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Oral Thin Film: A New Approach for Drug Delivery

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Abstract:

Hyperlipidemia remains a major global health concern and a leading risk factor for cardiovascular diseases. Conventional oral dosage forms of lipid-lowering agents like Simvastatin and Fenofibrate often face limitations such as poor aqueous solubility, extensive first-pass metabolism, variable bioavailability, and poor patient adherence. Oral thin film (OTF) technology has emerged as a promising fast-dissolving drug delivery system designed to overcome these limitations, offering improved drug dissolution, enhanced bioavailability, and ease of administration without the need for water. The present review focuses on the formulation and evaluation of oral thin films incorporating Simvastatin and Fenofibrate for synergistic management of hyperlipidemia. It highlights the pharmacological rationale for combining these agents, discusses formulation strategies including polymer selection, plasticizers, solubilization techniques, and manufacturing methods, and summarizes evaluation parameters such as mechanical properties, disintegration time, drug content, in-vitro dissolution, and stability studies. The review emphasizes the potential of oral thin films as a novel patient-friendly dosage form capable of improving therapeutic outcomes, bioavailability, and patient compliance in the treatment of hyperlipidemia. Further research and clinical studies are recommended to optimize formulation variables and validate clinical efficacy.

Keywords: Simvastatin; Fenofibrate; Oral thin films; Hyperlipidemia; Bioavailability enhancement; Fast-dissolving dosage forms; Patient compliance; Drug delivery system; Synergistic therapy; Cardiovascular disease.

Introduction

Oral thin films (OTFs) have emerged as an innovative drug delivery platform, providing a convenient, efficient, and patient-friendly alternative to traditional oral solid dosages like tablets and capsules. These films, also referred to as oral dissolving films (ODFs) or orodispersible films, are thin, flexible strips that rapidly dissolve when placed on the tongue or inside the cheek, delivering medication quickly into the bloodstream. Their unique composition often includes a polymer matrix that can hold a wide range of active pharmaceutical ingredients (APIs), alongside plasticizers, flavoring agents, sweeteners, and sometimes coloring agents, to enhance both effectiveness and patient acceptance.[1] The development of OTFs has been fueled by the growing need for patient-centric formulations, with demand particularly high in pediatrics, geriatrics, and patient populations with swallowing difficulties or compliance challenges.[2] Additionally, OTFs offer dose precision, improved safety, and a user-friendly format that encourages adherence. They also have the advantage of being easy to transport and handle without the need for water, unlike conventional tablets or capsules, making them highly convenient for on-the-go use.[3]

Oral Thin Films (OTFs) are a rapidly evolving drug delivery system designed as thin, flexible strips that dissolve quickly upon contact with saliva in the oral cavity, facilitating the release and absorption of the active pharmaceutical ingredient (API).

These films, also known as orodispersible or dissolvable films, are typically placed on the tongue or against the inner cheek, where they disintegrate within seconds to a few minutes, making them an ideal choice for patients who have difficulty swallowing conventional tablets or capsules, such as pediatric and geriatric populations. Composed primarily of a polymer matrix, OTFs provide a stable and flexible carrier for drugs and can include a range of excipients like plasticizers, flavoring agents, sweeteners, and sometimes coloring agents, which contribute to the product's stability, ease of use, and patient acceptability.[4]

Fast-dissolving oral films offer several advantages over conventional solid dosage forms, including increased flexibility and enhanced efficacy of the active pharmaceutical ingredient (API). These films dissolve and break down in under a minute with minimal saliva, requiring less moisture than oral disintegrating tablets (ODTs). Designed to deliver active therapeutic agents either locally or systemically within the oral cavity under the tongue, on the roof of the mouth, in the intestines, or by holding in the mouth.[5-6]

Oral Thin Drug Delivery Development

I. Strip forming polymers

The polymer must to be non-irritating, non-toxic, and devoid of any impurities that could leak out. It should have great spreadability and moisture levels. The polymer's tensile, peel, and shear strengths must be adequate. The most widely used film forming for a long time is pullulan, which is included in products like Benadryl and Listerine PocketPak.11

II. Plasticizers

Plasticizers are essential to the OS formulation because they make the strip more flexible and less brittle. They do this by reducing the polymer's glass transition temperature, which greatly enhances the strip's properties.

Glycerol, propylene, low-molecular-weight polyethylene glycols, phthalate derivatives including dimethyl, diethyl, and dibutyl phthalate, citrate compounds like tributyl citrate, triethyl citrate, acetic citrate, triacetin, and castor oil are examples of common plasticizer excipients.11

III. Active pharmaceutical ingredient

Due to size restrictions, it is challenging to combine high-dose molecules onto oral strips. Oral strips can normally include active pharmaceutical substances in weight percentages between 5% and 30%.

