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Oral Thin Film: A New Approach for Drug Delivery

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Abstract:

Oral thin films (OTFs) are gaining popularity in the pharmaceutical industry for their advantages over traditional oral dosage forms, especially for patients with swallowing difficulties, such as children and the elderly. OTFs provide a discreet, convenient, and fast-acting method of drug administration. They dissolve quickly in saliva, enabling rapid absorption through the oral mucosa, bypassing first-pass metabolism and enhancing bioavailability, which can reduce required doses and side effects. OTFs are particularly useful for poorly soluble drugs and allow for precise dosing, making them ideal for pediatric patients. They can also mask unpleasant tastes, improving patient acceptance. Research on OTFs is expanding, with innovations like pH-sensitive films, micro-pellet-loaded films, and the potential for delivering vaccines and probiotics. The OTF market is projected to reach $7.65 billion by 2028, growing at a 13.6% CAGR. Future developments focus on personalized OTFs, made possible by printing technologies like inkjet and 3D printing, offering tailored dosing and drug combinations. OTFs hold great promise to revolutionize drug delivery, benefiting both patients and healthcare providers.

Keywords: Oral thin film, Pediatric and geriatric drug dosing, market growth of OTF, Technologies of preparation of film.

Introduction

Although oral drug distribution is convenient, it can be challenging for certain populations, including pediatrics, the elderly, and those with dysphagia. These individuals often face difficulties swallowing traditional dosage forms like tablets and capsules. Even fast-dissolving tablets carry a risk of choking and lack universal acceptability. To address these issues, oral fast- dissolving films (OFDFs) have emerged as an innovative alternative. OFDFs are thin, polymer-based films that dissolve quickly on the tongue, making them easy to administer without water or chewing. This technology enhances patient compliance, particularly in elderly patients managing multiple medications and those with conditions such as Alzheimer's, Parkinson's, and schizophrenia. OFDFs are also beneficial for pediatric patients, offering a safe and easily administered alternative to traditional forms. [1] OTF becomes further popular for colorful, potent cures in discrepancy to immediate-release ODT. With ODT, healthcare professionals are facing non-compliance in the treatment of pediatric and senior cases.

ODT is designed for quick disintegration in the mouth, but fear of choking remains a concern for some patients. On the other hand, OTF expression can improve patient compliance by addressing swallowing issues. Senior patients often take multiple medications per day.

The convenience of administering lozenge forms is crucial for patients with Alzheimer's, bipolar disorder, migraines, Parkinson's disease, and schizophrenia. Among all types of lozenge forms, OTF is largely accepted due to its own advantages along with ease of oral delivery of colorful medicines (e.g., anesthetics, antihistamines, anti-asthmatics, cardiovascular medicines, neuroleptics, and medicines for erectile dysfunction [2]. Recent innovations have expanded OFDF capabilities, including the integration of nanotechnology to increase the solubility and bioavailability of weakly water-soluble medicines; for instance, nanonization and cyclodextrin inclusion complexes are utilized to enhance dissolution rates for BCS Class II drugs [3, 4]

Advantages of oral film:

1 Fast disintegration within seconds and quick onset of action
2 Easy administration
3 No fear of chocking like orally disintegrating tablet
4 Suitable for children and geriatric patients, bedridden individuals, and those with dysphagia, Parkinson's disease, mucositis or vomit.
5 Accurate dosing can be achieved
6 Improve the bioavailability of drugs having first-pass metabolism.
7 Thin and can be administered without water
8 Easy to transport and flexible, robust in nature. [7]

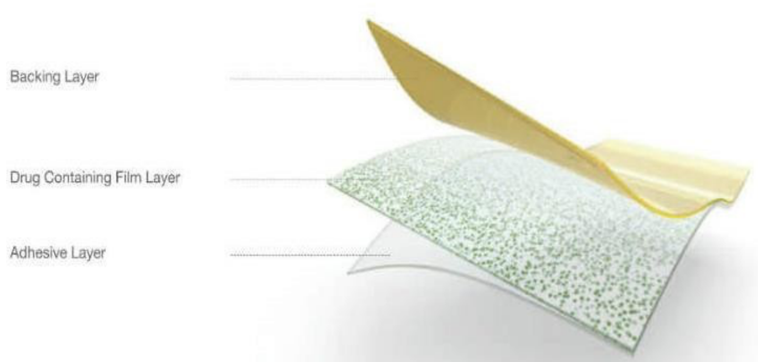

Figure 1: Oral thin films

Types of film

1. Film with flash release

2. Dispersible flash film

3. Mucoadhesive films that do not disintegrate

4. Mucoadhesive films that disintegrate moderately

Method of Preparation of Mouth Dissolving Film:-

1. Solvent Casting Method: Solvent casting is now the most popular production method for creating oral thin films. This approach involves dissolving the plasticizer and water-soluble polymer in distilled water. To release all trapped air bubbles, the solution is agitated for two hours using a magnetic stirrer and then left aside. Excipients and API are dissolved in the meantime, and both solutions are well agitated for 30 minutes before being combined.

At last, the solution is poured onto a level surface that can be used to form a film. After drying, the film is carefully removed. The creation of an abuse deterrent and microemulsion-based sublingual film of buprenorphine hydrochloride for breakthrough pain treatment was accomplished using the same solvent casting approach [22].

