EJPMR, 2026, 13(7), 520-529 **Review Article** **Impact Factor: 8.158**

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

ISSN (O): 2394-3211
ISSN (P): 3051-2573
Coden USA: EJPMAG

MUCOADHESIVE BUCCAL PATCHES: AN INTEGRATED PERSPECTIVE ON DRUG DELIVERY, MUCOADHESION, AND THERAPEUTIC APPLICATIONS

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DOI: https://doi.org/10.5281/zenodo.21294340

How to cite this Article: Kousalya B. M.[1], Mrs. Selvi A.[2]*. (2026). Mucoadhesive Buccal Patches: An Integrated Perspective On Drug Delivery, Mucoadhesion, And Therapeutic Applications. European Journal of Pharmaceutical and Medical Research, 13(7), 520-529.

Article Received on 16/06/2026 **Article Revised on 05/07/2026** **Article Published on 10/07/2026**

ABSTRACT

Mucoadhesive buccal patches have emerged as a promising drug delivery system owing to their ability to enhance drug bioavailability, improve patient compliance, and provide controlled drug release. The buccal route offers several advantages over conventional oral administration by bypassing first-pass hepatic metabolism and avoiding degradation of drugs in the gastrointestinal tract. Mucoadhesion plays a crucial role in prolonging the residence time of the dosage form at the site of application, thereby facilitating effective drug absorption through the buccal mucosa. The effectiveness of mucoadhesive buccal patches depends on various factors, including the properties of the polymer, the mechanism of mucoadhesion, and the physiological characteristics of the buccal mucosa. This review provides an integrated perspective on mucoadhesive buccal patches and their role in buccal drug delivery. It discusses the fundamentals of buccal drug delivery systems, the concept and mechanisms of mucoadhesion, and the major theories proposed to explain mucoadhesive interactions. Furthermore, the therapeutic applications of mucoadhesive buccal patches for both local and systemic drug delivery are explored. By consolidating current knowledge on mucoadhesive buccal patches, this review emphasizes their significance as an effective and patient-friendly drug delivery platform and highlights their potential for future pharmaceutical applications.

KEYWORDS: Mucoadhesive buccal patches, Buccal drug delivery system, Mucoadhesion, Buccal mucosa, Mucoadhesive polymers, Controlled drug release, Bioavailability, Therapeutic applications.

1. INTRODUCTION

1.1. BUCCAL DRUG DELIVERY SYSTEM

The oral route is the most preferred drug delivery method among the various choices for patients and medical professionals. The buccal area of the mouth cavity offers an alternative for drug delivery because it is easy to administer. The use of mucoadhesive polymers in buccal drug delivery has a greater application. Various mucoadhesive devices, including tablets, films, patches, disks, strips, ointments and gels, have recently been developed. However, buccal patch offers greater flexibility and comfort than the other devices. In addition, a patch can circumvent the problem of the relatively short residence time of oral gels on mucosa, since the gels are easily washed away by saliva. Buccal drug delivery is the process of administering a desired medication through the buccal membrane that borders the oral cavity. Buccal route of drug delivery provides the direct access to the systemic circulation through the jugular vein bypassing the first pass hepatic metabolism leading to high bioavailability. Drug delivery technologies modify drug release profile, absorption, distribution and elimination for the benefit of improving product efficacy and safety, as well as patient convenience and compliance.

Other advantages such as low enzymatic activity, suitability for drugs or excipients that mildly and reversibly damages or irritates the mucosa, painless administration, easy drug withdrawal, facility to include permeation enhancer/enzyme inhibitor or pH modifier in the formulation and versatility in designing as

multidirectional or unidirectional release systems for local or systemic actions.

1.2. ANATOMY OF ORAL CAVITY

The Oral cavity

The oral cavity is divided into two regions the lips and cheeks bound the outer oral vestibule and oral cavity formed by hard and soft palates, the floor or mouth and tonsils. The oral cavity is lined by a multilayered mucous membrane of a highly vascularized nature relatively thick and dense. Under the mucous membrane there are net of capillaries and arteries from which drug is penetrating into the systemic circulation. Inside the cheeks there is a lining of membrane that is buccal mucosa, and the term "buccal drug delivery" refers to drug release which can occur when a dosage form is placed in the outer vestibule between the buccal mucosa and gingival.

Physical Features of the Oral Cavity

The mucosal lining of the oral cavity is categorized based on its function into three distinct types:

- **Masticatory Mucosa**

It includes the tissue surrounding the teeth and the hard palate. These areas are characterized by keratinized epithelium, providing resilience and protection.

- **Lining Mucosa**

Found on the lips, inner cheeks, base of the mouth, the underside of the tongue, buccal mucosa, and the soft palate. These regions are covered with non-keratinized epithelium, allowing for flexibility and mobility.

