RESEARCH PAPER

Development and Evaluation of *Clitoria ternatea* Extract–Loaded Orodispersible Films as A Novel Antioxidant Delivery System

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ABSTRACT

Background: Oxidative stress plays a significant role in the progression of chronic diseases by causing cellular harm through reactive oxygen species (ROS). Increasing interest has been shown in natural antioxidants as safer substitutes for synthetic compounds like butylated hydroxyanisole and butylated hydroxytoluene. *Clitoria ternatea* (Fabaceae), often referred to as butterfly pea, is abundant in flavonoids and anthocyanins that demonstrate strong antioxidant and neuroprotective properties.

Objective: The purpose of this study was to formulate and assess *Clitoria ternatea* extract-loaded Orodispersible films (ODFs) as an innovative phytopharmaceutical product aimed at improving antioxidant effectiveness, stability, and patient adherence.

Methods: Aqueous extracts from the flowers were integrated into hydroxypropyl methylcellulose (HPMC) polymer matrices via the solvent casting technique. The resulting ODFs were analyzed for their physicochemical properties, mechanical strength, disintegration time, swelling index, and in vitro dissolution. Antioxidant potential was evaluated using DPPH, hydrogen peroxide scavenging, and ferric reducing antioxidant power (FRAP) assays. Spectroscopic (UV–Vis), thermal (DSC), and X-ray diffraction (XRD) analysis were conducted to examine the structural and compatibility characteristics.

Results: The optimized films were homogeneous, flexible, and dissolved rapidly (30 ± 2 s), exhibiting excellent folding endurance (>120). Antioxidant tests indicated concentration-dependent radical scavenging activity with IC_{50} values similar to those of the crude extract, confirming the preservation of phytochemical efficacy. DSC and XRD studies revealed that the extract was molecularly dispersed within the polymer matrix, suggesting an enhanced amorphous nature.

Conclusion: The developed *Clitoria ternatea* ODFs demonstrated significant antioxidant activity, stability, and rapid dissolution, indicating their potential as a novel and user-friendly delivery system for natural antioxidants in managing oxidative stress.

Keywords: *Clitoria ternatea*, Orodispersible film, Antioxidant activity, Phytopharmaceutical formulation, Oxidative stress

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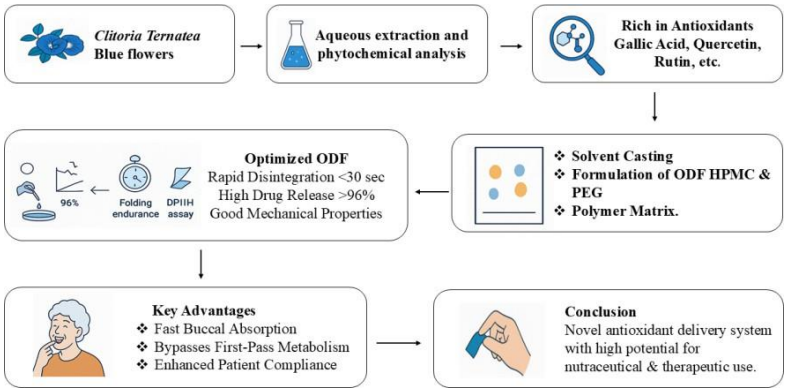
Graphical Abstract



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1. INTRODUCTION

Oxidative stress arises when the balance between the production of reactive oxygen species (ROS) and the body's antioxidant defense mechanisms is disrupted. In addition to impairing cellular function, excessive ROS can damage lipids, proteins, and nucleic acids, which can contribute to the development of chronic diseases, such as cancer, diabetes, cardiovascular problems, and neurodegeneration(1–4). By scavenging free radicals, chelating metal ions, and boosting natural defense enzymes, antioxidants prevent oxidative damage. Despite their widespread use, synthetic antioxidants like butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT) pose health and environmental hazards, including mutagenicity, endocrine disruption, and hepatotoxicity(5–8). As a result, natural antioxidants that are safer and have more uses are becoming more and more popular(9).

1.1. Rationale for Selecting *Clitoria ternatea*

Butterfly pea, or *Clitoria ternatea* (Figure 1) (Fabaceae), is a perennial herb that is widely used in traditional medicine to treat conditions related to oxidative stress, fever, and inflammation (10–12). It has recently drawn a lot of attention because of its potential use in modern health and agriculture, as well as its capacity to offer antioxidants and natural food coloring(13). Flavonoids (quercetin, kaempferol, and rutin), phenolic acids (gallic and chlorogenic acid), and anthocyanins are among its phytochemical constituents, which have strong anti-inflammatory and antioxidant properties(14,15). These substances serve as metal chelators, enzyme modulators, and free radical scavengers. Its therapeutic value has been validated by prior research showing that *C. ternatea* extracts have a strong antioxidant capacity that is comparable to that of conventional antioxidants(16).

