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A REVIEW MUCOADHESIVE BUCCAL PATCHES

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ABSTRACT

The buccal administration rote is a highly appealing option for delivering drugs systemically. Buccal drug administration enables direct entry into the systemic circulation via the internal jugular vein, bypassing hepatic first-pass metabolism and resulting in enhanced bioavailability. The placement of the product occurs between the upper gingiva (gums) and cheek in order to address both local and systemic conditions. This particular drug delivery approach in deemed advantageous in enhancing the bioavailability of medications. Buccal bio adhesive films offer unique advantages compared to conventional dosage forms in the treatment of various diseases by delivering topical drug at a controlled and gradual place within the oral cavity. This review paper covering various aspects such as the oral mucosa, formulation, mechanism of muco adhesion, active ingredient delivers through buccal route, factors affecting on buccal patches formulation. Furthermore, it also discusses future prospective of buccal patches in drug delivery system.

KEYWORDS: Mucoadhesion theory, buccal patches, Buccal drug delivery system.

1. INTRODUCTION[1,2]

With the growing use of innovative technologies to deliver therapeutically active medications, pharmaceutical formulation delivery will undergo a revolution. Enhancing target locations or site-targeting therapies is the main goal of current drug research and formulation development in order to lower total host spread. To address the constraints of traditional medication delivery, it is essential to administer the required drug through the oral-buccal area. For patients, the swallowing method is especially reliable and healthful for delivering medications into the bloodstream.

However, since almost all medications are taken orally in their standard dosage forms, it is challenging to monitor and identify gastrointestinal tract (GIT) processes. Its administration of drugs buccal (BDDS) has been studied as an alternative to using and adhering to conventional medication delivery systems.

The innovative approach to drug delivery focuses on sustained or controlled release, allowing for less frequent administration while minimizing the significant fluctuations in plasma drug levels typically seen with systemic methods. The oral cavity presents a promising site for targeted drug administration, leveraging the concept of Transmucosal Drug Delivery (TMDD) to facilitate direct absorption of therapeutic agents through the mucous membranes. This approach is classified according to the distinct characteristics of the oral cavity.

- Sublingual delivery involves the administration of medications through the membranes located on the underside of the tongue.
- Gingivitis infection: Delivery of medication via the gingival mucosa.
- Buccal allocation: The medication is given via the buccal region of the cheeks.

Definition of Buccal Patches[3,4]

- Buccal patches represent a unique form of drug formulation that facilitates the administration of medication via the buccal mucosa for effective drug delivery.
- A buccal patch is a slim, non-erodible film engineered to deliver medication at a controlled rate, optimizing therapeutic efficacy, specifically created for administration in patients who are unconscious or less cooperative.

Buccal delivery system[5]

Patients overwhelmingly favor taking medications orally, making it the top choice among all available delivery methods due to its ease, convenience, and comfort. Factors such as liver breakdown during initial passage and digestive enzyme degradation in the gut can significantly impact the efficacy of orally administered medications. Certain medications, particularly proteins and peptides, cannot be effectively consumed.

Research is being conducted on alternative mucosal sites for drug absorption, highlighting their potential for effective delivery. The mucous membranes lining various body cavities, including the rectum, eyes, nose, mouth, and vagina, provide a more direct and efficient pathway for systemic drug absorption, offering distinct benefits over conventional oral delivery methods. Extensive research has explored the oral mucosa's unique anatomy and physiology. The oral cavity encompasses various structures, including the cheeks, lips, palates, tongue, and mouth floor, which are lined by distinct mucosal regions. Notably, the mucosal surfaces of the tongue, particularly the lingual, buccal, and ventral regions, collectively account for roughly 60% of the total oral mucosal surface area, highlighting their significance in oral drug delivery and absorption.

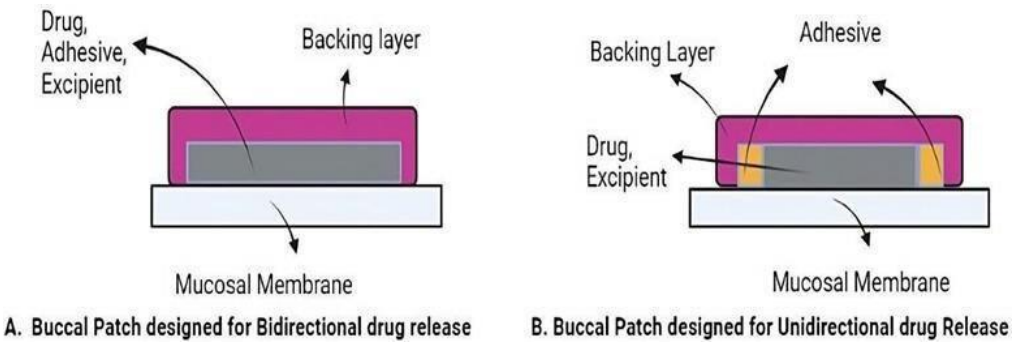

Figure No. 1: Buccal Delivery system.

