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FORMULATION AND *IN-VITRO* EVALUATION OF FOSINOPRIL FAST DISSOLVING FILMS

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Abstract

Objective: The present study was undertaken to develop fast dissolving oral films of fosinopril with the aim of enhancing patient compliance and achieving rapid drug release. Oral films provide an attractive alternative to conventional solid dosage forms, particularly for pediatric, geriatric, and dysphagic patients.

Methods: Fast dissolving oral films containing fosinopril were prepared by the solvent casting technique using different film-forming polymers, namely guar gum, xanthan gum, hydroxypropyl methylcellulose (HPMC E6), and polyvinyl alcohol (PVA). Eight formulations (F1–F8) were designed by varying polymer concentrations. Compatibility between the drug and excipients was investigated using Fourier Transform Infrared (FTIR) spectroscopy. The prepared films were evaluated for weight variation, thickness, tensile strength, folding endurance, disintegration time, mouth dissolving time, drug content, and in vitro drug release characteristics.

Results: All formulations exhibited satisfactory physicomechanical properties and acceptable drug content uniformity. Folding endurance values ranged from 32 ± 2.08 to 46 ± 3.60 folds, indicating adequate flexibility and mechanical resistance. Among the prepared formulations, F5 containing 2% w/v HPMC E6 demonstrated the most desirable characteristics with a disintegration time of 33.33 ± 3.05 seconds and a mouth dissolving time of 40.66 ± 3.04 seconds. The formulation showed a maximum drug release of 97.2% and maintained its stability under accelerated and long-term storage conditions.

Conclusion: The findings suggest that fast dissolving oral films of fosinopril can be successfully prepared by the solvent casting method. The optimized formulation exhibited rapid drug release, satisfactory mechanical properties, and good stability, making it a promising alternative to conventional oral dosage forms.

KEYWORDS: Fosinopril, Fast Dissolving Oral Film, Solvent Casting, HPMC E6, Drug Release, Patient Compliance.

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1. INTRODUCTION:

Oral drug delivery remains the most widely accepted and convenient route of administration because of its ease of use, patient acceptance, and cost-effectiveness [1]. Conventional tablets and capsules account for a significant proportion of marketed pharmaceutical products. However, many patients, particularly pediatric and geriatric populations, experience difficulty in swallowing solid oral dosage forms [2]. This condition, commonly known as dysphagia, can result in poor patient compliance and reduced therapeutic effectiveness.

To overcome these limitations, fast dissolving drug delivery systems have gained considerable attention [3]. These formulations rapidly disintegrate or dissolve in the oral cavity without the need for water, thereby enhancing convenience and improving adherence to therapy [4]. Among the various fast dissolving systems, oral thin films have emerged as a promising platform owing to their flexibility, ease of administration, accurate dosing, and rapid onset of action [5].

Fosinopril is an angiotensin-converting enzyme (ACE) inhibitor widely used in the management of hypertension and heart failure [6]. Although effective, patient compliance may be compromised when conventional dosage forms are administered to individuals with swallowing difficulties [7]. Incorporation of fosinopril into a fast dissolving oral film may provide faster drug release and improved patient acceptability [8].

The present study was therefore designed to formulate and evaluate fast dissolving oral films of fosinopril using different film-forming polymers and to identify an optimized formulation with desirable mechanical and drug release properties [9].

2. MATERIALS AND METHODS:

2.1 Materials

Fosinopril was used as the model drug. Hydroxypropyl methylcellulose (HPMC E6), polyvinyl alcohol (PVA), guar gum, and xanthan gum were employed as film-forming polymers. Sodium starch glycolate (SSG) was used as a superdisintegrant, polyethylene glycol 400 (PEG 400) as a plasticizer, vanillin as a flavoring agent, and sodium saccharin as a sweetening agent. All chemicals and reagents used in the study were of analytical grade.

2.2 Preparation of Fast Dissolving Oral Films

Fast dissolving oral films were prepared by the solvent casting method [10]. The required quantity of polymer was accurately weighed and dispersed in distilled water [11]. The polymer solution was allowed to hydrate overnight to obtain a clear and uniform dispersion [12].

Fosinopril, sodium starch glycolate, vanillin, and sodium saccharin were dissolved separately in a suitable quantity of distilled water [13]. The drug solution was gradually incorporated into the hydrated polymer solution under continuous stirring using a magnetic stirrer for one hour [14]. PEG 400 was added as a plasticizer and mixed thoroughly to obtain a homogeneous casting solution.

