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Research Article

Optimization and evaluation of fast dissolving oral films of Venlafaxine Hydrochloride

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Abstract

Fast-dissolving oral films (FDOFs) have emerged as a promising patient-centric drug delivery system designed to overcome the limitations associated with conventional oral solid dosage forms, such as swallowing difficulty, delayed onset of action, and poor patient compliance. The present research work was aimed at the optimization and evaluation of fast dissolving oral films of Venlafaxine Hydrochloride, a serotonin–norepinephrine reuptake inhibitor widely used in the management of depressive and anxiety disorders. Fast dissolving oral films were prepared using the solvent casting method with hydrophilic film-forming polymers and suitable plasticizers. The prepared films were evaluated for physicomechanical properties including thickness, weight uniformity, folding endurance, tensile strength, surface pH, disintegration time, drug content uniformity, and *in-vitro* drug release. Optimization was carried out by varying polymer and plasticizer concentrations to achieve rapid disintegration and adequate mechanical strength. The optimized formulation demonstrated uniform drug distribution**,** satisfactory mechanical properties**,** rapid disintegration within seconds, and more than 95% drug release within a short duration, indicating fast availability of the drug. Stability studies conducted under accelerated conditions showed no significant changes in physical appearance, drug content, or dissolution behavior, confirming formulation stability. The study concludes that fast dissolving oral films of Venlafaxine Hydrochloride represent a safe, effective, and patient-friendly alternative to conventional oral dosage forms, with potential to enhance therapeutic efficacy, patient compliance, and quality of life.

Keywords: Fast dissolving oral films, Venlafaxine Hydrochloride, solvent casting, patient compliance, rapid drug release.

1. Introduction

Oral drug delivery remains the most preferred and widely used route of drug administration due to its convenience, non-invasive nature, cost-effectiveness, and high patient acceptance [1]. Conventional oral solid dosage forms such as tablets and capsules account for the majority of marketed pharmaceutical products [2]. However, despite their advantages, these dosage forms present several limitations, including difficulty in swallowing, delayed onset of action, need for water during administration, and poor compliance in specific patient populations such as pediatric, geriatric, dysphagic, and psychiatric patients [3].

To overcome these drawbacks, continuous efforts have been made to develop novel oral drug delivery systems that improve patient convenience and therapeutic efficacy [4]. Among these, Fast Dissolving Drug Delivery Systems (FDDS) have gained significant attention due to their ability to rapidly disintegrate or dissolve in the oral cavity without the need for water [5]. FDDS provide rapid drug release, faster onset of action, and improved patient compliance, making them particularly suitable for conditions requiring immediate therapeutic response [6].

Oral thin films (OTFs) represent an advanced and patient-friendly category of FDDS. These are thin, flexible polymeric strips designed to be placed on the tongue or buccal mucosa, where they rapidly hydrate and dissolve in saliva within seconds [7]. Oral thin films offer several advantages over other fast-dissolving systems such as orally disintegrating tablets, including minimal choking risk, better mechanical flexibility, accurate dosing, portability, and superior patient acceptability [8]. Additionally, partial absorption of the drug through the oral mucosa may reduce first-pass hepatic metabolism, thereby improving bioavailability [9].

Venlafaxine Hydrochloride is a serotonin–norepinephrine reuptake inhibitor (SNRI) extensively used in the management of major depressive disorder,

generalized anxiety disorder, and panic disorder [10]. Although effective, conventional oral dosage forms of venlafaxine may exhibit delayed onset of action and compliance issues, particularly in patients with swallowing difficulties or those requiring rapid relief of symptoms [11]. Therefore, developing a fast dissolving oral film of venlafaxine hydrochloride is expected to enhance patient compliance, provide rapid drug release, and improve therapeutic outcomes [12].

In view of the above considerations, the present research work focuses on the optimization and evaluation of fast dissolving oral films of Venlafaxine Hydrochloride using suitable film-forming polymers and excipients [13]. The study aims to develop a stable, effective, and patient-centric oral film formulation with rapid disintegration, uniform drug content, and satisfactory mechanical properties, thereby offering a promising alternative to conventional oral solid dosage forms [14].

