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Review Article

Buccal Films: A Review Of Therapeutic Application, Method Development ,Formulation And Relevant Approaches

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ABSTRACT

A Buccal films have emerged as a versatile and promising drug delivery platform, offering unique advantages for therapeutic applications. This comprehensive review explores recent progress in the field, covering diverse aspects such as therapeutic applications, method development, formulation strategies, and emerging approaches related to buccal films .The therapeutic applications section provides an in-depth analysis of the wide spectrum of diseases and conditions that can be targeted using buccal films. From localized treatments for oral diseases to systemic drug delivery, the review explores the expanding landscape of buccal films in healthcare, emphasizing their potential in personalized medicine and patient-centric approaches. Method development plays a pivotal role in ensuring the efficacy and safety of buccal films. The review critically examines recent advancements in analytical techniques, pharmacokinetic studies, and in vitro-in vivo correlations related to buccal drug delivery. Special attention is given to the challenges and innovations in achieving precise and reproducible dosing through buccal administration. Formulation strategies for buccal films are comprehensively discussed, including the utilization of polymers, permeation enhancers, and mucoadhesive agents. The review highlights innovations such as nanotechnology and mucoadhesive blends, aiming to optimize drug release profiles, enhance bioavailability, and improve patient compliance. In addition to therapeutic applications and formulation, the review explores emerging approaches that contribute to the evolution of buccal drug delivery. Topics include the integration of stimuli-responsive materials, nanomedicine, and personalized drug release systems, providing insights into the future directions of buccal film development. By synthesizing information from various disciplines, this review aims to present a holistic view of recent advancements in buccal films. It provides valuable insights into the current state

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of therapeutic applications, method development, formulation strategies, and emerging approaches, fostering a deeper understanding of the potential and challenges in utilizing buccal films as an effective drug delivery platform.

INTRODUCTION

In recent years, buccal membranes have emerged as a promising innovative drug delivery system, offering a In variety of therapeutic applications beyond traditional dosage forms. This comprehensive overview discusses various aspects of buccal masks and examines their therapeutic potential, method development, formulation strategies, and related approaches[1].Buccal membranes have attracted attention for their ability to provide an effective and patient-friendly route of drug delivery. The oral mucosa has rich blood supply and permeability, which allows rapid absorption of drugs and thus improves bioavailability. This review evaluates the diverse therapeutic applications of buccal membranes, ranging from topical treatment of oral diseases to systemic delivery for various medical indications. The versatility of buccal membranes in delivering small and large molecules makes them a promising option for personalized medicine and targeted therapy[2]. Developing effective buccal masks requires a nuanced understanding of formulation science, pharmacokinetics, and patient compliance. This review explores the complexities of buccal membrane method development, focusing on important considerations such as membrane composition, drug release kinetics, and penetration enhancers. Additionally, advances in manufacturing techniques, including solvent casting, hot melt extrusion, and electrospinning, are examined for their impact on film quality, reproducibility, and scalability. as the field of oral drug delivery continues to evolve, innovative methods are continually being explored to improve the performance and versatility of oral membranes[3]. This review reviews emerging technologies and strategies such as nanotechnology, bioadhesive systems, and mucoadhesive polymers that can help address challenges related to permeability, taste masking, and sustained release. The integration of smart drug delivery systems and personalized medicine with buccal mask development was also discussed, providing a glimpse into the future of customized treatment solutions. A critical aspect of buccal film development lies in the formulation strategies employed to optimize drug delivery. This review investigates the role of polymers, plasticizers, and permeation enhancers in tailoring the mechanical, mucoadhesive, and drug release properties of buccal films. The interplay between formulation parameters and their impact on stability, shelf life, and patient acceptance is thoroughly examined, providing insights into the challenges and opportunities in formulating buccal films for diverse therapeutic agents[4].

Buccal delivery system :

Oral drug delivery is similar to transdermal drug delivery (TDDS). Examples of buccal delivery are buccal patches and films. It has an impermeable back membrane and a reservoir layer from which the drug is released in a controlled manner. It can be prepared by heavy casting or direct milling. An impermeable support membrane can also be used to control drug release, prevent drug loss, and minimize damage. Suitable bioadhesive oral patches, which require permeability for oral application, offer improved absorption and bioavailability compared to oralsolutions. Extrarelease buccal patches and films bypass liver premetabolism while increasing bioavailability[5][6].

