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Oral Thin Film: Innovations in drug Delivery systems

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Abstract:

Oral thin films (OTFs) have emerged as an advanced and patient-friendly drug delivery system designed to provide rapid onset of action, improved bioavailability, and enhanced compliance, especially among pediatric and geriatric populations. This review focuses on the formulation and evaluation of oral thin films containing Famotidine and Domperidone—two drugs commonly used in the management of gastroesophageal reflux disease (GERD) and associated nausea or vomiting. Famotidine, a histamine H_2-receptor antagonist, and Domperidone, a peripheral dopamine receptor antagonist with prokinetic activity, when co-formulated in an oral thin film, offer a synergistic therapeutic effect for gastric acid suppression and motility regulation. The review highlights various formulation strategies including solvent casting, hot-melt extrusion, and electrospinning methods, with emphasis on polymer selection (HPMC, PVA, Pullulan) and the role of plasticizers, saliva-stimulating agents, and flavoring agents in achieving desirable film characteristics. Evaluation parameters such as film thickness, folding endurance, surface pH, disintegration time, drug content uniformity, and in vitro dissolution are discussed in detail. The combination OTF of Famotidine and Domperidone provides a rapid-dissolving dosage form that bypasses first-pass metabolism, ensures quick therapeutic onset, and enhances patient adherence compared to conventional oral formulations.

Keywords: Oral thin film (OTF); Famotidine; Domperidone; Fast dissolving films; Gastroesophageal reflux disease.

Introduction

Thin-film drug delivery involves the administration of medications through the mouth (buccally or sublingually) and/or the small intestines using a dissolving film or oral drug strip (enterically). A film consisting of hydrophilic polymers dissolves quickly on the tongue or in the buccal cavity, transferring the medication to the circulatory system via dissolution when it comes into touch with fluids.[1] Oral thin films (OTFs) are an innovative drug delivery system that offers a convenient and efficient method of administering pharmaceutical and nutraceutical compounds. They are thin,

flexible, and dissolvable films designed to deliver active pharmaceutical ingredients (APIs) directly into the systemic circulation via the oral mucosa or gastrointestinal tract. These films provide a superior alternative to traditional oral dosage forms such as tablets and capsules, particularly for pediatric, geriatric, and dysphagic patients who experience difficulty swallowing.

The concept of oral thin films has evolved from transdermal patches, which were initially developed for drug delivery through the skin. With advancements in polymer science, oral films have been engineered to provide rapid disintegration, controlled drug release, and improved bioavailability. Since their introduction, OTFs have gained significant attention in the pharmaceutical industry due to their patient-friendly administration and potential to enhance therapeutic outcomes.

Gastroesophageal Reflux Disease (GERD) is a chronic digestive disorder characterized by the backflow of stomach acid into the esophagus. This condition occurs when the lower esophageal sphincter (LES) fails to close properly, allowing acidic gastric contents to irritate the esophageal lining. GERD is a common condition affecting millions worldwide, leading to discomfort and potential complications if left untreated.[2]

Evolution of Oral Thin Films

The concept of oral thin films has evolved from transdermal patches, which were initially developed for drug delivery through the skin. With advancements in polymer science, oral films have been engineered to provide rapid disintegration, controlled drug release, and improved bioavailability. OTFs have gained significant attention in the pharmaceutical industry due to their administration and potential to enhance therapeutic outcomes.

Oral Thin Drug Delivery Development [3]

• Strip forming polymers

The polymer used should be non-toxic, non-irritant, and free of contaminants that can be leached. It should have a high level of wetness and spreadability. The peel, shear, and tensile strengths of the polymer should be sufficient. The polymer should be easy to get by and not prohibitively costly. The film should be robust enough to withstand handling and transit without being damaged.

• Plasticizers

Plasticizer is an important component in the OS recipe. It improves the strip's suppleness while also reducing its brittleness. By lowering the polymer's glass transition temperature, plasticizer enhances strip characteristics dramatically. Plasticizer excipients include glycerol, propylene, low - molecular - weight polyethylene glycols, phthalates derivatives such as dimethyl, diethyl, and dibutyl phthalate, citrate compounds such as tributyl, triethyl, acetic citrate, triacetin, and castor oil.

