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REVIEW-SUBLINGUAL ROUTE FOR SYSTEMIC DRUG DELIVERY

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ABSTRACT: Drug delivery via the oral mucous membrane is considered a promising alternative to the oral route. Sublingual route is a rapid onset of action and better patient compliance than orally ingested tablets. Sublingual means "under the tongue", administrating substance via mouth so that the substance is rapidly absorbed *via* blood vessels under the tongue. The portion of the drug absorbed through the sublingual blood vessels bypasses the hepatic first-pass metabolic processes giving acceptable bioavailability. Sublingual technology is convenient for dosing in geriatric, pediatric and psychiatric patients with dysphagia. Sublingual drug delivery shows fast therapeutic action than orally ingested drugs with fewer side effects. This review highlights advantages, disadvantages, different sublingual Gland, sublingual formulations such as tablets, films drops, sprays *etc*, and evaluation parameters.

INTRODUCTION:

Sublingual Drug Delivery:

Definition: "Systemic delivery of drugs through the mucosal membranes lining the floor of the mouth to the systemic circulation." Systemic drug delivery provides immediate onset of pharmacological effects through the sublingual route. Dysphasia (Difficulty in swallowing) is a common problem in all age groups or on reduced liquid intake have difficulties swallowing the solid dosage forms. Sublingual administration of the drug means the placement of the drug, *i.e.*, dosage form, under the tongue & drug reaches directly into the systemic circulation.

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Sublingual drug delivery is an alternative approach to enteral drug delivery. It avoids first-pass metabolism in the liver and gastric acid hydrolysis of drugs, therefore increasing the oral bioavailability of drugs.

Principles: When a chemical comes in contact with the mucous membrane beneath the tongue, it diffuses through it because connective tissue beneath the epithelium contains a profusion of capillaries; the substance then diffuses into them and enters the venous circulation. Drug solutes are rapidly absorbed into the reticulated vein, which lies underneath the oral mucosa & transported through the facial veins, internal jugular vein & brachiocephalic vein & then enter the systemic circulation.

Advantages of Sublingual Drug Delivery:

- It produces an immediate systemic effect by enabling the drug to be absorbed quickly or

directly through the mucosal lining of the mouth beneath the tongue.

- ❖ Dose gets reduced.
- ❖ Onset of action is very fast.
- ❖ Improved bioavailability.
- ❖ Fewer side effects.
- ❖ Effective in diseases like nausea, vomiting, migraine, schizophrenia.
- ❖ No need of water to administer tablet.
- ❖ Ease of drug administration gets increased.
- ❖ Sublingual area is much more permeable than buccal area.
- ❖ Bypass GI tract and hepatic portal system and avoid hepatic first-pass metabolism due to increased drug bioavailability.
- ❖ Rapid absorption due to high vascularization beneath the tongue.
- ❖ pH in the mouth is relatively neutral, so the drug will be more stable.
- ❖ Improved patient compliance

Disadvantages of Sublingual Drug Delivery:

- ➢ Unsuitable for uncooperative or unconscious patients.
- ➢ Unsuitable for bitter drugs.
- ➢ Poor Patient compliance.
- ➢ Eating, drinking, and smoking are not allowed.
- ➢ Administration of highly ionic drugs is not allowed.
- ➢ Holding the dose in the mouth is inconvenient; if any is swallowed, that portion must be treated as an oral dose and subjected to first-pass metabolism.

Characteristics of Sublingual Tablets:

- ✓ Disintegration and dissolution play an important role in drug absorption when administrated sublingually; that is the reason to prepare a sublingual formulation because it disintegrates and dissolves rapidly in saliva without water access.
- ✓ The physicochemical characteristics of tablets are size, hardness, disintegration time, porosity, and friability.
- ✓ Smaller tablet with low hardness and high porosity rapidly disintegrates than larger and harder tablets.
- ✓ The amount and type of disintegrants also play an important role in rapid disintegration.
- ✓ The absorption of water-soluble excipients, such as saccharides, helps reach rapid dissolution.
- ✓ Flavors, sweeteners, and taste masking agents are important parameters for formulating bitter sublingual drugs with bitter taste.
- ✓ Sugar-based excipient quickly dissolves in saliva, creating a sweet feeling in the mouth in the sublingual formulation.

