

**A COMPREHENSIVE AND STRUCTURED OVERVIEW OF  
SUBLINGUAL FILM DRUG DELIVERY SYSTEMS**

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Article Received on 14 May 2026,

Article Revised on 04 June 2026,

Article Published on 16 June 2026,

<https://doi.org/10.5281/zenodo.20695769>

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**How to cite this Article:** Kiran Hanamantagouda Agasimundin\*, Snehalatha, Likhith G. K., Tejavardanareddy, Srilekha J. S. (2026). A Comprehensive And Structured Overview Of Sublingual Film Drug Delivery Systems. World Journal of Pharmaceutical Research, 15(12), 307-328.

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**ABSTRACT**

Sublingual drug delivery systems offer a promising alternative to conventional oral dosage forms by enabling rapid drug absorption and improved bioavailability while bypassing first-pass metabolism. The sublingual mucosa, being highly vascularized, facilitates direct entry of drugs into systemic circulation, resulting in faster therapeutic action. Among various dosage forms, sublingual films have gained attention due to their rapid disintegration, ease of administration and enhanced patient compliance, especially in pediatric, geriatric and dysphagic populations. The performance of these films depends on factors such as drug physicochemical properties, polymer selection and mucosal permeability. Recent advancements, including bioadhesive systems, solid dispersion techniques and taste-masking approaches have further improved their effectiveness and acceptability. Despite limitations such as dose constraints and possible mucosal irritation, sublingual films represent a convenient and efficient drug delivery platform with significant potential in modern pharmaceutical applications.

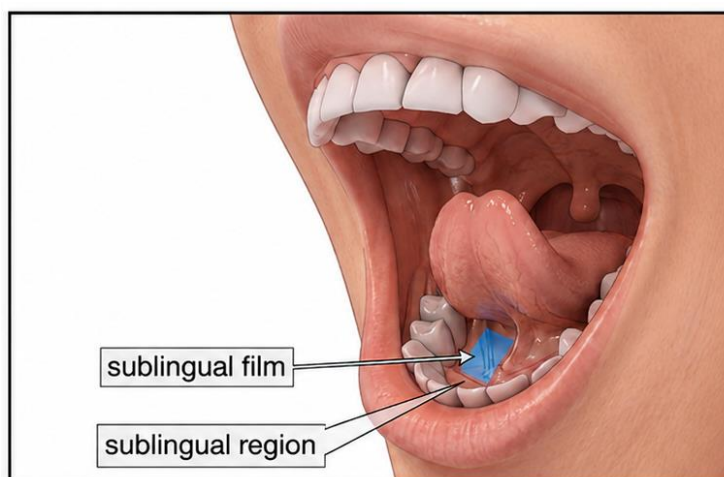
**KEYWORDS:** Sublingual films, Bioavailability, Fast disintegration, Mucoadhesive systems, Taste masking.

## INTRODUCTION

The oral route remains the most widely used method of drug administration, accounting for nearly 70% of all pharmaceutical dosage forms. However, conventional oral tablets often exhibit limitations such as delayed onset of action due to gastric emptying time and intestinal absorption. In addition, many drugs undergo extensive first-pass metabolism in the liver, resulting in reduced systemic bioavailability and the need for higher doses.<sup>[1-3]</sup>

Sublingual drug delivery provides an effective alternative by utilizing the highly vascularized area beneath the tongue for rapid absorption. The sublingual route is considered second only to subcutaneous injection in terms of speed of systemic absorption due to its rich blood supply and direct access to systemic circulation.<sup>[4]</sup>

The term sublingual, literally meaning “under the tongue” refers to a route of administration in which substances are delivered into the oral cavity and absorbed rapidly through the vascular network beneath the tongue rather than through the gastrointestinal tract. Substantial evidence indicates that the majority of agents administered sublingually are taken up primarily by passive diffusion, with the sublingual mucosa functioning in a manner analogous to an absorbent medium, readily facilitating uptake. However, not all substances are sufficiently permeable or accessible to the oral mucosa.<sup>[5]</sup>



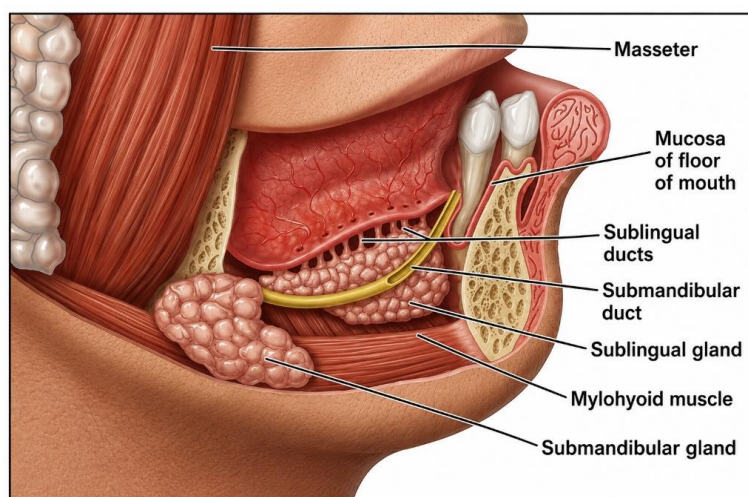
**Figure 1.1: Image showing the placement of a film in the Sublingual region.<sup>[6]</sup>**

Compared to conventional peroral administration, the sublingual route is particularly advantageous for drugs that are unstable in the acidic gastric environment or susceptible to enzymatic degradation in the gastrointestinal tract. Unlike orally administered drugs that must

pass through the portal circulation and liver, sublingual drugs bypass hepatic first-pass metabolism, resulting in enhanced bioavailability and therapeutic efficacy at lower doses.<sup>[7,8]</sup>

This review provides a comprehensive and structured overview of sublingual film drug delivery systems, encompassing formulation design, selection of suitable polymers and excipients, manufacturing techniques and evaluation parameters. It also discusses the anatomical and physiological considerations of the sublingual route, along with the advantages and limitations associated with this delivery system. Furthermore, the review highlights recent advancements and emerging trends in sublingual film technology, emphasizing their potential to enhance drug bioavailability, ensure rapid onset of action and improve patient compliance.

