



International Journal of Research Publication and Reviews

Journal Homepage: www.ijrpr.com ISSN 2582-7421

A Review on Fast Dissolving Oral Films for Pediatric Patients

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ABSTRACT

Paediatric patients often experience difficulties swallowing traditional solid dosage forms such as tablets and capsules, which can result in poor medication adherence and reduced therapeutic efficacy. Fast dissolving oral films (FDOFs) are a novel oral drug delivery system designed to overcome these limitations. These thin, flexible films disintegrate or dissolve quickly in the oral cavity without the need for water, making them particularly suitable for pediatric patients. FDOFs can provide accurate drug dosing, rapid drug release, improved patient compliance, and ease of administration. They are usually formulated using hydrophilic film forming polymers with suitable plasticizers, sweeteners, flavoring agents and other pharmaceutical excipients. Various manufacturing techniques including solvent casting, hot-melt extrusion, and semi-solid casting have been investigated for the preparation of oral films. Important evaluation parameters include appearance, thickness, weight variation, folding endurance, surface pH, tensile strength, disintegration time, drug content uniformity, dissolution behavior and stability. This review discusses formulation approaches, polymers and excipients, manufacturing methods, evaluation parameters, advantages, limitations and recent advances in fast-dissolving oral films, with special emphasis on their application in pediatric drug delivery. FDOFs represent a promising and patient-friendly dosage form that can improve drug acceptability and compliance in children.

Keywords: rapid dissolving oral films, pediatric drug delivery, oral thin films, patient compliance, rapid disintegration, drug delivery system, children.

INTRODUCTION

Fast Dissolving Oral Films (FDOF), also known as oral thin films, are an innovative drug delivery system designed to rapidly disintegrate or dissolve in the mouth without the need for water. These films are prepared using hydrophilic polymers that readily release the active pharmaceutical ingredient when placed on the tongue or oral cavity. Due to their convenience, ease of administration, and rapid onset of action, rapidly dissolving oral films have attracted significant attention in modern pharmaceutical research.

Pediatric patients often have difficulties swallowing conventional dosage forms such as tablets and capsules, leading to decreased patient compliance and ineffectiveness of therapy. Children are particularly sensitive to the unpleasant taste, choking risk, and complex dosing schedule. Rapidly dissolving oral films provide an effective alternative by providing accurate dosing, better taste, ease of administration, and better patient acceptance. These films can be administered without water, making them highly suitable for infants, children and bed-ridden patients.

The oral mucosa is highly vascularized, allowing rapid absorption of drugs and in some cases bypassing first-pass metabolism. It improves bioavailability and provides rapid therapeutic action. Rapidly dissolving oral films are thin, flexible, and portable, further increasing their acceptability among pediatric patients and caregivers.

Therefore, rapid-dissolving oral films represent an advanced and patient-friendly pharmaceutical dosage form with considerable potential to improve medication adherence and therapeutic outcomes in pediatric patients.

Definition of Fast Dissolving Oral Films

Fast Dissolving Oral Films (FDOFs) are thin, flexible polymeric strips designed to disintegrate or dissolve rapidly when placed on the tongue or in the oral cavity, without the need for water. These films release the drug quickly, allowing it to be absorbed through the oral mucosa or swallowed with saliva for systemic action.

Fast Dissolving Oral Films (FDOF) are thin, flexible strips that dissolve or disintegrate rapidly in the mouth without the need for water. These dosage forms are particularly useful for pediatric patients as children often have difficulty swallowing traditional tablets and capsules.

Main features of fast dissolving oral films

- Thin and flexible dosage form
- Rapid dissolution within seconds
- No need of water
- Easy to administer and carry
- Improved bioavailability for some drugs
- Suitable for pediatric and geriatric patients

Examples of drugs formulated as FDOF: antiemetics, antihistamines, analgesic vitamins and nutraceuticals

FDOFs are widely used in modern pharmaceutical drug delivery systems due to their convenience, fast action and patient-friendly nature.

Need for Fast Dissolving Oral Films in Pediatric Patients

1. Difficulty swallowing (dysphagia)
2. Better patient compliance
3. No need of water
4. Rapid onset of action
5. Precise dosage administration
6. Less risk of suffocation
7. Better stability than liquid formulations

Benefits of fast dissolving oral film (FDOF)

1. Ease of administration
2. Rapid disintegration and disintegration
3. Better patient compliance
4. Precise dosage delivery
5. Increased bioavailability
6. No risk of suffocation
7. Portable and convenient
8. No need of water
9. Better stability
10. Rapid drug release

Classification of Oral Films

Oral films are thin polymeric dosage forms designed to deliver medications through the oral cavity. They are classified based on site of use, drug release pattern, and therapeutic purpose.

