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SUBLABIAL STRIPS: AN EMERGING APPROACH FOR TRANSMUCOSAL DRUG DELIVERY

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ABSTRACT
Sublabial strips have emerged as advanced mucoadhesive polymeric platforms designed for efficient transmucosal drug delivery. These thin flexible films are administered between the upper lip and gingival mucosa where they rapidly hydrate and release the incorporated drug either immediately or in a controlled manner. Sublabial delivery bypasses hepatic first-pass metabolism and minimizes gastrointestinal degradation, thereby enhancing systemic bioavailability and therapeutic efficacy. The present review highlights the anatomy of oral mucosa, mechanism of drug permeation, formulation components, manufacturing techniques, evaluation parameters, therapeutic applications, recent advancements, and future perspectives associated with sublabial strip technology. Various preparation techniques including solvent casting, hot melt extrusion, electrospinning, and rolling methods have been critically discussed along with their advantages and limitations. Recent investigations involving nanotechnology, smart polymers, nanofiber systems, and AI-assisted formulation strategies have further expanded the pharmaceutical potential of sublabial strips. Despite several advantages, challenges such as moisture sensitivity, limited drug loading capacity, scale-up difficulties, and packaging instability continue to restrict commercialization. Nevertheless, continuous advancements in pharmaceutical technology may establish sublabial strips as promising next-generation patient-centric drug delivery systems.

KEYWORDS: Sublabial drug delivery, Mucoadhesive film, Oral transmucosal delivery, Fast dissolving strip, Nanofiber oral film, Buccal drug delivery.

1. INTRODUCTION

The oral route is considered the most preferred and widely accepted route for drug administration because of its convenience, cost effectiveness, and high patient compliance. However, conventional oral dosage forms such as tablets and capsules are often associated with hepatic first-pass metabolism, delayed onset of action, and gastrointestinal degradation of drugs. These limitations have encouraged researchers to develop alternative transmucosal drug delivery systems for improved therapeutic effectiveness.[1-3]

Among the various transmucosal approaches, sublabial strips have emerged as a promising and patient-friendly drug delivery system. Sublabial strips are thin polymeric films administered between the upper lip and gingival mucosa where they adhere to the mucosal surface and release the incorporated drug rapidly or in a controlled manner. Due to the rich vascularization of the oral mucosa, drugs delivered through this route can bypass hepatic first-pass metabolism and achieve enhanced bioavailability.[4-5]

Sublabial strips provide several advantages including rapid onset of action, ease of administration without water, improved patient compliance, and suitability for pediatric, geriatric, and dysphagic patients. Recent advancements in polymer technology, nanotechnology, and oral film manufacturing have significantly increased the pharmaceutical importance of sublabial drug delivery systems.[6-7]

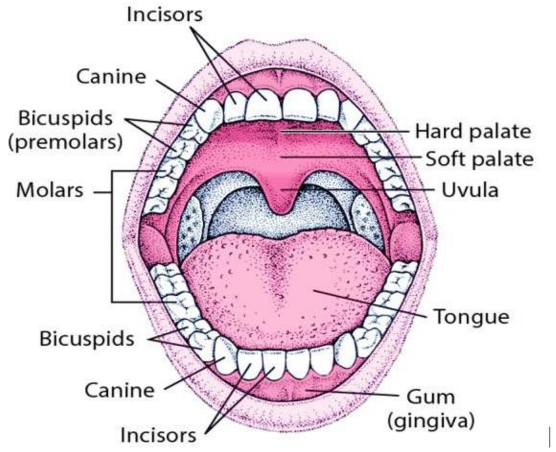

Fig. 1: Structure of Oral Cavity and Sublabial Region.