### Anatomy & Physiology



**Figure1.2: Image showing components of Sublingual mucosa.<sup>[9]</sup>**

The sublingual glands are located beneath the mucosa of the floor of the mouth, above the mylohyoid muscle and lateral to the tongue. They consist of one major gland along with several minor glands. Structurally, they appear oval in cross-section and elongated along the mandible. The glands lack well-developed ducts and secrete saliva through multiple small ducts (ducts of Rivinus) opening into the sublingual folds.

The sublingual glands receive their primary blood supply from the sublingual and submental arteries, which arise from the lingual and facial arteries, respectively. Both of these arteries are branches of the external carotid artery. Venous drainage occurs through the sublingual vein, which drains into the lingual vein and subsequently into the internal jugular vein.<sup>[10]</sup>

Although the oral epithelium generally exhibits limited permeability, the sublingual mucosa demonstrates relatively higher permeability compared to other regions of the oral cavity due to its thinner epithelial layer and rich vascularization. This enhanced permeability facilitates rapid drug absorption primarily via passive diffusion across the lipoidal membrane. Consequently, drugs administered through sublingual films can achieve a fast onset of action. The permeability of the sublingual route is largely governed by the physicochemical properties of the drug, including molecular weight, lipophilicity, degree of ionization and solubility. Additionally, formulation-related factors such as film composition, presence of permeation enhancers and hydration behaviour significantly influence the drug's ability to permeate through the sublingual mucosa.<sup>[11]</sup>

The pH of saliva in the sublingual mucosal region is primarily regulated by bicarbonate, phosphate and protein buffer systems, maintaining a range of approximately 6.0–7.5 depending on salivary flow rate. This near-neutral pH supports the integrity of the sublingual mucosa and influences drug ionization, thereby affecting permeability and absorption. Variations in local pH, especially under reduced salivary flow (xerostomia), may alter the microenvironment and impact drug dissolution and transport across the mucosa. Additionally, the thin salivary film covering the sublingual area creates a distinct microenvironment that may differ from whole saliva, influencing localized drug delivery performance.<sup>[12]</sup>

### Advantages and Limitations<sup>[13-18]</sup>

Sublingual films represent a novel and patient-oriented dosage form developed to improve drug delivery within the oral cavity. Compared to conventional dosage forms, these films offer greater formulation versatility and adaptability to the physiological conditions of the oral mucosa. Owing to these features, they have gained increasing interest as an alternative platform for delivering a wide range of therapeutic agents.

**Table 2.1: Comparison between Sublingual Films and Sublingual Tablets.**

Parameter	Sublingual Film	Sublingual Tablet
Dosage form	Thin, Flexible polymeric film	Solid compressed unit dosage form
Disintegration time	Very rapid (Sec)	Relatively slower (Sec to min)
Dissolution	Fast due to larger surface area	Slower compared to film
Mucoadhesion	Better adhesion to sublingual mucosa	Limited adhesion
Onset of action	Rapid onset due to quick hydration and absorption	Slightly delayed compared to films
Patient compliance	High (easy to administer, no water required)	Moderate (may cause discomfort in some patients)

Dose uniformity	Good (uniform drug distribution in film matrix)	May vary depending on compression uniformity
Formulation flexibility	High (can incorporate polymers, plasticizers, permeation enhancers)	Limited compared to films
Mechanical properties	Flexible, non-brittle	Rigid and may be fragile
Stability & handling	Good, portable, less fragile	May be prone to breakage or friability

**Table 2.2: Key Differences between Sublingual Films and Other Dosage Forms.**

Sl. No.	Dosage Form	Key Differences from Sublingual Films
1	Tablets/Capsules	Require swallowing and gastrointestinal processing; lack site-specific placement and adaptability in oral cavity
2	Liquid Formulations	Prone to dosing inaccuracies and lower stability; do not provide localized retention in oral mucosa
3	Buccal Systems	Designed for prolonged retention and slower drug release; less flexible and comfortable than films
4	Orally Disintegrating Tablets	Disintegrate in mouth but do not adhere to mucosa; higher chance of drug loss due to swallowing
5	Conventional Oral Dosage Forms	Subject to variable absorption conditions and formulation constraints; less adaptable to oral environment
6	Parenteral Dosage Forms	Invasive, require sterile conditions and trained personnel; lack patient-friendly administration

These distinctions highlight the unique positioning of sublingual films as a versatile and patient-friendly dosage form. Their ability to overcome limitations associated with conventional and alternative systems supports their growing importance in modern drug delivery.

### Limitations

Although sublingual drug delivery systems offer significant therapeutic benefits, they are not without drawbacks. Various physiological, formulation-related and patient-dependent factors can limit their effectiveness and acceptability.

#### ➤ Patient Compliance and Administration Challenges

These routes may be inconvenient for patients, as they require adherence to specific techniques to ensure that the dosage form remains in the sublingual or buccal region for adequate absorption without being swallowed.

#### ➤ Limited Drug Candidate Suitability

Not all drugs are suitable for administration via the sublingual or buccal route. Typically, only drugs that are effective at low doses can be delivered using this approach.

➤ **Unpleasant Organoleptic Properties**

Drugs administered through this route may possess an unpalatable or bitter taste and may cause irritation to the oral mucosa, which can negatively affect patient acceptability.

➤ **Risk of Incomplete Drug Delivery**

Irritation or unpleasant taste may result in voluntary expulsion or premature swallowing of the dosage form, thereby reducing drug absorption and therapeutic efficacy.

