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FORMULATION AND EVALUATION OF ORAL FAST DISSOLVING FILMS OF RHODIOLA ROSEA AND L – THEANINE FOR DEPRESSION MANAGEMENT

Ifarah Kazi*, Satish Katale, Samiksha Koparde, Mrs. Swati A. Patil

Assistant Professor Shree Saraswati Institute of Pharmacy, Tondavali, Kankavli.

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***Corresponding Author**
Ifarah Kazi
Assistant Professor Shree Saraswati Institute of Pharmacy, Tondavali, Kankavli.

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ABSTRACT

The present study aimed to develop and evaluate oral fast dissolving films (OFDFs) containing Rhodiola rosea and L-theanine for improved patient compliance and rapid drug release in depression management. Oral fast dissolving films were prepared by the solvent casting method using Hydroxypropyl methylcellulose (HPMC) as a film-forming polymer and glycerine as a plasticizer. Different formulation batches were prepared by varying the concentrations of polymer and plasticizer to obtain optimized oral fast dissolving films. The prepared formulations were evaluated for thickness, folding endurance, transparency, surface pH, swelling index, moisture absorption, moisture loss, content uniformity, disintegration time and in vitro drug release. The prepared films exhibited satisfactory physicochemical and mechanical characteristics. Among all formulations, batch F5 demonstrated the most desirable performance with a thickness of 0.06 mm, folding endurance of 230, surface pH of 6.5 and disintegration time of 17 seconds. The optimized formulation also showed a swelling index of 65.00%, moisture absorption of 5.00%, moisture loss of 2.50% and drug content uniformity of 99.0%. In vitro dissolution studies revealed approximately 98% drug release within 15 minutes, indicating rapid drug release behavior. The findings of the study suggest that oral fast dissolving films containing Rhodiola rosea and L-theanine may serve as a promising and patient-friendly drug delivery system for the management of depression and stress-related conditions. The optimized formulation demonstrated rapid disintegration, satisfactory stability and enhanced drug release characteristics, supporting its

potential application in fast oral delivery systems.

KEYWORDS: Depression, Oral Fast Dissolving Films, Nootropic Agents, Preformulation Studies, Formulation, Evaluation.

1. INTRODUCTION

1.1 Introduction to the disease

Depression is a serious and multifactorial psychiatric disorder characterized by persistent sadness, emotional instability, reduced interest in daily activities and impaired cognitive function. It is one of the most common mental health disorders worldwide and significantly affects social behavior, occupational performance and overall quality of life.[1,2] The disorder is commonly associated with symptoms such as anxiety, sleep disturbances, fatigue, lack of concentration and feelings of hopelessness. In severe cases, depression may adversely affect physical health and increase the risk of chronic medical conditions.

The pathophysiology of depression is complex and involves disturbances in neurotransmitters such as serotonin, dopamine and norepinephrine, along with psychological, environmental and genetic factors.[3,4] Stress, hormonal imbalance and altered neuronal signaling are also considered important contributors to the progression of depressive disorders. Although several synthetic antidepressant drugs are available for clinical treatment, their prolonged use is often associated with limitations including delayed onset of action, adverse effects, drug dependence and poor patient compliance.[5]

In recent years, increasing attention has been directed towards natural and herbal therapeutic agents because of their improved safety profile, reduced side effects and neuroprotective potential.[6] Natural bioactive compounds possessing adaptogenic, anxiolytic and antidepressant properties may provide an alternative approach for the management of stress-related neurological disorders. Therefore, the development of effective and patient-friendly drug delivery systems containing herbal bioactive agents has become an important area of pharmaceutical research.

1.2 Introduction to the oral films

Oral fast dissolving films (OFDFs) are thin, flexible polymeric dosage forms designed to rapidly disintegrate or dissolve in the oral cavity without the need for water.[7,8] These formulations provide rapid drug release and improved patient convenience due to their fast

hydration and disintegration properties.

Mechanism of Oral Fast Dissolving Films

The mechanism of OFDFs involves rapid absorption of saliva by hydrophilic polymers present in the film matrix, resulting in swelling, disintegration and subsequent drug release.[9] The large surface area of the films enhances wetting and facilitates faster dissolution of the incorporated drug.