2. Structure of Oral Mucosa and Drug Absorption

The oral mucosa consists of stratified squamous epithelium, basement membrane, lamina propria, and submucosal layers. Drug absorption through oral mucosa mainly occurs through passive diffusion via transcellular and paracellular pathways.[5,8]

The sublabial mucosa possesses moderate permeability and rich blood supply, enabling rapid systemic drug absorption. Lipophilic drugs mainly diffuse through transcellular pathways, whereas hydrophilic drugs pass through intercellular spaces. Several physiological and physicochemical factors influence drug permeation through oral mucosa including epithelial thickness, salivary flow, lipid solubility, molecular weight, and degree of ionization.[9,10]

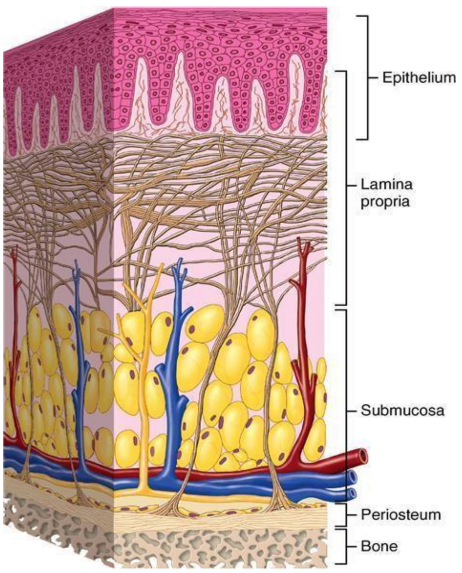

Fig. 2 Cross-sectional Structure of Oral Mucosa.

3. Sublabial Strips

Sublabial strips are advanced mucoadhesive polymeric dosage forms designed for administration in the sublabial cavity between the Lower lip and gingival mucosa. These thin flexible films rapidly hydrate in the presence of saliva and release the incorporated drug either immediately or in a controlled manner for local or systemic absorption.[1,2] The sublabial route has gained significant pharmaceutical interest because it bypasses hepatic first-pass metabolism and minimizes gastrointestinal degradation, thereby improving bioavailability and therapeutic efficacy of various drugs.[4] The rich vascularization of oral mucosa facilitates rapid drug permeation into systemic circulation and contributes toward faster onset of pharmacological action.[1]

Sublabial strips are generally prepared using hydrophilic polymers such as hydroxypropyl methylcellulose, pullulan, polyvinyl alcohol, sodium alginate, and other mucoadhesive polymers capable of forming thin and flexible films. Plasticizers, sweeteners, flavoring agents, saliva stimulants, and permeation enhancers are also incorporated to improve flexibility, palatability, and drug absorption characteristics.[2] These formulations offer several clinical and patient-oriented advantages including ease of administration without water, improved patient compliance, accurate dosing, portability, and reduced risk of choking. Such characteristics make them highly suitable for pediatric, geriatric, dysphagic, and ambulatory patients.[1,4]

Various manufacturing techniques including solvent casting, hot melt extrusion, electrospinning, and rolling methods have been investigated for the preparation of sublabial strips depending upon drug properties and desired release characteristics. Among these techniques, solvent casting remains the most widely utilized method because of its simplicity, cost effectiveness, and ability to produce uniform films. In recent years, nanotechnology-based oral films and electrospun nanofiber systems have further expanded the therapeutic potential of sublabial drug delivery systems. Despite several advantages, certain limitations including moisture sensitivity, limited drug loading capacity, and packaging challenges continue to affect large-scale commercialization of sublabial strips.

Nevertheless, continuous advancements in polymer science and pharmaceutical technology are expected to establish sublabial strips as promising next generation transmucosal drug delivery platforms.[1,2,4]

Fig. 3 Administration of Sublabial Strip.

4. Advantages of Sublabial Strips[1,4,5,7]

- Sublabial strips bypass hepatic first-pass metabolism, thereby improving systemic bioavailability of drugs.
- These dosage forms provide rapid onset of therapeutic action because of direct transmucosal absorption through the highly vascularized oral mucosa.
- Sublabial strips can be administered without water, enhancing convenience and patient compliance.
- The flexible and thin film structure improves ease of administration in pediatric and geriatric patients.
- Sublabial delivery systems are highly suitable for dysphagic and unconscious patients who experience difficulty in swallowing conventional tablets and capsules.
- The risk of choking is significantly reduced compared to conventional solid oral dosage forms.
- Accurate dosing can be achieved because of uniform drug distribution within the film matrix.
- The strips are portable, lightweight, and easy to handle during transportation and administration.
- Mucoadhesive properties prolong residence time at the site of administration and improve drug absorption.
- Sublabial strips improve therapeutic effectiveness by minimizing gastrointestinal degradation of susceptible drugs.
- These systems enhance patient acceptance because of pleasant taste and ease of use.
- Sublabial strips can be removed easily if therapy discontinuation becomes necessary.
- They are capable of providing both immediate and controlled drug release depending upon formulation design.
- The dosage form offers improved stability and flexibility when suitable polymers and plasticizers are incorporated.