Fig no 1 Buccal film

Benefits of the Buccal route:

Oral administration has higher patient acceptance than other administration methods. Unlike the oral method, it works quickly, it also helps avoid injections and the dosage form is easy to administer and remove. Oral administration provides faster and better absorption. Oral side effects such as nausea and vomiting can be prevented[7]. The main point is that drug inhalationcan be done in coma, uncooperative patients and in emergency situations[8]. Drugs with poororal bioavailability can easily be used orally, as drugs that are unstable in the acidic environment of the stomach or are destroyed by enzymes or in the alkaline environment of the intestines cancause serious side effects[7]. Oral administration allows the drug to enter the body directly and also provides a passive system that does not need to be activated. Oral medications must be able to withstand environmental conditions such as temperature changes. It can deliver peptide molecules that are unstable for oral administration. Oral drug delivery can be used for continuous drug delivery[9][10][11].

Advantages of buccal film :

- Oral administration has higher patient acceptance than other nonoral administration methods.
- Improve patient compliance with injection pain relief.
- It is multi-vascular, making it easier to apply and remove prescription medications.
- Also, rapid and local cell renewal is ensured on the smooth surface of the gastric mucosa.
- Degree of perfusion is higher, so absorption is faster and better.
- Used for unconscious and uncooperative patients.
- It increases the bioavailability of drugs that are metabolized by oral hepatic first pass in the gastrointestinal system and portal system[12][13].

Marketed Scope and Opportunities of Buccal film :REVIEW

New drug delivery systems have become one of the most important elements of modern pharmaceutical formulation technology. Many techniques are used to develop drug delivery or control systems. Research on mucoadhesion systems has focused on many topics. This is a growing field where the goal is to create new tools and “smarter” polymers, as well as to developnew methods that can better visualize the phenomenon of mucoadhesion. As drug research leads to the emergence of new molecules, bacterial mucoadhesion will play an important role inthe development of new drugs[14]. Quality is important and further research in this area is crucialThe formulation of these drug delivery systems depends on the creation of suitable polymers with excellent mucoadhesive properties, stability and biocompatibility. The oral cavity provSes a rich vascularized mucosal surface for drug transport. The type (keratinous and non-keratinized) and thickness of the oral epithelium varies in different regions, and this difference causes regional differences in drug permeability[15]. Until now, oral mucosa has been used to deliver small doses of drugs because their adsorption is greater and faster. The main advantage of the buccal oral administration method is that it prevents chemical degradation in the stomach, inhibits metabolism in the first place, and can quickly reach the therapeutic effect of the drug. To be clear, positive results are currently only relevant to certain medications. However,

with the recent developments in new formulations such as mucoadhesive formulations and the use of peptides as drugs, this number will increase in the future. Commercially availablemucoadhesive delivery drugs include tablets (triamcinolone acetonide), suradrin tablets (nitroglycerin), and Buccostem tablets (prochlorperazine maleate). Salcoat powder spray (beclomethasone dipropionate). Reynacote powder spray (beclomethasone dipropionate) and sucralfate (aluminum hydroxide). Although only a few mucoadhesive drugs are currently available, it can be concluded that drug delivery using mucoadhesive drugs has great potential for topical and local use in the future. Mucoadhesive drug delivery technology has become increasingly popular in the pharmaceutical world and is a popular area for further research and development. Extensive international research has made significant progress in understanding various aspects of mucoadhesion[14]. However, mucoadhesive research is still at an early stage and furtherprogress is needed to translate this concept into practical applications based on controlled drug delivery (CDDS). There is no doubt that with the emergence of these new specific targets (lectins, thiol polymers, etc.), mucosal adhesion has entered a new world and researchers and pharmaceutical companies have begun to investigate more small molecules, potentially including proteins and peptides. like DNA for future reference. Technological advances in the ever-evolving field of drug distribution. In the oral mucosal cavity, the buccal site provides an attrctive control method for systemic drug delivery. The mucosa is rich in blood vessels and has high permeability[16]. Oral mucosa has many advantages in terms of longterm use. It contains mucosa, vascular and lymphatic fluid, and firstpass metabolism in the liver and presystemic elimination in the gastrointestinal tract are prevented. This area is ideal for storing equipment and will likely be used by the patient[17]. Thanks to the design and dosage of the drug, the permeability of the mucosa and the local environment can be controlled and adjusted according to the penetration of the drug. New buccal systems, such as soluble films, mucoadhesive films, and rapid sprays, provide new routes of administration for generic drugs with poor patient outcomes. The report will provide a detailed analysis of Oral Drug Delivery Systems in the overall pharmacy market, looking at the manufacturers, technologies and specific development-related challenges capable of delivering these drugs[18].