Types of Oral Films

- Oral films are classified based on drug release behavior.
- Flash release films (fast dissolving films) dissolve rapidly within seconds.
- Mucoadhesive/sustained release films provide prolonged drug action by adhering to mucosa.
- Gastro-retentive films are formulated for extended gastric residence.[10,15]

Flash release films are preferred for rapid therapeutic effect and are used in the present formulation.[10,15]

Key Properties of OFDFs

- Uniform drug distribution ensures accurate and consistent dosing.[15]
- Rapid disintegration occurs within a few seconds upon contact with saliv.[13]
- Adequate mechanical strength is required to withstand handling and packaging.[14]
- Pleasant taste and mouthfeel are essential for better compliance.[10]
- Moisture stability is necessary to maintain film integrity during storage.[15]

Mechanism of Drug Release

- Absorption of saliva by the polymer matrix leading to hydration.[13]
- Swelling of the film, increasing surface area.[15]
- Rapid disintegration of the film structure.[10]
- Dissolution of the drug in saliva.[14]
- Absorption through oral mucosa or after swallowing.[13]

Advantages

- Rapid onset of action due to fast disintegration and dissolution.[10,13]
- Improved patient compliance, especially in pediatric, geriatric and psychiatric patients.[14]

- No need for water, making administration convenient.[10]
- Potential to bypass first-pass metabolism, enhancing bioavailability.[13]
- Ease of administration in patients with swallowing difficulties.[15]

Limitations

- Limited drug loading capacity, restricting use for high-dose drugs.[10]
- Sensitivity to moisture, requiring specialized packaging.[15]
- Taste masking difficulties, particularly for bitter drugs.[10]
- Mechanical fragility if formulation is not optimized.[14]
- Uniformity challenges during large-scale manufacturing.[15]

Drug Selection Criteria

- Low dose drugs are most suitable (generally small quantities required).[10]
- Good solubility in saliva ensures rapid dissolution.[13]
- Acceptable taste or ease of taste masking is necessary.[10]
- Requirement of rapid onset of action favors OFDF formulation.[13]
- Drugs with significant first-pass metabolism.[13]
- Adequate permeability across oral mucosa enhances effectiveness.[15]

Traditional dosage forms like tablets and capsules may create problems such as difficulty in swallowing, delayed drug action and low patient compliance, particularly among elderly, pediatric and psychiatric patients.[11] Oral fast dissolving films (OFDFs) have emerged as an innovative alternative for antidepressant drug delivery because they dissolve rapidly in the mouth and provide quick drug release.[12] These films can improve bioavailability and may reduce first-pass metabolism, resulting in faster therapeutic action.[9,11] OFDFs are convenient to use since they do not require water and are easy to carry and administer discreetly, which helps improve patient adherence.[7,9,10] After coming in contact with saliva, the film rapidly hydrates, disintegrates and releases the drug for absorption through the oral mucosa or gastrointestinal tract.[7,8] Therefore, OFDFs offer a patient-friendly and effective approach for improving treatment adherence and therapeutic outcomes in depression management.[10,12]

Previous studies have reported that oral fast dissolving films formulated using hydrophilic polymers exhibit rapid disintegration, improved drug release and enhanced patient compliance, making them suitable for immediate drug delivery applications.[15,16]

1.3 Introduction to the drugs: Introduction to Nootropics

Nootropics, commonly referred to as "cognitive enhancers" or "smart drugs," are substances that improve mental functions such as memory, learning ability, concentration and overall cognitive performance.[17] These agents act by modulating neurotransmitter systems, enhancing cerebral circulation and protecting neurons from oxidative stress.[18]

These plant based compounds often exhibit neuroprotective, antioxidant and adaptogenic properties, making them useful in the management of cognitive impairment and neurodegenerative disorders.[18]

1.3.1 Rhodiola rosea

Synonyms

Rhodiola rosea is commonly known as golden root, Arctic root and rose root due to the characteristic fragrance of its roots.[18]

Family

Rhodiola rosea belongs to the family Crassulaceae and is widely distributed in cold mountainous regions of Europe and Asia.[18]

Phytoconstituents

The major bioactive constituents present in Rhodiola rosea include rosavin, salidroside, flavonoids, tyrosol and phenolic compounds.[19] These phytoconstituents are reported to contribute significantly to its adaptogenic, neuroprotective and antidepressant activities.