5. Limitations of Sublabial Strips[3,6]

Despite numerous advantages, sublabial strips possess certain limitations that may affect formulation development and therapeutic performance.

- The drug loading capacity of oral strips is comparatively low, restricting their use to potent drugs administered in smaller doses.
- Drugs that produce irritation or unpleasant sensations in the oral cavity are generally unsuitable for sublabial administration.
- Stability issues may also arise because of moisture sensitivity and environmental humidity.
- In some cases, accidental swallowing of the strip may reduce therapeutic effectiveness.
- Taste masking remains another major challenge, particularly for bitter drugs.
- Additionally, specialized packaging materials are often required to protect the strips from mechanical damage and moisture exposure during storage.

6. Ideal Drug Candidates[5,9]

An ideal drug candidate for sublabial delivery should possess suitable physicochemical and pharmacokinetic properties for efficient transmucosal absorption.

- The drug should possess low dose requirement for effective therapeutic action.
- It should exhibit good permeability across the oral mucosal membrane for efficient transmucosal absorption.
- The drug should have adequate aqueous solubility to facilitate rapid dissolution in saliva.
- Molecules with low molecular weight are generally preferred because they permeate oral mucosa more efficiently.
- The drug should remain stable in salivary pH and oral cavity conditions.
- Drugs undergoing extensive hepatic first-pass metabolism are considered suitable candidates for sublabial delivery.
- The drug should possess short biological half-life where rapid absorption can improve therapeutic performance.
- Non-irritating drugs are preferred to avoid damage or discomfort to oral mucosal tissues.
- The drug should have acceptable taste and odor to improve patient compliance and palatability.
- Drugs requiring rapid onset of action are highly suitable for sublabial administration.
- The molecule should exhibit sufficient lipophilicity to enhance transmucosal permeation.
- The drug should be compatible with film-forming polymers and other formulation excipients.

7. Components of Sublabial Strips

7.1 Active Pharmaceutical Ingredient

The drug should exhibit sufficient potency and permeability for transmucosal absorption.

7.2 Film Forming Polymers

Film-forming polymers are the major structural components responsible for film formation and mucoadhesion.

Commonly Used Polymers

Polymer	Function
HPMC	Film former
Pullulan	Fast dissolving polymer
PVA	Flexible film matrix
Polymer	**Function**
Chitosan	Mucoadhesive polymer
Sodium alginate	Bioadhesive polymer
Carbopol	Strong mucoadhesion

7.3 Plasticizers

Plasticizers improve flexibility and mechanical strength. Examples.

- Glycerol
- Polyethylene glycol

- Propylene glycol

7.4 Sweeteners and Flavouring Agents

These agents improve palatability and patient acceptability. Examples.

- Aspartame
- Saccharin sodium
- Peppermint oil
- Menthol

8. Methods of Preparation[10]

8.1 Solvent Casting Method

Solvent casting is the most widely used method for preparing sublabial strips due to its simplicity and ability to produce uniform films. In this technique, film-forming polymers are dissolved in a suitable solvent, followed by addition of the drug, plasticizers, sweeteners, flavoring agents, and other excipients to obtain a homogeneous solution. The prepared solution is cast onto a flat surface and dried under controlled conditions to remove the solvent completely. After drying, the film is peeled off and cut into strips of desired size and dosage. This method provides smooth, flexible, and mechanically stable films with uniform drug distribution; however, it requires proper drying conditions to avoid residual solvent problems.