1.1 ADVANTAGE OF BUCCAL PATCHES[6,7]

- Buccal patches are acknowledged for their efficient penetration of the membrane that coats the oral cavity, rendering them ideal for intraoral application, which is both comfortable and gentle.
- Patients have the flexibility to adjust their dosage or the intervals between treatments, and they can cease pain relief during acute episodes. The oral route of administration enhances the delivery of medications. The innovative buccal formulation promotes better adherence among patients.
- The extensive surface area of the buccal membrane allows for enhanced delivery systems in various scenarios. Each oral cavity features two buccal sites, enabling the placement of the medication delivery system on both the left and right sides in a sequential manner on the buccal mucosa.
- The patch does not need to be chewed or swallowed.
- The possibility of choking is removed. This patch enhances the systemic bioavailability of medications by bypassing initial digestion in the liver.
- Gastrointestinal enzymes and acidic environments may protect the medication from degradation.
- It provides a quick onset of effects while minimizing side effects.
- Independent application is feasible.
- It improves bioavailability by extending the duration that the dosage remains in the system following ingestion.

1.2 DISADVANTAGES OF BUCCAL PATECHES[8]

- The available surface area for quick absorption is restricted.
- Medications this worsen mucosal congestion, particularly those with unpleasant tastes or odours, should be avoided.
- This method is unsuitable for medications that are unstable at oral pH levels.
- Extended salivation can facilitate a reduction in the medication’s concentrations.
- Administering high doses of these drugs poses significant challenges.

1.3 LIMITATION OF BUCCAL PATCHES[9,10,11]

- Saliva is simultaneously produced in the buccal cavity, which serves to dilute the drug at the location of absorptionand reduces drug concentrations at interface of the absorbent patch.
- Accidentally Swallowing saliva can lead to a decrease in a significant portion of floating or dissolving medications from the area where absorption occurs. This raises concerns regarding the effectiveness of the delivery mechanism.
- Avoid formulating medications with a bitter taste.
- Refrain from developing drugs that may trigger allergic reactions, irritate the oral mucosa, or cause tooth discoloration.
- The available surface area for absorption is limited.
- Consumption of food and beverages is strictly prohibited.

1.4 IDEAL PROPERTIES OF BUCCAL PATHCHES[12,13]

The following criteria should be met:

- The patient must consistently adhere to the treatment plan without interfering with their daily activities.
- There should be a high level of electromechanical impedance.
- Quick instant attachment to buccal mucosa.

- It adheres to the buccal mucosa quickly, is non-toxic, and isn't bothersome. pH-related biocompatibility.
- Not bothersome.
- pH-related biocompatibility.
- Enhanced adaptability.
- Directly next to the cheek mucous membrane.
- Increased shelf life.
- Optimal medication absorption rate and quickness.
- Controlled release of drugs.
- It must possess the optimal molecular weight.
- There must be an adhesive group.
- It ought to possess the necessary spatial conformation.
- Hold on to the connection point for a long time.
- Medicines are released in a controlled manner, with unidirectional path to the mucosa.

1.5 CRITERIA FOR BUCCAL PATCHES[14,15]

The patch ought to:

- It must be compatible with bio membranes and possess a restricted dispersion and high molecular weight.
- It should be environmentally friendly and neutral.
- The body mucosa should absorb those polymers and associated degradation products as they cannot be harmful.
- There should be some site specificity in the polymer's ability to attach to wet material surfaces.
- The polymer needs to be stable for the course of storage or exposure form's life.
- Polymers need to be affordable and easily available on the market.
- The drug is easily incorporated into the formulation.

1.6 NEEDS FOR DEVELOPMENT OF BUCCAL PATCHES MUCOADHESION METHOD[16]

The interaction with a surface and bonding, often referred to as pressure-sensitive stickiness, occurs when two distinct surfaces adhere to one another due to valence interfacial forces, a mutual barrier effect, or a combination of both. Biological attachment involves the binding of either natural or synthetic materials to living membranes, distinguishing it from mucoadhesion, which pertains to the adhesion of substances to epithelial membranes.

