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Mucoadhesive buccal films: A review

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Abstract
Mucoadhesive drug delivery systems are advanced pharmaceutical formulations designed to interact with the mucus layer covering mucosal epithelial surfaces and prolong the residence time of a dosage form at the site of administration or absorption. These systems utilize interactions between mucoadhesive polymers and mucin glycoproteins present in the mucus layer, thereby enhancing drug retention and improving therapeutic efficacy. Prolonged gastrointestinal (GIT) residence is particularly beneficial for drugs exhibiting a narrow absorption window, poor bioavailability, or requiring localized action within the gastrointestinal tract. Mucoadhesion occurs through several sequential processes, including intimate contact between the formulation and mucus, polymer hydration and swelling, interpenetration of polymer and mucin chains, and formation of secondary chemical or physical interactions. Various theories have been proposed to explain the mechanism of mucoadhesion, including wetting, diffusion, adsorption, electronic, fracture, and mechanical theories. The extent and strength of mucoadhesion are influenced by several formulation and physiological factors, such as polymer molecular weight, concentration, and hydration, and charge, degree of cross-linking, mucus turnover, pH, ionic strength, and gastrointestinal motility. Different mucoadhesive dosage forms have been investigated, including tablets, microspheres, nanoparticles, films, gels, patches, and capsules. These systems can enhance drug residence time, improve drug absorption, reduce dosing frequency, and potentially increase drug plasma concentrations and therapeutic activity. Consequently, mucoadhesive drug delivery represents a promising strategy for improving the bioavailability, controlled release, and site-specific delivery of pharmaceutical agents. This review discusses the fundamental mechanisms and theories of mucoadhesion, factors affecting mucoadhesive performance, and recent developments in various mucoadhesive dosage forms.

Keywords: Mucoadhesion system, mucoadhesive dosage forms, theories, mechanism of drug delivery

Introduction

The most popular method of administering drugs is orally, although this method must accept the drug's solubility and susceptibility to first pass metabolism. The parental route is an unpleasant method of administering medication. Topical medications are restricted to topical or local therapy. Alternative routes are required for medications with high molecular weight, low skin penetration, poor water insolubility, and substantial first pass metabolism. The oral route is perhaps the one that patients and medical professionals prefer among the different medication delivery methods [1]. According to current knowledge of the biochemical and physiological aspects of absorption and metabolism, many medications cannot be administered successfully by the traditional oral route because they undergo extensive pre-systemic clearance in the liver after administration, which frequently results in a lack of significant correlation between membrane permeability, absorption, and bioavailability. Exploring alternative ways for the delivery of such medications was prompted by the challenges involved with parenteral delivery and the low oral availability. As a result, more absorptive mucosa is taken into consideration as possible drug delivery sites. For systemic action, transmucosal drug delivery routes-that is, the mucosal linings of the nasal, rectal, vaginal, ocular, and oral cavities-offer clear advantages over peroral administration. The buccal mucosa is one of the transmucosal routes that is most suited for administering controlled release dosage forms due to its excellent accessibility, smooth muscular expanse, and generally immobile mucosa. Furthermore, compared to other non-oral transmucosal drug administration methods, buccal drug delivery has a high patient acceptance rate. High bioavailability results from direct access to the systemic circulation via the internal jugular vein, which circumvents the hepatic first pass metabolism and acid hydrolysis in the gastrointestinal (GI) tract. Another benefit of this approach is the buccal mucosa's quick cellular healing. For the majority of medications, the mucoadhesive route is growing in popularity [2].

Mucoadhesive drug delivery system through Buccal, sublingual, rectal and nasal mucosa can be faster and systemic mode of non-invasive drug administration to bypass first pass metabolism.

Advantages and disadvantages of the buccal drug delivery system

- In contrast to the other mucosal tissues, the buccal mucosa is relatively permeable and has a good blood supply.
- Bypass first pass metabolism
- Exhibits localized therapy
- Many medications would work better because they have a longer contact time with the mucosa.
- Patient acceptance is high as compared to other non-oral drug delivery methods.
- Lower administration frequency may result from increased residence time combined with controlled API release.