8.2 Hot Melt Extrusion

Hot melt extrusion is an advanced solvent-free technique used for the preparation of sublabial strips. In this method, the drug is mixed uniformly with thermoplastic polymers and other excipients such as plasticizers and sweetening agents. The mixture is introduced into an extruder where it is exposed to controlled temperature and pressure. The rotating screws inside the extruder continuously mix, melt, and convey the formulation material to produce a homogeneous molten mass. The molten mixture is then forced through a flat die to obtain thin film-shaped extrudates. These films are cooled, cut into suitable strip sizes, and packed in moisture-resistant packaging materials. The hot melt extrusion technique offers several advantages including uniform drug distribution, elimination of organic solvents, shorter processing time, and continuous manufacturing capability. The method also improves drug solubility and dissolution characteristics by converting crystalline drugs into amorphous forms. However, this technique is mainly suitable for heat-stable drugs and polymers because high processing temperatures may cause degradation of thermosensitive ingredients. Due to its scalability and reproducibility, hot melt extrusion has become an important industrial approach for manufacturing modern oral thin films and sublabial strips.

8.3 Electrospinning Method

Electrospinning is an advanced technique used for the preparation of nanofiber-based sublabial strips with rapid drug release and high surface area. In this method, a polymeric drug solution is loaded into a syringe and subjected to a high-voltage electric field, which produces fine nanofibers collected on a grounded surface. The obtained nanofiber film is then dried and processed into thin sublabial strips. Electrospun strips exhibit improved drug dissolution, enhanced mucoadhesion, and better permeation characteristics because of their porous structure and large surface area. This method is particularly useful for delivering poorly soluble drugs and achieving rapid therapeutic action. However, the technique requires specialized equipment and careful control of process parameters such as voltage, flow rate, and polymer concentration.

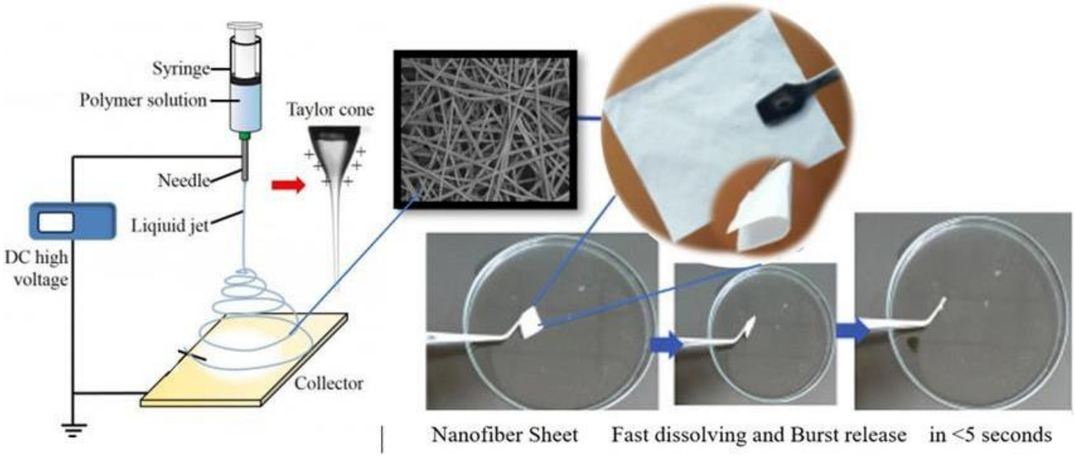

Figure 4: Nanofiber Formation by Electrospinning Technique.

8.4 Rolling Method

The rolling method is a continuous manufacturing technique used for the preparation of sublabial strips in which a drug-containing polymeric solution or suspension is continuously spread onto a carrier using rollers. The formulation mixture containing film-forming polymers, drug, plasticizers, and other excipients is prepared and fed between rollers to obtain a uniform film thickness. The formed film is then dried under controlled temperature conditions to remove the solvent and subsequently cut into strips of suitable size. This method is advantageous for large-scale production because it provides uniformity, reduced processing time, and continuous operation. However, careful control of rolling speed, drying temperature, and viscosity of the formulation is necessary to obtain strips with consistent quality and mechanical strength.