- **Specialized Mucosa**

Located on the tongue's upper surface (dorsum), this mucosa is highly keratinized and supports the tongue's specialized functions.

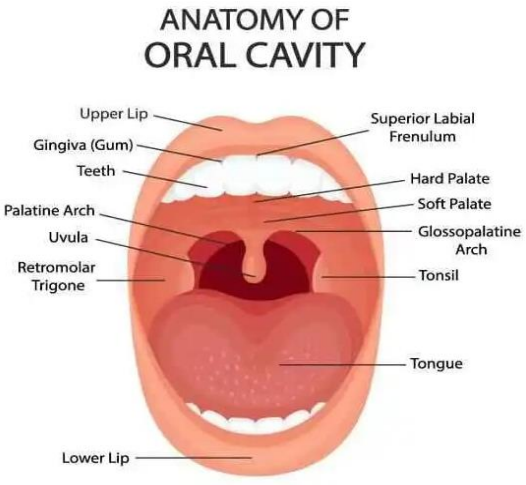

Figure 1: Anatomy of oral cavity.

Overview of Buccal Mucosa

Structure

Oral mucosa is divided into two part epithelium and basement membrane and connective tissue

- **Epithelium**

The epithelium serves as a protecting covering for the tissue and a barrier to the entry of foreign particle. It has thickness 500-800µm and consists of 40-50 layers of stratified squamous epithelial cell.

- **Basement membrane and connective tissue**

Basement membrane is a boundary between the basal layer of epithelium and connective tissue. It consists of extracellular materials. The organization which determines the mechanical stability, resistance to deformation, and extendibility of tissue is made up of bulk of connective tissue.

Permeability

The oral mucosa is generally considered a moderately permeable tissue, falling between the permeability of the epidermis and the intestinal lining. Studies suggest that the buccal mucosa's permeability is significantly higher than that of the skin, ranging from 4 to 4,000 times greater. Among the different regions of the oral mucosa, permeability varies, with sublingual mucosa being the most permeable, followed by buccal mucosa, and then palatal mucosa. These differences arise due to variations in tissue thickness and keratinization levels. The sublingual mucosa is thin and non-keratinized, the buccal mucosa is thicker but also non-keratinized, and the palatal mucosa is keratinized and of intermediate thickness.

The Mucus Layer

To the mucosal epithelial surface a translucent and viscid secretion which is a thin, continuous gel blanket are adherent called mucus. In the human the mean thickness of this layer varies from about 50 to 450µm. The goblet cells lining the epithelia or by special exocrine glands that secreted mucus. The exact composition of the mucus layer varies substantially depending on the species, the anatomical location, and the pathophysiological state.

However, it has the following general composition.

Water	95%
Glycoprotein and lipid	0.5-5%
Mineral salt	1%
Free proteins	0.5-1%

Functions of mucus

- Cell-cell adhesion
- Lubrication
- Bioadhesion
- Protective
- Barrier

Mucins and salivary composition

Mucins are secreted as large aggregates by prostaglandins, with molecular weights ranging from 1 to 10 million Da. These aggregates consist of monomers primarily connected through non-covalent interactions, though intermolecular disulfide bonds also contribute to their structure. The oligosaccharide side chains of

mucins typically contain about 8–10 monosaccharide units, including L-fucose, D-galactose, N-acetyl-D glucosamine, N-acetyl-D-galactosamine, and sialic acid. The amino acids serine, threonine, and proline are also prominent in mucins.

Due to the presence of sialic acids and ester sulfates, mucus carries a negative charge at saliva's physiological pH, which ranges from 5.8 to 7.4. Saliva primarily comprises water (99.5%), proteins, glycoproteins, and electrolytes. It contains high levels of potassium (7× plasma), bicarbonate (3× plasma), calcium, phosphorus, chloride, thiocyanate, and urea, while sodium is present in lower concentrations (1/10× plasma).

The pH of saliva typically ranges from 5.6 to 7. Saliva also contains enzymes such as α-amylase, which breaks 1–4 glycosidic bonds in starch; lysozyme, which protects by digesting bacterial cell walls; and lingual lipase, which aids in fat digestion.

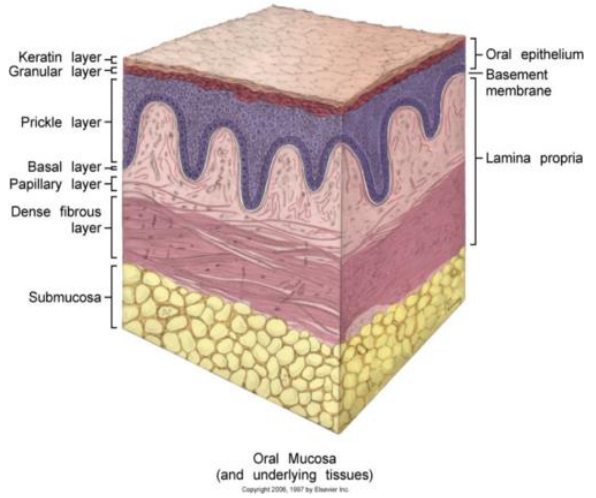

Figure 2: Oral mucosa.

