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PHARMACEUTICAL FORMULATION AND CHARACTERIZATION OF EUCALYPTUS OIL LOADED FAST DISSOLVING ORAL FILMS EMPLOYING DIVERSE POLYMERIC BASES

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Keywords:

Eucalyptus oil, fast dissolving film, HPMC, solvent casting, disintegration time

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ABSTRACT: Background: Fast-dissolving oral films (FDFs) represent a modern drug delivery system designed to disintegrate rapidly in the mouth without water, making them highly suitable for pediatric and geriatric populations. Eucalyptus oil, rich in 1,8-cineole, is utilized for its antimicrobial, anti-inflammatory, and soothing effects on oral and respiratory conditions. Integrating this essential oil into an FDF platform ensures a rapid onset of action and improves patient compliance for managing respiratory relief. **Objective:** The primary goal of this study was to formulate and characterize eucalyptus oil-loaded FDFs and evaluate the impact of different hydrophilic polymer types and their concentrations on the films' physicomechanical properties. **Methods:** Twelve formulations (F1 to F12) were prepared using the solvent casting technique. The study utilized four polymers at varying concentrations: HPMC E5, PVA, NaCMC, and PVP K30. Eucalyptus oil loading (5% w/w), PEG 400 as a plasticizer (15% w/w), and Tween 80 as a surfactant were maintained across formulations. The films were characterized for appearance, thickness, folding endurance, surface pH, moisture content, tensile strength, and disintegration time. **Key Results:** All films were smooth and flexible, with surface pH values (6.5–6.9) compatible with oral mucosa. Increasing polymer concentration led to a proportional rise in thickness (0.060 to 0.115 mm) and tensile strength (1.23 to 3.61 MPa). HPMC-based films exhibited superior folding endurance (up to 300 ± 12), while NaCMC films showed the fastest disintegration (minimum 20 ± 3s). Formulation F2 (HPMC E5 2.5%) was identified as optimal, featuring uniform thickness (0.076 mm), high folding endurance (265 ± 10), and rapid disintegration (26 ± 3s). **Conclusion:** The study concludes that polymer selection and concentration significantly influence FDF performance. HPMC E5 at 2.5% provides the ideal balance of mechanical integrity and rapid drug release. These films offer a stable and patient-compliant delivery platform for eucalyptus oil in treating mild respiratory infections.

INTRODUCTION: Fast-dissolving oral films (FDFs) are a cutting-edge drug delivery platform designed to disintegrate within seconds in the oral cavity without requiring water. This technology is particularly significant for pediatric and geriatric patients who often face challenges with swallowing conventional dosage forms.

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While various FDFs have been developed, there is a specific need for efficient delivery systems for natural essential oils that can provide immediate relief for respiratory and oral ailments [1, 5]. Eucalyptus oil, primarily composed of 1, 8-cineole, possesses potent antimicrobial, anti-inflammatory, and analgesic properties, making it highly effective

for treating sore throats, nasal congestion, and respiratory infections. However, incorporating volatile oils into a stable, fast-dissolving solid matrix presents a challenge, as these oils can affect the mechanical integrity and brittleness of the film [2].

The rationale for this research lies in bridging the gap between the therapeutic benefits of eucalyptus oil and the need for a rapid-onset, patient-compliant delivery system. Since the physicochemical and mechanical attributes of FDFs are governed by the choice of film-forming polymers, this study systematically explores the performance of HPMC, PVA, NaCMC, and PVP K30. By evaluating how polymer type and concentration influence parameters like disintegration time and tensile strength, this research identifies an optimal formulation to ensure effective delivery and mechanical stability.

MATERIALS AND METHODS [4]:

Materials: Eucalyptus oil, Hydroxy propyl methylcellulose E5 (HPMC E5), Poly Vinyl Alcohol (PVA), Sodium Carboxy methyl cellulose (NaCMC), Polyvinylpyrrolidone K-30 (PVP K30), Polyethylene glycol 400 (PEG 400), Tween 80, and analytical grade ethanol were procured from standard suppliers. All reagents used were of analytical grade.