1.2. Significance of Orodispersible Film Platform

Oral thin films are flat sheets that are given to patients orally. They are made of extremely thin polymeric strips with an active medicinal ingredient, and they are meant to dissolve in the mouth in a matter of seconds. This is advantageous as the medication is absorbed quickly through the mouth mucosa(9,17).

Oral thin films are used locally in the mouth to treat conditions including cold sores, toothaches, Oral ulcers, teething, etc. Oral thin films have various unique characteristics, like being administered without water, Fast disintegration and quick onset of action, Rapid release and unobstructive, thin, elegant film & mucoadhesive is excellent, available in a variety of sizes and shapes(18–20). Compared with conventional tablets and capsules, Orodispersible films (ODFs) offer faster onset of action, improved bioavailability, and greater patient compliance. Unlike traditional forms that undergo gastrointestinal absorption and first-pass metabolism, ODFs disintegrate within 30 seconds, enabling rapid buccal absorption. They require no water and are ideal for pediatric, geriatric, and dysphagic patients.

Incorporating plant-based extracts further enhances the solubility and stability of phytoconstituents.

1.3. Objective of the study

The present study focuses on the development and evaluation of *Clitoria ternatea* extract–loaded ODFs as a novel phytopharmaceutical delivery system for antioxidant therapy. The formulation was optimized using hydroxypropyl methylcellulose (HPMC) and polyethylene glycol (PEG 400) as film-forming and plasticizing agents, respectively. Comprehensive characterization—including phytochemical profiling, antioxidant assays (DPPH, hydrogen peroxide scavenging, and FRAP), and physicochemical and mechanical evaluation—was performed to assess the efficiency of the formulation. The study aims to establish *C. ternatea* ODFs as a promising antioxidant platform combining natural efficacy with patient-friendly delivery design.

Figure 1: *Clitoria ternatea* - The images show *Clitoria ternatea* flowers, commonly known as butterfly pea.

Table 1: Botanical description of *Clitoria ternatea(12)*

BOTANICAL DESCRIPTION			
Taxonomy Classification: Genus : *Clitoria* Species : *Clitoria ternatea* Family: Fabaceae Class : Dicotyledonae Order : Fabales Domain: Eukaryota Kingdom: Plantae Phylum: Spermatophyta	**Vernacular names:** Tamil – Kakkanam Telugu – Dintena Hindi – Aparajita English – Clitoria Kannada –GiriKarnika	**Flowering and Fruiting**: July-March.	**Plant Type:** Herbaceous Perennial Seed propagates Vine/climber

2. MATERIALS AND METHODS

2.1. Sample Collection and Preparation

Fresh flowers of *Clitoria ternatea* were collected from Tiruvannamalai District, Tamil Nadu, India. Healthy, disease-free blue petals were separated, washed with tap water followed by distilled water, and shade-dried at room temperature (~37 °C) for one week. The dried material was powdered using a mechanical grinder and stored in an amber container until extraction. For Soxhlet extraction, 50 g of powdered sample was extracted with 200 mL of distilled water at 100 °C (10–12 siphon cycles). The extract was filtered, concentrated using a rotary evaporator at 40 °C under reduced pressure, and stored at 4 °C for subsequent analysis (Figure 2)(21,22)

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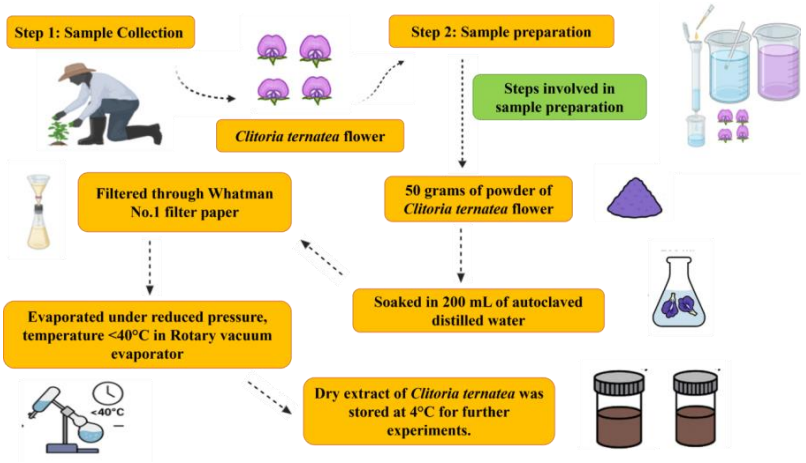

Figure 2: Sample collection and preparation of aqueous extract

2.2. Physico-chemical Characterization

Standard pharmacognostic parameters—moisture content, ash values (total and acid-insoluble), and extractive values (water- and alcohol-soluble)—were determined following WHO and Indian Pharmacopeia guidelines to assess the purity and quality of the raw material(21,22).

2.3. Phytochemical Screening

2.3.1 Thin-layer chromatography [TLC]

TLC was performed on pre-coated silica gel plates using hexane: ethyl acetate (7:3) as the mobile phase. The developed plates were visualized under UV light (365 nm), and retention factor (Rf) values were calculated and compared with reference standards (23–25).