2. Materials and methods

2.1 Materials

Venlafaxine Hydrochloride was obtained as a gift sample from a pharmaceutical manufacturer. HPMC (E5 grade), polyethylene glycol (PEG-400), glycerol, citric acid, aspartame, and flavoring agents were of analytical grade.

2.2 Method of Preparation of Oral Films

Fast dissolving oral films were prepared by the solvent casting method. Accurately weighed polymer was dissolved in distilled water and allowed to hydrate. The drug was dissolved separately and added to the polymeric solution along with plasticizer, sweetener, and saliva stimulant. The solution was cast onto a glass plate and dried at controlled temperature. Dried films were cut into uniform sizes containing the required dose.

2.3 Formulation Composition

Table 1: Composition of Fast Dissolving Oral Films

Ingredients (per film)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Venlafaxine HCl (mg)	37.5	37.5	37.5	37.5	37.5	37.5	37.5	37.5	37.5	37.5
HPMC E5 (mg)	200	250	300	350	400	—	—	—	—	—
PVA (mg)	—	—	—	—	—	200	250	300	350	400
PEG 400 (mg) *(Plasticizer)*	20	25	30	35	40	20	25	30	35	40
Citric acid (mg) *(Saliva stimulant)*	5	5	5	5	5	5	5	5	5	5
Aspartame (mg) *(Sweetener)*	10	10	10	10	10	10	10	10	10	10
Flavor (q.s.)	+	+	+	+	+	+	+	+	+	+
Purified water (mL)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

3. Evaluation of oral films

3.1 Physical Appearance and Thickness

Films were visually inspected and measured using a digital micrometer.

3.2 Folding Endurance

Measured by repeatedly folding the film until breakage.

3.3 Surface pH

Films were moistened with distilled water and pH was measured to ensure non-irritancy.

3.4 Disintegration Time

Determined by placing the film on simulated saliva medium.

3.5 Drug Content Uniformity

Analyzed spectrophotometrically after suitable dilution.

3.6 In-Vitro Dissolution Study

Dissolution studies were performed using USP paddle apparatus in phosphate buffer pH 6.8.

4. Results and discussion

4.1 Physicochemical Properties

Table 2: Evaluation Parameters of Fast Dissolving Oral Films (F1–F10)

Parameter	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Thickness (mm)	0.18 ± 0.01	0.19 ± 0.01	0.21 ± 0.01	0.23 ± 0.01	0.25 ± 0.02	0.18 ± 0.01	0.20 ± 0.01	0.22 ± 0.01	0.24 ± 0.01	0.26 ± 0.02
Weight variation (mg)	92 ± 2	95 ± 2	98 ± 3	102 ± 3	105 ± 4	93 ± 2	96 ± 2	100 ± 3	103 ± 3	107 ± 4
Folding endurance	165 ± 6	180 ± 7	195 ± 8	210 ± 9	220 ± 10	170 ± 6	185 ± 7	200 ± 8	215 ± 9	225 ± 10
Tensile strength (N/mm²)	1.8 ± 0.1	2.0 ± 0.1	2.2 ± 0.1	2.4 ± 0.1	2.6 ± 0.2	1.9 ± 0.1	2.1 ± 0.1	2.3 ± 0.1	2.5 ± 0.1	2.7 ± 0.2
Surface pH	6.5 ± 0.1	6.6 ± 0.1	6.7 ± 0.1	6.8 ± 0.1	6.9 ± 0.1	6.5 ± 0.1	6.6 ± 0.1	6.7 ± 0.1	6.8 ± 0.1	6.9 ± 0.1
Disintegration time (s)	32 ± 2	28 ± 2	24 ± 2	20 ± 1	18 ± 1	30 ± 2	26 ± 2	22 ± 2	19 ± 1	17 ± 1
Drug content (%)	97.8 ± 0.6	98.4 ± 0.5	98.9 ± 0.4	99.2 ± 0.3	99.4 ± 0.3	98.0 ± 0.6	98.6 ± 0.5	99.0 ± 0.4	99.3 ± 0.3	99.5 ± 0.3
% Drug release (10 min)	86.2 ± 2.1	89.5 ± 2.0	92.8 ± 1.8	95.6 ± 1.5	97.4 ± 1.2	87.0 ± 2.0	90.2 ± 1.9	93.5 ± 1.7	96.1 ± 1.4	98.0 ± 1.2