1.3. MUCOADHESION

Over the decades, mucoadhesion has become popular for its potential to optimize localized drug delivery, by retaining a dosage form at the site of action or systemic delivery by retaining the formulation in intimate contact with the absorption site. Mucoadhesive drug delivery systems are those that target a medication to a particular part of the body for extended periods of time by using the bioadhesion of particular polymers, which become sticky when moistened.

Mucoadhesion is referred to as the adhesion between a polymer and a mucus layer. The term mucoadhesion is often employed when a mucosal surface is the biological substrate. Likewise, in the gastrointestinal tract, the adhesion of semisolid forms to the mucus is demonstrated by mucoadhesion. Bioadhesion is the ability of a material (synthetic or biological) to adhere to a biological tissue for an extended period of time. The biological surface can be epithelial tissue or it can be the mucus coat on the surface of a tissue. If adhesion is to a mucous coat, the phenomenon is referred to as mucoadhesion.

Benefits of mucoadhesive delivery system on conventional delivery methods are in terms of controlled drug delivery, comparatively large permeability as the mucous membrane is well vascularised which rapidly uptake drug into the systemic circulation and improved bioavailability. Mucoadhesion, the ability to hold on to the mucosal layer for a specific period, is the main part in the design of these novel drug delivery systems.

1.3.1. MECHANISM OF MUCOADHESION

The mucoadhesion process is initiated through two stages, involving the connection between the mucoadhesive material (formulation) and the mucous membrane. The use of MRI is employed to detect the time and location of disintegration of the fast-releasing delivery system. Mucoadhesion involves attaching the drug, along with a suitable carrier, to the mucous membrane. The complex phenomenon of mucoadhesion involves wetting, adsorption, and interpretation of polymer chains. Different mechanisms of adhesion to mucosa could exist and depend on the nature of a dosage form.

- **Contact stage**

It explains the connection between the mucous membrane and the mucoadhesive polymer, with the dispersal and swelling of the formulation.

- **Consolidation stage**

The presence of moisture activates the mucoadhesive material in the consolidation step. The system is plasticized by moisture, enabling the mucoadhesive molecules to break free and be linked up by weak Van der Waals and hydrogen bonds. Essentially, two theories are used to explain the consolidation step: the diffusion theory and the dehydration theory.

The diffusion theory

The diffusion theory is the mutually interacting of mucoadhesive molecules and glycoprotein of mucus and building of secondary bonds by interpenetration of their chains.

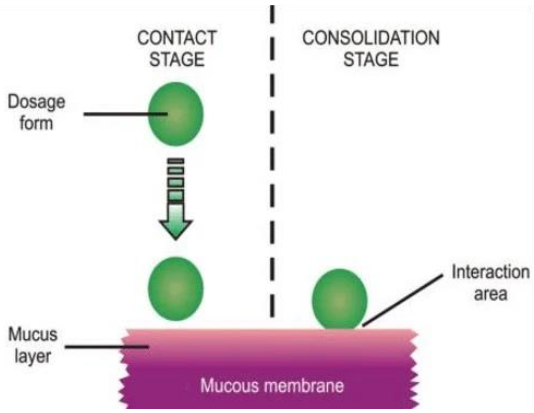

Figure 3: Two stages of mucoadhesion.

The dehydration theory

According to the dehydration theory the material gets gelify when it come in contact with the mucus in the aqueous environment. The drawing of water into the formulation due to concentration gradient until the osmotic balance is reached. This process increases the contact time of mucous membrane with the mixture of formulation and mucus. So, it is not the interpenetration of macromolecules chains, it is the water motion that lead to the consolidation of the adhesive bond. The dehydration theory is not applicable for highly hydrated forms or solid formulations.

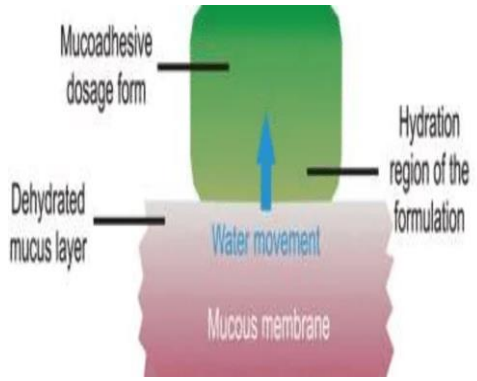

Figure 4: Dehydration theory of mucoadhesion.

1.3.2. THEORIES OF MUCOADHESION

The diffusion theory

A networked structure across the adhesive interface is formed by the presence of polymeric chain on the substrate surface. Upon initial contact with these two polymers, i.e., glycoproteins of the mucus and mucoadhesive polymer chain, an entangled network is created between the two polymers through the diffusion of the mucoadhesive polymer chain into the mucus network.