Experimental Design: Twelve formulations (F1 to F12) were designed by varying polymer type and concentration while maintaining constant eucalyptus oil loading (5% w/w of polymer) and PEG 400 (15% w/w of polymer). The solvent system used was distilled water: ethanol (80:20 v/v).

Preparation of Films: Films were prepared using the solvent casting method. The polymer was dissolved in distilled water (and heated to 50°C for PVA). Eucalyptus oil was emulsified with Tween 80 and PEG 400, then incorporated into the polymer solution. The mixture was degassed, poured into glass molds, and dried at 40°C. Films were peeled, cut into 2×2 cm strips, and stored in desiccators.

Evaluation Parameters:

Appearance: Transparent, smooth, and uniform films are critical for patient acceptability and indicate proper polymer oil compatibility. Any phase separation could suggest incompatibility of eucalyptus oil with the film matrix.

Thickness and Weight Variation: Ensures uniform distribution of eucalyptus oil and consistent dosing in each film. Minimal variation avoids under or over dosing, which is important for therapeutic efficacy and safety.

Folding Endurance: Reflects the flexibility and mechanical strength of the films. Fast dissolving films containing volatile oils like eucalyptus may become brittle, high folding endurance ensures they can withstand handling and packaging without breaking.

Surface pH: Maintaining a pH between 6.5 to 7.0 prevents oral mucosal irritation and ensures patient comfort, especially since essential oils can sometimes cause local sensitivity.

Moisture Content: Proper moisture content is critical to prevent volatilization or loss of eucalyptus oil, maintain stability, and avoid microbial growth.

Disintegration Time: Fast-dissolving films must disintegrate quickly in the oral cavity to release eucalyptus oil efficiently, ensuring rapid onset of therapeutic effect (e.g., for respiratory relief).

Tensile Strength: Adequate mechanical strength is needed to prevent film rupture during handling, storage, and transportation while still allowing rapid dissolution when administered.

TABLE 1: PHYSICOCHEMICAL AND MECHANICAL CHARACTERIZATION OF EUCALYPTUS OIL FAST DISSOLVING FILMS PREPARED WITH DIFFERENT POLYMER BASES AND CONCENTRATIONS

Formulation	Thickness (mm)	Weight (mg)	Folding Endurance (folds)	Surface pH	Moisture Content (%)	Disintegration Time (seconds)	Tensile Strength (MPa)
F1 (HPMC 1.5%)	0.062 ± 0.003	46.2 ± 1.8	210 ± 8	6.7 ± 0.1	3.8 ± 0.2	21 ± 2	1.81 ± 0.07
F2 (HPMC 2.5%)	0.076 ± 0.004	58.5 ± 2.4	265 ± 10	6.8 ± 0.1	4.2 ± 0.2	26 ± 3	2.13 ± 0.09
F3 (HPMC 3.5%)	0.092 ± 0.005	71.1 ± 3.0	300 ± 12	6.9 ± 0.1	4.9 ± 0.3	37 ± 4	2.51 ± 0.11

F4 (PVA 3.0%)	0.085 ± 0.004	65.4 ± 2.6	240 ± 9	6.6 ± 0.1	4.6 ± 0.2	42 ± 5	2.34 ± 0.09
F5 (PVA 5.0%)	0.097 ± 0.003	78.9 ± 3.1	195 ± 10	6.6 ± 0.1	4.8 ± 0.3	59 ± 6	3.15 ± 0.10
F6 (PVA 7.0%)	0.115 ± 0.006	95.2 ± 4.2	180 ± 12	6.5 ± 0.1	5.5 ± 0.3	80 ± 5	3.61 ± 0.12
F7 (NaCMC 0.5%)	0.060 ± 0.002	44.8 ± 1.6	225 ± 7	6.8 ± 0.1	3.2 ± 0.2	20 ± 3	1.23 ± 0.05
F8 (NaCMC 1.0%)	0.072 ± 0.004	55.3 ± 2.0	240 ± 9	6.9 ± 0.1	3.9 ± 0.2	32 ± 3	1.84 ± 0.06
F9 (NaCMC 1.5%)	0.083 ± 0.005	67.6 ± 2.8	210 ± 11	6.9 ± 0.1	4.4 ± 0.3	48 ± 4	2.25 ± 0.08
F10 (PVP K30 2%)	0.070 ± 0.004	53.2 ± 2.2	280 ± 10	6.7 ± 0.1	3.6 ± 0.2	28 ± 3	1.62 ± 0.07
F11 (PVP K30 4%)	0.081 ± 0.004	64.7 ± 2.5	290 ± 12	6.8 ± 0.1	4.0 ± 0.2	36 ± 4	1.94 ± 0.06
F12 (PVP K30 6%)	0.093 ± 0.005	79.4 ± 3.6	255 ± 11	6.8 ± 0.1	4.3 ± 0.3	47 ± 5	2.15 ± 0.09