The resulting solution was allowed to stand for sufficient time to remove entrapped air bubbles [15]. The bubble-free solution was cast onto a clean Petri dish and dried at room temperature for 24 hours [16]. After complete drying, the films were carefully peeled from the casting surface and visually inspected for imperfections [17]. Films of dimensions 1.5 cm × 1.5 cm (2.25 cm^2) were cut and stored in aluminum foil-lined butter paper within a desiccator until further evaluation. The composition of various oral thin film formulations was shown in table 1

2.3 Drug–Polymer Compatibility Studies

Compatibility studies between fosinopril and the selected excipients were carried out using Fourier Transform Infrared (FTIR) spectroscopy [18]. The spectra of pure drug and physical mixtures were compared to identify any significant shifts, disappearance, or appearance of characteristic peaks that could indicate chemical interactions .

Table 1 Composition of various oral thin film formulations

S no	Ingredients (mg/film)	F1	F2	F3	F4	F5	F6	F7	F8
1	Fosinopril	10	10	10	10	10	10	10	10
2	Guar gum*	0.4	0.7	-	-	-	-	-	-
3	Xantham gum*	-	-	0.4	0.7	-	-	-	-
4	HPMC E6*	-	-	-	-	2	3		
5	PVA*	-	-	-	-	-	-	2	3
6	SSG	2	2	2	2	2	2	2	2
7	PEG 400**	20	20	20	20	20	20	20	20
8	Vaniline	1	1	1	1	1	1	1	1
9	Sodium sacharine	1	1	1	1	1	1	1	1
10	Water	qs	qs	qs	qs	qs	qs	qs	Qs

2.4 Evaluation of Oral Films

The prepared films were evaluated for the following parameters [19]

- Physical appearance
  Weight variation
  Thickness
  Tensile strength
  Folding endurance
  Disintegration time
  Mouth dissolving time
  Drug content uniformity

- In vitro drug release

2.5 In Vitro Drug Release Study

Drug release studies were performed using phosphate buffer pH 6.8 as the dissolution medium. Samples were withdrawn at predetermined intervals and analyzed spectrophotometrically [20]. The cumulative percentage drug release was calculated and compared among all formulations.

3. RESULTS AND DISCUSSION:

FTIR studies demonstrated that the characteristic peaks of fosinopril were retained in the spectra of the drug–polymer mixtures. No significant changes in peak position or intensity were observed, indicating the absence of chemical interactions between the drug and formulation excipients.

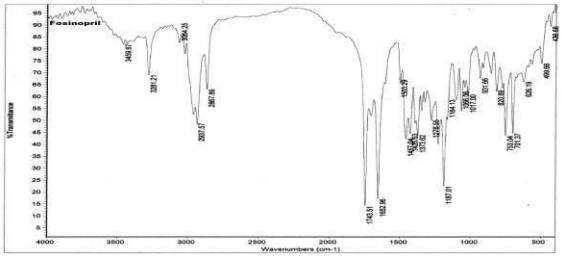


Fig:1 Drug- polymer compatibility studies by FTIR

All prepared films were smooth, flexible, and free from visible defects such as air bubbles, cracks, or surface irregularities. The films exhibited acceptable weight variation and thickness, indicating uniform distribution of formulation components throughout the casting solution.

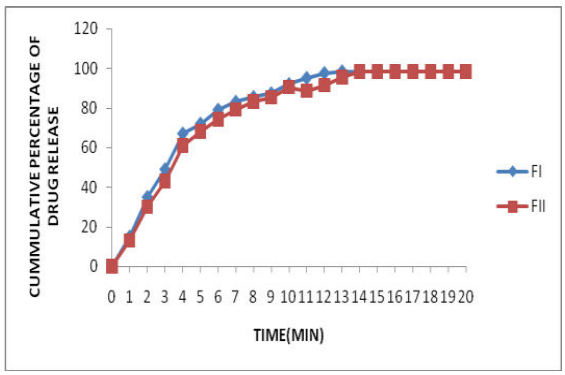
The tensile strength of the formulations ranged from 1.80 ± 0.01 MPa to 4.32 ± 0.02 MPa. An increase in polymer concentration generally resulted in improved tensile strength owing to enhanced intermolecular interactions within the film matrix. Folding endurance values ranged from 32 ± 2.08 to 46 ± 3.60 folds, suggesting satisfactory flexibility and resistance to mechanical stress during handling.

