev*. 2014; 8(15): 67-72.
10. Sathasivampillai, SV, Rajamanoharan, PRS, Munday M, and Heinrich M: Plants used to treat diabetes in Sri Lankan Siddha Medicine - An ethnopharmacological review of historical and modern sources. J of Ethnopharmacology 2017; 198: 531-99.
11. Laha S and Paul S. Costus igneus - a therapeutic anti-diabetic herb with active phytoconstitutents. Int J Pharm Sci & Res 2019; 10(8): 3583-91.
12. Naga Sowjanya J. A review on oral fast dissolving films. Int. J. of advances in pharmacy, biology & chemistry. 2013; 2(1): 51-58.
13. Prejeena V, Suresh SN and Varsha V: Qualitative phytochemical analysis of Costus igneus leaf extracts: Pharma Research Library. Int J Med Pharm Res 2015; 3(6): 1235-37.
14. Ramya USK and Chauhan JB: Phytochemical screening, antimicrobial activity and antioxidant activity of Costus igneus. European Journal of Molecular Biology and Biochemistry 2015; 2(2): 93-96.
15. Karla CSL, Luane FG, German SL, Douglas VT, Emily KGM *et. al.* Antioxidant activity evaluation of dried herbal extracts: an electroanalytical approach. Revista Brasileira de Farmacognosia 2018; 28(3): 325-332.
16. Pallavi K, Pallavi T: Formulation and evaluation of fast dissolving films of eletriptan hydrobromide. Int Jour curr pharm research 2018; 9: 13-1.
17. John reddy P, Sneha sri M, Karthikeya Srinivasa V, Anitha P, Ravindra Babu P. Chromatographic analysis of phytochemicals in Costus igneus and computational studies of flavonoids. Informatics in Medicine Unlocked 2018; 13: 34-40.
18. Irfan M, Rabel S, Bukhtar Q, Qadir Mi, Jabeen F, Khan A. Orally disintegrating films: a modern expansion in drug delivery system. Saudi pharm J. 2016; 24(5); 537-546.
19. Sharma D, Kaur D, Verma S, Singh D, Sing M et al., Fast dissolving oral films technology: a recent trend for an innovative oral drug delivery system. Int. J. Drug Deliv 2015; 7(2): 60-75.
20. Zhang H, Han Mg, Wang Y, Zhang J, Han ZM, Li SJ. Development of oral fast disintegrating levothyroxine films for management of phythyroidism in pediatrics. Trop. J. pharm. Res 2015; 14(10): 1755-1762.

ISSN PRINT 2319 1775 Online 2320 7876
, **UGC CARE Listed (Group -I) Journal Volume 11, Iss 11, 2022**

21. Zhang L, Aloia M, Pielech-Safira B, Lin H, Rajai Pm, Kunnath K. Impact of super disingegrants and film thickness on disintegration time of strip films loaded with poorly water soluble drug microparticles. J pharm sci 2018; 107(8):2107-2118.
22. Zhu Z, You X, Huang K, Raza F, Lu X, Chen Y. Effect of taste masking technology on fast dissolving oral film: dissolution rate and bioavailability. Nanotechnol. 2018; 29(30): 304-06.
23. Jadhav K, Shivraj J, Deepak S, Hina S, Hitesh K. Mouth dissolving film of domeridone: an approach towards formulation and its evaluation. Jour pharm resear int 2021. 33(44A): 140-150.
24. Swamy, Shiva Kumar S: Formulation and Evaluation of Fast Dissolving Oral Films of Palonosetron Hydrochloride Using HPMC-E5. Int Jour Pharm Chem Sci 2015;8: 23-9.
25. Sheoran Reena, Fast Dissolving Oral Films: A Review with Future Prospects, International Journal of Pharmacy & Pharmaceutical Research, 12(2), 2018, 15-32.
26. Hithun Devaraj, Senthil Venkatachalam and Arun Radhakrishnan; A Review on Formulation of Oral Dissolving Film; Journal of Chemical and Pharmaceutical Research, 10(4), 2018, 151-159.
27. Linku A, Sijimol J. Formulation and evaluation of fast dissolving oral film of anti-allergic drug. Asian Jour Pharm Res Dev 2018; 6(3): 5-16.