Note: Values are mean ± SD (n = 3). Thickness measured at five points per strip with a digital micrometer. Weight measured using an analytical balance. Folding endurance determined by manual folding method. Surface pH measured by moistening the film with 1 mL distilled water and using a calibrated pH electrode. Moisture content determined by loss on drying at 105°C until constant weight.

RESULTS AND DISCUSSION:

Physical Appearance and Uniformity: All the prepared Eucalyptus oil fast dissolving films (F1 to F12) were visually uniform, smooth, and flexible with no visible cracks or air bubbles. The colour of the films slightly varied based on polymer type HPMC based films appeared transparent to translucent, while PVA and NaCMC films showed a slight opacity. The films were easily peelable from Petri dishes, indicating appropriate plasticizer incorporation and solvent casting uniformity.

Thickness and Weight Variation: The thickness of the films ranged from 0.060 ± 0.002 mm (F7) to 0.115 ± 0.006 mm (F6), with corresponding weight variation between 44.8 ± 1.6 mg (F7) and 95.2 ± 4.2 mg (F6) **Table 1.** An increase in polymer concentration resulted in a proportional rise in both thickness and weight due to increased solid content in the film forming solution. HPMC and PVP films showed good uniformity (RSD < 5%), suggesting homogenous dispersion of solids and controlled solvent evaporation during film formation. These results align with literature reports where increased polymer content directly affects the film matrix density and weight uniformity (Singh *et al.,* 2021).

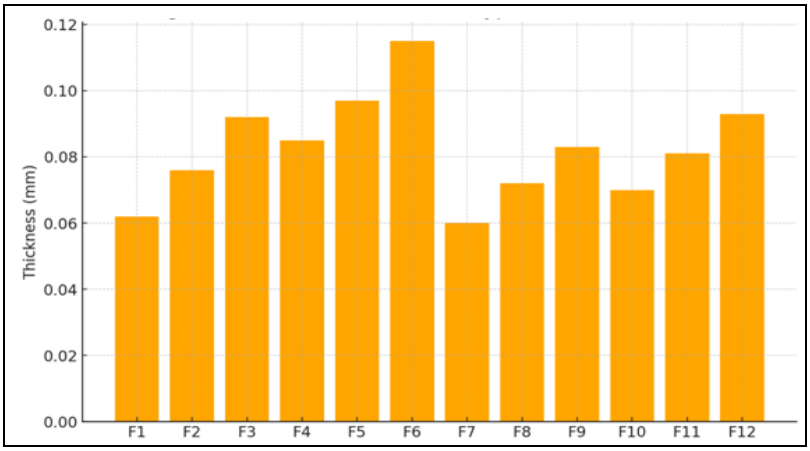

FIG. 1: THICKNESS OF FORMULATIONS (F1 TO F12)

Folding Endurance: The folding endurance values **Table 1** ranged from 180 ± 12 (F6) to 300 ± 12 (F3) **Table 1** folds, indicating satisfactory flexibility and mechanical strength of the films. HPMC based films (F1 to F3) exhibited the highest folding endurance due to their strong hydrogen bonding capability and good film forming characteristics. In contrast, PVA based films (F4 to F6) showed slightly lower endurance, which may be attributed to their higher brittleness at increased polymer concentrations. NaCMC and PVP based formulations also demonstrated good flexibility (≥200 folds), confirming the plasticizer's effectiveness (PEG 400) in maintaining film integrity. The data indicate that an optimum polymer to plasticizer ratio is crucial to achieve both strength and flexibility for oral handling.

