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Sublingual films: Formulation, characterization, and therapeutic applications

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Abstract
Fast-dissolving orally disintegrating films are formulated to dissolve quickly when they come into contact with wet surfaces or fluids, such as saliva, typically within seconds. Unlike tablets, capsules, or oral liquids, they do not require additional liquids like water, making them a highly convenient dosage form for patients. This formulation also offers significant marketing benefits. Orally disintegrating films are particularly advantageous for pediatric and geriatric patients, as well as those with a fear of choking, due to their ease of administration and popularity. Since the drug is absorbed directly into the bloodstream through the mucosal membrane in the mouth, it bypasses degradation in the gastrointestinal tract and avoids first pass metabolism. This enhances the drug's availability in plasma, thereby improving its therapeutic efficacy.

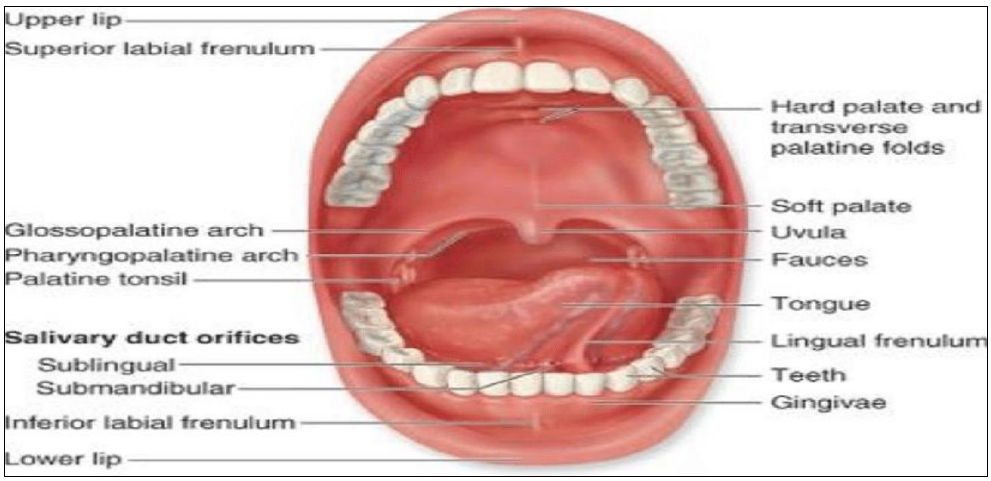
Keywords: Sublingual drug delivery, buccal and sublingual delivery systems, film-forming polymers, plasticizers, solvent casting method

Introduction

The oral route remains the most preferred method for systemic drug administration due to its convenience, safety and high patient compliance. Approximately 60% of pharmaceutical formulations are solid dosage forms, with tablets being the most widely accepted because of their ease of manufacturing, handling and transportation. However, geriatric, pediatric and bedridden patients often face difficulties swallowing conventional tablets or capsules, leading to the need for alternative dosage forms that offer ease of administration and rapid action.

To address this challenge, oral fast-dissolving films (FDFs) have emerged as a promising drug delivery system. These thin, flexible films rapidly disintegrate upon contact with saliva when placed on the tongue or sublingual mucosa, enabling quick drug release and absorption through the oral mucosa. This approach bypasses first-pass metabolism, thereby improving bioavailability and offering a faster onset of therapeutic action.

The delivery system consists of a very thin oral strip, which is simply placed on the patient's tongue or any oral mucosal tissue, instantly wet by saliva the film rapidly hydrates and adheres onto the site of application. It then rapidly disintegrates and dissolves to release the medication for oromucosal absorption or with formula modifications, will maintain the quick-dissolving aspects allow for gastrointestinal absorption to be achieved when swallowed.