The adherence to mu action is generally divided into two components: [17]

- Contact phase
- Accumulation phase

Contact Phase

The formulation interacts with the adhesive and the mucosa, causing it to spread and swell, which facilitates profound contact with the mucosal layer.

Accumulation Phase[18]

At this stage, the invasion of the cell by the biological adhesive occurs. At physiological pH, the mucosa can become unfavourably charged since sialic exists acid.

1.7 VARIABLES INFLUENCING MUCOADHESION[19]

- **Linked to resins factors:** Some properties with functioning polymers serve an important intestinal adhesion have. These include the swelling, concentration, molecular weight, specific strength adaptability and versatility of the polymer chain, which can affect mucoadhesion.
- **Environmental factors:** pH, functional strength and time of first polymer- substrate surface contact can affect mucosal adhesion.
- **Metabolic parameters:** Health status and mucus migration are crucial aspects of biology that could have consequences mucosal adhesion.

2. GENERAL FORMULATION CONSIDERATION[20]

2.1. Physical Issues

When creating a sublingual delivery system, it is essential to consider various physiological factors, including morphology, several key factors influence the efficacy of buccal drug delivery, including the unique properties of the oral mucosa, the dimensions of the absorption barrier, the amount of active pharmaceutical ingredient loaded, and the thickness of the mucosal membrane, temporal changes, the impact of saliva, and other environmental factors. A number of enzymes (esterases) exist in saliva. Carbohydrates, and phosphates) that can break down certain drugs. Although salivation contributes to the dissolution of drugs, accidental ingestion of saliva also affects drug bioavailability.

The pharmacological considerations regarding the absorption of medication via the oral mucosa are influenced by the drug's distribution coefficient. Medications with high lipophilicity are effectively absorbed.

2.2. Pharmacological Consideration

The extent to which a drug is absorbed through the buccal mucosa is significantly impacted by its lipophilicity and hydrophilicity balance, as quantified by its distribution coefficient, which determines its ability to partition between aqueous and lipid environments. Drugs that are liquid get taken in by the cells. Drugs which are permeable pass-through cells through the paracellular path. Other pharmacological choices include time spent there and the drug's volume on the nearby epithelium.

2.3. Pharmaceutical Consideration

When formulating dosage forms for drug delivery, it is essential to consider the absorption through the oral mucosa, sensory influences, and the enhancing effects of various excipients at the site of injection. Some supplements may be included to enhance the absorption of medication and flow. Mucoadhesives are Meanwhile, penetration enhancers play a crucial role in facilitating the transport of drugs across the mucosal barrier, thereby augmenting their absorption and bioavailability employed to keep close stable interaction between the drug and a site of absorption.

3. METHODS OF DEVELOPMENT BUCCAL BANDS

Procedures for applying buccal inlays can be classified as:

3.1. Machining in solvents method[22]

In this technique, the medication and all its excipients are disseminated together using a solvent made from organic materials and applied in a separate plate. After the solvent has evaporated, the covered release cushion sheet is the material is subsequently sliced into pieces of the desired dimensions and form. Bonded with just a small amount of impermeable back materials to create a laminate, The material is subsequently processed into precise, uniform dots that conform to specific dimensions and geometries.