Surface pH: The surface pH of all formulations was within the range 6.5 ± 0.1 to 6.9 ± 0.1 **Table 1,** which is close to the neutral pH of saliva. This ensures the films are non-irritant and safe for oral

mucosal application. No significant difference was observed among formulations, suggesting that neither polymer type nor concentration altered the surface pH considerably.

Moisture Content: The moisture content of films varied between 3.2 ± 0.2% (F7) and 5.5 ± 0.3% (F6) **Table 1.** Moisture retention was slightly higher in PVA based formulations, likely due to PVA's hygroscopic nature. Adequate moisture is essential for maintaining film flexibility, but excessive moisture can reduce film strength and shelf stability. The results indicate that all formulations maintained acceptable moisture levels within the ideal range (<6%) for oral films.

Disintegration Time: Disintegration time ranged from 20 ± 3 s (F7) to 80 ± 5 s (F6) **Table 1**. Films containing lower polymer concentrations (F1, F7 and F10) disintegrated rapidly within 20 to 30 seconds, while those with higher polymer loads exhibited delayed disintegration due to the denser matrix.

Among polymers, NaCMC films (F7 to F9) showed the fastest disintegration, attributed to NaCMC's hydrophilic and swelling properties. In contrast, PVA films disintegrated slower because of their semi-crystalline nature, which resists water penetration.

Overall, formulations F1 (HPMC 1.5%) and F7 (NaCMC 0.5%) showed the most desirable balance of mechanical integrity and rapid disintegration ideal for oral fast-dissolving delivery systems.

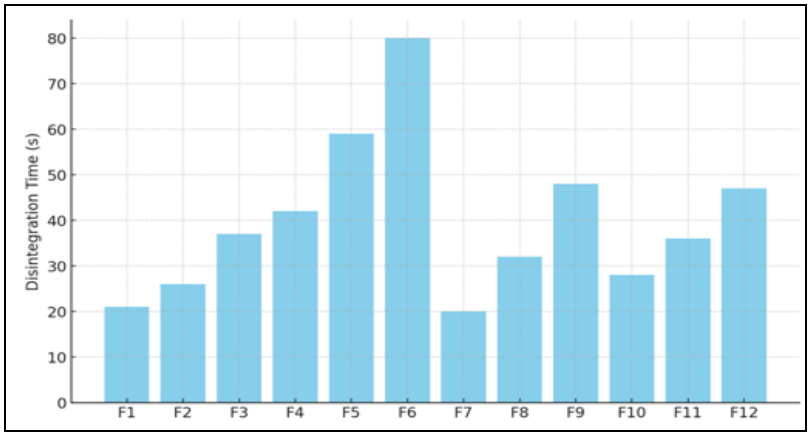

FIG. 2: DISINTEGRATION TIME OF FORMULATIONS (F1 TO F12)

Tensile Strength: The tensile strength of the films ranged between 1.23 ± 0.05 MPa (F7) and 3.61 ± 0.12 MPa (F6) **Table 1.** A clear trend was observed: tensile strength increased with polymer concentration. PVA films exhibited the highest tensile strength due to strong intermolecular hydrogen bonding and cohesive film structure, while NaCMC films were comparatively weaker. The moderate tensile strength of HPMC and PVP films indicates an optimal balance between strength and flexibility, making them easier to handle and package.