➤ **Potential Risk of Aspiration**

Although minimal, there exists a risk of accidental aspiration of the dosage form during administration.

➤ **Postural Requirements During Administration**

Patients are generally advised to remain in an upright position while administering the medication to reduce the likelihood of aspiration.

➤ **Unsuitability for Certain Patient Populations**

Sublingual and buccal routes are not recommended for use in unconscious or uncooperative patients due to the inability to ensure proper administration.

➤ **Limitations for Sustained Drug Delivery**

These routes are generally not suitable for sustained or prolonged drug release, as extended retention of the dosage form may cause discomfort.

➤ **Interference with Routine Activities**

The presence of the dosage form in the oral cavity may interfere with activities such as eating and drinking, potentially reducing patient compliance.

**Drug Selection Criteria<sup>[19]</sup>**

For a drug to be effectively delivered through the sublingual route, it must possess specific physicochemical characteristics that facilitate rapid absorption across the oral mucosa. These properties play a crucial role in determining the drug's suitability for formulation into sublingual dosage forms.

**Table 2.3: Physicochemical Criteria for Drugs Suitable for Sublingual Drug Delivery.**

Sl.No	Parameter	Desired Characteristics	Significance
1	Dose	Less than 20mg	Ensures efficient absorption due to limited surface area of the sublingual region
2	Taste	Not intensely bitter	Improves patient compliance and prevents premature swallowing or expulsion
3	Stability	Stable in saliva and aqueous environment	Maintains drug integrity during dissolution and absorption
4	Molecular Weight	Small to moderate (163-342)	Facilitates rapid permeation through the mucosal membrane
5	pKa	>2 (acidic drugs), <10 (basic drugs)	Promotes presence of unionized form at salivary pH for better absorption
6	Log P value	1.6-3.3	Provides balance between lipophilicity and aqueous solubility
7	Lipophilicity	Moderately lipophilic	Enhances passive diffusion across lipid rich mucosa
8	Hydrogen Bond Acceptors	Limited (approx. 1–5)	Reduces excessive intermolecular interactions, improving permeability
9	Hydrogen Bond Donors	Limited (approx. 0–2)	Supports better membrane diffusion
10	Polar Surface Area	Low (13-16)	Facilitates transport across biological membranes
11	Rotatable Bonds	Few (0.5-6)	Improves membrane permeability and drug stability

**Formulation Components<sup>[20-22]</sup>****1. Active Pharmaceutical Ingredient (API)**

- The API should ideally have.
- Low dose
- High permeability and moderate solubility
- Pleasant or maskable taste

Drugs with high bioavailability via transmucosal delivery are preferred.

**2. Film-Forming Polymers (Key Component)**

- These form the backbone of the film and control:
  - Mechanical strength
  - Disintegration time
  - Drug release behavior
- Common polymers:
  - Natural: Pullulan, gelatin, pectin, sodium alginate

- Synthetic/semi-synthetic: HPMC, PVA, PVP, CMC
- Typically constitute 30–70% of formulation
- Importance: Polymer selection directly influences flexibility, tensile strength and dissolution kinetics.

### 3. Plasticizers

- Improve flexibility and reduce brittleness of films
  - Mechanism: Reduce intermolecular forces between polymer chains
  - Examples.
    - Glycerol
    - Propylene glycol
    - PEG
- Plasticizers increase elongation and reduce tensile strength, improving film handling.

### 4. Permeation Enhancers

- Essential for sublingual delivery due to limited mucosal permeability
- Function.
  - Enhance drug transport across mucosa
- Examples.
  - Surfactants (Tween 80, sodium lauryl sulfate)
  - Bile salts
  - Fatty acids.

### 5. Mucoadhesive Agents

- Improve residence time under the tongue (important due to salivary washout)
- Examples.
  - Chitosan
  - Carbopol
  - HPMC
- Mucoadhesive polymers enhance bioavailability by prolonging contact with mucosa.

### 6. Taste Masking Agents

- Critical due to direct contact with taste buds
- Methods:

- Sweeteners (aspartame, saccharin, sucralose)
- Flavoring agents (mint, citrus)
- Complexation (cyclodextrins)
- Taste masking improves patient compliance significantly.

### 7. Saliva Stimulating Agents

- Promote rapid disintegration and dissolution
- Examples:
  - Citric acid
  - Malic acid
  - Tartaric acid

### 8. Stabilizers and Preservatives

- Maintain chemical and physical stability
- Examples.
  - Antioxidants (BHT, ascorbic acid)
  - Preservatives (parabens)

### 9. Coloring and Flavoring Agents

- Enhance aesthetic appeal and patient acceptability
- Usually used in small quantities (<2%)

### 10. Surfactants

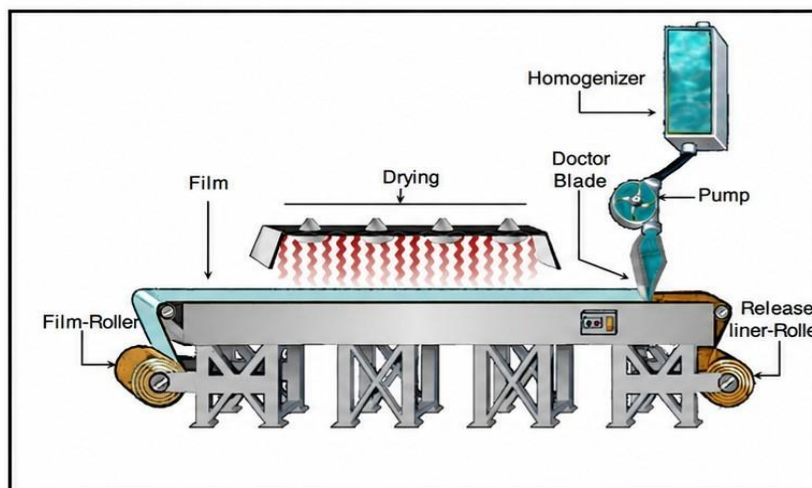
- Improve wetting and drug solubility
- Facilitate uniform drug distribution
- Typically used in 1–2% concentration

### Manufacturing methods<sup>[12]</sup>

Oral and sublingual films are developed using a combination of conventional manufacturing methods and advanced drug loading techniques to achieve uniformity, flexibility and precise dosing.