A piece of smooth muscle and mucosa is also stable and therefore suitable for control of stored paper. The drug is absorbed into the systemic circulation. The extensive soft tissue and weak mucosa make it suitable for archival management. The drug is absorbed into the systemic circulation through the deep lingual or facial vein, the internal carotid artery and the brachiocephalic vein bypassing the drug. Since it does not cause first-pass metabolism in the liver, various drug delivery methods have achieved high bioavailability, the oral route will be the most preferred route by patients and doctors. To form a film, put it on the patient's tongue or tissue, and it should be quickly moistened with saliva; It breaks down and dissolves rapidly, releasing the drug for absorption through the oral mucosa. > Environment. The sublingual film is made of hydrophilic polymers that can dissolve rapidly on the tongue or groove and deliver the drug into the body via the sublingual mucosa. Designed for drugs with rapid drug elimination, extensive first-pass metabolismand lower, improved bioavailability.

Table 1: comparative assessment between sublingual films buccal tablets and buccal films [4, 5]

Feature	Sublingual Films	Buccal Tablets	Buccal Films
Placement Site	Under the tongue (sublingual)	Between gum and cheek (buccal)	Between gum and cheek (buccal)
Onset of Action	Very Rapid (minutes)	Moderate to Fast	Rapid to Moderate
Drug Release	Immediate/Rapid	Sustained/Controlled	Controlled/Sustained
Permeability	High (thinner, 100–200 Mmu μ m)	Low to Moderate	Moderate to High
Mucoadhesion	Low (not intended for retention)	High (designed for retention)	Very High (flexible, adapts to mucosa)
Comfort/Flexibility	High (thin, flexible)	Low (hard, can cause irritation)	High (flexible, less irritation)
Key Advantage	Fastest onset of action	High dose capacity	Superior patient comfort
Limitation	Saliva/movement interferes	Can be uncomfortable	Cost of manufacturing

Structure And Compostion Of Sublingual Films [6, 7].

Sublingual films are thin, flexible, postage stamp-sized, single or multi-layered, and drug-loaded films designed for rapid dissolution under the tongue. They are designed for high, rapid and controlled drug absorption.

Structure of Sublingual Films

Sublingual films consist of a thin layer that acts as a carrier for the drug, with a size often ranging from 5-20 cm².

- **Dimensions:** Typical films are 0.5-1 inch x 0.5-1 inch, with a thickness of 0.015-0.05 inches.
- **Single Layer:** Most common structure, which contains all components mixed in a single polymer matrix.
- **Multilayer System:** Used for modified or sustained release.
- **Amorphous/Solid Solution:** The API is generally dispersed or dissolved in a polymer matrix, improving the texture, solubility, and uniformity of the drug in the film.
- **Drug Distribution:** Micronized APIs are preferred for better dissolution, uniformity and texture.

Composition of Sublingual Films

Sublingual films are composed of a matrix of water-soluble polymers, APIs, and various excipients.

- **Active Pharmaceutical Ingredient (API):** Typically 1-25% w/w, often micronized.
- **Film-Forming Polymers:** 45-65% w/w (e.g., HPMC, PVA, Pullulan, HPC, PVP).
- **Plasticizers:** 0-20% w/w (e.g., Glycerol, Propylene Glycol, PEG 400).
- **Saliva Stimulating Agents:** 2-6% w/w (e.g., Citric Acid, Malic Acid, Tartaric Acid).
- **Sweetening Agents:** 3-6% w/w (e.g., Sucrose, Saccharin, Acesulfame-K, Sorbitol).
- **Flavoring Agents:** Up to 10% w/w (e.g., Peppermint, Orange, Mint).
- **Surfactants/Coloring Agents:** q.s. (e.g., Sodium Lauryl Sulfate, Titanium Dioxide).

Mechanism of absorption of sublingual films: [8]

Drug solutes administered sublingually are quickly absorbed into the reticulated vein, which is located beneath the mouth mucosa. From there, they travel through the internal jugular vein, brachiocephalic vein, facial vein and reticulated vein before being emptied into the systemic circulation. Drugs administered sublingually enter the bloodstream through the tongue's ventral surface and the floor of the mouth. Sublingual medication absorption is 3 to 10 times greater than oral absorption and is only surpassed by hypodermic injection.