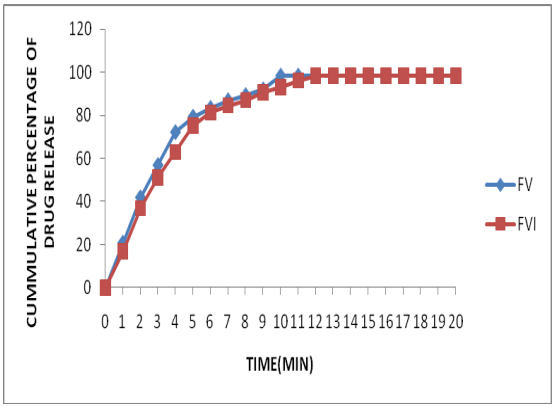
Disintegration and mouth dissolving times varied depending on the type and concentration of polymer employed. Films containing higher polymer concentrations required a comparatively longer time to disintegrate because of increased matrix density. Nevertheless, all formulations disintegrated within an acceptable time frame suitable for oral fast dissolving systems.

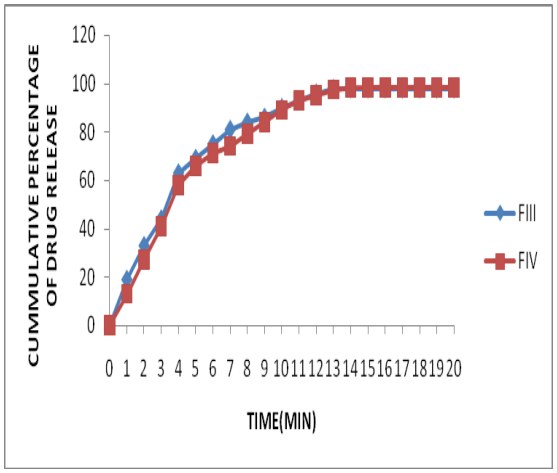
Drug content analysis revealed uniform distribution of fosinopril throughout the films, with values ranging between 94.4% and 99.4%. This confirmed the effectiveness of the solvent casting process in achieving content uniformity.

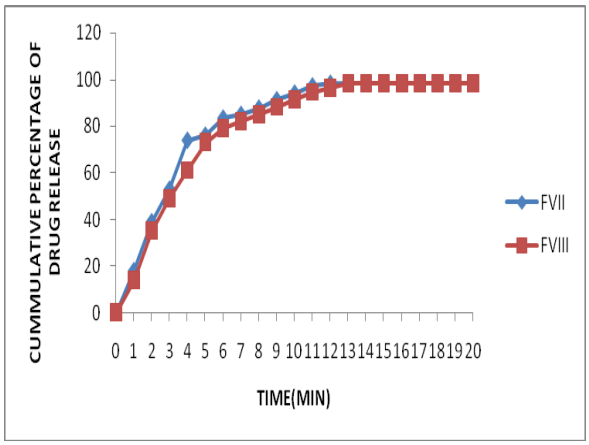
Among all formulations, F5 containing 2% w/v HPMC E6 exhibited the most favorable balance between mechanical strength and rapid disintegration. The formulation showed a disintegration time of 33.33 ± 3.05 seconds and a mouth dissolving time of 40.66 ± 3.04 seconds. In vitro dissolution studies demonstrated rapid release of fosinopril, with a cumulative drug release of 97.2%.

Dissolution profile of Oral fast dissolving films F1-F2









The superior performance of formulation F5 may be attributed to the hydrophilic nature of HPMC E6, which facilitates rapid hydration, swelling, and dissolution of the film matrix upon contact with saliva.

4. STABILITY STUDIES

The optimized formulation (F5) was subjected to stability studies under accelerated and long-term storage conditions. The formulation was evaluated periodically for physical appearance, drug content, disintegration time, and in vitro drug release.

No significant changes were observed in any of the evaluated parameters throughout the study period. These findings indicate that the formulation possesses satisfactory stability and retains its performance characteristics during storage.

5. CONCLUSION:

Fast dissolving oral films of fosinopril were successfully developed using the solvent casting method. The prepared films exhibited satisfactory physicomechanical properties, acceptable drug content uniformity, and rapid drug release characteristics. FTIR analysis confirmed compatibility between the drug and excipients employed in the formulation.

Among the evaluated formulations, F5 containing 2% w/v HPMC E6 demonstrated the most desirable characteristics, including rapid disintegration, adequate tensile strength, good folding endurance, and enhanced drug release. Stability studies further confirmed the robustness of the optimized formulation.

The developed fast dissolving oral film system represents a promising alternative to conventional oral dosage forms and may offer improved convenience, faster onset of action, and enhanced patient compliance, particularly in pediatric, geriatric, and dysphagic populations.

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