Mechanism of Action

The antidepressant and adaptogenic effects of Rhodiola rosea are mainly associated with modulation of neurotransmitters such as serotonin, dopamine and norepinephrine.[19] It has also been reported to reduce stress-induced fatigue and improve cognitive performance by influencing neuronal signaling pathways and stress response mechanisms.

Pharmacological Activities

Rhodiola rosea exhibits several pharmacological properties including antidepressant, anxiolytic, neuroprotective, anti-fatigue and antioxidant activities.[19] Due to these therapeutic effects, it has gained considerable attention as a potential natural agent for the management of stress-related neurological disorders.

Several studies have demonstrated the antidepressant, adaptogenic and neuroprotective potential of Rhodiola rosea in stress-related neurological disorders.[18,19]

1.3.2 L – Theanine

Synonyms

L-theanine is also known as γ-glutamylethylamide and N-ethyl-L-glutamine.[20]

Family

L-theanine is primarily obtained from the leaves of Camellia sinensis belonging to the family Theaceae.[20]

Morphology

L-theanine is a naturally occurring non-protein amino acid predominantly present in green tea leaves. It is a water-soluble compound responsible for the characteristic umami taste of green tea.[20]

Pharmacological Activities

L-theanine possesses several pharmacological activities including anxiolytic, neuroprotective, anti-stress and cognitive enhancing properties.[21] In addition, it may improve concentration, reduce anxiety and support emotional well-being, making it a promising bioactive agent for stress and depression management.

Several studies have demonstrated the antidepressant, adaptogenic and neuroprotective potential of Rhodiola rosea in stress-related neurological disorders.[18,19]

1.3.3 Combination Therapy

The combination of Rhodiola rosea and L-theanine may provide synergistic therapeutic benefits due to their complementary adaptogenic, anxiolytic and neuroprotective activities. Rhodiola rosea primarily contributes to stress resistance and antidepressant activity, while L-theanine promotes relaxation and emotional balance.[18–21] Therefore, incorporation of these bioactive agents into oral fast dissolving films may offer a patient-friendly and rapidly acting formulation for the management of depression and stress-related disorders.

Therefore, the present study was designed to formulate and evaluate oral fast dissolving films containing Rhodiola rosea and L-theanine using the solvent casting method. Different formulation batches were prepared and evaluated to optimize the physicochemical properties,

disintegration behavior and in vitro drug release characteristics of the films.

2. MATERIALS AND PROPOSED METHODOLOGY

2.1 Materials

Table. 1.1 Materials

Sr.no.	Ingredients	Category
1	Rhodiola Rosea	Therapeutic agent
2	L- Theanine	Therapeutic agent
3	Hydroxy propyl methyl cellulose	Polymer
4	Glycerine	Palsticizer
5	Sucrose	Sweetening agent
6	Peppermint oil	Flavouring agent
7	Citric Acid	Saliva stimulant
8	Crosspovidone	Disintegrants
9	Distilled water	Vehicle

1. Active Pharmaceutical Ingredient (API)

The active pharmaceutical ingredient is responsible for producing the desired therapeutic effect in oral fast dissolving films. Selection of a suitable drug depends on factors such as low dose requirement, good aqueous solubility, stability in saliva and rapid onset of action. Drugs used in the management of stress and depression, such as Rhodiola rosea and L-theanine are considered suitable candidates due to their compatibility with oral film delivery systems.[26, 28]

2. Film-Forming Polymer

Hydroxypropyl methylcellulose (HPMC) is used as a film-forming polymer due to its excellent film-forming ability, hydrophilic nature, and rapid hydration characteristics. It provides mechanical strength and facilitates quick disintegration of the film upon contact with saliva.[29]

3. Plasticizer

Glycerine is incorporated as a plasticizer to enhance flexibility and reduce brittleness of the film. It improves mechanical properties such as elasticity and tensile strength by decreasing intermolecular forces between polymer chains.[29]

4. Sweetening Agent

Sucrose is added as a sweetening agent to improve the palatability of the formulation and mask the unpleasant taste of the drug. Sweeteners play an important role in enhancing patient

compliance, especially since the dosage form dissolves in the oral cavity.[26,27]

5. Flavoring Agent

Peppermint oil is used as a flavoring agent to enhance taste and provide a pleasant mouthfeel. It also helps in masking drug bitterness, thereby improving overall acceptability.[26,27]

6. Saliva Stimulating Agent

Citric acid is incorporated to stimulate saliva production which promotes rapid hydration and disintegration of the film, leading to faster drug release.[26,27]

