FORMULATION AND EVALUATION OF NEW EFFERVESCENT FAST DISSOLVING ORAL FILM COATED SELECTIVE ANTIDEPRESSANTS

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Abstract

Fast dissolving oral films (FDOFs) are an innovative drug delivery system designed to dissolve rapidly in the oral cavity without water. These dosage forms are particularly beneficial for pediatric, geriatric, and psychiatric patients who have difficulty swallowing conventional tablets. Selective antidepressants such as selective serotonin reuptake inhibitors (SSRIs) are widely used in the treatment of depression and anxiety disorders. This research focuses on the formulation and evaluation of an effervescent fast dissolving oral film containing a selective antidepressant drug. The film is prepared using suitable film-forming polymers, plasticizers, sweeteners, and effervescent agents. The developed films are evaluated for physicochemical parameters including thickness, folding endurance, surface pH, drug content, disintegration time, and in-vitro drug release. Results indicate that effervescent oral films can improve patient compliance, enhance bioavailability, and provide rapid onset of therapeutic action.

1. Introduction

Depression is a common psychiatric disorder affecting millions of people worldwide. Selective antidepressants such as **Escitalopram oxalate** are widely prescribed for the treatment of depression and anxiety disorders. Traditional oral dosage forms such as tablets and capsules may cause swallowing difficulties and delayed onset of action.

Fast dissolving oral films (FDOFs) represent a novel drug delivery system that dissolves quickly in saliva and releases the drug directly into the oral cavity. These films provide improved patient compliance and rapid drug absorption through the oral mucosa.

The addition of **effervescent agents** (such as citric acid and sodium bicarbonate) enhances film disintegration and improves mouth feel by producing carbon dioxide when exposed to saliva.

2. Advantages of Effervescent Fast Dissolving Oral Films

1. Rapid disintegration in saliva
2. No need for water during administration
3. Improved patient compliance
4. Faster onset of action
5. Enhanced bioavailability by avoiding first-pass metabolism
6. Accurate dosing
7. Suitable for pediatric and geriatric patients
8. Fast dissolving oral films containing antidepressants can dissolve within seconds and provide improved drug release and therapeutic effect.

3. Materials

Typical materials used in formulation include:

3.1 Active Pharmaceutical Ingredient (API)

Selective antidepressants such as:

- Escitalopram oxalate
- Paroxetine hydrochloride
- Venlafaxine hydrochloride

3.2 Film Forming Polymers

- Hydroxypropyl methylcellulose (HPMC)

- Polyvinyl alcohol (PVA)
- Pullulan
- Sodium alginate

.3 Plasticizers

- Polyethylene glycol (PEG-400)
- Glycerol
- Propylene glycol

3.4 Effervescent Agents

- Sodium bicarbonate
- Citric acid
- Tartaric acid

3.5 Other Excipients

- Sweeteners (Aspartame, Saccharin sodium)
- Flavoring agents
- Saliva stimulating agents
- Coloring agents

4. Method of Preparation

The **solvent casting method** is most commonly used.

Steps

1. **Polymer solution preparation**
    - Dissolve film forming polymer (HPMC/PVA) in distilled water.
2. **Drug incorporation**
    - Dissolve antidepressant drug in suitable solvent and add to polymer solution.
3. **Addition of excipients**
    - Add plasticizer, sweetener, flavoring agent, and effervescent components.

4. **Casting the film**
    - Pour the solution into a petri dish or casting plate.
5. **Drying**
    - Dry at room temperature or in a hot air oven.
6. **Cutting the film**
    - Cut the dried film into required dimensions (e.g., 2 × 2 cm).
7. **Packaging**
    - Store in moisture-resistant packaging.

5. Evaluation of Fast Dissolving Oral Films

5.1 Physical Evaluation

- Appearance
- Transparency
- Surface texture

5.2 Thickness

Measured using a digital micrometer at different points.

5.3 Weight Variation

Films are weighed individually to ensure uniformity.

5.4 Folding Endurance

Film is repeatedly folded at the same point until it breaks.

5.5 Surface pH

Determines irritation potential to oral mucosa.

5.6 Drug Content Uniformity

Measured using UV spectrophotometry.

5.7 Disintegration Time

Time required for film to completely dissolve in simulated saliva.

5.8 In-Vitro Dissolution Study

Conducted using USP dissolution apparatus to determine drug release profile.

5.9 Stability Study

Films are stored at accelerated conditions (40°C ± 2°C / 75% RH) for several months to evaluate stability.