2.3.2. Qualitative analysis of phytoconstituents

Primary and secondary metabolites such as carbohydrates, alkaloids, tannins, flavonoids, phenols, terpenoids, steroids, and saponins were screened using standard phytochemical tests(25,26).The presence of major constituents, including gallic acid, quercetin, kaempferol, luteolin, and rutin, was confirmed

2.4. Antioxidant study

Antioxidants shield cells from the harmful effects of reactive oxygen species, often known as free radicals, which include peroxyl radicals, hydroxyl radicals, singlet oxygen, superoxide, and peroxynitrite. Oxidative stress causes cellular damage(27).

2.6.1. DPPH radical scavenging assay

The DPPH assay was performed according to Brand-Williams et al. (1995)(28). Briefly, 1 mL of 0.1 mM DPPH solution in methanol was mixed with 1 mL of extract or ODF solution (100–1000 µg/mL). After incubation for 30 min in the dark, absorbance was measured at 517 nm. Gallic acid served as the reference antioxidant. Percentage inhibition and IC_{50} values were calculated.

2.6.2. Hydrogen peroxide scavenging assay

Hydrogen peroxide (100 mM) in phosphate buffer (pH 7.4) was treated with varying concentrations of extract (100–1000 µg/mL). After 10 min incubation, absorbance was recorded at 230 nm, and scavenging activity was calculated as per the standard protocol (29).

2.6.3. Ferric reducing antioxidant power method

The reducing power of the extract was evaluated according to Benzie and Strain(30,31).. Samples were reacted with potassium ferricyanide and trichloroacetic acid, and the absorbance of the resulting ferrous complex was measured at 593 nm. Gallic acid was used as the standard antioxidant.

2.7. Formulation of an herbal antioxidant oral thin film of *Clitoria ternatea*

The antioxidant oral film of *Clitoria ternatea* was formulated using the solvent casting process. The medicine was dissolved in 5 ml of distilled water and combined with the excipient solution after the excipients were precisely weighed and dissolved in 25 ml of water. For three hours, the mixture was gently stirred using a magnetic stirrer to prevent the production of bubbles. To dry the solution and evaporate the water, the viscous, clear solution was transferred onto a disposable Petri dish (60mm) and placed in the oven for the entire night. The film was carefully taken out of the Petri dish and sliced into tiny (2 cm × 2 cm) pieces(32–35). Table 2 demonstrates the six placebo formulations made from the excipients with varying polymer concentrations. The antioxidant oral film of *Clitoria ternatea* was created using the best two formulas, F2 and F6.

Table 2: Placebo formulations that are prepared in the study

Ingredients	F1	F2	F3	F4	F5	F6
PEG 400	4.29% w/v	1.43% w/v	1.43% w/v	1.43% w/v	2.86% w/v	2.86% w/v
HPMC	17.14% w/v	17.14% w/v	17.14% w/v	17.14% w/v	17.14% w/v	17.14% w/v
IPA	10mL	10mL	10mL	10mL	10mL	10mL
SSG	0.1gm	0.1gm	0.1gm	0.1gm	0.1gm	0.1gm
Water	25mL	25mL	25mL	25mL	25mL	25mL
Flavoring agent	q. s	q. s	q. s	q. s	q. s	q. s

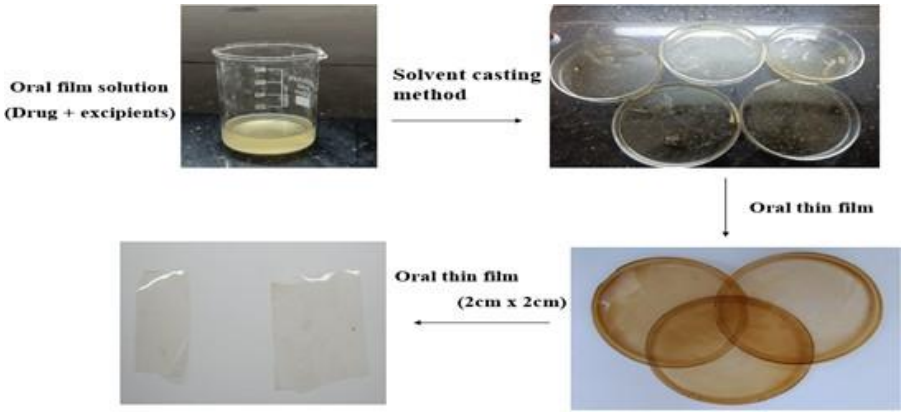

Figure 3: Formulation of herbal antioxidant oral thin film of *clitoria ternatea* -The oral film solution, containing the drug and excipients, is prepared and poured into Petri dishes using the solvent casting method. After drying, thin films are formed, which are then peeled and cut into 2 cm × 2 cm pieces.