The wetting theory

The spreading of the material, mostly mucoadhesive liquids or low viscous formulations, is described by the Wetting theory on biological tissues. An extension of Young's basic equation can calculate the degree of spreading. Bioadhesion is expressed as an incrustation process wherein mucosal surface irregularities are penetrated by the bioadhesive polymers.

The cohesive theory

The occurrence of bioadhesion is basically due to the intermolecular interactions among like molecules.

The mechanical theory

The diffusion of the liquid adhesives into the micro-cracks and irregularities present on the substrate surface, thereby forming an interlocked structure that gives rise to adhesion, is explained by the mechanical theory. The presence of irregularities in the mucosal surface creates a liquid adhesiveness, increasing the area of contact between the polymer and the mucosa.

The electronic theory

The transfer of electrons among the surfaces is proposed by the electronic theory, resulting in the formation of an electrical double layer, thereby giving rise to attractive forces. The electronic hypothesis is concerned with the principle that divergent electrical charges are acquired jointly by mucoadhesive and biological materials. Thus, when both resources come into contact, electrons are exchanged to construct a two-fold electronic layer at the boundary, where the mucoadhesive potency is determined by the striking forces within these electronic layers.

The adsorption theory

The mucoadhesive device is adhered to the mucus by secondary chemical interactions, such as Van der Waals and hydrogen bonds, electrostatic attractions, or hydrophobic interactions, according to the Adsorption Theory. For example, in polymers containing carboxyl groups, the prevalent interfacial forces are constituted by hydrogen bonds. Researchers have considered such forces to be the most important in the adhesive interaction phenomenon number of interactions can achieve intense global adhesion.

The fracture theory

This theory explains the forces required to separate the two surfaces after adhesion has taken place.

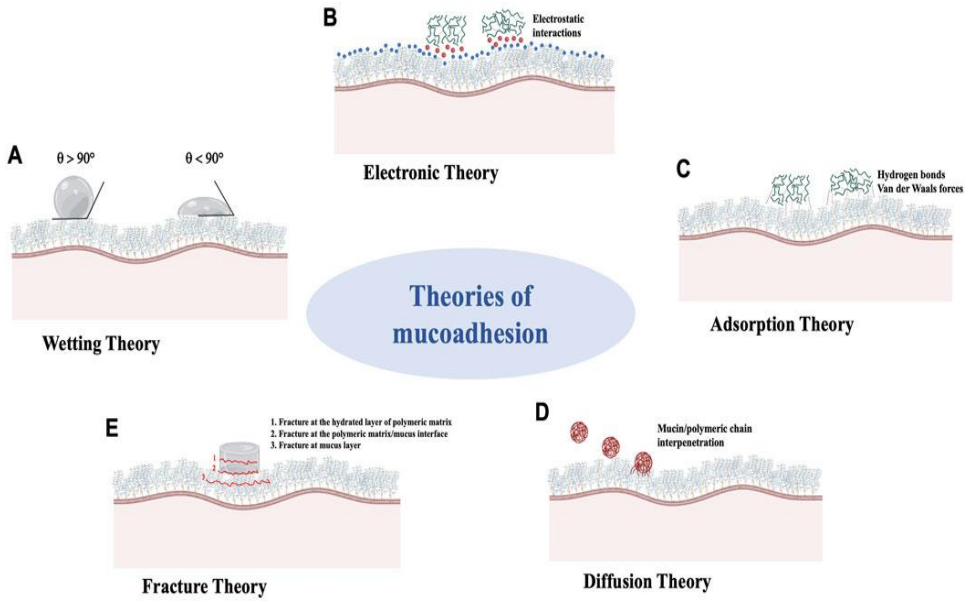

Figure 5: Theories of mucoadhesion.

1.3.3. FACTORS AFFECTING MUCOADHESION

1. Polymer related factors

Molecular weight

The mucoadhesive strength of a polymer increases which molecular weight about 100000. Direct correlation between the mucoadhesive strength of Polyoxyethylene polymers and their molecular weight lies in the range of 2, 00,000 – 7, 00,000.

Flexibility of polymer chain

It is important for interpretation as water soluble polymer becomes cross linked, the mobility of the individual polymer chain decrease, as the cross-linking density increases, the effective length of chain which can penetrate into mucus layer decreases even further and mucoadhesive strength is reduced.

Cross linking density

The average pore size, the number and average molecular weight of the cross- linked polymer and the density of cross-linked polymer are three important and inter-related structural parameters of a polymer network. Therefore, it seems reasonable that with increasing density of cross-linking diffusion of water into the polymer network at lower rate which in turn causes an insufficient swelling of the polymer.