6. Results and Discussion

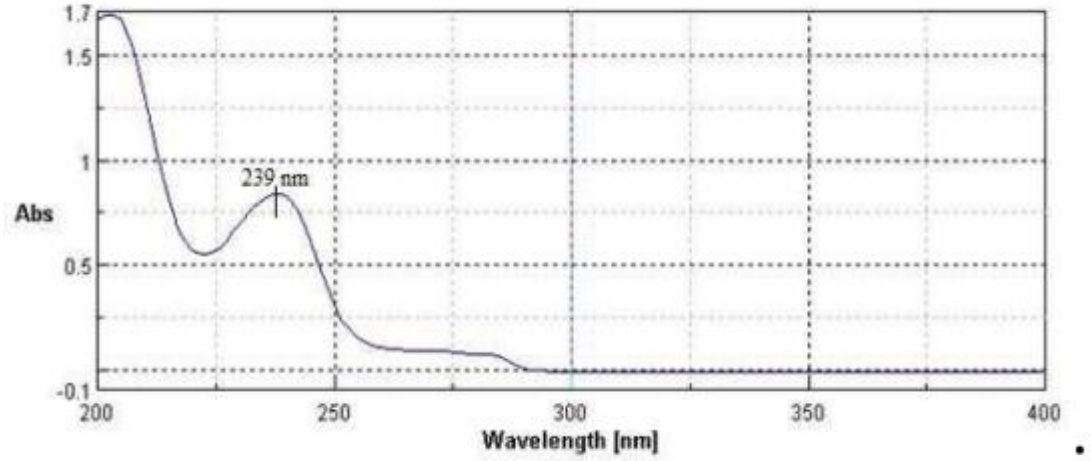
Solubility Studies

The solubility profile of Escitalopram API was evaluated in various solvents to understand its dissolution behavior and suitability for formulation development. The API was found to be slightly soluble in distilled water, indicating limited aqueous solubility, which may affect its release in purely aqueous media. In phosphate buffer pH 6.8, simulating intestinal conditions, the API was freely soluble, suggesting that it can dissolve efficiently under physiological pH and ensuring adequate bioavailability upon oral administration.

Solvent	Solubility
Distilled water	Slightly soluble
Phosphate buffer pH 6.8	Freely soluble
Simulated saliva fluid	Moderately soluble

Determination of λmax

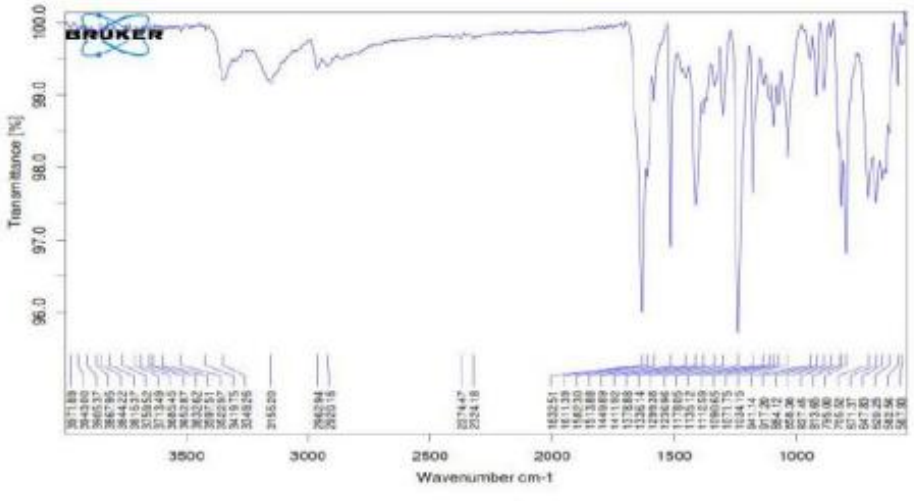
Escitalopram oxalate exhibited a sharp and distinct absorption peak in phosphate buffer pH 6.8. The maximum absorbance was observed at approximately 239 nm (±2 nm). The obtained λmax indicated good sensitivity and reproducibility. This wavelength was considered suitable for quantitative estimation of escitalopram during drug content and dissolution studies.



λmax of Escitalopram oxalate

Drug–Excipient Compatibility Studies (FTIR)

FTIR spectrum of pure escitalopram oxalate showed characteristic peaks corresponding to functional groups such as aromatic C–H stretching, C–F stretching, and amine groups. FTIR spectra of physical mixtures exhibited all major characteristic peaks of escitalopram oxalate.



FTIR Spectra of Pure Drug

Drug Content Uniformity

The drug content of the optimized effervescent fast dissolving oral films was found to be 95.5%, indicating that the formulation process ensured uniform and accurate incorporation of the active pharmaceutical ingredient in each film. Maintaining consistent drug content is critical to ensure that each film delivers the intended therapeutic dose reliably. A value of 98.5% falls well within the generally acceptable limits (typically 95–105%), demonstrating good content uniformity and precision in the formulation process.

Parameter	Result
Drug content (%)	95.5

Disintegration Time

The disintegration time of the optimized effervescent fast dissolving oral films was found to be 22 seconds, indicating that the films dissolve rapidly upon contact with saliva. A short disintegration time is a critical parameter for fast-dissolving oral films, as it ensures quick drug release and rapid onset of action, enhancing patient compliance, especially for populations who may have difficulty swallowing conventional tablets or capsules

Parameter	Result
Disintegration time (sec)	22

In-Vitro Effervescence Time

The effervescence behavior of the optimized fast dissolving oral films was evaluated by measuring the onset and completion times of effervescence. The films exhibited an onset of effervescence at 6 seconds, indicating that the reaction between the effervescent components and

Parameter	Time (seconds)
Onset of effervescence	6
Completion of effervescence	18

- High folding endurance
- Uniform drug distribution
- Good mechanical strength
- High percentage drug release (>90%)

The presence of effervescent agents enhances the disintegration rate and improves patient acceptability.

7. Conclusion

Effervescent fast dissolving oral films represent a promising drug delivery system for selective antidepressants. This dosage form provides rapid drug release, improved bioavailability, and better patient compliance compared with conventional tablets. The solvent casting method allows easy preparation and scalability for industrial production. Future studies may focus on improving taste masking, stability, and large-scale manufacturing techniques.

8. References

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