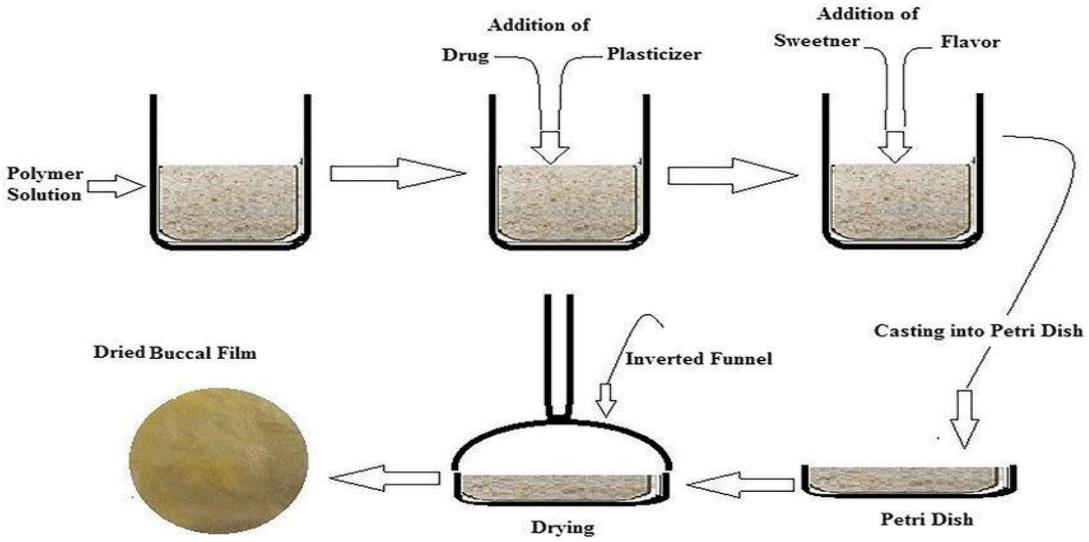

Figure 2: Solvent Casting Method.

3.2. Straight milling[21]

This technique avoids the use of chemicals to create the glue. Pharmaceuticals and additives are typically combined through mechanical methods such as grinding or mixing when liquid is not available. The blend is subsequently cast onto a release liner and allowed to build up to a predetermined depth, achieving the desired dimensional consistency. After that, substrates are laminated as previously mentioned. The liquid-free method is favoured since it cannot retain the chemical and does not result in solvent-related health issues, even if there is a slight variation in patched performance comparing patches manufactured using the two procedures.

3.3. Extruding hot melt[23]

Pharmaceutical materials undergo a process of combination and melting, followed by perforation, to create a more consistent product that can be offered in multiple formats, such as tablets, or patches, granules.

3.4. Solid dispersion extrusion[33]

The immiscible medicinal ingredient is extruded in this procedure, and a solid mixture is subsequently made. Finally, a die is used to shape the solid mixture into a film.

3.5. Semi-solid casting[24]

In the somewhat solid casting procedure, a film-forming polymer is created initially into an aqueous solution. The resulting solution is combined with a solution prepared using ammonium or sodium hydroxide that contains acid-insoluble polymeric materials, such as (cellulose acetic phthalate and cellulose acetate butyrate). The right quantity of softener is then incorporated to create a mass that resembles gel. The gel mass is then loaded into a foil or cassette and placed on a drum with a specified temperature. The film's dimensional thickness is calibrated within a precise range of 0.015 to 0.05 inches. ratio of 1:4 can be utilized for acid-insoluble moulded polymers.

3.6. Roller method[25]

In the rolling approach, the medium is coated with a drug containing solution or slurry. Freshwater and the majority of the solutions consist of combinations of alcohol and water. Roll of air out films are then cut into the necessary shapes & thickness.

4. SELECTION OF EXIPIENTS

The active ingredients in buccal patches are complemented by the presence of excipients.

1. Active ingredients

The chemical compounds employed in sublingual patching should possess a variety of qualities, such as a low normal amount of the medicine. For regulated drug delivery, medicines that have a physiological half-life of 2 to 8 hours make ideal choices. When administered orally, the highest active component[31] exhibits more volatility or value. The absorption of drugs when consumed oral ought to be passive.[32]

2. Polymers

(Adhesive coatings) Most crucial bio sticky polymeric in mucosa medication delivery systems are polymeric (adhesive coatings). A matrix device that combines the medication with a matrix of polymers in order to regulate the drug's release schedule. The subsequent characteristics are necessary for a buccoadhesive drug distribution system's optimal polymer. It has to be harmless to the environment and inert. The polymer must not be harmful and be able to be taken by the mucosa, as well as the by-products of its decomposition.[29] It should have some local selectivity and stick to moist cell surfaces fast. Throughout the drug's preservation or shelf life, the polymer shouldn't break down. The polymer has to be readily accessible and reasonably priced economically.[30]

3. Selection criteria for composites

- Non-irritating, environmentally friendly, and devoid of volatile impurities.[26]
- It must have sufficient mechanical strength and attach to the oral mucosa fast, the bio glue region's strength at shear.
- Excellent wettability, solubility, swelling, and biodegradable properties.[27]
- Must interact strongly non-covalently with epithelium or mucosal surfaces.
- It needs to have a substantial molecular mass and a restricted dispersion.[28]

4. Plasticizer

The plasticizer exerted a profound impact on the patches' physical properties. Mechanical characteristics such patch elongation, tensile strength. A change in plasticizer concentration has an impact on these characteristics. Glycerine PEG-100, 400, propylene glycol (PG), dibutyl phthalate, and other substances are frequently employed as plasticizers. [5]

5. Sweetening agent

Sweeteners now make up a sizable portion of medication that is intended to be dissolved or broken down in oral cavity. Conventional sugars, including fluid forms of glucose, fructose, sucrose, dextrose, and isomaltose, serve as traditional sweetening agents. Polyhydric alcohols like sorbitol, mannitol, and isomaltose can be added to a mixture because they also have a fantastic mouth feel and a cooling effect.