Table 3: Composition of the antioxidant oral film of *Clitoria ternatea*

S.NO	Ingredients	Quantity	Concentration (% w/v)
1	Extract of *Clitoria ternatea*	40mg (0.04 g)	0.11%
2	PEG 400 (polyethylene glycol)	0.5g	4.29%
3	HPMC (hydroxypropyl methylcellulose)	6g	17.14%
4	IPA (isopropyl alcohol)	10mL	-
5	Sodium starch glycolate (SSG)	0.1g	0.29%
6	Flavoring agent	q. s	-
7	Water	25mL	-

3. EVALUATION OF ORAL THIN FILM

Physicomechanical and performance evaluations were performed according to standard procedures (33–37).

3.1. Thickness

Measured at five points using a digital micrometer.

3.2. Folding endurance

Determined by repeatedly folding the film at the same site until it broke**.**

3.3. Surface PH

Recorded by placing a moistened pH electrode on the film surface

3.4. Swelling index

Assessed in simulated saliva, the percentage swelling was calculated until a constant weight.

3.5. Disintegration test

Determined using both the Petri dish and slide-frame methods, the time for complete film disintegration was recorded(38,39).

3.8. Dissolution test

Conducted using USP Apparatus I (basket method) in 900 mL of 0.1 N HCl at 37 ± 0.5 °C, 50 rpm (35).

3.9. X-ray diffraction (XRD)

Used to evaluate the crystalline versus amorphous nature of the extract in films (40,41).

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3.10. Differential scanning calorimetry (DSC)

Performed to assess thermal behavior and drug–polymer compatibility(41,42).

3.11. UV Absorption spectra of *Clitoria ternatea*

λmax of extract determined between 200–800 nm to confirm the presence of polyphenolic chromophores (43).

4. RESULTS AND DISCUSSION

4.1. Phytochemical and Physicochemical Characterization

The aqueous extract of *Clitoria ternatea* produced a dark violet residue with a pleasant aroma and a mildly astringent flavor. The extraction yield was 8.7% w/w, indicating efficient extraction (Table 4). The physicochemical parameters, including total ash, acid-insoluble ash, and extractive values, complied with WHO-recommended standards, signifying high quality and purity of the raw drug material(21,22). Preliminary phytochemical screening (Table 5 & Figure 5) validated the presence of flavonoids, phenolic acids, tannins, terpenoids, and glycosides, while alkaloids and saponins were not detected. These findings align with existing literature that identifies C. ternatea as a valuable source of natural antioxidants (44–47). TLC profiling (Figure 4) revealed multiple violet bands under UV 365 nm, with Rf values matching those of quercetin and gallic acid standards, confirming the presence of these major phenolic compounds responsible for antioxidant activity.

Table 4: Physico-chemical properties results

S.NO	Properties	Results	
1	Ash Values	**Types of Ash**	**% of ash**
		Total Ash	7.05
		Water-soluble Ash	1.36
		Acid-Soluble Ash	1.42
2	Moisture Content/loss on drying	12.02 %	
3	Extractive values	**Type of extract**	**Extractive value (%w/w)**
		Water	10.83
		Alcohol	8.53
4	Sugar estimation	0.315%	

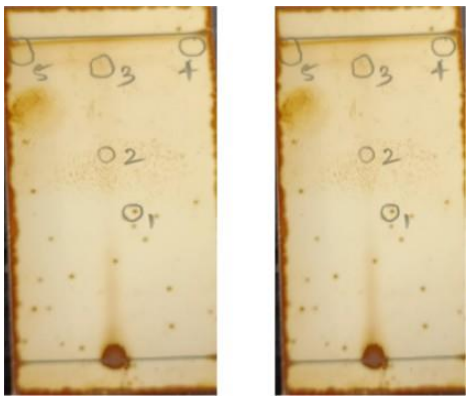


Figure 4: Aqueous extract of *Clitoria ternatea* in thin-layer chromatography

Table 5: Result of phytochemical analysis of *Clitoria ternatea* (+) – presence, (-) – Absence

S. NO	Phytochemical constituents	Result
1.	Test for Carbohydrates	+
2.	Test for Tannins	+
3.	Test for Saponins	+
4.	Test for Flavonoids	+
5.	Test for Alkaloids	+
6.	Test for Quinones	+
7.	Test for Glycosides	-

8.	Test for Cardiac Glycosides	+
9.	Test for Terpenoids	+
10.	Test for phenols	+
11.	Test for Steroids	+

Figure 5: phytochemical analysis of *clitoria ternatea* -The herbal formulation of antioxidant oral thin film of *clitoria ternatea* showed the presence of Alkaloids, Tannins, Flavonoids, Saponins, Phenols, Terpenoids, steroids, Carbohydrates, etc.