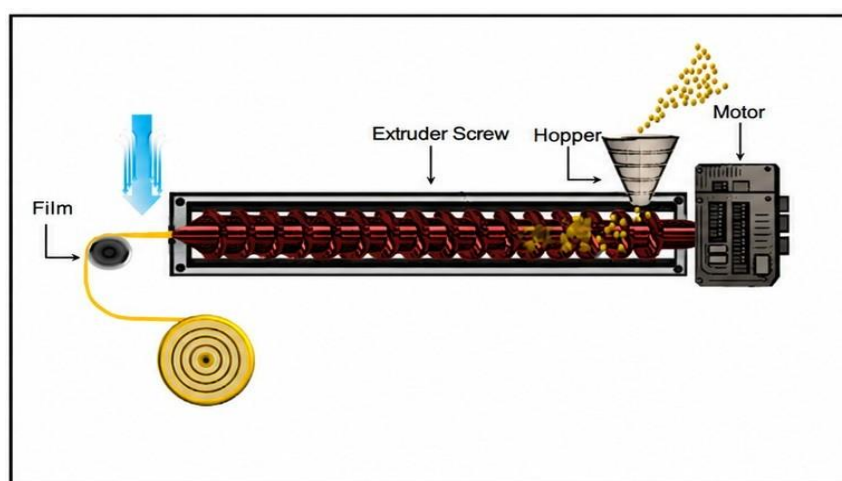
**1. The solvent casting Technique:** It is the most widely used technique for the preparation of oral films. In this method, the polymer is dissolved in a suitable solvent, followed by the addition of drug and other excipients to form a homogeneous solution. The resulting mixture

is cast onto a flat surface and dried under controlled conditions to remove the solvent, forming a thin and uniform film. The dried film is then cut into appropriately sized strips and packaged. This method provides excellent uniformity and smooth film formation; however, it is limited by issues such as residual solvent and longer drying time.



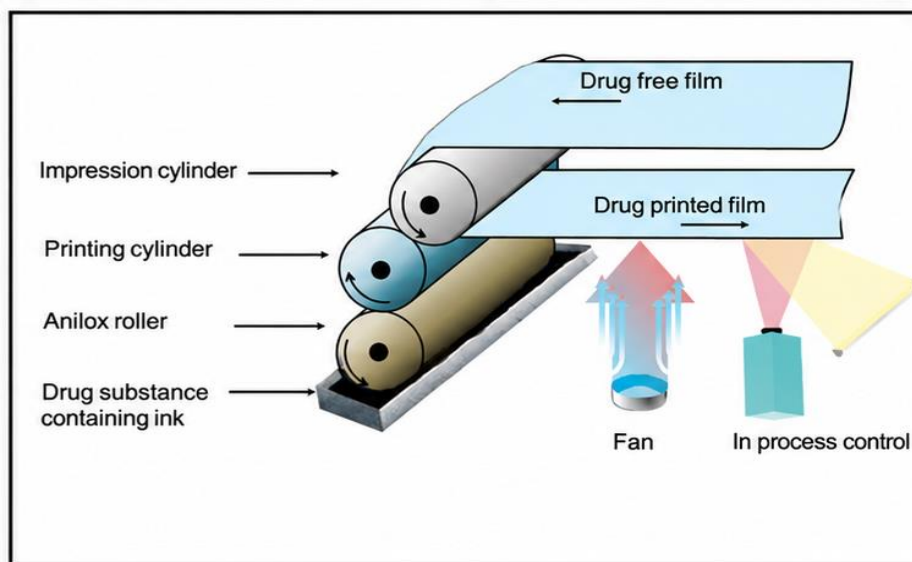
**Figure 1.3: Schematic representation of Solvent casting method for preparation of Sublingual films.**

**2. Hot melt extrusion Technique:** It involves the processing of a mixture of drug and thermoplastic polymers at elevated temperature and pressure. The mixture is melted and forced through an extruder to produce a continuous film, which is then cooled and cut into the desired size. This solvent-free technique avoids solvent-related problems and improves content uniformity, but it is not suitable for thermolabile drugs and requires specialized equipment.



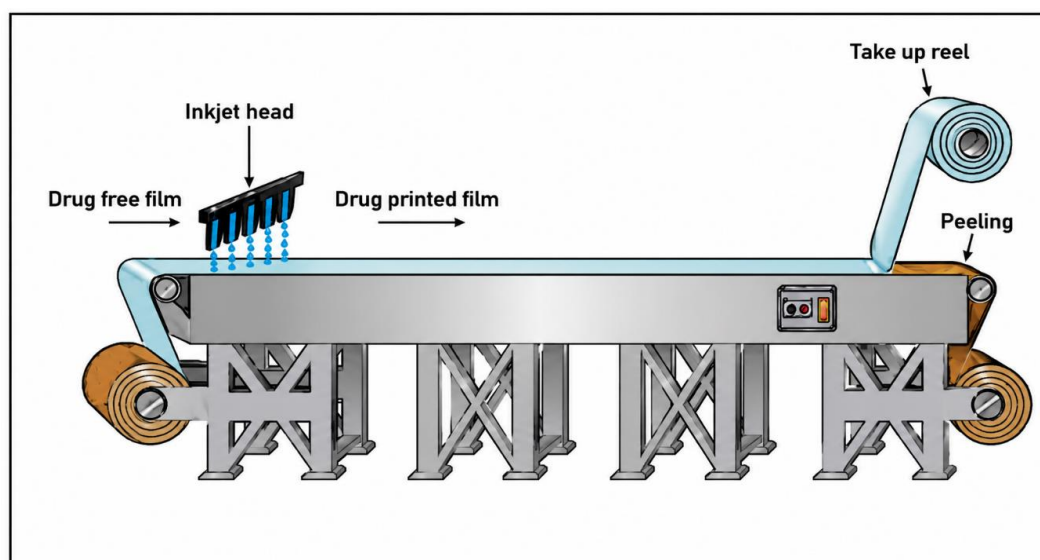
**Figure1.4: Schematic representation of Hot melt extrusion method.**

**3. Flexographic printing:** It is a high-speed roll-to-roll process in which drug-loaded ink is transferred onto the film surface using a flexible printing plate mounted on a rotating cylinder. The ink is regulated by an anilox roller and uniformly deposited onto the substrate. This technique is highly suitable for large-scale production.