5. ANATOMY OF BUCCAL MUCOSA [34]

The buccal mucosa is typically subdivided into three main morphological groups:

1. Stratified squamous epithelium
2. Basement membrane
3. Lamina propria

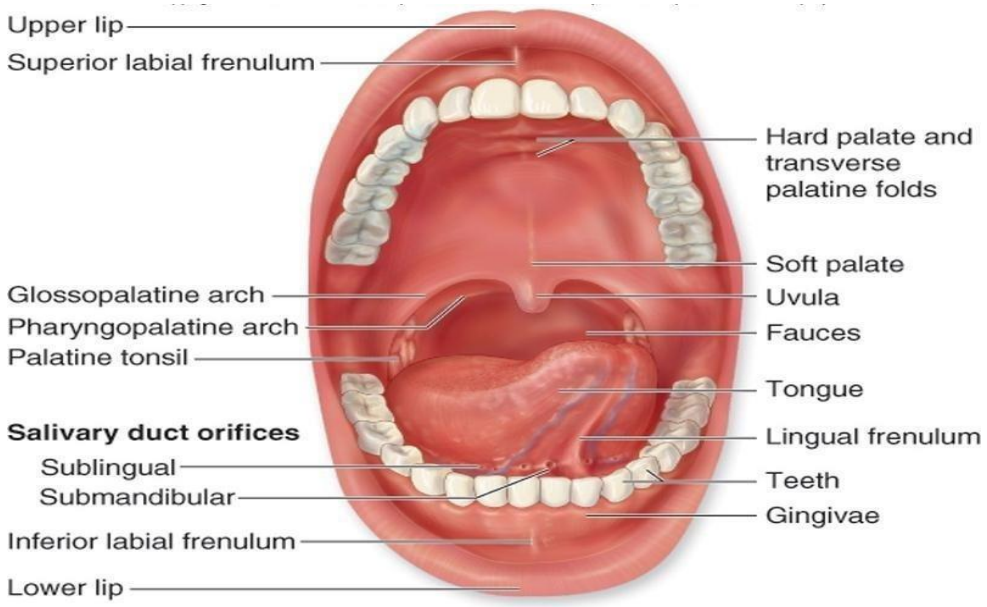

Figure 3: Anatomy of Buccal Mucosa.

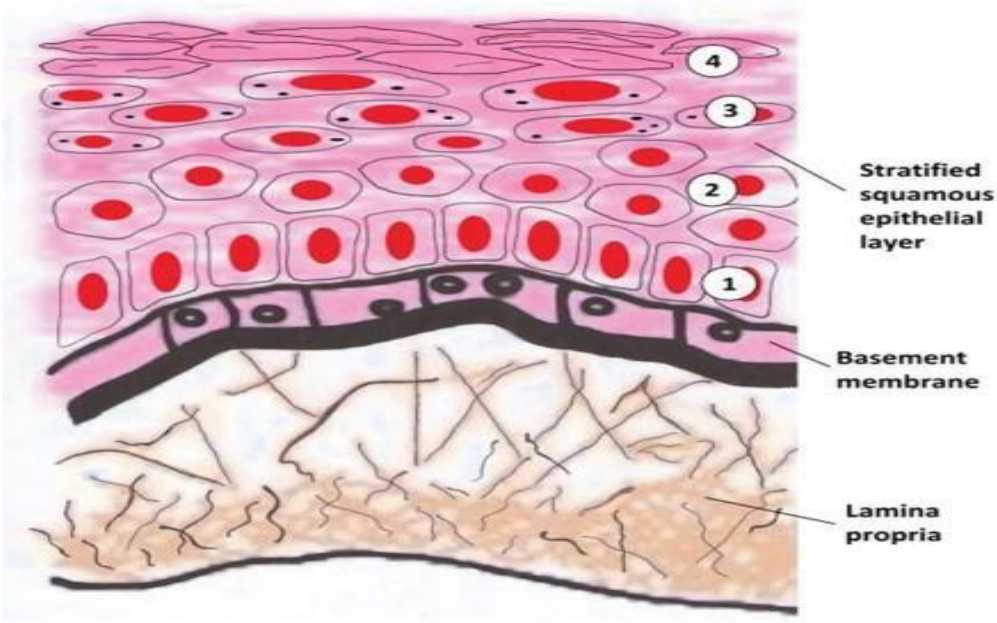

Figure 4: Layer of Buccal Mucosa.