4.2. Antioxidant Activity

4.2.1. DPPH Radical Scavenging Assay

The DPPH radical scavenging assay (Figure 6, Table 6) showed a concentration-dependent increase in antioxidant activity for both the extract and the Orodispersible films (ODFs). The IC_{50} value of the extract was 390.6 µg/mL, while that of the ODF was 375.2 µg/mL, indicating a slight enhancement in antioxidant efficiency following formulation. This finding suggests that the polymeric matrix preserved and potentially improved the accessibility of polyphenolic compounds for free radical scavenging. The strong correlation ($R^2 > 0.98$) between concentration and % inhibition indicates good linearity. These results are consistent with prior studies confirming the potent antioxidant properties of C. ternatea flowers(16,21) .

4.2.2. Hydrogen Peroxide Scavenging Assay

The data from the hydrogen peroxide scavenging assay (Figure 7) displayed a similar concentration-dependent activity trend. At a concentration of 1000 µg/mL, the extract and ODFs demonstrated 76.4% and 79.1% inhibition, respectively, suggesting that the formulation did not affect the functional antioxidant potential of the active compounds. The improved activity observed in ODFs may be due to better diffusion and interaction of hydrophilic polyphenols in the aqueous environment, facilitated by HPMC(48) .

4.2.3. Ferric Reducing Antioxidant Power (FRAP)

The reducing power increased progressively with concentration (Figure 8), with the ODF displaying slightly greater absorbance than the crude extract. This finding confirms that the redox-active compounds were preserved and effectively stabilized within the polymeric film matrix (30,31). Collectively, the results affirm that the antioxidant integrity of C. ternatea was maintained throughout the formulation process.

Table 6. DPPH radical scavenging activity of *Clitoria ternatea* extract, extract-loaded ODF, placebo ODF, and gallic acid standard (triplicate values, n = 3).

Concentration (µg/mL)	Extract (% Inhibition, Mean ± SD)	Extract-ODF (% Inhibition, Mean ± SD)	Placebo ODF (% Inhibition, Mean ± SD)	Gallic Acid (% Inhibition, Mean ± SD)
100	17.13 ± 0.47	18.60 ± 0.10	1.50 ± 0.00	41.60 ± 0.00
200	32.50 ± 1.21	33.50 ± 0.10	1.80 ± 0.00	66.10 ± 0.00
400	50.87 ± 0.38	47.20 ± 0.26	1.80 ± 0.17	80.40 ± 0.00
600	65.37 ± 0.06	61.33 ± 0.12	2.00 ± 0.00	88.50 ± 0.00
800	73.13 ± 1.05	74.00 ± 1.00	2.10 ± 0.00	90.80 ± 0.00
1000	80.70 ± 0.10	78.57 ± 0.06	2.30 ± 0.00	96.57 ± 0.06