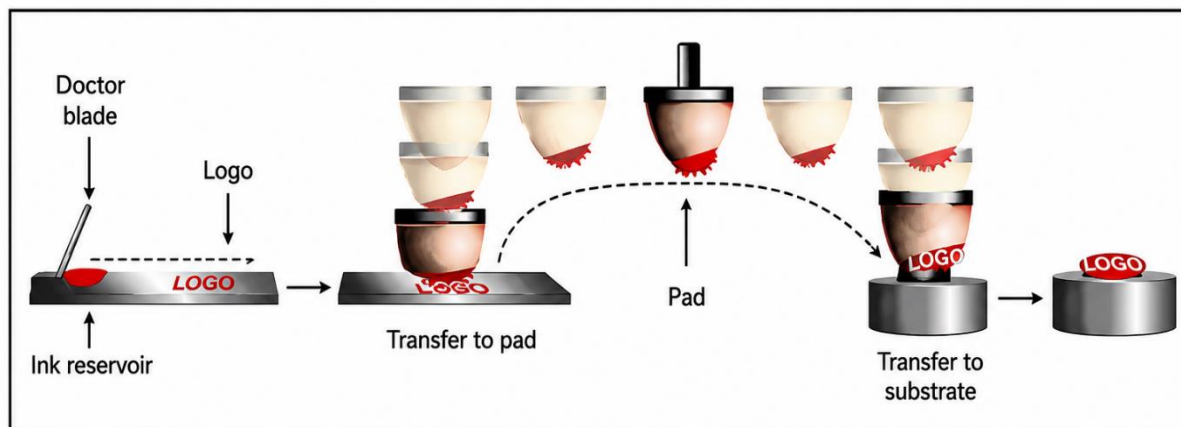
**Figure1.5: Schematic representation of Flexographic printing method.**

**4. Inkjet printing:** It is a non-contact technique that delivers precise amounts of drug solution as micro-droplets onto the film surface through a controlled nozzle system. It allows accurate dosing and minimal material wastage, making it particularly suitable for personalized medicine and low-dose drug delivery.



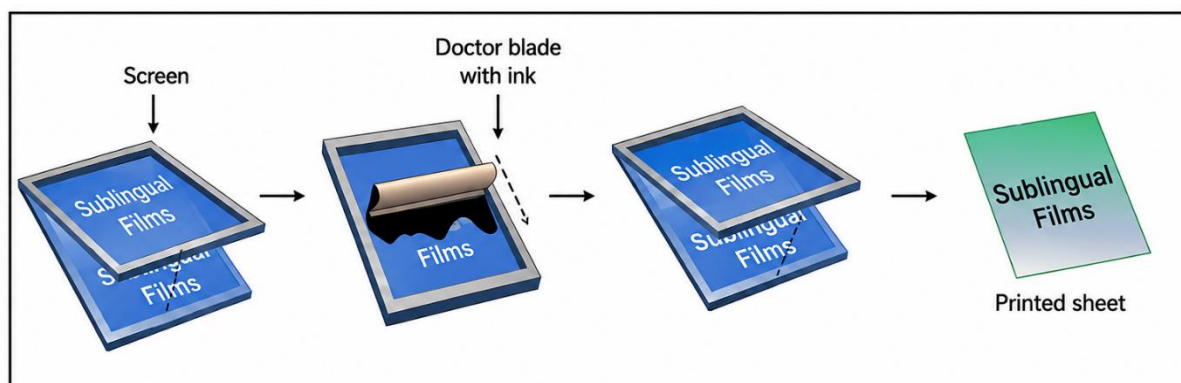
**Figure1.6: Schematic representation of Inkjet printing method.**

**5. Pad printing:** It is an indirect printing method in which the drug formulation is transferred from a printing plate to a soft elastomeric pad and then onto the film surface. This technique is useful for printing on small or irregular surfaces but is generally limited to small-scale applications.



**Figure 1.7: Schematic representation of Pad printing method.**

**6. Screen printing:** It utilizes a mesh screen and a squeegee to transfer the drug formulation onto the film. The formulation passes through the open areas of the mesh, forming a uniform layer on the substrate. This method is widely used for controlled and reproducible drug deposition.



**Figure 1.8: Schematic representation of Screen printing method.**

### Evaluation Parameters<sup>[23-27]</sup>

#### i. Physical Appearance and Surface Morphology

The prepared films are visually inspected for uniformity in colour, transparency, smoothness and absence of air bubbles or cracks. A consistent and elegant appearance ensures uniform drug distribution and improves patient acceptability. Advanced techniques such as scanning

electron microscopy may be used to analyse surface morphology and detect structural irregularities.

#### ii. Thickness (mm)

Film thickness is measured at different points using a micrometer screw gauge to ensure uniformity. Consistent thickness is essential for maintaining dose accuracy and uniform drug release across all film units.

#### Equation

$$\text{Mean Thickness} = \frac{\sum t}{n}$$

**Standard limit:** Variation should generally be within  $\pm 5\%$  of the mean value to ensure dose uniformity (commonly accepted pharmacopeial practice).