Advantages And Disadvantages Of Sublingual Films

Advantages

1. This delivery method is significantly easier to use than tablets or capsules, which patients with mental, paediatric and elderly conditions may find difficult to swallow.
2. Compared to liquid dose forms, this method of administration allows for more accurate dosing and more comfortable medication delivery.
3. It facilitates rapid or direct absorption of the medication through the mucosal lining of the mouth beneath the tongue, resulting in an instant systemic action.
4. The drug's bioavailability is increased by avoiding the GI tract, the hepatic portal system and the hepatic first pass metabolism.
5. Quick absorption because of the tongue's high vascularization.
6. The medicine will be more stable because the pH in the mouth is comparatively neutral.
7. Better adherence from patient.

Disadvantages

1. Not appropriate for patients who are unconscious or unwilling.
2. Not appropriate for bitter medications.
3. Smoking, eating, and drinking are prohibited.
4. It is prohibited to provide highly ionic drugs.
5. It is inconvenient to hold the dose in the mouth; if any is swallowed, the part needs to be handled as an oral dose and go through first pass metabolism.
6. It is not feasible to administer large dosages of medication.
7. The films are sensitive to moisture, and their packaging is not cost-effective.

Limitations of Sublingual Films [9, 10].

Sublingual films are primarily limited by their inability to deliver high-dose medications, their unsuitability for drugs with unpleasant tastes, and their restriction to short-term, acute treatment rather than sustained-release applications. They require patient cooperation, making them unsuitable for unconscious or uncooperative individuals.

Key limitations include:

- **Low Drug Loading:** Generally limited to smaller doses (up to ≈is approximately equal to≈65 mg), making them unsuitable for drugs requiring high dosages.
- **Taste and Irritation:** Bitter-tasting or irritating drugs cannot be effectively administered via this route.
- **Drug Type Restriction:** Primarily suitable for drugs that pass through passive diffusion.

- **Administration Constraints:** Patients cannot eat, drink or smoke while the film dissolves and it is not suitable for, or effective in, unconscious patients.
- **Environmental Sensitivity:** Films are sensitive to moisture, requiring specialized, often costly packaging.
- **Unsuitable for Sustained Release:** Not designed for prolonged or slow-release medication, as they are designed for fast dissolution.

Applications Of Sublingual Films [11].

1. **Emergency and Acute Condition Management**

- **Cardiovascular Diseases:** Sublingual films containing Nitroglycerin are used for treating angina pectoris.
- **Acute Hypertension:** Nifedipine, a calcium channel blocker, is delivered via this route for hypertensive urgency.
- **Breakthrough Cancer Pain:** Fentanyl citrate and buprenorphine are frequently administered via sublingual films to manage rapid-onset pain.
- **Migraine and Asthma:** Sumatriptan succinate and Salbutamol sulphate have been investigated for inclusion in fast-dissolving films to treat acute attacks.

2. **Treatment of Central Nervous System (CNS) Disorders**

- **Schizophrenia and Bipolar Disorder:** The FDA approved the sublingual formulation of dexmedetomidine (Igalmi) for acute agitation, as highlighted in studies on mental disorders.
- **Parkinson's Disease:** Selegiline hydrochloride, used for treating Parkinson's, has been developed into sublingual films to overcome poor oral bioavailability and avoid first-pass metabolism.

3. **Geriatric and Pediatric Patients (Dysphagia)**

These films are highly useful for patients with dysphagia (swallowing difficulties), the elderly and children, as they require no water and dissolve instantly.

- **Improved Compliance:** Studies show that pediatric and geriatric patients prefer these films over traditional tablets.
- **Alzheimer's Care:** The films are effective for patient groups who may resist medication.