7. Disintegrant

Crospovidone is used as a superdisintegrant to enhance the rate of film disintegration by improving wettability and porosity of the film matrix.[26,29]

8. Vehicle

Distilled water is used as a solvent for the preparation of the film to ensure uniform distribution of all ingredients.[26]

3.2. Preformulation Studies

1. Organoleptic Properties

The initial evaluation of the drug substance involves the assessment of organoleptic characteristics such as colour, odour and physical appearance. These properties provide a preliminary indication of the identity and purity of the drug and help in detecting any visible impurities or degradation. Such evaluation is simple yet essential before proceeding with further analytical studies.[30] Similar preliminary assessments are routinely recommended in oral film formulation studies to ensure consistency and quality of the drug substance.[31]

2. Melting Point Determination

Melting point analysis was carried out using the capillary method to determine the purity and crystalline nature of the drug. A sharp and narrow melting range indicates a high degree of purity, whereas any deviation may suggest the presence of impurities. This parameter also serves as an important reference for identifying possible changes during formulation development.[33] Melting point evaluation is widely used in preformulation as a reliable indicator of drug stability and compatibility.[33]

3. Solubility Studies

Solubility studies were performed in different solvents such as water, ethanol and methanol to understand the dissolution behavior of the drug. The drug was found to be more soluble in organic solvents than in aqueous media, indicating its poor water solubility. This information is critical for selecting suitable formulation strategies to enhance drug release and bioavailability.[31,32] Such solubility assessment is particularly important in the development of oral films, where rapid dissolution is required for effective drug delivery.[32]

3.3 Formulation Batches

Table. 1.2 Formulation Batches.

Ingredients	F1	F2	F3	F4	F5
L- theanine (mg)	25	25	25	25	25
Rhodiola rosea (mg)	50	50	50	50	50
HPMC (gm)	2.5	3.5	3	3	3
Glycerin (ml)	1	1	0.5	1.5	1
CPV (gm)	0.15	0.15	0.15	0.15	0.15
Citric Acid (gm)	0.1	0.1	0.1	0.1	0.1
Sucrose (gm)	0.5	0.5	0.5	0.5	0.5
Peppermint Oil (ml)	0.15	0.15	0.15	0.15	0.15

Oral fast dissolving film formulations F1–F5 were prepared by varying the concentrations of polymer and plasticizer while keeping the drug concentration constant. Lower concentrations of HPMC resulted in thinner films with relatively lower mechanical strength and faster disintegration, whereas higher polymer concentrations produced thicker films with improved structural integrity and altered disintegration behavior. Variations in glycerin concentration influenced film flexibility, smoothness and folding endurance. Formulation F5 was prepared using optimized concentrations of polymer and plasticizer to achieve a balanced combination of mechanical strength, flexibility and disintegration properties. Other excipients including crospovidone, citric acid, sucrose and peppermint oil were maintained constant in all formulations to ensure uniformity in taste, flavor and auxiliary characteristics.[33,34,35]

3.4 METHODOLOGY

Solvent Casting Method

The solvent casting method is one of the most widely employed techniques for the preparation of oral fast dissolving films (OFDFs) due to its simplicity, uniform film formation and suitability for heat-sensitive drugs [27,36]. The method involves preparation of a homogeneous polymeric solution containing the active pharmaceutical ingredient and

excipients, followed by casting and controlled drying to obtain thin films.

1. Selection of Materials

Suitable film-forming polymers such as HPMC were selected based on film-forming ability, compatibility and disintegration characteristics. Plasticizers and other excipients including sweeteners, flavoring agents and disintegrants were incorporated to improve flexibility, palatability and film performance.[27,36]

2. Preparation of Polymeric Solution

The required quantity of polymer was accurately weighed and dispersed in distilled water under continuous stirring until a clear and uniform polymeric solution was obtained.

3. Incorporation of Plasticizer and Excipients

Plasticizer and other excipients were added sequentially to the polymeric solution with continuous stirring to ensure uniform distribution throughout the formulation.[27,36]

4. Drug Incorporation

Rhodiola rosea extract and L-theanine were dissolved or dispersed in a suitable solvent and gradually incorporated into the polymeric mixture with continuous stirring to obtain a homogeneous solution.