2. Environment related factors

pH

pH was found to have a significant effect on mucoadhesion. pH influences the change on the surface of both mucus and polymers mucus will have a different change density depending on pH because of differences in dissociation of functional groups on the carbohydrate moiety and amino acids.

Applied strength

To place a solid mucoadhesive system, it is necessary to apply a defined strength, depending on the type of polymer poly (acrylic acid\divinyl benzene) or carbopol, the adhesion strength increases with the applied strength or with the duration of its application, up to an optimum. If high pressure is applied for a long period of time, polymers become mucoadhesive even through they do not have attractive interactive with mucin.

Initial contact time

Initial contact time between the mucoadhesive and mucus layer determines the extent of swelling and interpretation of the mucoadhesive polymer chains. More adhesive strength increases as the initial contact time increases.

3. Physiological factors

Mucin turnover

The natural turnover of mucin molecules from the mucus layer is important for at least two reasons. Firstly, the mucin turnover is expected to limit the residence time of the mucoadhesive on the mucus layer. Secondly, mucin turnover results in substantial amounts of soluble mucin molecules. These molecules interact with mucoadhesive before they have a chance to interact with mucus layers. The gas mucosa accumulates secreted mucin on the luminal surface of the tissue during early stage of fasting. The accumulated mucin is subsequently released by freshly secreted acid or simply by the passage of ingested food; the exact turnover rate of mucus layer to be determined.

Disease state

The physiochemical properties of the mucus are know to change during disease conditions such as common cold, gastric ulcers, ulcerative colitis, cystic fibrosis, bacterial and fungal infections of female reproductive tract and inflammatory conditions of the eye. If mucoadhesive are to be used in the disease states, the mucoadhesive property needs to be evaluated under the same conditions.

1.4. MUCOADHESIVE BUCCAL PATCH

Flexible films may be used to deliver drugs directly to a mucosal membrane. They also offer advantages over creams and ointments in that they provide a measured dose of drug to the site. Buccal adhesive films are already in use commercially. They present a greater patient compliance compared with tablets owing to their physical flexibility that causes only minor discomfort to the patient. Patches are laminated and generally consist of an impermeable backing layer and a drug containing layer that has mucoadhesive properties and from which the drug is released in a controlled manner.

Figure 6: Mucoadhesive buccal patch.

1.4.1. TYPES OF MUCOADHESIVE BUCCAL PATCH

Matrix Type

The matrix-shaped buccal patch contains the drug, adhesive, and additives. Once the medicine is evenly distributed in a hydrophilic or lipophilic polymer matrix, the medicated polymer is shaped into a medicated disc with a predetermined surface area.

Reservoir Type

The drug and additives are kept separate from the adhesive in a cavity in the reservoir-system buccal patch. An impermeable backing is offered to prevent medication loss, reduce patch deformation and disintegration while in the mouth, and control the drug distribution route. Additionally, the patch can be made to dissolve almost instantaneously or break down very slowly in the mouth. This technique makes use of a reservoir with a cavity for the medication and additives that are kept apart from the adhesive. An impermeable backing is utilized to prevent medication loss, reduce patch deformation and disintegration in the mouth, and control the direction of drug distribution. When the patch is placed in the mouth, it can either be designed to break down slightly or when the patch is put in the mouth, it can either be made to break down very little.

1.4.2. METHODS OF PREPARATION OF MUCOADHESIVE BUCCAL PATCH

Mucoadhesive buccal patches can be prepared by methods mentioned below,

Solvent Casting Method

Initially, all ingredients were accurately weighed, and then all ingredients were added gradually to the solvent until a clear solution was observed. Two drops of plasticizer were added by continuous stirring in a magnetic stirrer. The above solution was then poured into a petri dish with uniform distribution by cleaning the petri dish with Glycerin. Kept drying for 24hr by using inverted funnel cover for uniform drying of buccal patch. After solvent evaporation thin film is formed that is desired for cutting the patches into desired size and shape.

Direct Milling

The buccal patches were prepared using this method. In this method, solvents are not used without the use of solvent drugs, and ingredients are mixed using the direct milling method. The resultant material was rolled onto the release liner until the desired thickness was achieved. Subsequently, the backing membrane was laminated onto the sheet of the coated release liner to form a laminate and finally cut into the desired size and shape.

Hot Melt Extrusion: In this method, all ingredients are taken into solid dosage form, and all ingredients are melted using an extruder that contains a heater and melts the solid dosage into the film. Subsequently, the films were cooled, and the desired shape was cut and packaged.

Solid Dispersion Extrusion

First, the more active ingredients are dispersed into the suspended carrier in the solid state owing to the presence of amorphous hydrophilic polymers. Drug dissolved into a suitable solvent and added a suitable polymer without removing the liquid solvent below 70 °C using dies, and the solid dispersion was converted into a film.