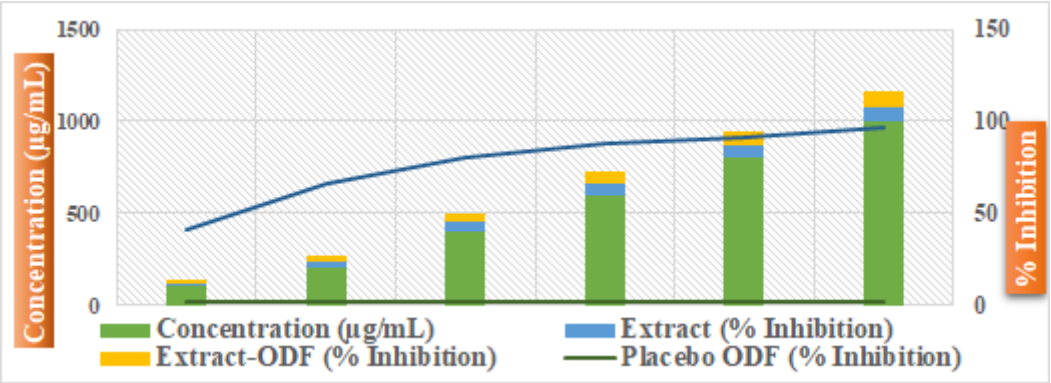


Figure 6: DPPH radical scavenging assay

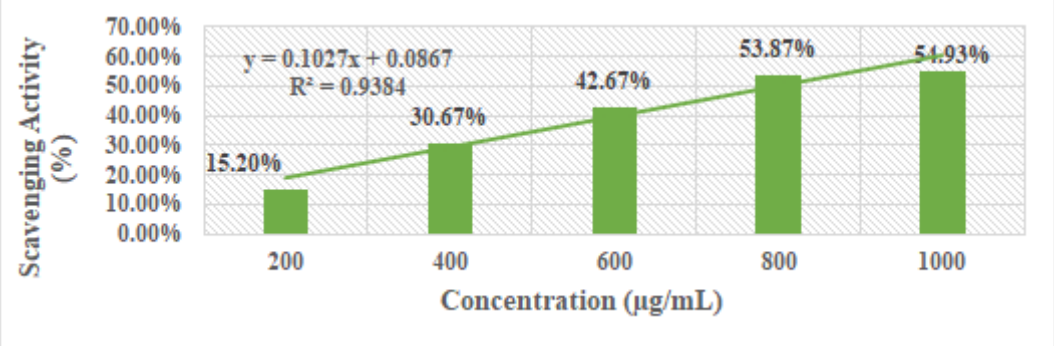


Figure 7: Hydrogen peroxide scavenging assay

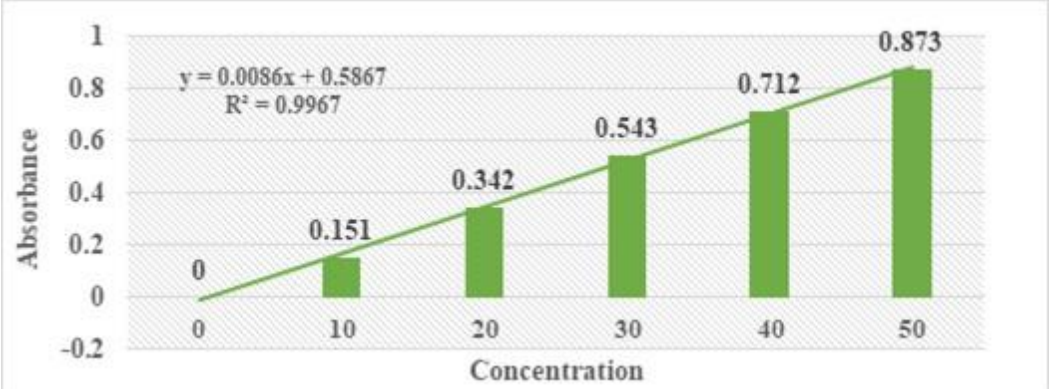


Figure 8: Ferric reducing antioxidant power method.

4.3. Evaluation of Orodispersible Films

The produced ODFs displayed a smooth, flexible texture and a consistent appearance, characterized by a violet color. The Physico-mechanical assessment (Table 7) revealed a film thickness varying from 0.18 ± 0.02 mm to 0.25 ± 0.03 mm, with a folding endurance surpassing 120 folds, which indicates robust mechanical strength. A surface pH of 6.4–6.8 confirmed buccal compatibility, and the swelling index was recorded between 72–83%, demonstrating appropriate hydration capacity. The films showed quick disintegration times of 28–36 seconds (Figure 9; Table 8), indicating their effectiveness for immediate release in the oral cavity without the need for water. An in vitro dissolution test was conducted in 0.1 N HCl at a temperature of 37 ± 0.5 °C, utilizing the USP Apparatus I (basket method). The optimized ODF (F6) released 85.4% of the extract within 6 minutes, compared to only 52.8% released from the crude extract suspension in the same duration (Figure 10). The swift dissolution from ODFs is attributed to the hydrophilic polymer HPMC, which enhances wettability along with a uniform distribution of phytoconstituents, and the inclusion of sodium starch glycolate that aids in hydration and film disintegration. These findings demonstrate that the formulated ODFs not only exhibit appropriate mechanical and disintegration

characteristics but also ensure rapid and efficient release of *C. ternatea* antioxidants, thereby supporting immediate pharmacological action and enhanced bioavailability (30,36).

Figure 9: In vitro Disintegration Test

Table 7: Physicochemical evaluation of *Clitoria ternatea* oral thin films (F1–F6)

S.NO	Disintegration method	Time (seconds)
1.	Slide frame method	30 sec
2.	Petri-dish method	23.5 sec

Table 8: Result of In-vitro disintegration test

Formulation	Visual Appearance	Thickness /mm	Folding endurance (n)	Surface PH	Swelling index %
F1	Semi-translucent	0.08 ± 0.01	160 ± 5	6.2 ± 0.1	10.11 ± 0.4
F2	Transparent, peelable	0.04 ± 0.01	120 ± 4	6.7 ± 0.2	48.32 ± 1.2
F3	Transparent, peelable	0.06 ± 0.01	140 ± 3	6.3 ± 0.1	33.33 ± 0.9
F4	Transparent, peelable	0.08 ± 0.01	120 ± 4	6.4 ± 0.1	29.31 ± 1.0
F5	Transparent, peelable	0.07 ± 0.01	110 ± 3	6.4 ± 0.1	30.00 ± 0.8
F6	Transparent, peelable	0.05 ± 0.01	120 ± 5	6.4 ± 0.1	43.55 ± 1.1

