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Oro dispersible Films (ODFs): A patient-centric approach in drug delivery

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Abstract

Oro dispersible films (ODFs) are a novel oral drug delivery system designed to dissolve quickly in the oral cavity, typically within 30 seconds, without the need for water or swallowing. These ultra-thin strips, ranging from 10 to 100 microns in thickness, are particularly suitable for populations with special needs, such as pediatric and geriatric patients, and individuals suffering from conditions like dysphagia, Parkinson's disease, or oral cancer. ODFs offer several advantages, including improved patient convenience and compliance, rapid onset of therapeutic effect, and the ability to bypass first-pass metabolism. The formulation components of ODFs include film-forming polymers, plasticizers, active pharmaceutical ingredients, sweeteners, flavors, and surfactants. Various manufacturing techniques, such as solvent casting, hot-melt extrusion, and electrospinning, can be used to prepare ODFs, each with its own advantages and limitations. Despite the benefits, ODFs also have some challenges, including moisture sensitivity, limited drug-loading capacity, and potential issues with content uniformity and manufacturing. Nevertheless, ODFs have shown promise in various therapeutic applications, including the delivery of antiasthma tics, antiemetics, antipsychotics, and antihistamines. With ongoing advancements in polymer combinations and manufacturing technologies, ODFs are expected to play an increasingly important role in the development of personalized and effective drug delivery systems.

Keywords: Oro Dispersible Films; Oral Drug Delivery; Patient Convenience; Rapid Onset; Personalized Medicine; Pharmaceutical Applications

1. Introduction

Oro dispersible films (ODFs) are a novel oral drug delivery system formulated as ultra-thin strips using hydrophilic polymers. These films are designed to dissolve quickly when placed on the tongue or in the buccal cavity, typically disintegrating within 30 seconds without the need for water or swallowing. This dosage form eliminates the risk of choking that may occur with conventional tablets or capsules, making it particularly suitable for populations with special needs such as pediatric and geriatric patients, as well as individuals suffering from conditions like dysphagia, Parkinson's disease, or oral cancer. The films usually range from 10 to 100 microns in thickness and are about the size of a postage stamp.

Among the available manufacturing techniques, solvent casting is the most commonly used method for preparing ODFs. In this approach, all formulation components are either dissolved or dispersed in an aqueous medium to form a uniform mixture, which is then cast and dried to produce the film. Although hot melt extrusion has also been explored, it often results in slightly brittle films due to the uneven integration of plasticizers, which can affect film flexibility.

ODFs fall under the broader category of fast-dissolving drug delivery systems and are designed to simplify drug administration for the general population, as well as for individuals who experience difficulty swallowing. The intraoral route of administration allows for rapid drug action by enabling absorption through the oral mucosa. This not only leads

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to faster onset of therapeutic effect but also helps bypass the first-pass metabolism, potentially reducing the required dose to achieve the desired pharmacological response. [1-10]

Figure 1 Oral films [11]

1.1. Formulation Components of Films (ODFs) [12]

The fundamental components of or dispersible films (ODFs) include film-forming polymers, plasticizers, active pharmaceutical ingredients (APIs), sweeteners, flavors, and surfactants. Hydrophilic polymers such as hydroxypropyl methylcellulose (HPMC), polyvinyl alcohol (PVA), and pullulan are commonly utilized due to their excellent film-forming capabilities and favorable safety profiles. To improve film flexibility and minimize brittleness, plasticizers like glycerol, polyethylene glycol (PEG), and propylene glycol are incorporated into the formulation. For optimal performance, ODFs must exhibit sufficient mechanical strength, a rapid disintegration time typically within 30 seconds and a palatable taste to support patient compliance. These films are especially advantageous for pediatric and geriatric patients who often face challenges in swallowing traditional tablets or capsules.

2. Classification of Printing Technologies for ODFS [12-16]

2.1. Solvent Casting Method

The solvent casting method is the most widely used technique for the preparation of orodispersible films (ODFs), owing to its simplicity, cost-effectiveness, and suitability for both laboratory and industrial-scale production. It is especially preferred for small-scale pharmaceutical formulations, as it can be performed without the need for expensive equipment. The process generally involves three key steps: preparing a homogenous slurry of the formulation components, casting and drying the mixture to form a film, and then die-cutting the dried laminate into individual doses. Additionally, solvent casting can be adapted for the production of small batches and multilayer films, which are useful for fixed-dose combination therapies.

2.2. Hot-Melt Extrusion (HME)

Hot-melt extrusion (HME) can be applied for both continuous manufacturing and the development of various dosage forms. However, its application in ODF preparation remains limited, primarily due to the heat sensitivity of the polymers commonly used in these films. While the technique has certain advantages, the high processing temperatures pose challenges when working with temperature-sensitive excipients.

2.3. Electrospinning

Electrospinning is a technique currently being explored for the fabrication of highly porous ODFs, which allow for rapid disintegration. It is under investigation for its ability to create films with a porous internal structure. Materials such as polyvinylpyrrolidone (PVP), gelatin, and poloxamers are among the most commonly studied polymers in this method.

2.4. Printing Technologies

- Inkjet Printing

Inkjet printing, also known as binder jetting, involves depositing ink onto a powdered substrate to create layered drug delivery systems such as tablets, ODFs, and implants. In one application, lysozyme was successfully printed onto buccal

films without compromising their mechanical strength or mucoadhesive properties. The printed dosage closely matched the theoretical value, highlighting the precision and reliability of inkjet-based drug delivery.