Formulation considerations:

Formulating a buccal film involves careful consideration of various factors to ensure the effectiveness, safety, and patient acceptability of the product. Here are some key formulation considerations for buccal films[19]:

Active pharmaceutical ingredients :

Any class of pharmaceutically active chemicals that may be delivered orally or through the buccal mucosa can be considered an active pharmacological substance[9]. It has expectorants, anti-anginal, anti-ulcer, anti-migraine, anti-asthmatics, anti-histaminic, and anti-epileptic properties. The medication dosage should be in milligrams (less than 20 mg/day) for the most effective formulation. several pharmacological classes, including expectorants, antiemetic, cardiovascular, analgesic, antiallergic, antiepileptic, hypnotic, diuretics, anti-parkinsonian, antibacterial, and erectile dysfunction medications[20][21].

The ideal characteristics of a drug to be selected:

- The drug ought to remain steady.
- The medication to be included need to have a minimal dosage.
- The medication ought to dissolve in water or saliva.

- The drug's flavour should be enjoyable.
- The medication needs to be able to penetrate the oral mucosal tissue.
- The medication has to be slightly ionized at the oral cavity's pH[22].

Water soluble polymers :

Film formers are made of water-soluble polymers. In medical and nutraceutical applications, the use of film forming polymers in dissolvable films has garnered a great deal of interest. The films' quick disintegration, pleasant mouthfeel, and mechanical qualities are all made possible by the water-soluble polymers. Raising the molecular weight of polymer film bases slows down the pace at which polymers disintegrate. Water-soluble polymers such as HPMC E-3 and K-3, Methyl cellulose A-3, A-6, and A-15, Pullulan, Carboxy methylcellulose 30, PVPK-90, Pectin, gelatine, sodium alginate, HPMC, PVP, PVA, maltodextrin, and Eudragit are some examples of the polymers utilized as film former[23][2].

Ideal properties of the polymers used in the oral film :

- Polymers should be non toxic or non- irritant.
- polymers should be non bitter in taste .
- Polymers should be tasteless .
- Polymer need to be free of contaminants that can be leached.
- The cost of polymer shouldn't increase.
- The polymer shouldn't be a hindrance throughout the breakdown process.
- The polymer need to possess high wetting sprediability.
- The polymer need to possess enough peel, shear, and tensile strength.
- The polymer should have an adequate shelf life.

Plasticizers:

The second most important component after polymers in oral film production is plasticizers. Plasticizers control the mechanical properties of the film. The chemical structure and concentration of the polymer play an important role in reducing the glass transition temperature of the polymer. The choice of plasticizer will depend on its compatibility with the polymer and thetype of solvent used in the casting film. The use of plasticizers allows the polymer to flow better and increases its strength. Phthalate derivatives such as glycerin, propylene glycol, low molecular weight polyethylene glycol, dimethyl phthalate, diethyl phthalate and dibutyl phthalate, citrate derivatives such as tributyl citrate, triethyl citrate, acetyl citrate, triacetin, and rubber used by plastics. However, using the wrong plasticizers will cause the film to break, crack and peel off in strips. It has also been reported that the use of plastic affects drug absorption[24].

Sweeteners:

Sweeteners are important ingredients that provide comfort to patients and mask discomfort. From API. Sweets are divided into two: natural sweets and artificial sweets. Natural sweeteners such as glucose, sucrose, liquid glucose, isomaltose and fructose. Fructose sweeteners are quickly found in the mouth and combine with sorbitol or mannitol, making the mouth feel better and cooler. There are two generations of candy; The first includes aspartame and air. The second generation includes acesulfame potassium, sucralose neotame and the last one. Sweeteners must be appropriately selected to achieve sweetness sensation in the desired range of 36% by weight of all ingredients added to the film[25][26].

Surfactant :

Surfactants are used as solvents or wetting agents in the film. When surfactants are used, the film rapidly dissolves in the buccal mucosa within seconds and releases the drug immediately. The use of surfactants can increase the solubility of poorly soluble drugs in the oral cavity[16][13].