Semisolid Casting Method

Some polymers are water soluble, and some are water insoluble in that the water-soluble film forming polymers are dissolved into the acid insoluble polymer in the ratio of 1:4 respectively. Resultant mass in that add the suitable plasticizer then cast into films or in ribbon form by using heat-controlled drums. The diameter was limited to 0.015-0.05 inches.

1.4.3. EXPLORING THE COMPONENTS OF MUCOADHESIVE BUCCAL PATCH

Drug

The key characteristics of the drug that influence its diffusion between the patch and the buccal include its melting point, molecular weight, and chemical functionality. When designing a buccal mucoadhesive drug delivery system, pharmacokinetic properties should serve as the foundation for selecting the right drug. A range of APIs could be delivered via buccal film technology. However, it is challenging to insert large dose molecules into buccal film due to the dosage form's size limitations. The buccal patches can typically include 5%w/w to 30%w/w of active medicinal substances.

The drug should have following characteristics:

- Medications having a biological half-life of two to eight hours are the best options for regulated drug administration; the traditional single dose of the medicine must be modest.
- Drug absorption should be passive when administered orally.
- The medication's Tmax varies widely or has a greater value when taken orally; it should not taste terrible and should not cause irritation, tooth discoloration or erosion, or allergic reactions.

Polymer

The primary factor is most likely polymer hydration and swelling characteristics. Increased mucous cohesive qualities that support mucoadhesion may result from polymer hydration and, in turn, mucus dehydration. The flexibility of polymer chains and the interpenetration of polymer and mucin chains should be favored by swelling. Therefore, polymers with varying properties must be taken into account depending on the type of formulation. Examples include carbopol, polyvinyl alcohol, hydroxy, ethylcellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, and other mucoadhesive polymers. In matrix devices, where the medication is incorporated in a polymer matrix that regulates the duration of the drug's release, the main molecule that constitutes most mucus polymers is also used. Mucoadhesive polymers interact with the mucus layer covering the mucosal epithelial cells and might be synthetic or natural.

Backing Membrane

The polymer whose solution can be casted into thin poreless uniform water impermeable film can be used to prepare backing membrane of patches. It should have good flexibility and high tensile strength and low water permeation. They should be stable on long storage maintaining their initial physical properties. The cellulose acetate in concentration of 2.4% w/v in acetone with 10% of plasticizer (PEG 4000 or glycerol) of total polymer weight when air dried produces a thin film suitable for backing membrane purpose. Similarly, 2-4% w/v solution of ethyl cellulose in 1:4 mixture of alcohol: toluene and suitable plasticizer can be casted into film.

Plasticizer

These are the materials used to achieve softness and flexibility of thin films of polymer or blend of polymers. Examples of common plasticizers used are glycerol, propylene glycol, PEG 200, PEG 400, castor oil etc.

Penetration enhancer

Substances that help to promote drug permeation through the buccal epithelium are referred to as penetration enhancers, permeation promoters, or absorption enhancers. Ideally chemicals used as penetration enhancers should be safe, nontoxic, pharmacological, and chemically inert, nonirritant, and non-allergenic. In addition, the tissue should revert to its normal integrity and barrier properties on removal of the chemical, surfactants, anions such as sodium laurate and sodium lauryl sulfate, cations such as cetylpyridium chloride.

Different mechanisms of actions of penetration enhancers:

- Disruption of the intercellular lipid domain and protein domain integrity.
- Extraction of membrane fluidization and reverse micellisation in the membrane, creating aqueous channels.
- Increase the fluidity of phospholipids in the intercellular lipid domain.
- Neutralizing the charge of the mucosal surface and by opening the tight junctions.

Sweetening Agent

Sweetening agents are useful in food and medicinal items that disintegrate or dissolve in the oral cavity. Common sweeteners include fructose, glucose, liquid glucose, sucrose, dextrose, and maltose. Unlike sucrose and dextrose, fructose's sweetness is rapidly absorbed in the mouth. However, using natural sweeteners presents serious difficulties for people with diabetes. Consequently, the use of artificial sweeteners in food and pharmaceutical preparations is growing. The first generation of artificial sweeteners includes saccharin, cyclamate, and aspartame, followed by acesulfame-K, sucralose, alitame, and neotame, which are classified as second generation artificial sweeteners. Sucralose, aspartame, mannitol, etc.

1.4.4. CHARACTERISATION OF MUCOADHESIVE BUCCAL PATCH

Thickness Uniformity of the Patches:

From each formulation, three patches were taken. At three different places micrometer screw gauge was placed and measured patch thickness and mean value calculated.

Folding Endurance

Three patches from each formulation with size 2×2cm^2 cut by means of a sharp blade. Folding endurance was determined. The mean value was calculated.

Uniformity of Weight of the Patches

Three patches from each formulation of size 1×1cm^2 taken and weighed on a digital balance. The average weight were calculated.