5. Removal of Entrapped Air

The prepared solution was allowed to stand undisturbed to remove entrapped air bubbles and obtain a uniform casting solution.

6. Casting of Film

The prepared solution was poured onto a suitable flat surface and uniformly spread to achieve consistent film thickness.[27,36]

7. Drying Process

The cast films were dried under controlled conditions until complete solvent evaporation occurred, resulting in thin and flexible films.[27,36]

8. Film Removal and Cutting

After drying, the films were carefully peeled off and cut into suitable dimensions to obtain uniform dosage units.

9. Storage

The prepared films were stored in airtight containers or moisture-resistant packaging to protect them from environmental moisture and maintain stability.[27,36]

3. EVALUATION TEST

1. Thickness

The thickness of the fast dissolving film was determined using a micrometer screw gauge or vernier caliper by taking measurements at different points across the film surface. Uniform thickness is important to ensure dose accuracy and reproducibility of the film.[36,37]

Thickness = Main Scale Reading (MSR) + (Vernier Scale Reading (VSR) × Least Count)

2. Folding Endurance

Folding endurance was determined by repeatedly folding the film at the same position until it broke or developed visible cracks. The number of folds required to break the film was recorded as the folding endurance value. A higher folding endurance indicates good flexibility and mechanical strength.[36,37]

3. Transparency

Transparency of the film was evaluated using a UV spectrophotometer by measuring the transmittance at 600 nm. Transparent films indicate uniform distribution of drug and excipients within the formulation.[36,37]

Transparency = $\log T_{600} / b = -\varepsilon c$

Where: T_{600} = Transmittance at 600 nm

b = Thickness of the film (mm)

c = Concentration

4. Disintegration Test

The disintegration test was carried out to determine the time required for the film to disintegrate in a suitable medium simulating oral cavity conditions. Fast dissolving films are generally expected to disintegrate within 5–30 seconds.[36,37,39]

5. Surface pH

Surface pH was determined to ensure compatibility with the oral mucosa and to avoid irritation. The film was allowed to swell on distilled water and the pH was measured using a pH electrode or pH paper. Ideally, the surface pH should be close to neutral.[36,37]

6. Swelling Index

Swelling behavior of the film was evaluated by placing a pre-weighed film in distilled water and measuring the increase in weight at specific time intervals.[36,37]

Swelling Index (%) = $[(Wt - W_0) / W_0] \times 100$ Where: W_0 = Initial weight of film

Wt = Weight of swollen film at time t

7. Percentage Moisture Absorption

Percentage moisture absorption was determined by placing the films in a desiccator containing a saturated salt solution under high humidity conditions and recording the weight change after a specified period.[36,37]

% Moisture Absorption = [(Final weight − Initial weight) / Initial weight] × 100

8. Percentage Moisture Loss

Percentage moisture loss was evaluated by storing the film in a desiccator containing anhydrous calcium chloride and measuring the weight difference after a specified period.[36,37]

% Moisture Loss = [(Initial weight − Final weight) / Initial weight] × 100 This study indicates the stability and brittleness of the film under dry conditions.

9. Content Uniformity

Content uniformity was evaluated by randomly selecting films from each batch and analyzing the drug content using a suitable analytical method such as UV–Visible spectrophotometry. The drug content was expressed as a percentage of the labeled claim to confirm uniform drug distribution and dose accuracy.[36,37,40]

10. Dissolution Test

The dissolution test was performed to evaluate the rate and extent of drug release from the film using a suitable dissolution medium and pharmacopoeial dissolution apparatus. Proper method optimization was carried out to obtain reliable drug release data.[36,37,38]

4. RESULT AND DISCUSSION

4.1 Preformulation Studies

1. Organoleptic Properties

Table 1.3 Organoleptic properties.

Organoleptic Properties	Rhodiola Rosea	L - Theanine
Colour	Light brown to Reddish brown	White to off - white
Odour	Characterisic	Odourless
Taste	Slightly Bitter	Slightly Sweet

The organoleptic properties of Rhodiola rosea and L - theanine were found to be satisfactory and suitable for formulation of oral fast dissolving films.

2. Melting Point Determination

Table. 1.4 Melting Point Determination.

Drug	Melting Point
Rhodiola Rosea	165°C
L - Theanine	212°C

The observed melting points of Rhodiola rosea and L- theanine were found within the reported range, confirming their purity and suitability for formulation.