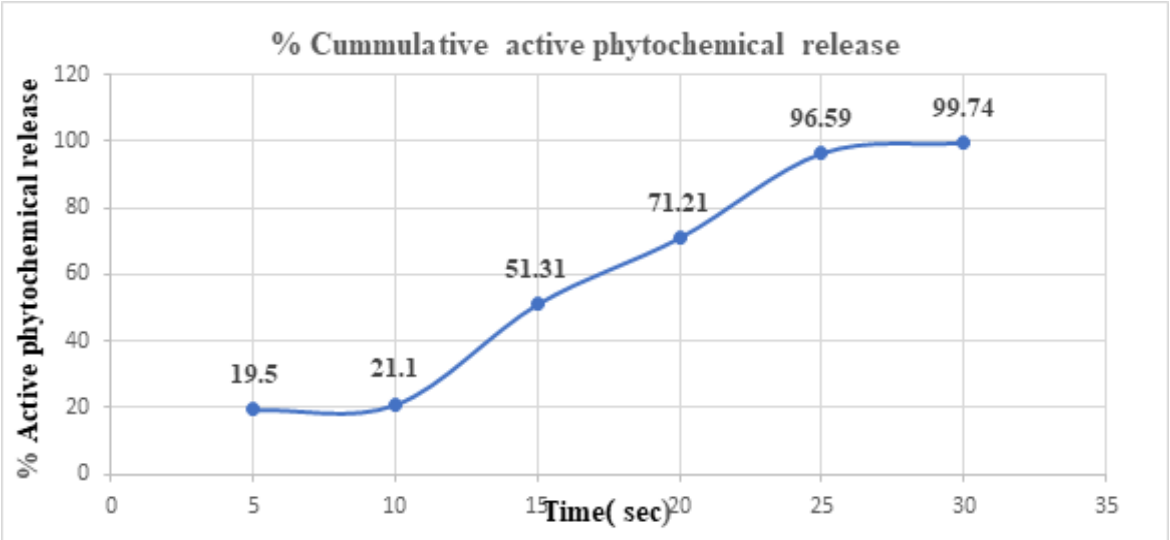


Figure 10: The active phytochemical release profile for the formulations of *Clitoria ternatea* oral thin film

4.4. Thermal and Structural Investigations

The DSC thermogram for the pure extract (Figure 11) showed a broad endothermic transition in the range of 110–130 °C, which is associated with moisture evaporation, followed by a sharp peak around 220 °C that signifies the degradation of polyphenols. In the ODF thermogram, these peaks were notably broadened and shifted, indicating molecular dispersion and a lack of phase separation (37,41). The XRD patterns (Figure 12) displayed distinct crystalline peaks in the extract that were substantially reduced in the ODF, suggesting partial amorphization and enhanced solubility (40,41). This transition to an amorphous state facilitates dissolution and could improve the bioavailability of antioxidant components. Previous studies have highlighted similar structural changes in polymer-based film formulations that contain flavonoid-rich extracts(21,46).

4.5. UV–Visible Spectral Analysis

The UV–Vis absorption spectrum of the *C. ternatea* extract (Figure 13 (a)) revealed a strong λmax at 586 nm, confirming the presence of anthocyanin chromophores. The ODF spectrum (Figure 13(b)) exhibited the same λmax, indicating that the core phytochemical constituents remained chemically stable throughout the formulation process (43). There were no observed spectral shifts or additional peaks, which confirms the absence of degradation or interactions between the polymer and the drug.