Percentage Swelling Index

The polymeric patches incise into 1×1 cm^2 were weighed exactly and kept immersed in 50ml of phosphate buffer pH6.8. At 5, 10, 30, 60 minutes intervals patches were taken out carefully. Blotted using filter paper for removing buffer solution on their surface and weighed accurately until constant weight was evaluated at the time, and then percent swelling was calculated with the formula.

SI= W2-W1/W1

Drug Content Uniformity of Patches

From each formulation, three patches took into the separate 100ml volumetric flask. The amount of drug in the buccal patches being determined by dissolving 1cm^2 patch in 100ml phosphate buffer saline (pH6.8) and shaken vigorously at room temperature for 24 hours. Using Whatman filter paper this solution filtered and diluted properly and analysed in UV spectrophotometer at 250nm. Final reading was taken from averages of the three patches.

Surface pH of Patches

Three patches of each formulation permitted to swell and it was done by allowing it to get in contact with 0.5ml of distilled water (pH6.5±0.5) for about 1hour in room temperature. pH was marked down by making electrode touch in with the surface of the patch.

In-vitro Release Studies

Type II (paddle type) USP dissolution apparatus was chosen to perform the in-vitro release studies. The medium was 900ml of isotonic phosphate buffer pH6.8 as the at 37±0.5°C and 50rpm. Forunidirectional liberation, one side of the patch attached to a glass disk and the disk was kept into the bottom of the dissolution vessel, so that patch surface get an exposed medium. At present time intervals, an aliquot of 5ml sample was introverted and comparable volume was added with fresh phosphate buffer pH6.8 at same temperature. These samples then analysed spectrophotometrically and average cumulative percentage drug released was determined. The data obtained were statistically analysed.

Stability Studies

Medicated patches that are chosen for stability testing. For the determination of physical and chemical stabilities patches were positioned in a glass beaker lined with aluminium foil and kept in room temperature (30±2°C) and refrigerator temperature (4±2°C) for 45days. Changes in appearance and drug content of the stored patches evaluated each weekend. The data offered were the mean of three determinations.

Percentage Moisture Absorption

An initial, accurate weight buccal patch was placed in a desiccator. The desiccator should be containing 100ml solution of aluminium chloride in it. Relative humidity should be 76% and 86%. After three days, the patch was removed and weighed.

Percentage Moisture loss

Percentage moisture loss can be defined as the weight loss of substance subdued to drying, comparable to percentage the initial weight. This evaluation test accessing the moisture content of the pharmaceuticals patches or products. Excess moisture reduced shelf life, and leading to the microbial growth, degradation. The buccal patch was weighed, placed into a desiccator containing anhydrous calcium chloride, and weighed again for three days.

Moisture absorbance and moisture loss will be calculated by using

SI%= (Initial weight-final weight/Initial weight) x 100

1.5. ADVANTAGES OF MUCOADHESIVE BUCCAL DRUG DELIVERY SYSTEM

- Rapid onset of action compared with the oral route
- Buccal patches can be removed if requested to be discounted
- Improve patient compliance
- Avoiding hepatic first-pass metabolism by reducing enzymatic reactions.
- Self-medication therapy is highly flexible in terms of size, shape, and physical state.
- Buccal drug delivery systems are suitable for drugs that are unstable in the alkaline environment of intestinal pH when administered orally
- Enhancement of bioavailability by reducing the dose frequency and side effects.
- Easy to administer and terminate is painless.
- It can be administered to unconscious patients
- High blood supply and rich absorption owing to the passive system are not required for the activation of ATP molecules.
- Drugs are easily dissolved due to salivary secretion.
- Patients of pediatric and old age may experience vomiting and nausea. Thus, a reduction in cost may be achieved.
- Buccal drug delivery system are targeted drug delivery systems.
- Compared with the skin, the buccal mucous is highly perfused with blood vessels, leading to greater permeability.
- This saves time because it requires a very short treatment period.

1.6. DISADVANTES OF MUCOADHESIVE BUCCAL DRUG DELIVERY SYSTEM

- Eating drinking should be avoided
- A drug at a high dose cannot be administered via the buccal route. Daily dose is limited.
- Some drugs have a bitter taste and odors cannot be administered.
- Drugs unsuitable for buccal administration cannot be administered through the oral cavity.
- Only a small dose of the drug is administered by passive diffusion through the buccal drug delivery system.
- The total surface area of the oral cavity for absorption was 170 cm.