#### iii. Weight Variation (mg)

Individual films are weighed using an analytical balance to assess weight consistency. Minimal variation in weight indicates uniform distribution of formulation components, particularly the active pharmaceutical ingredient.

#### Equation

$$\% \text{ Weight Variation} = \frac{|W_i - W_{\text{avg}}|}{W_{\text{avg}}} \times 100$$

#### USP guideline (adapted)

- Limit typically  $\pm 7.5\%$  (for small dosage forms)
- Ensures uniform distribution of API.

#### iv. Folding Endurance (No of folds)

Folding endurance is determined by repeatedly folding the film at the same point until it breaks. This parameter reflects the flexibility and mechanical strength of the film, which is important for handling, packaging and transportation.

**Standard limit:** Should withstand at least 50–200 folds (Based on which type of polymer used) without breaking for acceptable flexibility.

**v. Tensile Strength and Percentage Elongation**

Tensile strength measures the maximum stress the film can withstand before breaking, while percent elongation indicates its elasticity. These properties are evaluated using a texture analyser and are critical for determining the film's mechanical robustness and flexibility.

$$\text{Tensile Strength (N/mm}^2\text{): } TS = \frac{F}{A}$$

**Where:**

F = Force at break, A = Cross-sectional area

$$\text{Percent Elongation (\%E): } \%E = \frac{Lf - L0}{L0} \times 100$$

**Typical limits**

- TS: 2–10 MPa (depending on polymer)
- %Elongation: 10–50%
- These ranges indicate good mechanical strength and flexibility.

**vi. Surface pH**

The surface pH of the film is measured after moistening it with distilled water. Ideally, the pH should be close to neutral to avoid irritation or discomfort when the film is placed under the tongue.

**Standard limit**

- Should be within 6.0–7.5 (close to salivary pH)
- Prevents mucosal irritation (important for sublingual delivery).

**vii. Disintegration Time (sec)**

Disintegration time is the time required for the film to break down completely in simulated saliva. For sublingual films, rapid disintegration is essential to ensure quick drug release and onset of action.

**USP ODT guideline (adapted)**

- Should be  $\leq 30$  seconds (ideal for sublingual films)
- Some studies accept up to 60 seconds.

**viii. In-Vitro Dissolution Study**

Dissolution studies are conducted using suitable dissolution media such as simulated saliva fluid. This test evaluates the rate and extent of drug release from the film, which is crucial for predicting in-vivo performance.

**Cumulative Drug Release (%).**

$$\% \text{Drug release} = \frac{\text{Amount of drug released}}{\text{Total drug content}} \times 100$$

**Standard expectation**

- $\geq 80$ –85% drug release within 5–15 minutes
- Ensures rapid onset of action.

**ix. Drug Content Uniformity (%)**

Drug content is determined by dissolving the film in an appropriate solvent and analyzing it using UV spectroscopy or HPLC. Uniform drug content ensures consistent dosing and therapeutic efficacy.

**Equation**

$$\% \text{ Drug content} = \frac{\text{Actual drug content}}{\text{Theoretical drug content}} \times 100$$

**USP limit**

- Must be within 85%–115% of label claim
- Relative standard deviation (RSD) should be low (<6%).

**x. Moisture Content and Moisture Uptake (%)**

Moisture content is determined by drying the film, while moisture uptake is assessed under controlled humidity conditions. These parameters are important for evaluating the stability, mechanical integrity and susceptibility to microbial growth.

**Moisture Content**

$$\% \text{ Moisture Content} = \frac{W_i - W_f}{W_i} \times 100$$

**Moisture Uptake**

$$\% \text{ Moisture Uptake} = \frac{W_f - W_i}{W_f} \times 100$$

**Typical limits**

- Moisture content: 1–5%
- Excess moisture can lead to microbial growth and reduced stability.

**xi. Mucoadhesive Strength**

Mucoadhesive strength is measured using specialized instruments that determine the force required to detach the film from mucosal tissue. Adequate mucoadhesion ensures prolonged residence time and enhanced drug absorption.

**Detachment Force**

$$\text{Mucoadhesive Strength} = \frac{\text{Force required to detach}}{\text{Area}}$$

**Typical range**

- 5–20 N/m<sup>2</sup> (depends on polymer and formulation)
- Adequate adhesion ensures prolonged residence time.

**xii. Permeation Studies**

Permeation studies are typically carried out using Franz diffusion cells with biological or synthetic membranes. These studies evaluate the ability of the drug to permeate through the sublingual mucosa, which directly impacts bioavailability.

**Flux (µg/cm<sup>2</sup>/min)**

$$J = \frac{dQ}{dt} \times A$$

**Where**

dQ/dt = rate of drug permeation

A = surface area

**Permeability Coefficient (cm/sec)**

$$P = \frac{J}{C}$$

**Standard expectation**

- Should show consistent and significant drug permeation across mucosa
- No strict USP limit, but comparative studies are used.

**Applications**<sup>[28-32]</sup>

Sublingual films have emerged as a promising drug delivery system due to their rapid disintegration, enhanced bioavailability and ease of administration. Their applicability spans a wide range of therapeutic areas, particularly where rapid onset of action is essential.

**1. Breakthrough Pain Management**

Sublingual films are effectively used for delivering potent opioids such as fentanyl, providing rapid onset of analgesia in cancer patients experiencing breakthrough pain.

**2. Opioid Dependence Therapy**

Films containing buprenorphine and naloxone are widely utilized in opioid substitution therapy, offering controlled dosing, improved compliance and reduced abuse potential.

**3. Antiemetic Therapy**

Sublingual films of drugs like ondansetron and granisetron are beneficial in the management of chemotherapy-induced nausea and vomiting, ensuring quick relief.

**4. Cardiovascular Disorders**

These films are explored for drugs used in angina and hypertension, where rapid systemic availability is critical for therapeutic effectiveness.