Stratified squamous epithelium typically measures between 500 and 800 micrometers in thickness and can be classified as either keratinized or non-keratinized.

- Keratinized epithelium exhibits significant mechanical strength and chemical resistance.
- It is commonly found in distinct areas of the mouth, particularly the mucous membranes lining the gums and the tongue's upper aspect.
- This type of epithelial lining, characterized by its non-keratinized nature, exhibits a degree of pliability and is typically situated in areas such as the oral floor, labial mucosa, and buccal mucosa.
- The oral cavity's buccal and sublingual regions, which are key sites for drug administration, are characterized by a distinctive non-keratinized epithelial architecture.

6. MUCO ADHESION THEORY[35]

A mucoadhesive substance is characterized by its ability to engage with biological materials, allowing it to adhere to them or maintain their cohesion for an extended duration. Several theoretical frameworks have been proposed to explain the mechanisms underlying mucoadhesion and bioadhesion, including:

6.1. The Wetting Hypothesis

6.2. The Interdiffusion Model

6.3. The Electronic Double Layer Theory

6.4. The Fracture Energy Theory

6.5. The Adsorption Mechanism

6.1. The Wetting Hypothesis

- The concept of wetting describes the tendency of a liquid to establish and preserve intimate contact with a solid surface, facilitated by the short-range intermolecular interactions between the two.
- The extent of wetting is dictated by the subtle balance between the attractive forces that facilitate liquid spread on a solid surface and the internal forces that govern liquid self- cohesion.
- This concept of wetting is especially applicable to liquid formulations that interact with mucous membranes, enabling them to spread evenly and extensively across these surfaces.
- The degree of adhesion is affected by the contact angle; a lower contact angle indicates a greater affinity.

The adhesion work can be expressed as. WA=Γa+Γb-Γab

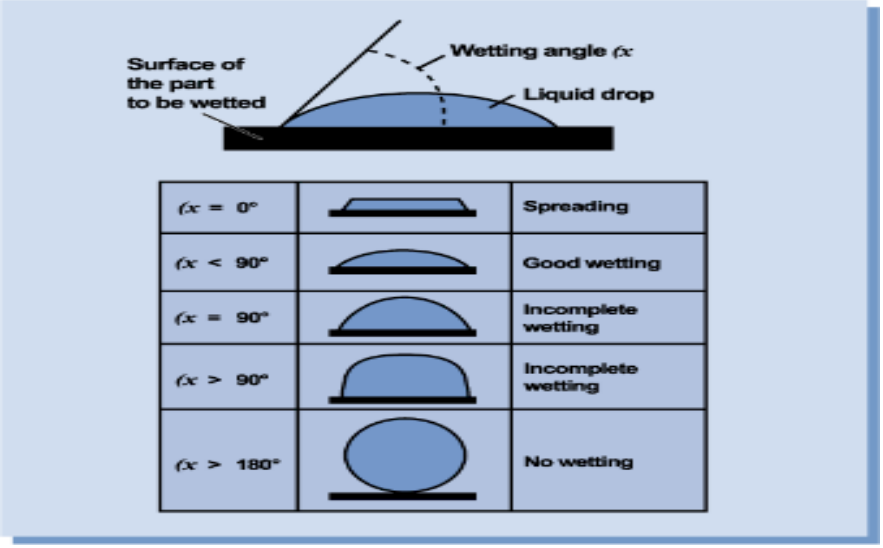

Figure 6: Contact angle [0° to 180°].

6.2. The Interdiffusion Model

- This theory explains how chains of polymers and chains of mucins. interweave to a significant extent, resulting in the formation of a long-lasting adhesive connection.
- In this scenario, the polymer exhibited a strong interaction with the mucus, and as time progressed, the concentration gradient at the boundary promoted the movement of polymer chains into the mucus layer.
- As the polymer chains penetrate more deeply into the substrate, the adhesive force increases, indicating a positive relationship between the degree of interpenetration and the strength of adhesion.

- The process of diffusion necessitates that the involved substances, including polymers and other molecules, exhibit certain characteristics that enable them to interact, penetrate, and blend with one another.