IV. Sweetening, flavoring and coloring agents

Taste and color are important considerations in thin film medication technology, particularly for formulations meant for youngsters. Both natural and artificial sweeteners are used to improve the flavor of mouth-dissolving films since different people have different tastes. Pigments such as titanium dioxide are used for coloring.12

V. Stabilizing and thickening agents

Before casting, stabilizing and thickening chemicals are used to improve the suspension's or strip preparation solution's viscosity and consistency. In order to achieve uniform drug content in all dosage forms—especially those containing modest dosages of extremely strong medications—this modification is crucial. This criterion is satisfied by thin film formulations, which provide a consistent dispersion of medicine throughout the manufacturing process. Since maintaining homogenous dispersions is essential, it is advised to employ Laser Scanning Confocal Microscopy (LSCM) to monitor the production process in order to guarantee quality in the final pharmaceutical dosage form

Advantages of Oral Thin Films (OTF)[7-10]

1. Improved Patient Compliance:

OTFs are especially beneficial for patients who have difficulty swallowing pills, such as children, the elderly, or patients with dysphagia. They dissolve quickly on the tongue, eliminating the need for water or chewing, which enhances ease of use and patient adherence.

2. Rapid Onset of Action:

Since OTFs dissolve and release active ingredients directly in the oral cavity, they enable faster absorption, especially through sublingual or buccal mucosa, providing quicker relief than traditional oral dosage forms.

This is advantageous for medications requiring rapid onset, like pain relievers or anti-emetics.

3. Enhanced Bioavailability:

OTFs can bypass the gastrointestinal tract and avoid first-pass metabolism in the liver, improving the bioavailability of certain drugs. This can lead to more consistent dosing and therapeutic effects with lower doses than conventional oral forms.

4. Precision Dosing:

Unlike liquid formulations or other dissolving forms, OTFs provide precise doses of medication, reducing the risk of dosing errors and ensuring that patients receive an exact amount of the active ingredient.

5. Convenience and Portability:

OTFs are compact, lightweight, and easy to transport, making them ideal for on-the- go patients who might not have access to water. Their discreet form also appeals to users who prefer a less conspicuous dosing option.

6. Reduced Risk of Choking:

With no need for swallowing, OTFs are safer than tablets or capsules for certain patient populations. The quick-dissolving nature further minimizes the risk of choking, particularly in pediatric or geriatric patients.

Disadvantages of Oral Thin Films (OTF)[11]

1. Limited Drug Load Capacity:

The thin and compact nature of OTFs limits the amount of active ingredient that can be incorporated, making them less suitable for drugs that require higher doses. For high-dose medications, other dosage forms may be more practical.

2. Stability Challenges:

OTFs are sensitive to moisture and temperature, and without proper packaging, they may lose their effectiveness or degrade quickly. Specialized packaging is often needed, which can increase production costs.

3. Technical Manufacturing Complexity:

The production of OTFs requires precise control over thickness, uniformity, and content distribution. Techniques like solvent casting or hot-melt extrusion need to be carefully managed, making the manufacturing process more complex and potentially more costly than traditional forms.

4. Limited Suitability for All Drugs:

Not all drugs can be delivered through the mucosa effectively, and some may be too irritating or unstable in the mouth. Drugs requiring high bioavailability or stability in the gastrointestinal tract might be unsuitable for OTF formulations.

5. Taste Masking Challenges:

Despite improvements in taste-masking technology, some drugs have strong, unpleasant flavors that can be difficult to fully mask, which may reduce patient acceptance.

Methods For Preparation of Oral Thin Films (OTFS) [12,13]

The major methods are:

Solvent Casting Method: The polymer is dissolved in a suitable solvent such as water or alcohol, followed by the addition of plasticizers like glycerin or PEG to improve flexibility. The drug, sweeteners, flavors and other excipients are then incorporated into the polymeric solution. After removing air bubbles, the solution is cast on a flat surface or mold and dried under controlled temperature to form a thin uniform film, which is then cut into small strips containing accurate dose. This method is simple, cost-effective, and suitable for heat-sensitive drugs.

Hot Melt Extrusion (HME): The drug and polymer are physically mixed and fed into a heated extruder. The mixture melts and is homogenized under pressure, then extruded through a flat die to obtain a continuous film. This method does not require solvents and produces films with excellent mechanical strength, but it is not ideal for thermolabile drugs due to high processing temperatures.

Semisolid Casting Method: This Method involves forming a thick, semisolid mass of polymer, plasticizer, and drug, which is spread over a casting plate using a scraper or roller. Upon drying, it forms a thin flexible film. This technique is mainly used for polymers that cannot dissolve easily but swell into a gel-like consistency.

Solid Dispersion Method: It is used mainly for poorly soluble drugs. The drug is first dispersed within a polymer matrix by solvent evaporation or fusion, and the resulting solid dispersion is then mixed with a film-forming solution to produce OTFs. This improves drug solubility and uniform distribution across the film.

Rolling Method: Another industrial method is the Rolling Method, in which a solution or suspension of drug and polymer is rolled continuously between rotating rollers. As the solvent evaporates during rolling, a consistent thin film is formed, which is later collected and cut. This technique is suitable for large-scale continuous manufacturing.

Electrospinning Method:

These are also used for very fast-dissolving films. In this method, a high-voltage electric field is applied to a drug–polymer solution, producing fine nanofibers that deposit on a collector and are subsequently pressed into thin films. This method generates extremely thin films with high surface area and very rapid disintegration.

3D Printing Method: Recently, 3D Printing has emerged as a modern method for preparing personalized oral films. Drug-loaded polymeric inks are printed layer by layer to obtain films with precise doses and customized drug release profiles.

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