**5. Neurological and Psychiatric Disorders**

Sublingual films are used for delivering drugs intended for conditions such as anxiety, schizophrenia and insomnia, enabling faster onset and improved patient adherence.

**6. Allergic and Emergency Conditions**

Fast-dissolving sublingual films are being investigated for emergency use in conditions such as anaphylaxis and acute allergic reactions due to their rapid drug release.

**7. Hormonal Drug Delivery**

Hormones such as estrogen and other systemic agents can be delivered via sublingual films to bypass hepatic first-pass metabolism and improve bioavailability.

**8. Paediatric and Geriatric Applications**

Sublingual films are particularly advantageous for patients with dysphagia, including paediatric and geriatric populations, due to ease of administration without water.

## 9. Anti-migraine Therapy

Drugs used in migraine management can be formulated as sublingual films to provide rapid onset of relief during acute attacks.

### Recent Advances<sup>[33-36]</sup>

Recent advancements in sublingual film technology have significantly improved drug delivery efficiency, formulation stability and patient compliance. Several formulation strategies have been validated through experimental studies, as outlined below.

#### 1. Fast-Disintegrating Film Matrices

Optimization of polymer blends has enabled ultra-rapid disintegration of films within seconds.

**Example:** Ondansetron sublingual films developed using HPMC showed rapid disintegration and faster drug release profiles.

#### 2. High Drug-Loading Capacity Films

Advanced film-forming techniques allow incorporation of higher drug doses without compromising mechanical integrity.

**Example:** Fentanyl sublingual films used for breakthrough cancer pain demonstrate effective delivery of potent drugs in small film sizes.

#### 3. Solid Dispersion-Based Sublingual Films

Solid dispersion techniques improve solubility of poorly water-soluble drugs.

**Example:** Sublingual films of itraconazole prepared using solid dispersion showed enhanced dissolution and bioavailability.

#### 4. Bioadhesive Sublingual Films

Mucoadhesive polymers enhance residence time and drug absorption.

**Example:** Bioadhesive films of propranolol hydrochloride demonstrated prolonged mucosal contact and improved drug permeation.

#### 5. Combination Drug Films

Dual-drug sublingual films provide synergistic therapeutic action.

**Example:** Buprenorphine–naloxone sublingual films are widely used in opioid dependence therapy, improving compliance and reducing misuse.

## 6. Advanced Taste-Masking Techniques

Modern approaches improve palatability without affecting drug release.

**Example:** Taste-masked films of rizatriptan using ion-exchange resins showed improved patient acceptability.

## 7. Stability-Enhanced Film Formulations

Efforts focus on improving shelf-life and resistance to environmental conditions.

**Example:** Furosemide-loaded sublingual bioadhesive films showed improved physicochemical stability and enhanced bioavailability.

## 8. Improved Manufacturing Techniques

Techniques like solvent casting and hot-melt extrusion ensure uniform drug distribution and scalability.

**Example:** Nisoldipine sublingual films prepared via solid dispersion and solvent casting exhibited uniformity and enhanced dissolution.

## CONCLUSION

Sublingual film drug delivery systems represent a significant advancement in the field of drug delivery by offering rapid drug absorption, avoidance of first-pass metabolism and improved bioavailability. Their ease of administration, portability and patient-friendly nature make them particularly suitable for special populations such as paediatric and geriatric patients, as well as for conditions requiring immediate therapeutic action.

The success of sublingual films largely depends on appropriate selection of drug candidates, optimization of formulation parameters and enhancement of mucosal permeability. Recent innovations, including bioadhesive films, solid dispersion-based systems and advanced taste-masking techniques have further expanded their therapeutic potential and applicability.

However, certain challenges such as limited drug loading capacity, possible mucosal irritation and difficulties in delivering sustained-release formulations still need to be addressed. Future research should focus on overcoming these limitations through novel materials and advanced manufacturing techniques.

Overall, sublingual films hold considerable promise as an efficient and convenient drug delivery system, with growing applications in modern pharmaceuticals and significant potential for future development.

**ACKNOWLEDGE**

The authors gratefully acknowledge SJM College of Pharmacy, Chitradurga and its library for providing access to relevant scientific literature and research resources. The authors also express their sincere appreciation to their mentors and the institution for their continuous support, invaluable guidance and constructive discussions throughout the preparation of this review article.

**REFERENCE**

1. Jain NK, Sharma SN. A textbook of professional pharmacy. 6th ed. New Delhi: Vallabh Prakashan, 2016.
2. Birudaraj R, Berner B, Shen S, Li X. Buccal permeation of buspirone: mechanistic studies on transport pathways. *J Pharm Sci*, 2005; 94(1): 70-78.
3. Ishikawa T, Koizumi N, Mukai B, Utoguchi N, Fujii M, Matsumoto M. Pharmacokinetics of acetaminophen following sublingual administration. *Chem Pharm Bull (Tokyo)*, 2001; 49(6): 734-739.
4. Price TM, Blauer KL, Hansen M, Stanczyk FZ, Lobo RA. Single-dose pharmacokinetics of sublingual versus oral estradiol. *Obstet Gynecol*. 1997; 89(3): 340-345.
5. Narang N, Sharma J. Sublingual mucosa as a route for systemic drug delivery. *Int J Pharm Pharmac Sci*, 2011; 3(2): 18-22.
6. <https://www.zimlab.in/blog-posts/formulation-aspects-of-sublingual-technology>
7. Chinchore MV, Kakade SM, Bhosale AV. Development and evaluation of amlodipine besylate sublingual films. *Int J Pharm Sci Rev Res*, 2014; 26(2): 67-72.
8. Gordon A, Roland D. Biopharmaceutics classification system: scientific basis and applications. *J Pharm Sci*. 1997; 86(5): 542-548.
9. La'Porte SJ, Juttla JK, Lingam RK. Imaging the floor of the mouth and the sublingual space. *Radiographics*, 2011; 31(5): 1215-30.
9. Grewal JS, Bordoni B, Shah J, Ryan J. Anatomy, head and neck, sublingual gland. *InStatPearls [Internet]* 2023. StatPearls Publishing.
10. Bahraminejad S, Almoazen H. Sublingual and buccal delivery: a historical and scientific prescriptive. *Pharmaceutics*, 2025; 17(8): 1073.
11. Aframian DJ, Davidowitz T, Benoliel R. The distribution of oral mucosal pH values in healthy saliva secretors. *Oral diseases*, 2006; 12(4): 420-3.