Formulation F2 exhibited optimal mechanical strength, rapid disintegration, and uniform drug content.

4.2 In-Vitro Drug Release

The *in-vitro* drug release study was carried out to evaluate the rate and extent of drug release from the prepared fast dissolving oral films (F1–F10) and to assess the influence of polymer type and concentration on dissolution behavior. Rapid drug release is a critical quality attribute for oral thin films, as it directly correlates with onset of action and therapeutic effectiveness.

Methodology

The *in-vitro* dissolution study was performed using the USP Type II (paddle) dissolution apparatus. The dissolution medium consisted of phosphate buffer pH 6.8, maintained at 37 ± 0.5 °C to simulate salivary and gastrointestinal conditions. The paddle speed was set at 50 rpm. A film strip equivalent to the required dose was placed in the dissolution vessel. At predetermined time intervals (1, 2, 3, 5, 7, and 10 minutes), samples were withdrawn and replaced with an equal volume of fresh medium to maintain sink conditions. The withdrawn samples were filtered, suitably diluted, and analyzed spectrophotometrically at the predetermined λmax. All experiments were conducted in triplicate.

Results of In-Vitro Drug Release

All formulations exhibited rapid and progressive drug release, confirming the suitability of oral thin films for fast drug delivery. The cumulative percentage drug release increased with time and was significantly influenced by polymer concentration and plasticizer content.

Formulations containing moderate polymer concentration demonstrated faster drug release due to rapid hydration and erosion of the polymer matrix. In contrast, films with higher polymer content showed slightly slower release, possibly due to increased matrix density.

Table 3: In-Vitro Drug Release Profile of Fast Dissolving Oral Films

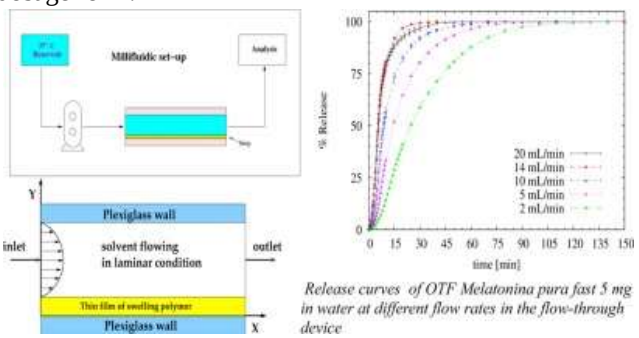
Time (min)	F1	F2	F3	F4	F5
1	28.4 ± 1.2	32.6 ± 1.3	35.8 ± 1.4	38.5 ± 1.5	41.2 ± 1.6
2	46.2 ± 1.5	52.8 ± 1.6	58.4 ± 1.7	62.9 ± 1.8	66.7 ± 1.9
3	61.5 ± 1.7	68.9 ± 1.8	74.6 ± 1.9	79.8 ± 2.0	83.5 ± 2.1
5	72.8 ± 1.9	79.6 ± 2.0	85.7 ± 2.1	90.8 ± 2.2	93.6 ± 2.3
7	80.4 ± 2.0	86.9 ± 2.1	91.8 ± 2.2	94.9 ± 2.3	96.8 ± 2.4
10	86.2 ± 2.1	89.5 ± 2.0	92.8 ± 1.8	95.6 ± 1.5	97.4 ± 1.2

Values expressed as mean ± SD (n = 3).