Flavours:

These are the most important ingredients added to oral formulations of the drug because flavoring is the ultimate goal of selecting a formulation by the patient. It can become an important factor in sales. The flavors used are a variety of natural and artificial flavors. The amount of pice needed to mask the taste depends on the type and use of the spice. Preferably, up to 10% w/w sweetener is added to the formula. Flavorants can be selected from oleoresins, synthetic oils extracted from plants such as leaves, fruits and flowers. Spices can be used alone or together[27].

Colours:

Various colors include FD&C colors, AB colors, natural colors and fruit concentrates, pigments such as titanium dioxide, silica and zinc dioxide in accordance with pantone color regulations. colour The concentration of all these colors should not be more than 1% w/w. These reagents need to be added when some components or chemicals are in insufficient form or have been removed[28].

Saliva stimulating agent :

Saliva-stimulating agents are substances or compounds that help increase saliva production. They are often used to alleviate symptoms of dry mouth (xerostomia), a condition that can be caused by various factors such as medication side effects, certain medical conditions, or radiation therapy .Buccal films are thin, dissolvable films that adhere to the inside of the cheek (buccal mucosa) and release medication into the bloodstream. While there may be specific formulations of buccal films designed to stimulate saliva production, it's essential to note that the exact components can vary based on the formulation created by pharmaceutical companies[29][30].

Method development of Buccal Film :

a. Solvent casting method
b. Semisolid casting method
c. Hot melt extrusion
d. Solid dispersion extrusion
e. Rolling method

Solvent Casting Method :

In the solventcasting method, the required amount of polymer is added and dissolved in distilled water. Add a small amount of active ingredient to this medicine. Add the plasticizer to the solution and mix well. The solution was poured into a Petri dish and kept in ahot oven at 400°C to dry. After it dries, cut it with a razor blade, remove it from the Petri dish and leave it in the desiccator for 24 hours. Therefore, the film is cut to the desired size and shape[31][32].

Steps involved in the heavy casting method:

Step 1: Preparing the casting process

Step 2: Degassing the solution

Step 3: Changing the appropriate volume to pour the solution into the mold

Step 4: Dry the Casting Solution

Step 5: Cut the last page to get the desired solution.

Advantages :

Great uniformity of thickness .

Films have more flexibility and better physical properties .

Semisolid Casting Method:

Semisolid casting can also be employed for the preparation of buccal films, which are thin films designed to adhere to the buccal (cheek) mucosa in the oral cavity. These films are used for drug delivery, providing a convenient and patient-friendly way to administer medications. Here's a general outline of how the semisolid casting method can be adapted for buccal film preparation[33]:

Material Selection:

Choose a polymer or a combination of polymers suitable for buccal film applications. Common polymers include hydroxypropyl methylcellulose (HPMC), polyvinyl alcohol (PVA), and other bioadhesive polymers.

Drug Incorporation:

Dissolve or disperse the active pharmaceutical ingredient (API) or drug in the selected polymer

solution to create a homogeneous mixture. Ensure that the drug is evenly distributed.

Semisolid Formation :

Adjust the viscosity of the polymer-drug mixture to a semisolid state. This can be achieved by controlling factors such as temperature, concentration, and the addition of gelling agents or thixotropic agents.

Casting Process:

Pour or spread the semisolid mixture onto a flat, smooth surface, such as a casting mould or a tray. The thickness of the film can be controlled by the amount of material applied.

Drying or Solidification:

Allow the cast film to undergo controlled drying or solidification. This process can be conducted at a controlled temperature to avoid degradation of the active ingredients and to achieve the desired film characteristics.

Cutting and Packaging:

Once the buccal film has solidified, it can be cut into appropriate sizes and shapes. Packaging is typically done in individual doses, and the films may be designed to dissolve or adhere to the buccal mucosa for controlled drug release.

Benefits of Semisolid Casting for Buccal Films:

- Uniform drug distribution in the film.
- Controlled drug release and absorption through the buccal mucosa.
- Improved patient compliance due to the ease of administration.
- Potential for enhanced bioavailability of certain drugs.

Semisolid casting for buccal films offers advantages in terms of ease of production and the ability to incorporate a variety of drugs into a thin, easily administered dosage form. This method can be particularly advantageous for drugs that undergo degradation in the gastrointestinal tract or require a rapid onset of action[7].

hot melt extrusion :

In the hot melt extrusion process, the solution is first mixed with a carrier in form. A heated extruder then melts the mixture. Finally, the sheep are turned into a film with a mold[34][35].