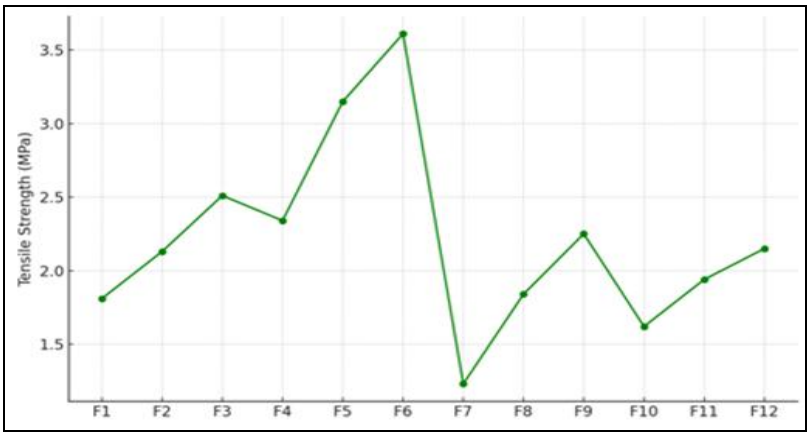

FIG. 3: TENSILE STRENGTH OF FORMULATIONS (F1 TO F12)

Correlation of Polymer Type and Concentration with Film Properties:

From the combined analysis of parameters:

- **HPMC based films** demonstrated excellent flexibility and mechanical strength with moderate disintegration time.
- **PVA based films** showed high tensile strength and thickness but slower disintegration, indicating suitability for sustained release systems.
- **NaCMC based films** exhibited the fastest disintegration but relatively lower tensile strength, suitable for rapid drug release formulations.
- **PVP based films** maintained a balance of flexibility and disintegration time, making them ideal candidates for fast-dissolving oral applications.

Statistical Analysis: A one way ANOVA ($p < 0.05$) indicated significant differences among formulations in terms of thickness, weight, and disintegration time, confirming that polymer concentration significantly influences the physicochemical characteristics of the films.

- Polymer type and concentration significantly influenced film thickness, tensile strength, and disintegration time ($p< 0.05$).
- HPMC 2.5% (F2) and NaCMC 0.5 to 1.0% (F7 to F8) achieved optimal balance of strength and disintegration.
- Correlation analysis indicated that as tensile strength increased, disintegration time also increased.
- No significant difference was observed in surface pH among formulations ($p> 0.05$).

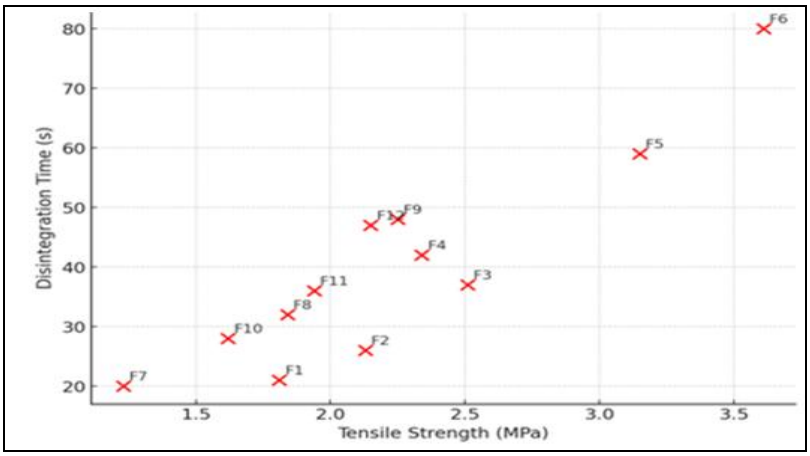

FIG. 4: CORRELATION OF DISINTEGRATION TIME AND TENSILE STRENGTH OF FORMULATIONS (F1 TO F12)

CONCLUSION: This study successfully developed eucalyptus oil-loaded fast-dissolving films using a solvent casting method. The research demonstrates that polymer type and concentration are the primary determinants of film performance.

HPMC E5 at a 2.5% w/w concentration (F2) emerged as the optimal formulation, providing a superior balance of mechanical strength (2.13 ± 0.09 MPa), high folding endurance (265±10), and rapid disintegration (26±3s). While NaCMC offered the fastest disintegration, it exhibited brittleness at higher concentrations. Conversely, PVA produced dense matrices better suited for sustained release. These findings establish a patient-compliant platform for the rapid delivery of essential oils to treat respiratory and oral infections. Future research should prioritize in vitro release kinetics, antimicrobial efficacy, and sensory evaluation to further validate the clinical potential of these formulations.

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CONFLICTS OF INTEREST: Nil

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