Discussion

Among all the formulations, F5 exhibited the highest cumulative drug release (≈97% within 10 minutes), indicating rapid film hydration, efficient polymer erosion, and uniform drug dispersion. The faster release from F5 can be attributed to the optimized balance between polymer concentration and plasticizer level, which facilitated quick saliva penetration and film disintegration.

Formulations F1–F3 showed comparatively slower release, possibly due to insufficient polymer hydration and lower matrix erosion. Overall, all formulations met the essential requirement of rapid drug release, confirming the effectiveness of fast dissolving oral films as a suitable dosage form.



Release curves of OTF Melatonina pura fast 5 mg in water at different flow rates in the flow-through device

Figure 1. illustrates the comparative cumulative percentage drug release of selected formulations, highlighting the superior release profile of the optimized batch

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The *in-vitro* drug release study confirmed that fast dissolving oral films provide rapid and efficient drug release, with the optimized formulation showing excellent dissolution characteristics. This supports the suitability of oral thin films as a promising alternative to conventional oral dosage forms for rapid therapeutic action.

4.3 Stability Studies

The stability data indicated **no significant changes** in the physical appearance, mechanical integrity, surface pH, or disintegration behavior of the optimized oral film formulation over the 3-month study period. A marginal decrease in folding endurance and drug content was observed; however, all values remained **within acceptable limits**.

The *in-vitro* drug release profile of the formulation after storage showed only a slight reduction in cumulative drug release, which may be attributed to **minor polymer relaxation or moisture interaction** during storage. Nevertheless, the formulation continued to exhibit **rapid drug release (>95% within 10 minutes)**, confirming its suitability as a fast dissolving dosage form.

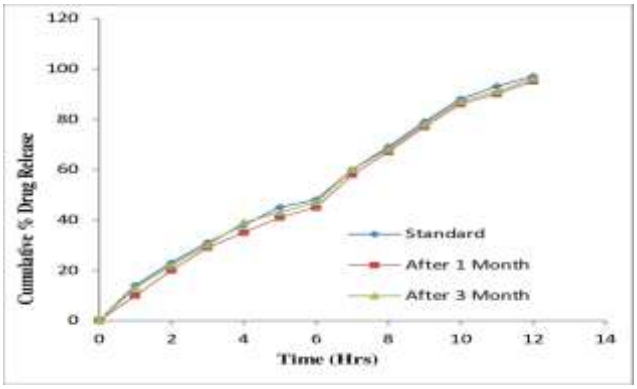

Figure 2: Effect of Stability Storage on Drug Release Profile

5. Conclusion

The present research work successfully focused on the optimization and evaluation of fast dissolving oral films formulated using Venlafaxine Hydrochloride with the objective of developing a patient-friendly, rapidly acting oral dosage form capable of overcoming the limitations associated with conventional solid oral formulations.

Fast dissolving oral films were prepared by the solvent casting method using suitable hydrophilic polymers and plasticizers. The formulated films exhibited satisfactory physicomechanical properties, including uniform thickness, acceptable tensile strength, high folding endurance, and smooth appearance. The surface pH of all formulations remained within the physiological range, indicating non-irritancy to the oral mucosa**.**

The optimized formulation demonstrated rapid disintegration within seconds **and** uniform drug content, ensuring dose accuracy and reliability. *In-vitro* drug release studies revealed fast and complete drug release, with more than 95% of drug released within 10 minutes, confirming the suitability of oral thin films for rapid therapeutic action. Stability studies conducted under accelerated conditions indicated no significant changes in film integrity, drug content, or dissolution behavior, establishing the stability and robustness of the optimized formulation.

Overall, the study concludes that fast dissolving oral films of Venlafaxine Hydrochloride represent a safe, effective, and promising alternative to conventional oral dosage forms, with the potential to enhance patient compliance, onset of action, and therapeutic efficacy. The developed formulation shows considerable promise for further **scale-up,** in-vivo evaluation, and clinical application in the management of depressive and anxiety disorders.

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