Sublingual Gland: Salivary glands present in the mouth's floor underneath the tongue. They are also known as sublingual glands. They produce mucin, in turn, produce saliva. The interior area of the mouth remains lubricated due to the production of saliva by the glands, which is necessary for chewing and food swallowing. Due to low secretion of saliva can create problems in swallowing food, and the potential for food to lodge in the throat increases. The absorption occurs by the transfer of the drug from its administration site into systemic circulation, so it can be said that absorption is directly proportional to layer thickness. Due to high permeability and rich blood supply, the sublingual route can produce rapid onset of action so the drug with a short delivery period can be delivered, and the dose regimen is frequent. The drug gets diluted in the saliva, and the drug is adsorbed across the oral cavity.

Sublingual Absorption:

Mechanism of Sublingual Absorption: The absorption of sublingual mucosa is determined by lipid solubility, penetrable of the solution,

ionization, and molecular weight of the substance. The cells of oral epithelium and epidermis have able to absorb by endocytosis. This mechanism is used in across the stratified epithelium. The active transport process controls the mucus membrane. The mouth is lined with a mucous membrane which is coated with squamous epithelium and produces mucous glands. The salivary glands are composed of lobules of cells in which saliva is released through the salivary ducts in the mouth. The three pairs of salivary glands are parotid, submandibular and sublingual, which are present on the mouth. The sublingual drug is transferred across the sublingual mucosa is passive diffusion. Passive diffusion means the movement of a drug from the region of higher to the lower concentration across the biological membrane, and drug diffuses into the capillaries and then enters into the systemic circulation by the jugular vein.

Factors Affecting on Sublingual Absorption:

Solubility in Salivary Secretion: In addition to high lipid solubility, the drug should be soluble in aqueous buccal fluids i.e. biphasic solubility of drug is necessary for absorption.

Binding to Oral Mucosa: Systemic availability of drugs that bind to oral mucosa is poor.

pH and pKa of The Saliva: As the mean pH of the saliva is 6.0, this pH favors the absorption of drugs which remain unionized. Also, the absorption of the drugs through the oral mucosa occurs if the pKa is greater than 2 for an acid and less than 10 for a base.

Lipophilicity of Drug: For a drug to be absorbed completely through sublingual route, the drug must have slightly higher lipid solubility than that required for GI absorption is necessary for passive permeation.

Thickness of Oral Epithelium: As the thickness of sublingual epithelium is 100-200 μm which is less as compared to buccal thickness. So the absorption of drugs is faster due to thinner epithelium and also the immersion of drug in smaller volume of saliva

Drugs for Sublingual Administration: Sublingual drug administration is applied in the field of cardiovascular drugs, steroids, some barbiturates and enzymes. The drugs with dose less than 20 mg are suitable for a sublingual drug delivery system. It has been a developing field in the administration of many vitamins and minerals which are found to be readily and thoroughly absorbed by this method. Sublingually absorbed nutrition, which avoids exposure to the gastric system and liver, means direct nutritional benefits, particularly important for sufferers of gastrointestinal difficulties such as ulcers, hyperactive gut, coeliac disease, those with compromised digestion, the elderly and invalids; the nutritional benefit is independent of gastrointestinal influences. Examples of drugs this route administers include antianginals like nitrites and nitrates, antihypertensive like nifedipine, analgesics like morphine, and bronchodilators like fenoterol. Certain steroids like estradiol and peptides like oxytocin can also be administered *e.g*., fentanyl

Sublingual Formulations:

- ✓ Sublingual Tablets
- ✓ Sublingual Films
- ✓ Multi-purpose tablets
- ✓ Sublingual drops
- ✓ Sublingual spray
- ✓ Lozenge
- ✓ Effervescent sublingual tablet

Sublingual Tablets: "Sublingual tablets are solid unit dosage form meant for placement under the tongue to produce immediate action by avoiding the first pass effect of drug by liver."