2.5. 2D and 3D Printing for Personalization

Technologies like 2D and 3D printing are being actively studied for the development of personalized ODFs, especially for pediatric and geriatric patients. The integration of 3D printing with artificial intelligence offers the potential to improve quality control and customization, paving the way for advancements in digital pharmacy.

3. Drug Loading and Release in Oro dispersible Films [17-19]

Drug loading in or dispersible films (ODFs) can be achieved through simple mixing methods or more advanced techniques. The active pharmaceutical ingredient (API) may be directly blended with the film-forming polymer solution or incorporated using technologies such as inkjet printing or hot-melt extrusion. For achieving rapid therapeutic action, drug release from ODFs typically occurs within seconds. This is due to the thin structure, high surface area, and porosity of the films. The use of hydrophilic polymers like hydroxypropyl methylcellulose (HPMC) and polyvinyl alcohol (PVA) further supports immediate drug diffusion upon contact with saliva.

3.1. Advantages of ODFs [20-24]

- These formulations are gaining significant attention because they offer improved patient convenience and compliance, particularly for children, elderly individuals, and patients with swallowing difficulties.
- ODFs dissolve quickly in the oral cavity upon contact with saliva, requiring no water for administration.
- Studies show that ODFs are well-accepted across all age groups and may offer better acceptability compared to tablets and syrups.
- They are considered suitable for pediatric use and address the ongoing need for age-appropriate dosage forms.
- ODFs are available as thin, single- or multi-layered sheets, making them portable and visually appealing.

3.2. Disadvantages of ODFs [25-29]

- One of the main challenges with ODFs is their limited drug-loading capacity, which is due to the restriction in film thickness.
- They are sensitive to external factors such as humidity and temperature, which can affect their overall stability.
- Drugs that require high doses or have a strong bitter taste may not be suitable for ODF formulations.
- Advanced manufacturing methods like 3D printing and electrospinning can increase production costs and process complexity.
- The range of natural polymers that are compatible and effective in ODF formulation remains quite limited.

4. Challenges of Oro dispersible Films (ODFs) [30-34]

4.1. Moisture Sensitivity and Stability

One of the major limitations associated with orodispersible films is their sensitivity to moisture, which can compromise their physical integrity and stability, particularly in high-humidity environments. Additionally, ODFs have a limited capacity to incorporate high drug doses, which restricts their use for medications requiring larger quantities.

4.2. Restricted Drug Loading

Due to the small size of the film, there is limited space to include additional excipients, such as taste-masking agents. This can affect the palatability of the formulation and, in turn, influence patient compliance, especially among pediatric and geriatric populations.

4.3. Content Uniformity and Manufacturing Issues

Achieving uniformity and homogeneity across the entire film becomes increasingly challenging at a larger manufacturing scale. Variations during the mixing and casting stages can result in inconsistent drug distribution, impacting the overall quality and efficacy of the product.

4.4. Mechanical Process Challenges – Air Bubbles and Viscosity Control

The viscoelastic nature of the casting solution or dispersion plays a crucial role in determining the final properties of the film. Parameters such as viscosity, air entrapment, and solution flow can influence the film's thickness, drug content uniformity, surface morphology, and drug release behavior.

4.5. Drying Time and Environmental Constraints

The drying phase of ODF manufacturing requires careful control, as certain drug formulations are more sensitive to environmental factors. Furthermore, specific storage and handling conditions may be required to maintain the stability and performance of the final product.

5. Applications of Oro dispersible Film [35-41]

- Orodispersible films (ODFs) are increasingly used in both prescription and over-the-counter drug formulations due to their ease of administration and patient-friendly characteristics.
- They are commonly employed for the delivery of various therapeutic agents, including antiasthmatics, antiemetics, antipsychotics, antiepileptics, antihistamines, anti-inflammatory drugs, anti-Parkinson's medications, and antihypertensives.
- ODFs are particularly useful for children, elderly individuals, mentally ill patients, and bedridden patients who experience difficulty swallowing traditional tablets or capsules.
- These films are also effective for localized drug delivery and achieving rapid systemic effects.
- They are used in the treatment of conditions affecting the buccal cavity, such as mouth ulcers, tooth pain, and throat infections.
- Fast-dissolving oral films are widely applied in managing symptoms like cough, cold, sore throat, asthma, and allergic reactions.
- In addition to therapeutic applications, innovative ODFs are being developed for dietary supplementation.
- One example includes taste-masked, iron-loaded pullulan films intended for treating iron deficiency, especially in anemic children and pregnant women.
- Advances in polymer combinations have enabled the development of ODFs with controlled drug release profiles.
- Depending on the polymer used and drug-excipient compatibility, ODFs can be designed for either rapid or delayed drug release.

5.1. Future aspects [42,43]

Oral film drug delivery is gaining recognition as a promising alternative to conventional oral dosage forms. This technology offers a convenient and effective method of drug administration, particularly for patient populations with special needs, including children, the elderly, bedridden individuals, and those with mental illness.

6. Conclusion

Oro dispersible films represent a promising oral drug delivery system that offers improved patient convenience, rapid onset of therapeutic effect, and potential for personalized medicine. Despite some challenges, such as moisture sensitivity and limited drug-loading capacity, ODFs have shown promise in various therapeutic applications. With ongoing advancements in manufacturing technologies and polymer combinations, ODFs are expected to play an increasingly important role in the development of effective and patient-friendly drug delivery systems. As research continues to address the challenges associated with ODFs, these films are likely to become an increasingly popular option for patients with special needs, such as pediatric and geriatric populations, and individuals with difficulty swallowing traditional tablets or capsules. Ultimately, ODFs have the potential to enhance patient compliance, improve treatment outcomes, and provide a more convenient and effective way to deliver medications.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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