4. **Over-the-Counter (OTC) and Nutraceuticals**

- **Nutritional Supplements:** Vitamin B12 and Vitamin D are available in sublingual film formats for rapid absorption, note researchers.
- **Motion Sickness and Pain:** OTC films for motion sickness are marketed in the US.

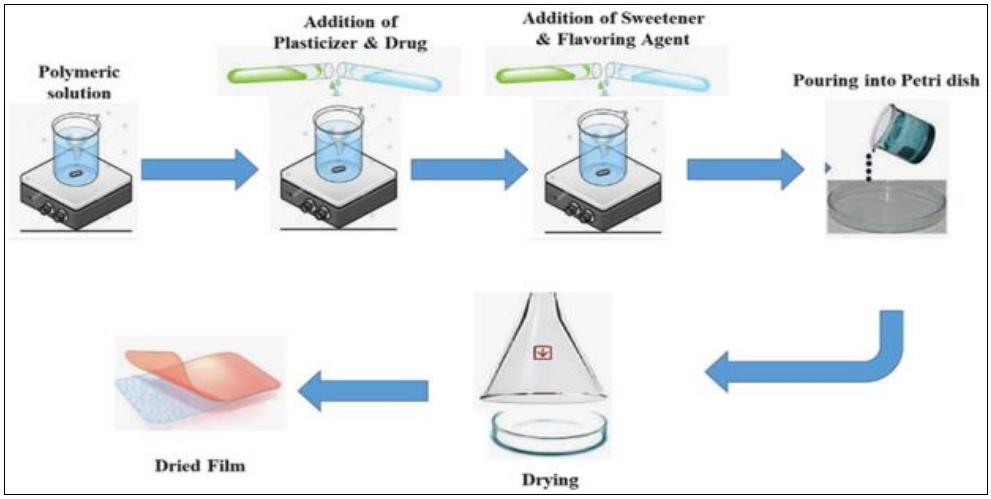
5. **Specialized Drug Delivery (Niosomal/Complex)**

- **Niosomal Films:** Metoprolol tartrate has been successfully delivered via niosomal sublingual films to enhance bioavailability and prolong therapeutic effects.
- **Solid Dispersions:** Mosapride citrate and similar drugs can be formulated into sublingual films using solid-dispersion techniques to improve solubility.

Method of Preparation [12, 13].

1. **Solvent Casting Method**

It is a very old technique for making films. This process involves first dissolving the water-soluble polymers in water at 1,000 rpm and then heating the mixture to 60°C. Every other excipient colors, flavourings, sweeteners, etc. is dissolved independently. After that, both of the solutions are fully combined while being stirred at 1,000 rpm. The API is dissolved in an appropriate solvent and added to the resultant solution. Vacuum is used to remove the trapped air. The final solution is formed into a film, left to dry and then cut into the desired size pieces.