- Buccal drug delivery removes the harsh environmental conditions that occur in oral drug delivery.
- It provides a various different ways to administer hormones, narcotic analgesics, steroids, enzymes, cardiovascular agents, and other medications.
- It allows for localized tissue permeability alteration, protease inhibition, and immunogenic response reduction. As a result, therapeutic agents such as peptides, proteins, and ionized species can be easily administered [3].

Disadvantages

- The total surface area of the oral cavity membranes usable for drug absorption is 170 cm^2, with non-keratinized tissues, such as the buccal membrane, accounting for 50 cm^2.
- The mucosa's barrier properties.
- The medication is diluted as a result of the continuous secretion of saliva (0.5-2 l/day).
- The risk of choking if the delivery system is swallowed involuntarily is a concern.
- Swallowing saliva may result in the loss of dissolved or suspended drugs, as well as the inadvertent removal of the dosage type.

Mechanism of mucoadhesion [4]

Adhesion is the state in which two surfaces are joined together by valence interfacial forces, interlocking action, or both. It occurs when a pressure-sensitive adhesive material comes into contact with a surface.

Mucoadhesion is the attachment of a material to mucus and/or an epithelial surface, whereas bioadhesion is the adhesion of a synthetic or natural material to a biological surface. Depending on the type of dose form and how it is administered, mucoadhesion happens in two stages:

Stage-I (Contact Stage):

A bioadhesive and a membrane come into close contact when the bioadhesive surface is wet, spread, and swollen. Other forces can occasionally be involved, such as the mechanical system in vaginal delivery, aero dynamics in nasal delivery, and peristaltic motions in intestinal dosage form distribution.

Stage-II (Consolidation Stage):

Vander Wall forces, electrostatic attractions, hydrogen bonds, and hydrophobic interactions are the reasons why moisture breaks molecules and initiates interpenetration or dominant attractive connection between two surfaces. Attractive forces must triumph over repulsive forces for full bioadhesion. Two possibilities explain the consolidation step:

Diffusion theory

Mucus glycol proteins interact with the mucoadhesive molecules by interpenetrating their chains and forming secondary bonds. This is a chemical as well as mechanical interaction.

Dehydration theory

After contact with mucus, material undergoes dehydration until osmotic pressure balance and gelly mixture of mucus with material is obtained. Solid or hydrated formulation does not work by this theory.

Theories of Mucoadhesion

There are five different theories, which explain phenomenon of muco-adhesion:

Electronic theory

This theory is based on the fact that biological materials and the mucus layer contain opposing electrical charges that can form a double electronic layer at the edge, which aids in determining the mucoadhesive strength.

Wetting theory

By opposing the surface tension at the contact, liquid or less viscous molecules penetrate the mucosal surface and fix themselves. This characteristic is related to the molecule's spread ability, wetness and contact angle.

Diffusion Theory

According to this theory, mucoadhesive polymer breaks the glycoprotein chain network and diffuses into the mucus layer. Diffusion coefficients and the molecular weight of both phases determine this diffusion, which is time-dependent.

Adsorption Theory

The most widely recognized theory of the mechanism of mucoadhesion is adsorption theory, which involves weak Vander Waals forces and hydrogen bond mediated adhesion. In order to display semi-permanent surface contacts, primary and secondary bonding is involved [4].

Types of mucoadhesive dosage forms [5]

The buccal mucosa's potential as a drug delivery channel was recognized centuries ago, despite the fact that it has lately been extensively investigated as a novel drug delivery route. As a result, researchers today are investigating the different ways that drugs might be delivered, particularly thru the oral mucosa, and developing innovative drug delivery methods.

Tablets

Tablets have a diameter of about 5-8 mm and are tiny, flat, and oval. Mucoadhesive tablets, in contrast to traditional tablets, don't cause significant discomfort when speaking or drinking. These are applied directly to the mucosal surface in order to deliver drugs locally or systemically. They soften, stick to the mucosa, and stay there until they dissolve or are released. In general, mucoadhesive tablets have the potential to be utilized for controlled release medication administration; however, there are further benefits when mucoadhesive qualities are combined with tablets. For example, it offers efficient absorption and enhanced bioavailability of the drugs due to a high surface-to-volume ratio and facilitates a much more intimate contact with the mucous layer. Mucoadhesive tablets can be tailored to adhere to any mucosal tissue, including those found in the stomach, thus offering the possibilities of localized as well as systemic controlled release of drugs [5].