Method	Advantages	Limitations
Solvent Casting	Simple	Residual solvent
Hot Melt Extrusion	Solvent free	Heat instability
Electrospinning	Rapid release	Costly
Rolling Method	Continuous process	Complex control

9. Evaluation Parameters[1-10]

Comprehensive evaluation of sublabial strips is essential to ensure physicochemical stability, mechanical integrity, therapeutic performance, and patient acceptability, formulation quality, mechanical stability, drug content uniformity, and therapeutic performance. Various physicochemical, mechanical, and performance-related parameters are evaluated to determine the effectiveness and acceptability of the dosage form.

1. Physical Appearance

Physical appearance evaluation includes visual inspection of the strip for color, transparency, smoothness, flexibility, homogeneity, and presence of air bubbles or surface imperfections. An ideal sublabial strip should possess a smooth surface with uniform appearance and should be free from cracks or particulate matter.

2. Thickness Measurement

Thickness of the strip is measured using a digital micrometer or Vernier caliper at different points of the film. Uniform thickness is important because it directly influences drug content, mechanical strength, and dissolution characteristics. Variability in film thickness may result in inconsistent drug release profiles.

3. Weight Variation

Individual strips are weighed separately using an analytical balance to determine uniformity in weight. Minimal weight variation indicates uniform distribution of polymers and active pharmaceutical ingredients throughout the film matrix. This analysis determines for dose accuracy and quality control.

4. Drug Content Uniformity

Drug content analysis is performed to determine uniform distribution of the active pharmaceutical ingredient within the strip. A specific area of the film is dissolved in a suitable solvent and analyzed using UV spectrophotometry or high-performance liquid chromatography. Uniform drug content is essential to ensure therapeutic consistency and dosage accuracy.

5. Surface pH

Surface pH of the strip is measured by placing the film in contact with distilled water followed by determination using a pH meter or pH paper. Surface pH should remain close to salivary pH to avoid irritation, discomfort, or damage to oral mucosal tissues during administration. Surface pH should remain within salivary pH range of 6.5–7.0 to avoid mucosal irritation.

6. Folding Endurance

The performance of sublabial films largely depends upon factors such as polymer composition, plasticizer proportion, and the environmental conditions employed during drying of the films. Folding endurance measures the mechanical flexibility and resistance of the strip to repeated folding. In this test, the strip is folded repeatedly at the same position until it ruptures. A higher folding endurance value indicates better mechanical strength and flexibility, which are essential for handling, packaging, and administration. An ideal strip generally exhibits folding endurance greater than 200 folds.

7. Tensile Strength

Mechanical characteristics of sublabial strips are markedly affected by polymer concentration, quantity of plasticizer incorporated, and film drying conditions during formulation development. Tensile strength is the maximum stress that the strip can withstand before breaking when subjected to pulling force. This measurement reflects the mechanical integrity and durability of the formulation. Tensile strength is influenced by polymer concentration, plasticizer content, and film thickness.

8. Percentage Elongation

Percentage elongation indicates the elasticity and extensibility of the strip before rupture. It is calculated by measuring the increase in strip length under tensile stress. Higher percentage elongation values indicate improved flexibility and mechanical performance of the film. Variations in polymer content, plasticizer ratio, and drying parameters significantly influence the tensile strength, flexibility, and overall mechanical stability of sublabial strips.

9. Moisture Content

Moisture content determination is important because excess moisture may affect film stability, mechanical strength, and microbial growth. The strips are weighed before and after drying in a desiccator or hot air oven, and percentage moisture loss is calculated. Controlled moisture content helps maintain stability and flexibility of the formulation.

10. Moisture Uptake Study

Moisture uptake studies evaluate the hygroscopic nature of sublabial strips by exposing them to controlled humidity conditions. Increased moisture absorption may alter drug release behavior, film integrity, and storage stability. This study is particularly important for moisture-sensitive formulations.

11. In-vitro Disintegration Time

Disintegration testing determines the time required for the strip break down completely in the presence of simulated salivary fluid. Rapid disintegration is essential for immediate drug release and faster onset of action. Disintegration time is influenced by polymer type, thickness, and formulation composition. Fast dissolving strips generally disintegrate within 30–60 seconds.