12. Borges AF, Silva C, Coelho JF, Simões S. Oral films: current status and future perspectives: I—galenical development and quality attributes. *Journal of Controlled Release*, 2015; 206: 1-9.
13. Bhyan B, Jangra S, Kaur M, Singh H. Orally fast dissolving films: innovations in formulation and technology. *Int J Pharm Sci Rev Res*, 2011; 9(2): 9-15.
14. Nibha KP, Pancholi SS. An overview on: Sublingual route for systemic drug delivery. *Intra-oral Spray Technology*, 2012; 3: 1-3.
15. Sakthivel M, Prathap B, Mahendiran R, Arivananthan M, Parthiban M, Naveetha M. Review about liquid dosage form, 2021; 6(5): 24-30
16. Hirani JJ, Rathod DA, Vadalia KR. Orally disintegrating tablets: a review. *Trop Jour of Pharm Res*, 2009; 8(2): 161-172
17. Song Y, Day CM, Afinjuomo F, Tan JQ, Page SW, Garg S. Advanced strategies of drug delivery via oral, topical and parenteral administration routes: where do equine medications stand?. *Pharmaceutics*, 2023; 15(1): 186.
18. Hua S. Advances in nanoparticulate drug delivery approaches for sublingual and buccal administration. *Frontiers in pharmacology*, 2019; 10: 1328.
19. PA R, Malode AJ. A review: On sublingual tablets. *Ind. J. Res. Methods Pharm. Sci*, 2022; 1(6): 01-11.
20. Salawi A. An insight into preparatory methods and characterization of orodispersible film—A review. *Pharmaceutics*, 2022; 15(7): 844.
21. Rimkiene L, Baranauskaite J, Marksa M, Jarukas L, Ivanauskas L. Development and evaluation of Ginkgo biloba L. extract loaded into carboxymethyl cellulose sublingual films. *Applied Sciences*, 2020; 11(1): 270.
22. Ferlak J, Guzenda W, Osmałek T. Orodispersible films—current state of the art, limitations, advances and future perspectives. *Pharmaceutics*, 2023; 15(2): 361.
23. Gholve S, Savalsure S, Bhusnure O, Suryavanshi S, Birajdar M. Formulation and evaluation of oral fast dissolving sublingual film of propranolol HCl. *International Journal of Pharma Research and Health Sciences*, 2018; 6(2): 65-72.
24. De Caro V, Ajovalasit A, Sutura FM, Murgia D, Sabatino MA, Dispenza C. Development and characterization of an amorphous solid dispersion of furosemide in the form of a sublingual bioadhesive film to enhance bioavailability. *Pharmaceutics*, 2017; 9(3): 22.
25. Alhamhoom Y, Sharma A, Nanjappa SH, Kumar A, Alshishani A, Ahmed MM, Farhana SA, Rahamathulla M. Development and evaluation of solid dispersion-based sublingual films of nisoldipine. *Pharmaceutics*, 2023; 16(11): 1589.

26. Sukumaran SK. Formulation and Evaluation of Sublingual Film Loaded with Granisetron Hydrochloride. *Asian Journal of Pharmaceutics (AJP)*, 2021; 15(1).
27. Yang L, Fan X, Zhang J, Ju J. Preparation and characterization of thermoresponsive poly (N-isopropylacrylamide) for cell culture applications. *Polymers*, 2020; 12(2): 389.
28. Karki S, Kim H, Na SJ, Shin D, Jo K, Lee J. Thin films as an emerging platform for drug delivery. *Asian Journal of Pharmaceutical Sciences*, 2016; 11(5): 559–574.
29. Bala R, Pawar P, Khanna S, Arora S. Orally dissolving strips: A new approach to oral drug delivery system. *International Journal of Pharmaceutical Investigation*, 2013; 3(2): 67–76.
30. Visser JC, Woerdenbag HJ, Hanff LM, Frijlink HW. Personalized medicine in pediatric patients: oral film formulations of drugs. *International Journal of Pharmaceutics*, 2017; 523(1): 327–335.
31. Speer I, Preis M. Oromucosal film preparations: classification and characterization methods. *Expert Opinion on Drug Delivery*, 2016; 13(9): 1303–1317.
32. Boateng JS, Auffret AD, Matthews KH, Humphrey MJ, Stevens HNE, Eccleston GM. Characterisation of freeze-dried wafers and solvent evaporated films as potential drug delivery systems to mucosal surfaces. *International Journal of Pharmaceutics*, 2010; 389(1-2): 24–31.
33. Hoffmann EM, Breitenbach A, Breitzkreutz J. Advances in orodispersible films for drug delivery. *Expert Opin Drug Deliv*, 2011; 8(3): 299–316.
34. Preis M. Orally disintegrating films and mini-tablets—innovative dosage forms for pediatric use. *AAPS PharmSciTech*, 2015; 16(2): 234–241.
35. Siepmann J, Siepmann F. Mathematical modeling of drug delivery from polymeric films. *Int J Pharm*, 2013; 453(1): 12–24.
36. Arya A, Chandra A, Sharma V, Pathak K. Fast dissolving oral films: an innovative drug delivery system. *Int J ChemTech Res*, 2010; 2(1): 576–583.