3. Solubility Studies

Table. 1.5 Solubility Studies.

Drug	Solubility Studies
Rhodiola Rosea	Partially Soluble
L - Theanine	Freely Soluble

The solubility studies indicated that L – theanine exhibited good aqeous solubility whereas Rhodiola rosea showed partial solubility characteristics.

4.2 Evaluation

Table. 1.6 Result And Discussion.

Evaluation Parameters	F1	F2	F3	F4	F5
Thickness (mm)	0.06	0.08	0.07	0.05	0.06
Folding Endurance	220	300	260	240	230
Transparency	32.17	38.96	27.91	39.22	32.78
Disintegration Test (sec)	40	60	48	80	17
Surface pH	6.5	7	6.0	5.5	6.5
Swelling Index	46.15 %	51.21 %	42.10 %	54.76 %	65.00 %
Percentage Moisture Absorption	15.38 %	14.63 %	13.16 %	9.52 %	5.00 %
Percentage Moisture Loss	7.69%	7.32%	5.26 %	4.76 %	2.50 %
Content Uniformity	95.8 %	102.6 %	97.2 %	103.4 %	99.0 %

The evaluation results demonstrated that all prepared oral fast dissolving film formulations possessed acceptable physicochemical and mechanical characteristics. Thickness values ranged from 0.05–0.08 mm, indicating uniform film formation and dose distribution. Folding endurance values confirmed adequate flexibility and mechanical strength of the films, suggesting their suitability for handling and packaging. Surface pH values were found to be

within the acceptable oral range, indicating compatibility with the oral mucosa and minimal risk of irritation. The swelling index increased progressively among the formulations, with F5 exhibiting the highest swelling behavior (65.00%), which contributed to rapid hydration and disintegration. Moisture absorption and moisture loss studies indicated satisfactory stability of all formulations, while the optimized batch F5 showed the lowest moisture absorption (5.00%) and moisture loss (2.50%), suggesting improved storage stability. Drug content uniformity values were within acceptable limits, confirming uniform distribution of the active ingredients throughout the film matrix. Among all formulations, F5 demonstrated the most desirable overall performance owing to its balanced mechanical properties, rapid disintegration, enhanced swelling behavior, satisfactory drug content uniformity, and improved stability characteristics, thereby indicating its suitability as the optimized formulation for oral fast dissolving film delivery.

5.3. In Vitro Dissolution study

Table. 1.7 Dissolution Test.

Time (min)	F1	F2	F3	F4	F5
2	20	18	22	25	30
4	35	32	38	42	50
6	48	45	52	58	70
8	60	58	66	72	85
10	72	70	78	85	95
15	85	82	88	92	98

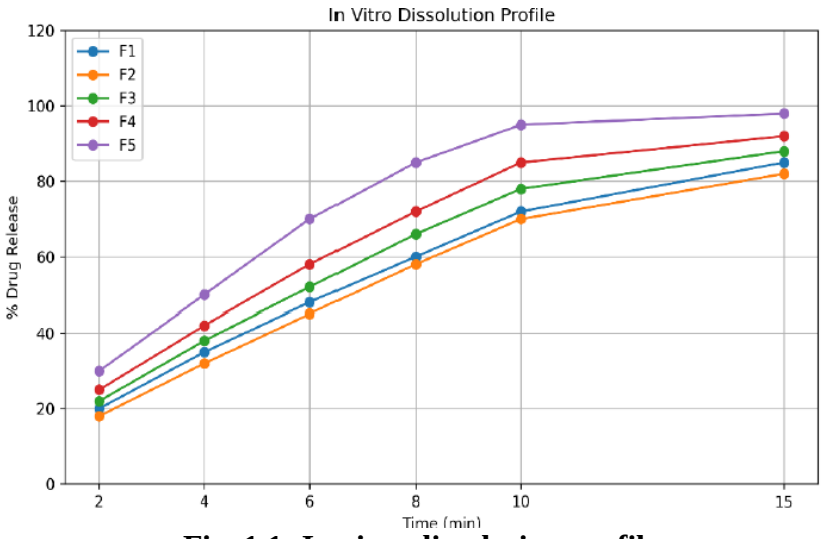

Fig. 1.1: In vitro dissolution profile.