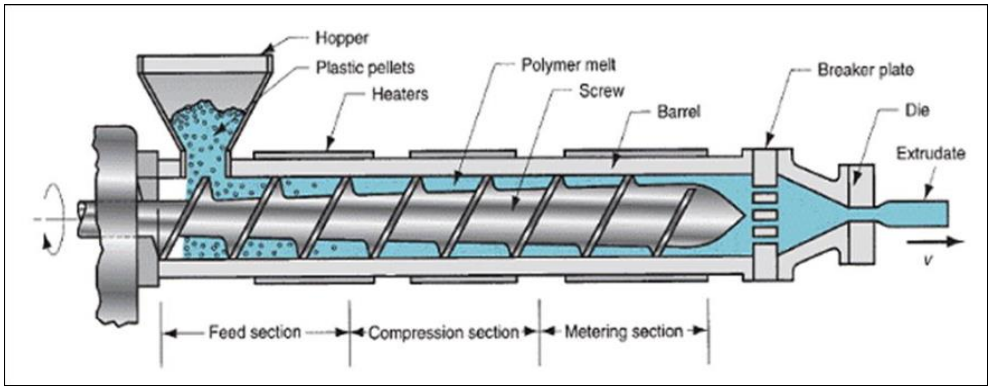


2. **Semisolid Casting Method**

When working with acid-insoluble polymers, the semisolid casting process is typically employed. This process creates a water-solublefilm-forming polymer solution, which is subsequently added to an acid-insoluble polymer solution created with sodium or ammoniumhydroxide. To create the gel mass, plasticiser is then added. The gel mass's properties are influenced by the amount of plasticisersupplied. A heat-controlled roller/drum is then used to cast the gel mass into a ribbon film. the proportion of film-forming and acidinsoluble polymers. This process creates a film that is between 0.015 and 0.05 inches thick.

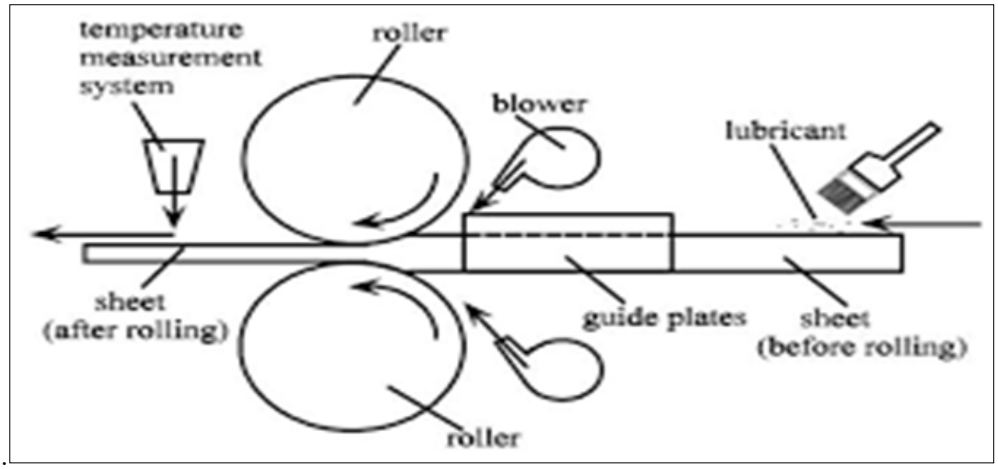
3. Hot Melt Extrusion

First, the medication and carriers are combined in a solid state using the hot melt extrusion process. The mixture is then melted by theextruder's heaters. Lastly, the dies form the melt into films. Hot melt extrusion has some advantages. Better content uniformity andanhydrous process with fewer operating units. Improved bioavailability and dissolution rate are the results of the API and othercomponents. heated to a point where the mixture melts and is subsequently extruded to create thin films. Using the right method, thesolvent is totally eliminated.



4. Rolling method

The rolling method involves rolling a drug-containing solution or suspension on a carrier. Alcohol and water make up the majority ofthe solvent. Using a high shear processor, the film is dried on rollers and a cutter to the appropriate shapes and sizes. Additionalingredients, such as active agents, are dissolved in a tiny amount of aqueous solvent. A homogeneous, viscous solution is createdwhen water-soluble hydrochloride is dissolved in water.



Evaluation parameter of sublingual film [14].

1. **Thickness:** The thickness of the film was measured with the help of Vernier Calliper at three different places and theaverages of three values can be calculated. This is necessary to ensure uniformity in the thickness of thefilm, which is directly related to dose accuracy in the film.

2. **Weight variation: The** cast film was cut into four centimeter squares in three distinct spots. The weight of each film wastaken, and the weight variation was determined.

3. **pH value:** To determine the pH value, dissolve one oral film in 10ml pure water and measure the pH of the resultingsolution. It is necessary that the pH of the film be approximately consistent.

4. **Folding endurance:** Folding endurance was determined by repeatedly folding the film in the same place until the strip broke.The folding endurance value was calculated by counting the number of times the film could be foldedwithout breaking.