• Active pharmaceutical ingredient

High-dose molecules are challenging to include in OS due to the size constraint of the dosage form. In general, active medicinal substances can be integrated in the oral strip in amounts ranging from 5% to 30% by weight.

• Sweetening, flavoring and coloring agents

Taste and colour are essential aspects of thin film drug technology. In the case of children, the sweetness of the formulation is particularly crucial. Natural and artificial sweeteners are utilised to improve the flavour of mouth dissolving formulations since flavour preferences vary from person to person. For colouring, pigments such as titanium dioxide are used.

• Stabilizing and thickening agents

The stabilizing and thickening agents are used to increase the viscosity and consistency of the strip preparation solution or suspension before casting by increasing the viscosity and consistency of the dispersion or solution. Thin film formulations satisfy this criteria by containing homogeneous medication dispersions throughout the production process. The use of Laser Scanning Confocal Microscopy (LSCM) to monitor the production process was advised since this criteria is critical for the quality of the thin film and final pharmaceutical dosage form.

Types of Oral Thin Films

- Fast Dissolving Films (FDFs): These disintegrate within seconds upon contact with saliva, ensuring rapid drug release.
- Sustained Release Films: Designed to release the drug over an extended period for prolonged therapeutic effects.
- Mucoadhesive Films: Adhere to the mucosal surface to facilitate prolonged drug absorption.
- Transmucosal Films: Target systemic drug delivery through the buccal or sublingual route, bypassing the first-pass metabolism.

Manufacturing Techniques [4]

One of the following methods or combinations could be utilized in the preparation of oral dissolving/disintegrating thin films:

• Solvent and semisolid casting method

Because of its simplicity of preparation, cheap processing cost, and ease of application, the solvent casting method is the most widely used method for preparing OTFs. To make a viscous solution, the medication and additional excipients are added to the mixture. This method's solution is put into a petri dish, and the solvents are allowed to evaporate. These are maintained at room temperature for 20-25 or 24-48 hours depending on the solvent solution employed, or in the oven for a shorter length of time at 40°C-50°C. After the solvents have evaporated, the films are 15-20 mm in diameter and 0.2-0.3 mm thick, and they must be carefully detached from the petri dishes. They are sliced into appropriate size pieces depending on the amount of active ingredient they contain. The semisolid gel mass is poured into appropriate moulds and dried using gel-forming polymers in the semisolid process. After that, they're sliced into the appropriate sizes.

• Hot melt extrusion method

The hot melt extrusion process is commonly used to make long-acting tablets, granules, subcutaneous, and transdermal delivery devices. An extruder with heaters is used to combine and melt the mixture comprising the formulation components. As a result, moulds are used to transform the liquid mixture into a film.

• Solid dispersion extrusion

In this method, the solid dispersion is prepared by extruding the formulation components with the drug and then made into a thin film with molds.

• Rolling method

Water and/or water/alcohol combinations are typically utilised as solvents in this procedure. The active ingredient and other components are solved in a tiny quantity of aqueous solvent using the high shear processor.

The viscous mixture is rolled and put onto the carrier roller. The resultant films are cut to the required sizes before being cured in a controlled environment.

Advantages of Oral Thin Films [5]

- Improved Patient Compliance: Ideal for pediatric and geriatric populations.
- Rapid Onset of Action: Facilitates faster absorption compared to tablets and capsules.
- Enhanced Bioavailability: Bypasses hepatic first-pass metabolism.
- Ease of Administration: No need for water or special handling.
- Precision Dosing: Ensures accurate drug delivery with minimal wastage.

Applications of Oral Thin Films [6]: Oral thin films are widely used in various therapeutic areas, including:

- Pain Management: Rapid relief through transmucosal absorption.
- Neurological Disorders: Delivery of drugs for epilepsy, Parkinson's disease, and migraine.
- Antiemetics: Prevention and treatment of nausea and vomiting.
- Nutraceuticals: Delivery of vitamins, minerals, and herbal extracts.

Challenges and Future Prospects [7]: Despite their advantages, oral thin films face challenges such as:

- Limited Drug Load Capacity: Only suitable for drugs requiring low doses.
- Moisture Sensitivity: Requires specialized packaging to prevent degradation.
- Taste Masking Issues: Certain APIs have strong bitterness requiring advanced flavoring techniques.

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