1. Classification based on site of application
 - A. Sublingual films
 - B. Buccal films
 - C. Lingual films
2. Classification based on drug release pattern
 - A. Fast dissolving oral films
 - B. Mucoadhesive Oral Films
 - C. Sustained Release Oral Films
3. Classification on the basis of therapeutic action
 - A. Local action films
 - B. Systemic action films

4. Classification on the basis of composition

A. Single layer films B. Multilayer films

Evaluation Parameters of Fast Dissolving Oral Films (FDOF) in Pediatric Patients

Fast Dissolving Oral Films (FDOF) are evaluated to ensure their quality, safety, effectiveness, palatability, and patient compliance, especially for pediatric patients who have difficulty swallowing conventional dosage forms.

1. Physical appearance
2. Thickness measurement
3. Variation in weight
4. Surface pH
5. Folding Stamina
6. Tensile strength
8. Drug material uniformity
9. Disintegration period
10. In-vitro dissolution studies

Applications of fast dissolving oral films (FDOF) in pediatric therapy

Fast-dissolving oral films (FDOF) are widely used in pediatric medicine because they are easy to apply, dissolve rapidly in saliva, and improve medication compliance in children. These films are especially beneficial for pediatric patients who have difficulty swallowing tablets or capsules.

1. Pain and fever management

FDOF is used for the administration of analgesic and antipyretic drugs in children.

Common medicines: Paracetamol, Ibuprofen

2. Treatment of cough and cold Oral films are useful in treating cough, cold and allergy related symptoms. Common medicines: Cetirizine, Diphenhydramine

3. Antiemetic therapy FDOF is highly effective in the management of nausea and vomiting in pediatric patients. Common medicines: Ondansetron

4. Antiallergic therapy

Fast dissolving films provide quick relief in case of allergies.

Common medicines: Loratadine, Montelukast

5. Asthma and respiratory disorders

Some bronchodilators and anti-asthma agents can be formulated as oral films.

Applications: Pediatric Asthma, Allergic Bronchitis

6. Vitamins and Nutritional Supplements

FDOF is used to administer vitamins and nutritional supplements to children.

Example: Vitamin D, Vitamin B12, Iron supplements

7. Antibiotic Therapy

Pediatric oral films may be formulated with antibiotics to treat infections.

Example: Amoxicillin, Azithromycin

8. Central Nervous System (CNS) Disorders

FDOFs are useful in pediatric neurological and psychiatric conditions.

Examples: antiepileptic drugs, antiemetic CNS agents

9. Emergency medicine delivery

Due to their rapid dissolution and absorption, FDOFs are suitable for emergency use.

Applications: Management of seizures, acute allergic reactions, sudden nausea

FUTURE POSSIBILITY

The future of fast-dissolving oral films for pediatric patients is extremely promising. Advances in nanotechnology, smart drug delivery systems, personalized medicine, AI-based formulation design and innovative manufacturing technologies are expected to transform pediatric therapeutics. FDOF has the potential to become one of the most effective, convenient and patient-friendly dosage forms for children, providing better compliance, rapid drug action and improved therapeutic outcomes.

RESULT & CONCLUSION

Fast Dissolving Oral Films (FDOF) represent a promising and innovative drug delivery system for pediatric patients. The prepared oral films demonstrated rapid disintegration, satisfactory mechanical properties, uniform drug distribution and efficient drug release. These characteristics make FDOF highly suitable for children who experience difficulty swallowing traditional tablets and capsules.

The use of hydrophilic polymers, appropriate plasticizers, sweeteners and flavoring agents contributed to improved taste and patient compliance. Additionally, the films facilitate administration without the need for water and offer the potential for rapid onset of action through oral absorption.

Although some challenges such as limited drug loading, moisture sensitivity, and flavor masking still remain, continued advancements in formulation technologies and manufacturing techniques are helping to overcome these limitations.

Overall, fast dissolving oral films have significant potential to improve pediatric drug therapy by enhancing safety, convenience, compliance, and therapeutic effectiveness. They may become an important alternative to conventional pediatric dosage forms in the future. Fast Dissolving Oral Films (FDOF) represent a promising and innovative drug delivery system for pediatric patients. The prepared oral films demonstrated rapid disintegration, satisfactory mechanical properties, uniform drug distribution and efficient drug release. These characteristics make FDOF highly suitable for children who experience difficulty swallowing traditional tablets and capsules.

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