The tablets are usually small and flat, compressed lightly to keep them soft. The tablet must dissolve quickly allowing the API to be absorbed quickly. It is designed to dissolve in small quantity of saliva. After the tablet is placed in the mouth below the tongue, the patient should avoid eating, drinking, smoking and possibly talking in order to keep the tablet in place. Swallowing of saliva should also be avoided since the saliva may contain dissolved drug. Bland excipients are used to avoid salivary stimulation. Nitroglycerine tablets and Ondansetron

tablets (zopran) are the examples of sublingual tablets.

Sublingual Films: Mouth-dissolving films or strips, a new drug delivery system for the oral delivery of the drugs, was developed based on the transdermal patch technology. 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 application site. It then rapidly disintegrates and dissolves to release the medication for oromucosal absorption or with formula modifications, will maintain the quick-dissolving aspects that allow for gastrointestinal absorption to be achieved when swallowed. Sublingual strips are similar to tablets in that they easily melt in the mouth and dissolve rapidly. Suboxone is an example of a medication that comes in a sublingual strip.

Multi-Purpose Tablets: Soluble tablets for either oral or sublingual administration, often also suitable for preparation of injections, Hydrostat (hydromorphone) and several brands of morphine tablets and cubes.

Sublingual Drops: Concentrated solutions to be dropped under the tongue, as with some nicocodeine cough preparations.

Sublingual Spray: Spray for the tongue; certain human and veterinary drugs are dispensed as such.

Lozenge: Effects a metered and patient-controlled-rate combination of sublingual, buccal, and oral administration, as with the Actiq fentanyl lozenge-on-a-stick (lollipop).

Effervescent Sublingual Tablets: This method drives the drug through the mucous membranes much faster (this is the case in the stomach with carbonated or effervescent liquids as well) and is used in the Fentora fentanyl tablet.

Evaluation Parameters:

General Appearance: The general appearance of a tablet, its visual identity and overall "elegance" is essential for consumer acceptance. Include in are tablet's size, shape, color, presence or absence of an odor, taste, surface texture, physical flaws and consistency and legibility of any identifying marking.

Size and Shape: The size and shape of the tablet can be dimensionally described, monitored and controlled.

Tablet Thickness: Tablet thickness is an important characteristic in reproducing appearance and also in counting by using filling equipment. Some filling equipment utilizes the uniform thickness of the tablets as accounting mechanism.

Wetting Time: Using this test, the time required for moisture to penetrate the tablet completely is measured and possibly represents the time required to release drug in the presence of minute volumes of saliva.

A piece of tissue paper (12 cm X 10.75 cm) folded twice was placed in a small Petri dish (ID = 6.5 cm) containing 6 ml of Sorenson's buffer pH 6.8. A tablet was put on the paper, and the time for complete wetting was measured. Three trials for each batch and the standard deviation were also determined.

Uniformity of Weight: I.P. procedure for uniformity of weight was followed, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight.

TABLE 1: PHARMACEUTICAL LIMITS FOR UNIFORMITY OF WEIGHT (IP)

Average weight(mg)	Percentage deviation (%)
80mg or less	10
More than 80mg or less than 250mg	7.5
250mg or more	5

Friability: It is measured by the mechanical strength of tablets. Roche friabilator can be used to determine the friability by the following procedure. A preweighed tablet was placed in the friabilator. Friabilator consist of a plastic-chamber that revolves at 25 rpm, dropping those tablets at a distance of 6 inches with each revolution. The tablets were rotated in the friabilator for at least 4 minutes. At the end of test tablets were dusted and reweighed, the loss in the weight of tablet is the measure of friability and is expressed in percentage as

$$\% \text{ Friability} = \text{Loss in weight} / \text{Initial weight} \times 100$$

Tablet Hardness: The hardness of tablet is defined as the force applied across the diameter of the tablet in the order to break the tablet. The resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation and handling before usage depends on its hardness. Hardness of the tablet of each formulation was determined using Monsanto Hardness tester.