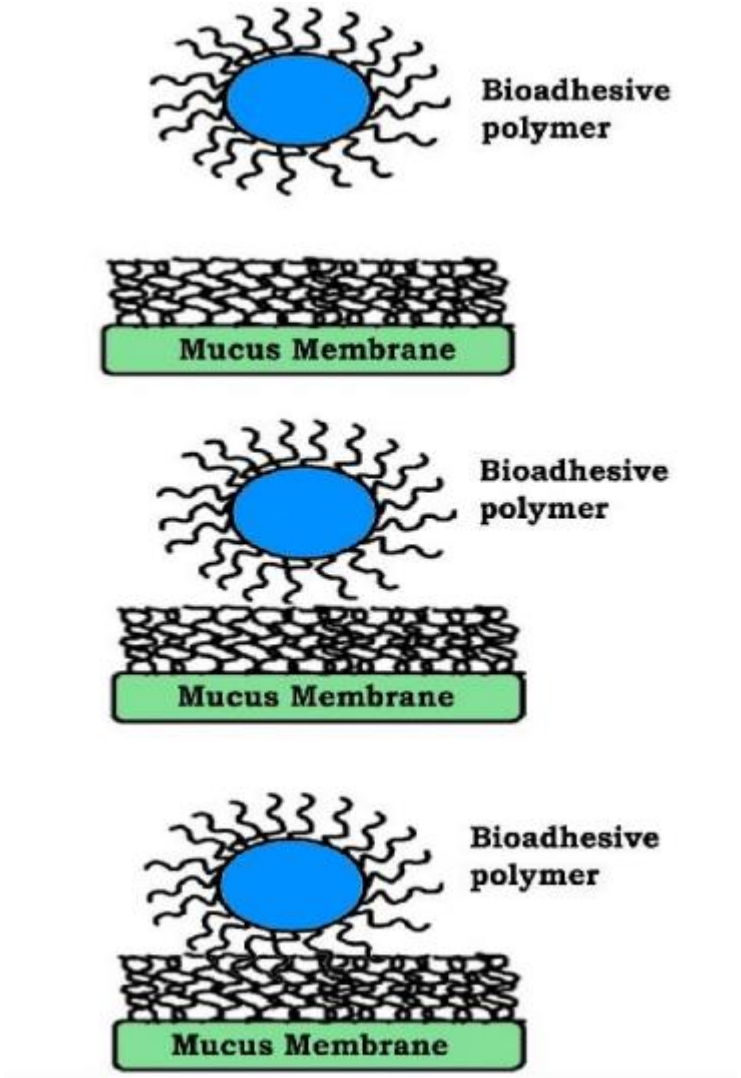

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Figure 6: Interdiffusion and Interpenetration.

6.3. The Electronic Double Layer Theory

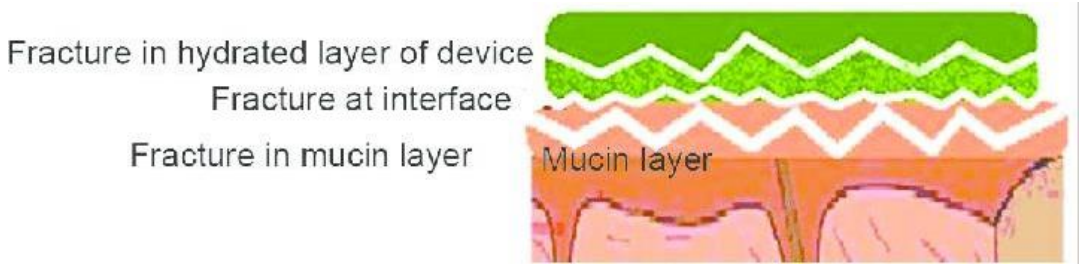
- This theory posits that electronic transfer takes place an adhesive polymer interacts with the network of mucus glycoproteins, attribute to disparities in the electronic charge distributions of the involved substances.
- As a consequence, an electronic double-layer structure emerges at the interface, characterized by the spatial distribution of charges.
- Attachment takes place as a result of the attractive forces present within the double layer.

6.4. The Fracture Energy Theory

- This theory examines the mechanisms underlying the detachment of two surfaces that have formed an adhesive bond, shedding light on the factors influencing bond failure.
- This concept assesses the amount of stress or force required to disrupt the adhesive bond between two surfaces, providing insight into the bond's resilience.