12. In-vitro Dissolution Study

Dissolution studies are performed to evaluate the rate and extent of drug release from the strip. The test is usually carried out using USP dissolution apparatus in simulated salivary fluid under controlled conditions. Drug release data help predict in-vivo therapeutic performance of the formulation.

13. Mucoadhesive Strength

Mucoadhesive strength determines the adhesive capability of the strip toward oral mucosal tissues. Adequate mucoadhesion ensures prolonged residence time and improved drug absorption. The test is generally performed using modified physical balance methods or texture analyzers with animal mucosa models.

14. Swelling Index

Swelling studies evaluate the hydration behavior of the polymeric strip upon contact with saliva or aqueous media. Swelling characteristics influence drug release rate, mucoadhesion, and mechanical properties of the formulation. Excessive swelling may reduce patient comfort and formulation stability.

15. Stability Studies

Stability studies are conducted according to ICH guidelines to evaluate the effect of temperature and humidity on formulation stability over time. Parameters such as appearance, drug content, mechanical properties, and dissolution profile are assessed during storage. Stability studies help determine shelf life and packaging requirements of sublabial strips.

Parameter	Purpose	Instrument/Method
Thickness	Uniformity	Vernier Caliper
Tensile Strength	Mechanical strength	Tensile Tester
Surface pH	Mucosal compatibility	pH Meter
Drug Content	Dose accuracy	UV Spectrophotometer
Disintegration Time	Rapid release	Petri Dish Method
Dissolution Study	Drug release	USP Dissolution Apparatus

10. Applications of Sublabial Strips[5,7,15]

Sublabial strips have been investigated for a wide range of pharmaceutical applications involving both local and systemic drug delivery. Due to their rapid absorption profile, these systems are particularly useful in pain management and emergency cardiovascular therapy where immediate therapeutic action is required. Antiemetic drugs administered through sublabial strips can provide rapid relief from nausea and vomiting. Nicotine-containing strips have also demonstrated usefulness in smoking cessation therapy by improving patient convenience and compliance. In addition, sublabial systems have shown promising potential for hormonal delivery, pediatric drug administration, and central nervous system therapeutics. Their ability to avoid gastrointestinal degradation and improve bioavailability makes them attractive for delivery of drugs with extensive first-pass metabolism.

11. Recent Advances[14,16]

Recent investigations have demonstrated significant advancements in sublabial strip technology through incorporation of nanoparticles, nanofibers, lipid carriers, and smart polymers. Electrospun nanofiber films have shown improved dissolution and transmucosal permeability because of their high surface area. Artificial intelligence-assisted formulation optimization and 3D printing technologies have further enabled development of personalized oral films with customized dosing profiles. Researchers are also exploring biodegradable polymers and stimuli-responsive systems for advanced controlled drug delivery applications. Recent investigations published between 2021 and 2025 demonstrated that nanotechnology-integrated oral films can significantly improve transmucosal permeability and drug stability. Modern pharmaceutical research is also focusing on AI-assisted formulation optimization, precision dosing systems, and biodegradable polymeric films for future oral transmucosal applications.

12. Future Perspectives[14,16]

Future research on sublabial strips is expected to focus on peptide delivery, vaccine films, personalized medicine, nanotechnology-based systems, and AI-assisted pharmaceutical optimization. Advances in smart responsive polymers and computational formulation design may further improve drug permeability, stability, and therapeutic efficiency. Continued industrial and clinical investigations may facilitate commercialization of sublabial strips as next-generation patient-centric transmucosal drug delivery systems.

13. CONCLUSION

Recent advancements in sublabial strip technology have significantly improved formulation performance and therapeutic applicability. Researchers are increasingly incorporating nanoparticles, nanofibers, and lipid-based carriers into oral films to enhance drug solubility, permeability, and controlled release characteristics. Electrospinning technology has enabled the production of nanofiber-based oral films possessing rapid dissolution and increased surface area. Smart mucoadhesive polymers capable of responding to pH and environmental changes are also being explored for advanced controlled drug delivery applications. Furthermore, 3D printing technologies have opened new possibilities for personalized oral films with customized dosing patterns. Herbal bioactive compounds and natural polymers are also gaining attention because of their improved safety and biocompatibility profiles.

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