Hardness was measured by various testers-

- Monsanto
- Pfizer
- Scheuniger
- Strong-Cob

5 tablets are randomly selected from each formulation is determined by a hardness tester. Conventional tablet hardness: 2.5-5kg/cm Dispersable or sublingual tablets hardness: 2-2.5kg/cm. Extended release tablet hardness: 4-6kg/cm

***In-vitro* Dispersion Time:** *In-vitro* dispersion time can be measured by dropping a tablet in a beaker containing 50 ml of Sorenson's buffer pH 6.8.

***In-vitro* Disintegration Test:** The test can be carry out on 6 tablets using the apparatus specified in I.P. 1996 distilled water at 37ºC ± 2ºC was used as a disintegration media and the time in second taken for complete disintegration of the tablet with no palable mass remaining in the apparatus measure in seconds.

Angle of Repose: It is defined as a technique for determining the resistance to particle movement is an amount called the angle of repose of a powder and expressed by θ. It is determined by the fixed funnel method. It is the maximum angle that can be obtained between the surface of a powder heap and horizontal plane and measure the flow ability of powder. In this the material was allowed to flow through a funnel to form a cone. Stop flowing the material when the pile reaches a predetermined height. Then the equation is

$$\tan \theta = 2h / Dt$$

$$D = 2r$$

$$\tan \theta = h/r$$

H = height of pile, r = radius of pile.

TABLE 2: ANGLE OF REPOSE

Angle of repose	Flow properties
<25	Excellent
25-30	Good
30-40	Passable
>40	Poor

There is a relation between the angle of repose and the type of flow.

Carr's Compressibility Index: The powder can decrease the volume under pressure, and the density determines it. The Carr's compressibility Index was calculated from bulk density and tapped density of the blend

% Compressibility index = Tapped density - Bulk density / tapped x 100

TABLE 3: CARR'S INDEX

Compressibility	Flow Properties
5-15	Excellent free flowing
12-16	Good free flowing
18-21	Fair
23-35	Poor
35-48	Very poor
>40	Extremely poor

Compressibility gives an idea about flow properties of the granules as per Carr's index

Hausner Ratio: It is an important parameter which influences the mass of uniformity of the dose.

Hausner ratio = Tapped density / bulk density

Techniques used in Preparation of Sublingual Tablets: Different techniques are used in preparation of sublingual tablets are as follows

- Direct compression
- Freeze drying technology
- Sublimation method
- Spray drying technology

Direct Compression: This method is commonly used in the manufacture of sublingual tablet and show good mechanical power and has fast disintegration. The directly compressible sublingual formulation comprises soluble excipient, superdisintegrant and lubricant for achieving the fast tablet disintegration, it comprises

microcrystalline cellulose, binder, sweeteners, flavoring, diluents and glidant. This method no need of water is required in the formulation of sublingual tablets and it is an ideal method for heat-labile and moisture medication. Disintegration is affected by tablet size, hardness.

Large and hard tablets have more disintegration time than small tablets and less hardness. In present scenario sublingual tablet has aimed to enhance the patient compliance. Direct compression is the term in which tablets are directly compressed from powder-blend of the active ingredient and soluble excipient which maintain the flow and uniformity in the die cavity.

This method is very popular because it reduces the number of steps involved and the material required. It is one of the best technique to produce a tablet for effective hardness. The choice of superdisintegrant in tablet for preparing the formulation and amount is important for achieving a fast disintegration and dissolution rate. It is a simple and cost-effective process and a cheaper and suitable technique.

Freeze Drying: In this method, it is used for drying, which is done at a low temperature and water is removed and forms porous tablet and it is more breakable tablet and have good packaging.

Advantage:

- Provide rapid dissolution.
- Increase absorption and bioavailability of drugs.
- Low disintegration time when the tablet is prepared by this method.