- Failure typically manifests at the most vulnerable component, often resulting from a unified failure at one of the adhesion interfaces. To calculate the Maximum Detachment Strength (Sm), the maximum force required to separate the surfaces (Fm) is divided by the total bonded surface area (Ao), resulting in the formula:

$$Sm = Fm / Ao.$$



6.5. The Adsorption Mechanism

- The binding of the polymer to the mucous membrane is facilitated by surface forces that establish connections with the chemically reactive groups exposed on the membrane's surface.
- Two distinct categories of chemical interactions take place, influencing the overall binding mechanism:

1. The primary bonds can be categorized into three main types: covalent, ionic, and metallic bonds, which differ in their underlying chemical bonding mechanisms.

- Long-lasting adhesion resulting from exceptional firmness.
- They lack the necessary properties for effective mucoadhesion.

2. Secondary interactions, including hydrogen bonding and van der Waals forces, are essential for establishing the adhesive bonds that characterize mucoadhesion.

- The inherently weaker nature of semi-permanent bonds means they can be readily disrupted, requiring minimal energy to break the bond.
- Highly preferred for mucoadhesion.

7. EVALUATION TEST OF BUCCAL PATCHES[36]

7.1. Moisture Content

- The individual films are weighed and placed in a desiccator containing calcium chloride at room temperature for 24 hours.
- After this period, the films are weighed again and this process continues until a stable weight is achieved.
- The percentage of moisture content is determined using the formula:

  % moisture content = (initial weight - final weight) / initial weight × 100.

7.2. Swelling Index

- The films were individually assessed and placed on the surface of an agar plate, which was kept in an incubator at a temperature of 37 ± 0.2 degrees Celsius to facilitate the expansion of the samples.
- At consistent time intervals, an increase in the weight of the films was recorded, followed by precise measurements of the weight.

7.3. Surface pH

- The surface pH of the films can be evaluated by allowing three films from each formulation to swell for two hours on an agar plate.
- A pH meter was utilized to measure the pH directly on the surface of the swollen film, and an average value was calculated.

7.4. Folding Endurance

- The folding endurance of the films was evaluated by manually folding a single film at a consistent point until it either fractured or reached a maximum of 300 folds.
- This measure of folding endurance indicates the highest number of times the film can be folded at the same spot before failure occurs.

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RESULT AND DISCUSSION

Mucoadhesive buccal patches have shown promising results in recent studies. One study found that these patches can provide sustained release followed by a more gradual release phase. This is particularly useful for drugs that require prolonged exposure to the mucosa, such as antifungal medications.

The same study also found that the physicochemical, the bioadhesive and swelling characteristics of the patches exhibited considerable variation based on the viscosity of the polymers employed and their specific combinations.

This highlights the importance of carefully selecting the materials utilized in the development of mucoadhesive buccal patches have been explored for the treatment of various conditions, including aphthous ulcer cardiovascular disease, fungal/ microbial infection.

For example, one study found that a mucoadhesive buccal patch containing carvedilol, an antihypertensive drug, could provide effective treatment for hypertension while minimising side effects.

Overall, the results of recent studies suggest that mucoadhesive buccal patches represent a promising method for drug delivery, offering potential uses across multiple therapeutic fields. Nonetheless, additional research is essential to thoroughly investigate their capabilities and enhance their formulation and design.

CONCLUSION

Drugs are effectively and reliably absorbed via the extensive vascular and lymphatic networks of the buccal mucosa. Additionally, patches circumvent the pre-systemic metabolism that occurs in the gastrointestinal tract and the liver's first-pass effect. These patches offer a safe and convenient method for administering medications in the buccal cavity, as buccal drug administration can be halted immediately in the event of toxicity. Consequently, buccal drug delivery

has emerged as a compelling alternative for the administration of potent peptide and protein therapeutics, as well as a promising area for ongoing research aimed at achieving systemic delivery.

ACKNOWLEDGMENT

"We recognize the increasing concern surrounding aphthous ulcers, a serious condition that millions around the globe. We commend the dedication of researchers, scientists, and healthcare professionals who are striving towards its prevention and management. Recent developments in formulation techniques have shown potential in addressing aphthous ulcer. Additionally, we are thankful to Loknete Dr. J. D. Pawar College of Pharmacy, Manur, Kalwan for their facilities and resources. We also extend our gratitude to our guide for their steadfast support. This review seeks to deliver a thorough overview of the latest trends in formulation methods for the treatment of aphthous ulcer, aiming to enhance treatment results and improve patient care"

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