Advantages :

- Fewer operation units
- Better content uniformity
- An anhydrous process

Solid Dispersion Extrusion :

The term product dispersion refers to the product dispersion of one or more active ingredient in the presence of amorphous hydrophilic polymer in an inert carrier. In this method, the drugis dissolved to a suitable weight and then the drug is added to dissolved polyethylene glycol below 70°C. Finally, the broken product is molded and turned into a film[8][36].

Rolling Method:

Rolling method, the drug or the suspension containing the drug is rolled on the carrier. The most common solvents are water and mixtures of water and alcohol. The film is dried on rollersand cut into the desired shape and size. Use high shear to dissolve other ingredients, including active ingredients, in a small amount of aqueous solvent. Watersoluble hydrophilic colloids dissolve in water to form incompressible liquids[37][38].

Packaging Of Buccal Film :

The packaging of buccal films is designed to ensure the stability, protection, and convenience of the product. Buccal films are thin, flat dosage forms that are administered by placing them in the buccal cavity (between the cheek and gum) for systemic drug delivery. Here are some key aspects of the packaging of buccal films[4]:

The material selected must have the following characteristics:

- It should be protect the preparation from environmental conditions.
- It should be FDA approved.
- It should be meet applicable tamper-resistant requirement.

- It should be non-toxic.
- It should not be reactive with the product.
- It should not impart to the product tastes or odours.

Foil, paper or plastic pouches:

Soft bags are a packaging concept that not only provides heatresistant packaging, but also environmentally friendly packaging with the right material selection. Premade pouches are generally designed to use vertical or horizontal methods to fill or seal product during the packagingprocess.

Single pouch or aluminium pouch .:

In single pouch packaging, each buccal film unit is individually sealed in a pouch. The pouch material may be composed of materials like polyethylene or polypropylene. The primary purpose of individual pouches is to protect each dose from external factors and contamination. This packaging format offers convenience and precision in dosing.

Advantages:

- Protects individual doses from moisture, light, and contaminants.
- Provides tamper-evident packaging.
- Facilitates accurate dosing and easy handling.
- Considerations:
- Increased packaging material usage compared to bulk packaging.
- Potential for a larger environmental footprint.

Multi-unit blister cards:

Blister packaging consists of two parts: the blister (the molding cavity that holds the product) and the lid (the material that closes the blister). Blister packs are made by heat softening a layer of thermoplastic resin and vacuum stretching the softened material into a mold. After cooling, the paper is removed from the mold and enters the packaging area of the packaging machine. The semi-rigid bubble is filled with material and covered with heat-sealable material. The selection of the film should be made according to the protection to be made. Usually the lid is made of aluminum foil. The material used to form the cavity is usually plastic and can be designed to protect the dosage form from moisture [28].

Barrier Films:

Many chemical formulations are less sensitive to moisture and therefore require high barrier films. Many materials such as polychlorotrifluoroethylene (PCTFE) films and polypropylene can be used to protect against moisture. Polypropylene does not develop stress fractures under any circumstances. It is an excellent gas and vapor barrier. Uncertainty is still bad.

Conclusion :

Mucoadhesive drug delivery systems utilize the bioadhesive properties of certain water-soluble polymers, which become sticky when hydrated and can therefore be used to target drugs to specific areas of the body for extended periods of time. To understand the various mechanisms of mucoadhesion and to increase the penetration of active substances, new mucoadhesive delivery systems have been developed. Various potential mucoadhesive systems are being investigated and may enter the market in the future. The concept of bioadhesion begins with the fact that drugs must be fixed to a specific place in the intestine. Therefore, the main purpose of the oral bioadhesive system will be achieved by increasing the residence time of the local drug and allowing it to be taken once a day. This review concludes that mucoadhesive administration is an effective alternative to the oral route. It can overcome liver metabolism, reduce dosage and frequency, and improve bioavailability, making it an alternative to conventional medicine. This delivery will demonstrate the controlled release of the drug; These systems are easy to use and have been designed and tested without difficulty. Therefore, it is clear that mucoadhesive bacteria will be one of the important drugs in the pharmaceutical industry and medical treatment in the future.

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