The in vitro dissolution study demonstrated a progressive increase in drug release from all oral fast dissolving film formulations with increasing time. Among the prepared batches,

formulation F5 exhibited the highest drug release profile, achieving approximately 98% drug release within 15 minutes, whereas F1, F2, F3, and F4 showed comparatively lower release rates. The enhanced dissolution behavior of F5 may be attributed to the optimized concentration of HPMC and glycerin, which promoted rapid hydration, swelling, and disintegration of the film matrix. The faster drug release observed in F5 indicates efficient dissolution of the active ingredients and improved availability for absorption. Overall, the dissolution results confirmed that formulation F5 possessed superior release characteristics and was identified as the optimized formulation for rapid oral drug delivery in depression management.

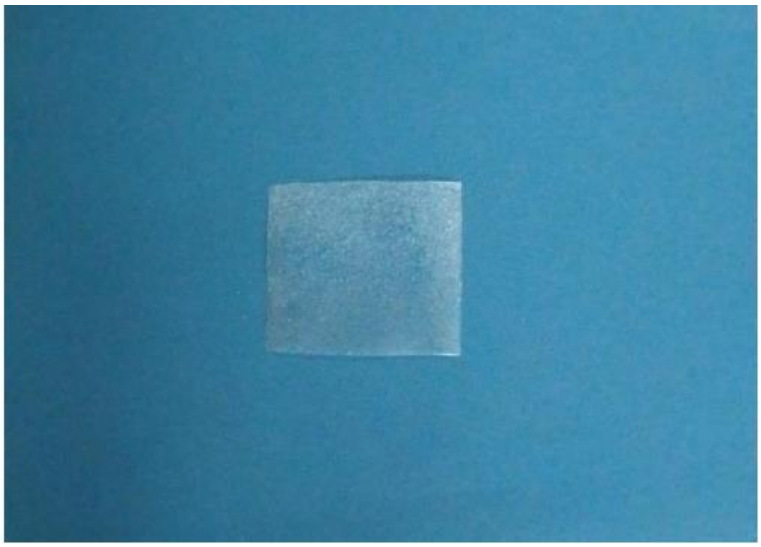

Fig. 1.2: Oral fast dissolving film.

Based on the overall evaluation parameters and in vitro dissolution studies, formulation F5 was identified as the optimized batch among all the prepared formulations. The formulation exhibited satisfactory thickness (0.06 mm), good folding endurance (230), acceptable surface pH (6.5), highest swelling index (65.00%), lowest moisture absorption (5.00%), lowest moisture loss (2.50%), and excellent drug content uniformity (99.0%). Furthermore, F5 demonstrated the shortest disintegration time (17 seconds) and the highest in vitro drug release (98% within 15 minutes), indicating rapid hydration, efficient disintegration, and enhanced drug release characteristics. These findings suggest that formulation F5 possesses the most desirable physicochemical, mechanical, and dissolution properties, making it the most suitable formulation for oral fast dissolving film delivery of Rhodiola rosea and L-theanine for depression management.

5. CONCLUSION

The present study successfully developed and evaluated oral fast dissolving films containing Rhodiola rosea and L-theanine using the solvent casting method. The prepared formulations exhibited satisfactory physicochemical properties, mechanical strength, surface pH and drug content uniformity. Variations in polymer and plasticizer concentrations significantly influenced film characteristics, disintegration behavior and drug release profile.

Among all formulations, batch F5 was identified as the optimized formulation due to its rapid disintegration, enhanced swelling behavior, lower moisture absorption and moisture loss, and superior in vitro drug release profile. The optimized formulation demonstrated satisfactory stability, flexibility and approximately 98% drug release within 15 minutes, indicating its suitability for rapid oral drug delivery.

The combination of Rhodiola rosea and L-theanine in oral fast dissolving film form may provide a convenient and patient-friendly approach for depression and stress-related disorder management. The developed formulation offers advantages such as ease of administration, improved patient compliance and faster onset of action compared to conventional oral dosage forms.

Overall, the findings suggest that oral fast dissolving films represent a promising delivery system for natural bioactive agents and may contribute to the development of effective therapeutic formulations for neurological and psychological disorders.

Further studies involving stability analysis, in vivo evaluation and clinical investigations are required to establish the therapeutic efficacy, safety and commercial applicability of the developed formulation. Future formulation approaches may also focus on advanced polymers, taste-masking strategies and large-scale manufacturing techniques to improve patient acceptability and industrial feasibility.

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