Films/Patches [6]

In terms of comfort and flexibility, mucoadhesive films might be better than adhesive tablets. They can also get beyond the oral gels' comparatively short residence duration on the mucosa, which is quickly erased by saliva. Additionally, when oral illnesses are administered locally,

the films assist shield the surface of the wound, which lessens discomfort and improves the course of treatment. The perfect film should be soft, elastic, and flexible while still being sturdy enough to resist breaking from the strain of mouth movements. For it to stay in the mouth for the intended amount of time, it must also have strong mucoadhesive properties.

Buccal patches are defined as laminates consisting of a mucoadhesive surface for mucosal adhesion, an impermeable backing layer, and a drug-containing reservoir layer that releases the drug in a controlled manner. Drugs can be applied directly to a mucosal membrane using patches. These are comparable to those utilized in transdermal medication administration. Because of their physical flexibility, which only slightly discomforts the patient, they exhibit higher patient compliance than tablets. Additionally, they have an advantage over creams and ointments in that they provide a precise dosage of medication to the spot.

Gels and ointments

Gels and ointments are examples of semisolid dose forms that have the benefit of easily dispersing throughout the mouth mucosa. However, compared to tablets, patches, or films, drug dosing from semisolid dosage forms could not be as precise. Mucoadhesive compositions have been used to overcome poor gel retention at the application site. A phase transition from liquid to semisolid occurs in some mucoadhesive polymers, such as sodium carboxymethylcellulose, carbopol, hyaluronic acid, and xanthan gum. This alteration increases viscosity, which leads to a regulated and prolonged release of medications. Another interesting dosage type for buccal medication administration is hydrogels.

Mucoadhesive Buccal Films

Numerous mucoadhesive products, including pills, patches, devices, strips, ointments, gels, disks, and more recently, films, have been developed. Because oral gels are rapidly removed by saliva, films can get around the problem of the gels' comparatively short residence duration on mucosa. For a buccal film to be held in the mouth for the intended amount of time, it must be soft, flexible, expandable, and robust enough to withstand breaking due to stress from oral activities. It must also have sufficient mucoadhesive strength.

Manufacturing methods of mucoadhesive buccal films:

The following methods can be used to manufacture the mucoadhesive buccal films.

1. Solvent casting
2. Semisolid casting
3. Hot melt extrusion
4. Solid dispersion extrusion
5. Rolling

1. Solvent casting method

The solvent casting process involves dissolving water-soluble polymers in water and dissolving the medicine and other excipients in an appropriate solvent. The two solutions are then combined, agitated, and cast into a petriplate before being dried.

2. Semisolid casting

The first step in the semisolid casting process is to generate a water-soluble film-forming polymer solution. The resultant solution is mixed with an acid-insoluble polymer solution (such as cellulose acetate phthalate or cellulose acetate butyrate) made in sodium hydroxide or ammonium. After that, a gel mass is created by adding the proper amount of plasticizer. Lastly, heat-controlled drums are used to cast the gel mass into the films or ribbons. The film is between 0.015 and 0.05 inches thick. The acid-insoluble to film-forming polymer ratio ought to be 1:4.

3. Hot melt extrusion method

In hot melt extrusion method firstly the drug is mixed with carriers in solid form. Then the extruder having heaters melts the mixture. Finally the melt is shaped in to films by the dies.

4. Solid dispersion extrusion

In this method immiscible components are extrude with drug and then solid dispersion are prepared. Finally the solid dispersions are shaped in to films by means of dies.

5. Rolling method

The rolling method involves rolling a drug-containing solution or suspension on a carrier. Water and alcohol make up the majority of the solvent. Using a high shear processor, the film is dried on rollers and cut into the appropriate shapes and sizes. Other ingredients, such as active agents, are dissolved in a tiny amount of aqueous solvent. Water soluble hydrochloride is dissolved in water to create a uniform, viscous solution.