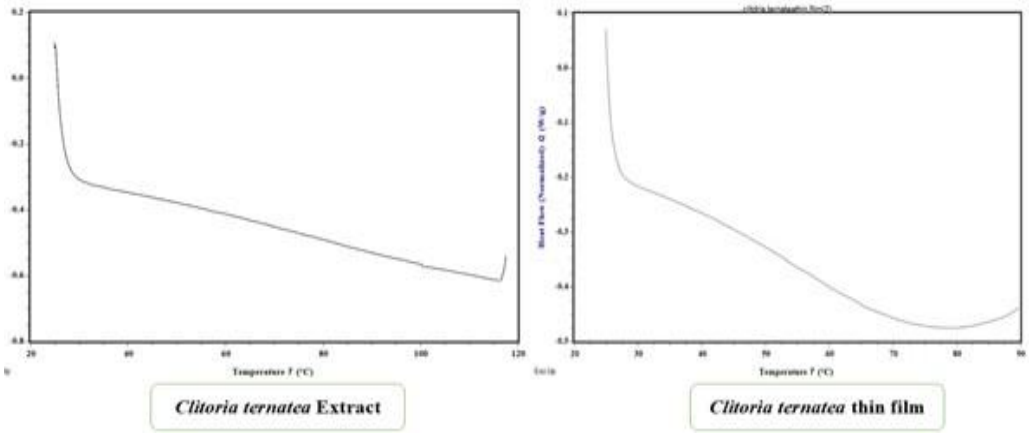


Figure 11: DSC for *Clitoria ternatea* extract and oral thin film

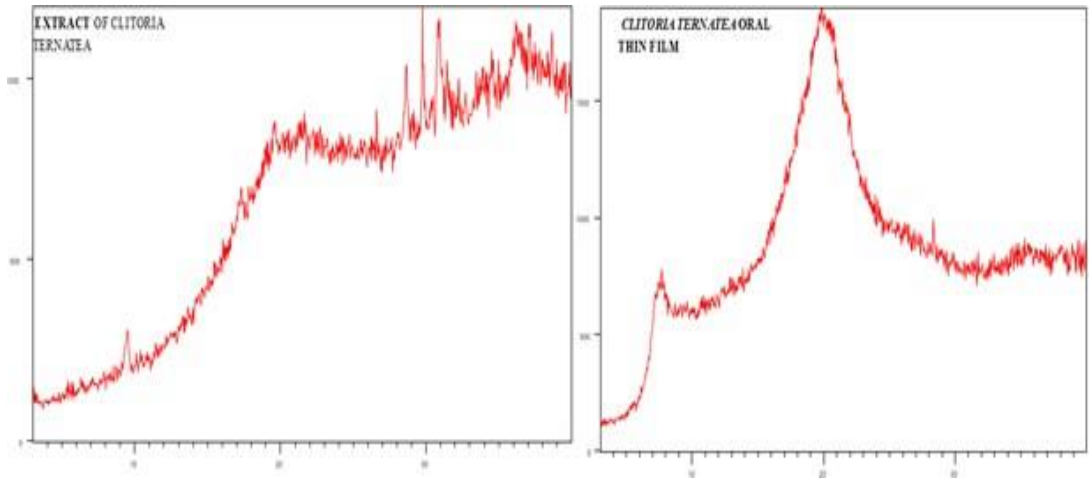
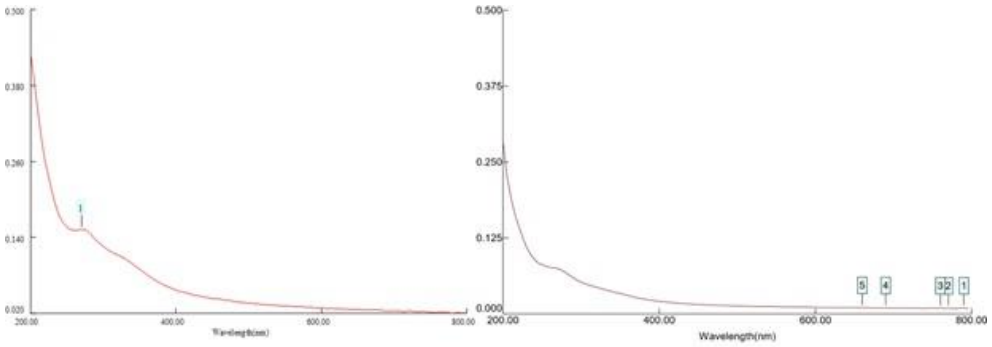


Figure 12: X-ray Diffractograms of *Clitoria ternatea* oral thin film and *Clitoria ternatea* extract



13(a) 13(b)

Figure 13: UV spectrum of *Clitoria ternatea* extract and oral thin film

4.6. Integrated Discussion

The results from the phytochemical, antioxidant, thermal, and structural assessments (Tables 4–8; Figures 5-13) collectively demonstrate that *Clitoria ternatea* ODFs retain the bioactive characteristics of the extract and show strong antioxidant efficacy comparable to the crude extract. The films exhibited uniformity, quick disintegration, and mechanical strength, promoting patient convenience and efficient drug release. Incorporating C. ternatea into ODFs offers a novel, user-friendly method for delivering natural antioxidants via the buccal route. These findings align with other research on herbal ODFs, supporting the viability of this delivery method for phytoconstituents with limited solubility and bioavailability (21,46). The developed ODF system serves as an effective link between traditional herbal treatments and contemporary drug delivery technologies.

5. CONCLUSION

This study effectively created and assessed Orodispersible films (ODFs) containing *Clitoria ternatea* extract as an innovative phytopharmaceutical formulation for antioxidant therapy. The films showed excellent physical and mechanical properties, rapid disintegration, and high folding endurance, suggesting favorable handling and acceptance by patients. Spectroscopic (UV–Vis), thermal (DSC), and X-ray diffraction analyses demonstrated molecular dispersion and compatibility between the extract and polymer components, ensuring the formulation's stability. The ODFs displayed significant in vitro antioxidant activity akin to that of the pure extract, with a slight increase in radical scavenging and reducing power, confirming that the phytochemical efficacy was retained after the formation of the films. Integrating C. ternatea extract into an ODF format thus offers a contemporary, patient-friendly method for delivering natural antioxidants with enhanced solubility and bioavailability. In summary, this research lays a promising groundwork for the development of C. ternatea ODFs as a fast-dissolving herbal dosage form for addressing conditions related to oxidative stress. Future research should aim at conducting in vivo pharmacokinetic studies, stability assessments, and clinical validation to apply these findings in therapeutic settings.

Declarations

Ethics approval: Not applicable

Availability of data: The data utilized in this study can be obtained from the corresponding author upon reasonable request.

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Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work, the author(s) used Grammarly, Inc. to check the grammar and Turnitin to check the plagiarism. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the publication.

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