2. Hot melt extrusion: Initially, a solid mixture of medicine and carrier is combined in the hot melt extrusion process. After that, the mixture is melted using an extruder with heaters. Finally, the dies form the melt into films [23].

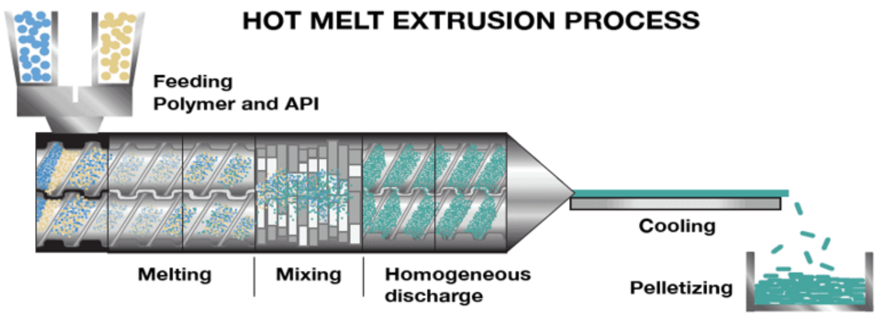

Figure 2: Hot melt extrusion method

3. Semi-solid casting: To create a homogenous viscous solution, a solution of an acid-insoluble polymer (such as cellulose acetate butyrate and phthalate) is combined with a solution of a water-soluble film-forming polymer. It is coated on untreated casting film following sonication. The film should be between 0.015 and 0.05 inches thick after drying. Utilizing the acid-insoluble polymer in a 1:4 ratio with the film- forming polymer is recommended [24].

4. Rolling method: This technique involves rolling a drug-containing solution or suspension on a carrier. The primary solvents are alcohol and water mixtures. After drying on the rollers, the film is cut into the appropriate sizes and shapes [25].

5. Solid dispersion extrusion: Initially, a solid dispersion is created by using a drug to extrude immiscible components, which is then formed into films using dies [26].

Evaluation tests

Morphology study: Scanning Electron Microscopy (SEM) is used to examine the films' morphology at a specific magnification [27].

Organoleptic evaluation: To do this, taste sensors and carefully made equipment are employed in vitro techniques. These in vitro taste evaluation devices are suitable for high-throughput oral pharmaceutical formulation taste screening [28].

Thickness: At various sites, it can be measured with a micrometer screw gauge. Determining the uniformity of the film's thickness is essential since it has a direct bearing on the strip's dosage accuracy. Folding endurance:

The folding durability of the prepared films was measured with great attention. A film strip was repeatedly chopped and folded until it broke 29. The number of times the film could be folded in the same spot without breaking was used to calculate the value of folding endurance [30].

Weight Variation: The formulations were divided into 4 cm2 films by different batches, and the weights were noted on an electronic balance. For every formulation, three random videos were selected [31]. Ten films from each batch were separately weighed on a digital electronic balance for the weight variation test, and the average weight was calculated [32].

Tensile strength: Tensile strength is the maximum stress applied at the point where the strip specimen fractures. The following equation illustrates how it is calculated: dividing the applied load at rupture by the cross-sectional area of the strip [33].

Tensile strength = Load at breakage / Strip thickness× Strip width

Percentage moisture loss: To confirm the integrity and physical stability of the film, a moisture loss test was conducted [34]. A two-by-two centimeter film was cut and weighed. Following that, the film was kept for three days in a desiccator filled with fused anhydrous calcium chloride. The film patch was taken off and weighed again after three days. The following formula was used to determine the film's percentage moisture loss [35].

Percentage Moisture Loss = (Initial Weight - final weight)/Initial Weight × 100

Drug content: Using a UV spectrophotometer, ascertain the formulation's percentage drug content from the calibration curve [36].

Viscosity: Utilizing a Brookfield viscometer, determine the optimized formulation's viscosity [37]. Disintegration test: Fast dissolving oral strips can be used in accordance with the CDER guidance's 30 second or less disintegration time criteria for orally disintegrating tablets. While there isn't a specific suggestion for oral rapid dissolving films or strips, Jain and Mundada (2015)38 suggest using this as a qualitative guideline for quality control testing or in the development phase. Ten milliliters of pH 6.8 phosphate buffer were added to a petri plate, and the film was then layered on top. Every ten seconds, shake the Petri plate [39]. The amount of time it took for the film to break down was noted [40].

Stability studies: In accordance with ICH guidelines, oral film samples must be kept for three months at 40±0.5°C and 75±5% RH in order to conduct stability tests. The samples were removed at 0, 30, 60, 90, and 180 days to be checked for drug content [41].

Conclusion

The most accurate and widely accepted oral dosage form that circumvents the hepatic system and exhibits a greater therapeutic response is the fast-dissolving oral film.

Pharmaceutical firms like this dose form since it is both industrially acceptable and has high patient compliance, particularly in the case of pediatric and geriatric patients.

Oral films are a useful tool for product life cycle management; they can take the position of over-the-counter (OTC) medications, both generic and name brand. This technique extends the patent life of current items and is a useful tool for product life cycle management.

Oral medication delivery systems have adopted a revolutionary method with fast dissolving films. A lot of research is being done in this area on a variety of medication categories, and oral fast-dissolving films have become a revolutionary trend. This formulation solves the issue that other sound formulations have.

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