Evaluation of buccal films [7]

Surface pH

By dissolving pieces (6 cm^2) of each buccal film in 10 mL of distilled water, the pH of the films was ascertained. Films were fully dissolved, and the electrode of a pH meter was placed on the dissolved film solution's surface to measure the pH [7].

Mechanical properties

Since quick dissolving films are subjected to severe mechanical stresses during production, packing, and adhesion to the oral mucosa, an understanding of their mechanical characteristics is essential. As a result, we evaluated the produced films' thickness, tensile strength, elongation, and folding durability.

Film thickness

An electronic digital micrometer was used to measure each film's thickness. The thickness of ten randomly chosen film sections of each formulation was measured. Each film's thickness was measured five times, and the average thickness was determined.

Tensile strength and elongation [8]

A tensile tester was used to determine the tensile strength and percent elongation. In short, the tensile tester was used to hold a piece of film with a defined thickness and width. An imaginary line connecting the grips' sites of attachment was drawn by aligning the long axis of the film with the tensometer grips. The grips were adjusted uniformly and tightly enough to keep the film from slipping during the test without crushing the sample. The highest stress applied just prior to the film sample breaking is known as the tensile strength.

It is calculated from the applied load at rupture and the cross-sectional area of fractured film applying the following equation (Eq. (1)) [9, 10]:

$$\text{Tensile strength} = \frac{\text{load at failure (N)}}{\text{Film thickness (mm)* film width (cm)}}$$

Elongation as a function of the applied load was recorded at the moment of rupture. Elongation is the increase in length produced in the gage length of the sample by a tensile load. It is usually measured at the moment of film rupture (percent elongation at rupture) and can be calculated using the following equation (Eq. (2) [11-12].

$$\text{Percent elonagation} = \frac{L - Lo}{Lo} * 100$$

Where Lo is the original distance between the two grips of the tensometer and L is the distance between the two grips at the moment of film rupture.

Folding endurance

Folding endurance was measured by repeatedly twisting the film up and down at the same spot until it broke or tore. The value of folding endurance is the number of times the film can be twisted up and down without breaking. For every formulation, three randomly chosen film pieces were examined [13].

Water sorption

Water sorption may be a problem for packaging and storage because the film-forming polymer (PVP) is hydrophilic and hygroscopic. Water sorption lengthens the film's disintegration time, increases the weight of the film, and reduces medication stability. Three portions of each film were weighed in order to evaluate water sorption. After that, the film pieces were fastened with a pinch, let to come to room temperature, and weighed every five minutes until the weight did not increase [14]

Weight variation and drug content

Three film sections (6 cm^2) of each formulation were weighed separately using a digital scale in order to evaluate the weight variance of the films [14]. A 6 cm^2 (2 cm * 3 cm) sample was utilized to measure the drug content. After dissolving each film piece in 100 milliliters of ethanol, the absorbance was determined using spectrophotometry [15, 16].

***In vitro* drug release study**

In short, one drop of phosphate buffer (pH 6.8) was applied to the surface of three film sections (6 cm^2) of each created formulation that were attached on top of conical flasks. It was noted how long it took the drop to go through the film [17-18]. Each film's equivalent portion was precisely weighed and put into separate dissolution vessels with 500 mL of phosphate buffer (pH 6.8), maintained at 37 ± 0.5°C, and agitated at 50 rpm. At appropriate time intervals (1, 2, 3, 4, 5, 10, 15, 20, 25 and 30 min), 5 ml of the dissolution medium were withdrawn and replaced with an equal volume of fresh buffer to keep the volume of the dissolution medium. The withdrawn samples were filtered and the drug content was determined spectrophotometrically.

Conclusion

The mucoadhesive system's most potential drug delivery method is buccal. Buccal drug distribution can use a variety of dose forms, including pills, films, patches, gels, and ointments. Because buccal films are easier to prepare, put drugs into, and characterize, they are more widely used. This non-invasive drug delivery method can be used to distribute medications that go thru first pass metabolism as buccal films.

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