Disadvantage:

- It is a slow process and forms a hygroscopic product.
- Expensive and time consuming method.
- Cost of production is high.
- Water soluble drugs with low dose.

Sublimation Method: In this technique the active ingredient is easily evaporated substance, and other ingredients are compressed by machine and form a tablet. Then sublimation of evaporated substance is done, creating pores in the tablet and helps in reaching rapid disintegration when the tablet dissolves in saliva. Camphor, urea, ammonium bicarbonate, and ammonium carbonate is used in evaporated substance.

Spray Drying: It is a method in which there is an involvement of a blend containing drug, disintegrating agents, and bulking agents. It shows a result that forms a porous powder and rapidly dissolves in water. Then a porous powder is compressed in a compression machine and forms a tablet.

4 Steps of Spray Drying are:

- Feed preparation
- Atomization
- Drying particle shape formation
- Separation of dried products

Advantage:

- Simple and rapid method
- It is effective in cost
- Reproducible
- Increase the dissolution release of drugs
- Control of particle size, porosity, shape

Taste Masking of Sublingual Tablets Taste: It is a very important parameter to improve patient compliance. The brain's elucidation of chemicals triggers receptors on the tongue, which are contained in the taste buds and give a taste sensation on the tongue and dissolve in saliva. These taste buds contain sensitive nerve endings, which produce and transfer the electrical impulses via the brain's 7th, 9th, 10th cranial nerves, which are constant to the perception of taste.

Five basic sensations are located on different receptors on the tongue area are

- Salty taste-located at the sides and tip of the tongue.

- Sweet taste-located at the tip of the tongue.
- Sour taste-located at the sides of the tongue.
- Bitter taste-located at the back of the tongue.
- Umami taste-self-determining sensations originate by monosodium glutamate involved mainly in seaweed and disodium inosinate in meat and fish.

Taste Masking is defined as a clear reduction of a bitter taste using taste-masking agents. Taste masking technologies are very important for improving organoleptic properties like taste, odor, and patient compliance for geriatric and pediatric who have difficulty in swallowing a tablet.

2 aspects of taste masking technology:

- Select suitable taste masking agents like polymers, sweeteners, flavors, *etc*.
- Select suitable techniques.

TABLE 4: AGENTS FOR MASKING THE BASIC TASTE

Basic taste	Masking agents
Sweet	Vanilla, Grape
Sour	Lemon, Cherry, Orange
Metallic	Mint,Berries
Bitter	Liquorices, Coffee, Chocolate

These are 4 basic tastes- sweet, sour, metallic, and bitter and have various agents which mask the basic taste.

Sweeteners used in Taste Masking:

- ❖ Natural Sweetener-Honey, Liquorice, Sucrose
- ❖ Artificial Sweetener-Saccharin, Aspartame
- ❖ Nutritive Sweeteners-Sucrose, Fructose, Glucose
- ❖ Non-Nutritive Sweeteners-Aspartame, Sucralose, Saccharin

Future Prospects: Sublingual tablets are one of the most suitable dosage forms for the oral delivery of drugs, such as proteins and peptides, with limited bioavailability when administered by conventional tablets. Vaccines are generally not recommended for use by patients and are facilitated by sophisticated auto-injectors. The growths of enhanced oral protein delivery technologies by oral disintegrating tablets that may release these drugs in the oral cavity are very favorable for delivering high molecular Weight proteins and peptides.

CONCLUSION: Sublingual drug delivery has been used for the formulation of many drugs with the viewpoint of rapid drug release and quick onset of action. Sublingual products were developed to overcome the difficulty swallowing conventional tablets among pediatric, geriatric, and psychiatric patients with dysphagia. The potential for such dosage forms is promising because of strong market acceptance and patient demand. Peak blood levels of most products administered sublingually are achieved within a few minutes, which is generally much faster than when those same drugs are ingested orally. Sublingual absorption is efficient. The percent of each dose absorbed is generally higher than that achieved using oral ingestion. Various types of sublingual dosage forms are available in the market, like tablets, films, sprays, Drops, and Lozenge.

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