5. **Content uniformity:** To determine the drug content, dissolve the film in 100 ml of an appropriate solution to obtain a 20 g/mlsolution. An aliquot of 2ml sample can be removed and diluted to 10ml with a solution.The solution can then be filtered through a Whatman filter and spectrophotometrically evaluated.

6. **Young's modulus:** Young's modulus, also known as elastic modulus, is a measure of strip stiffness. It is defined as the appliedstress over strain ratio in the region of elastic deformation. Strips that are hard and brittle have a hightensile strength and a young's modulus with a small elongation.

7. ***In vitro* dissolution study:** The *in vitro* dissolution study can be performed in 500 ml of pH 6.8 phosphate buffer using a (USP) XIVpaddle apparatus II at 3700.5°C and 50 rpm. Each square cut film sample was

immersed in the dissolutionmedia for 30 minutes, with appropriate aliquots collected at prescribed intervals. A UV Spectro-photometer is used to determine the drug concentration.

8. **Morphology study:** A motic electron photomicrograph can be used to study the morphology of the created film. At 100 Xmagnification, motic electron photomicrographs can be obtained.

9. **Stability study:** Stability studies on the prepared formulations of an oral rapid dissolving film are being conducted toinvestigate the effect of temperature and humidity on the drug's stability. The film can be stored inaluminum foil and subjected to room temperature stability testing. At 90 and 180 days, the sample can bewithdrawn and subjected to disintegration tests and *in vitro* dissolution studies to evaluate disintegrationtime and cumulative% drug release.

10. **Tensile strength:** Tensile strength is defined as the maximum stress that can be applied to a film specimen before it breaks31. It is calculated as follows: applied load at rupture divided by the cross-sectional area of the film.

Characterisation Of Sublingual Films [15].

- **Physical Properties:** Weight variation, thickness (typically measured with micrometer) and surface texture.
- **Mechanical Strength:** Tensile strength, % elongation, and folding endurance (measures flexibility and ability to withstand handling).
- **Surface pH:** Essential to ensure the film does not irritate the oral mucosa, generally aimed at a range of 6.5 – 7.5.
- **Drug Content/Uniformity:** Confirms consistent drug distribution throughout the film, usually required to be within 95–105%95 – 105 %95–105% or similar, ensuring accurate dosing.
- **Disintegration Time:** Crucial for sublingual, with optimal films dissolving within 30 to 60 seconds.
- ***In vitro* Dissolution/Drug Release:** Measures the speed and extent of drug release, frequently tested in simulated saliva.
- **Moisture Content/Absorption:** Evaluates the moisture content using a desiccator or moisture analyzer to assess stability and prevent premature brittleness.
- **Compatibility Studies (FTIR/DSC):** FTIR (Fourier Transform Infrared Spectroscopy) and DSC (Differential Scanning Calorimetry) are used to ensure no chemical interaction between the drug and excipients.
- **Morphology (SEM):** Scanning Electron Microscopy is used to assess the surface, porosity and distribution of particles.
- **Bioadhesion/Retention:** Evaluates how well the film adheres to the sublingual mucosa, often tested using simulated tissue.

Conclusion

Fast-dissolving films represent a significant advancement in drug delivery systems, offering unique benefits for pediatric and geriatric populations who may struggle with traditional dosage forms. By utilizing the sublingual route, these films ensure rapid disintegration and direct absorption into systemic circulation, bypassing first-pass metabolism. This results in higher bioavailability and a faster onset of action compared to oral administration. Consequently, sublingual thin films are not only a preferred choice for improving patient compliance but are also indispensable in emergency scenarios—such as allergic reactions or asthmatic attacks where immediate therapeutic intervention is critical. Key Takeaways Summary Target Audience: Ideal for pediatric and geriatric patients due to ease of use. Mechanism: Direct systemic absorption via the sublingual route avoids first-pass metabolism. Primary Benefit: Immediate onset of action, making them crucial for emergencies (e.g., asthma, allergies). Efficiency: Higher percentage of drug absorption compared to standard oral routes.

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