1.7. APPLICATION OF MUCOADHESIVE BUCCAL DRUG DELIVERY SYSTEM

Cardiovascular diseases

Atenolol, a β-blocker, is commonly used to treat cardiovascular problems including excessive blood

pressure, angina, arrhythmias, and heart attacks. Traditional atenolol tablets may cause changes in plasma concentrations, which could lead to adverse effects or reduced receptor-site activity. An oral controlled-release mucoadhesive tablet was developed to improve its efficacy in treating hypertension, with atenolol as the prototype medicine. This pill provides prolonged buccal delivery and sustained release over a longer period. Carvedilol, a non-selective beta-adrenergic antagonist, is used to treat hypertension and stable angina pectoris. Mucoadhesive tablets of carvedilol have been developed for this purpose. This hydrophilic polymer formulation utilizes hydroxypropyl methylcellulose (HPMC K4M and K15M) and Carbopol 934 (CP 934) to provide controlled and zero-order release. Increased polymer concentration in formulations resulted in sustained carvedilol release, according to studies. The rapidly hydrating polymer effectively controlled the release of carvedilol from buccal tablets.

Anti-inflammatory therapy

Inflammatory processes are a key cause of oral cavity illnesses. Topical application of nonsteroidal anti-inflammatory medications, such as flurbiprofen, flufenamic acid, and ibuprofen, can treat numerous oral cavity diseases, including gingivitis, periodontitis, stomatitis, and ulcers. Advantages include reduced therapeutic dose, localized drug delivery in target tissues, and fewer systemic side effects.

Antimicrobial therapy

Traditional dose forms such as solutions, gels, suspensions, and mouthwashes are frequently unsuccessful in treating oral candidiasis because they are quickly removed from the oral cavity. A bilayer mucoadhesive tablet containing nystatin was formulated. The formulation enabled the quick release of nystatin from a lactose based layer, followed by a regulated release from a polymeric layer over six hours.

Antiemetics

Ondansetron hydrochloride is a 5HT3 serotonin antagonist used to prevent nausea and vomiting during emetogenic cancer treatment. (70) A buccal mucoadhesive tablet containing ondansetron was produced and assessed. It used CP 934, sodium alginate, SCMC low viscosity, and HPMC 15cps as mucoadhesive polymers to impart adherence and ethyl cellulose as an impermeable backing layer. The medication stability in the optimized adhesive tablet was evaluated for 6 hours in natural human saliva. Both the medicine and the device remained stable. Domperidone buccal bioadhesive hydrophilic matrix tablets were formulated with HPMC and Carbopol. Increased polymer content led to increased bioadhesive strength. A two-way ANOVA based factorial investigation found that polymers significantly influenced the bioadhesive characteristics of compressed matrices.

Hypoglycaemic agents

Hypoglycemic drugs such as glipizide and glibenclamide have lately received interest for their possible use in buccal administration. Due to its short biological half-life of roughly 3.4 hours, glipizide must be taken twice or thrice daily in doses ranging from 2.5 to 10 mg. Mucoadhesive buccal films containing glipizide were formulated utilizing the solvent casting method with polymers such as HPMC, SCMC, CP934P, and Eudragit RL-100. The study investigated the effects of glipizide on the swelling behavior and residence time of several mucoadhesive polymers. The results indicated that medicated films had a considerably higher swelling index than plain films. In addition, adding the water-insoluble medication increased the films' water absorption capability. These results indicate that the buccal route could efficiently deliver therapeutic dosages of glipizide.

Antimigraine

Sumatriptan succinate, a 5-HT1 receptor agonist is used to treat migraines, was developed into mucoadhesive bilayered buccal patches for alternate drug delivery. Increasing the concentration of chitosan resulted in stronger mucoadhesive patches. The study found that chitosan concentration had a greater impact than PVP K30 concentration. Increased chitosan and PVP K-30 levels resulted in increased swelling of patches. Drug release increased with higher PVP K30 concentrations and decreased with lower chitosan concentrations.

Antihistamine

Chlorpheniramine maleate (CPM) is an antihistamine H1 receptor antagonist used to treat a variety of allergies. (75) Using HEC as a water-soluble polymer in mucoadhesive buccal patches improves CPM bioavailability by bypassing first-pass metabolism. The study found that the dosage form was non-irritating and did not produce mucosal damage or irritation during buccal delivery. The optimized buccal patch had 1.46 times the bioavailability of the oral dosage form, resulting in a statistically significant difference.

1.8. CONCLUSION

Buccal drug delivery systems represent a promising frontier in non-invasive therapeutic administration, offering a compelling alternative to traditional oral and parenteral routes. Their ability to bypass first-pass metabolism, provide rapid onset of action, and improve patient compliance makes them particularly suited for both systemic and localized treatments. Advancements in mucoadhesive polymers, permeation enhancers, and nanocarrier technologies are continually enhancing drug residence time and bioavailability in the buccal cavity. Research is required to produce new mucoadhesive polymers that are biodegradable, biocompatible, nontoxic, attach to specific cells or mucosa, and act as enzyme inhibitors for successful protein and peptide delivery. With the right dosage form design and formulation, the permeability and the local environment

of the mucosa can be controlled and manipulated in order to accommodate drug permeation. However, the need for safe and effective buccal permeation/absorption enhancers is a crucial component for a prospective future in the area of buccal deliver.

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