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Formulation and Evaluation of Mucoadhesive Buccal Films

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ABSTRACT:

Buccal films are innovative drug delivery systems designed to release medication through the mucosal lining of the inner cheek. This route provides a convenient and non-invasive alternative to conventional drug administration by allowing direct absorption into the bloodstream and avoiding gastrointestinal degradation and first-pass metabolism. Mucoadhesive buccal films are formulated using polymers such as hydroxypropyl cellulose, sodium carboxymethylcellulose, and chitosan, which help the film adhere to the mucosa and control the release of the drug. Common manufacturing techniques include solvent casting, hot-melt extrusion, and direct milling, all of which produce flexible, stable films suitable for sustained or controlled release. Factors such as polymer molecular weight, hydration rate, and drug–polymer interactions play an important role in determining the film's performance and bioavailability. Although challenges such as limited drug loading, mucosal irritation, and saliva dilution exist, buccal films offer several advantages including ease of administration, good patient compliance, and faster onset of action. Future developments such as nanocarrier integration, smart polymers, and 3D printing technologies are expected to make buccal films more effective, customizable, and commercially feasible for both small molecules and biologics.

Keywords: Mucoadhesive buccal film, Oral Mucosa, Muco-adhesion, Non-invasive delivery, Bio-responsive, Patient compliance.

INTRODUCTION:

The buccal mucosa is a perfect transmucosal route for both local and systemic drug delivery, which makes it a good fit for mucoadhesive drug delivery systems. The buccal route, which involves going through the mucosa of the inner cheek, is an enticing alternative. Drugs taken buccally can enter the systemic circulation directly through the rich vascular network of the submucosal region, avoiding GI degradation and hepatic first-pass metabolism. For the right drugs, absorption can be achieved fairly successfully due to the buccal mucosa's moderate permeability and good vascularization. The procedure is non-invasive, reasonably comfortable, and appropriate for patient self-administration. The dosage form can also be removed in the event of irritation or other adverse effects. [1-3]

One of the most promising buccal delivery systems is mucoadhesive film. These thin, flexible dosage forms maintain close contact with the absorption site, extend residence time, and reduce the risk of dislodgement by adhering to the mucosal surface. Compared to patches or tablets, films are often more patient-tolerated, more flexible, and lighter. Despite promising in vitro and in vivo results, mucoadhesive buccal films have not yet been widely translated from laboratory to commercial clinical application. Significant challenges include issues with film stability, scale-up production, intra- and inter-subject variability (e.g., changes in mucin turnover, saliva flow, and mucosal thickness), and reliable in vitro–in vivo correlation (IVIVC). [4]

By combining mucoadhesive polymers (like hydroxypropyl cellulose, sodium carboxymethylcellulose, and chitosan derivatives) with permeation enhancers or enzyme inhibitors, these films can preserve localized high drug concentration gradients at the mucosal interface, enhancing permeation and bioavailability. Films can be engineered for controlled or sustained release, which evens out plasma fluctuations and reduces the frequency of dosing. [5-6]

Mucoadhesive buccal films are easy to self-administer, affordable, and enhance patient compliance. They were developed to provide local treatment for oral infections, including candidiasis. Oral drug delivery has evolved from conventional tablets and capsules to oral dispersible tablets and, ultimately, mouth dissolving films (MDFs). MDFs are small, stamp-sized films that dissolve rapidly in saliva on the tongue and release the medication. These films are approved for prescription use in the US, EU, and Japan and offer significant market advantages over other oral dosage forms. [7]

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There are many different types of mucoadhesive dosage forms that have been developed, such as tablets, gels, ointments, and films. Because of their comfort, flexibility, longer mucosal residence time, and better dosing accuracy, buccal films are preferred over gels, ointments, and tablets. [8]

ANATOMY AND PHYSIOLOGY OF ORAL MUCOSA:

A moist, sticky substance called the oral mucosa acts as a lubricant to reduce friction between moving cells. Of the four primary locations for drug delivery the buccal cavity, lingual region, palate, and gingival region the buccal route is the most frequently utilized, making it an important site. Stratified squamous epithelium, basement membrane, lamina propria, and submucosa are the four primary structural layers that make up the oral mucosa.

The buccal, sublingual, and soft palate regions are more drug-permeable due to their non-keratinized epithelium and lack of ceramides and acyl-ceramides, which are typically barrier components. The lining mucosa of the mouth floor, lips, cheeks, and soft palate is flexible and non-cornified. It is made up of superficial, intermediate, prickle-cell, and basal layers. Furthermore, the oral cavity's structural and functional diversity is provided by the keratinized and non-keratinized layers of the specialized mucosa. [9]

The mucus layer on the epithelial surface of drug delivery systems promotes cell adhesion, muco-adhesion, and oral lubrication. The buccal region's smooth, relatively immobile surface makes it ideal for securing drug delivery systems in place. Because adhesion to the oral mucosa enhances drug absorption and prolongs the residence time at the administration site, the buccal mucosa is suitable for long-term systemic drug delivery. [10]

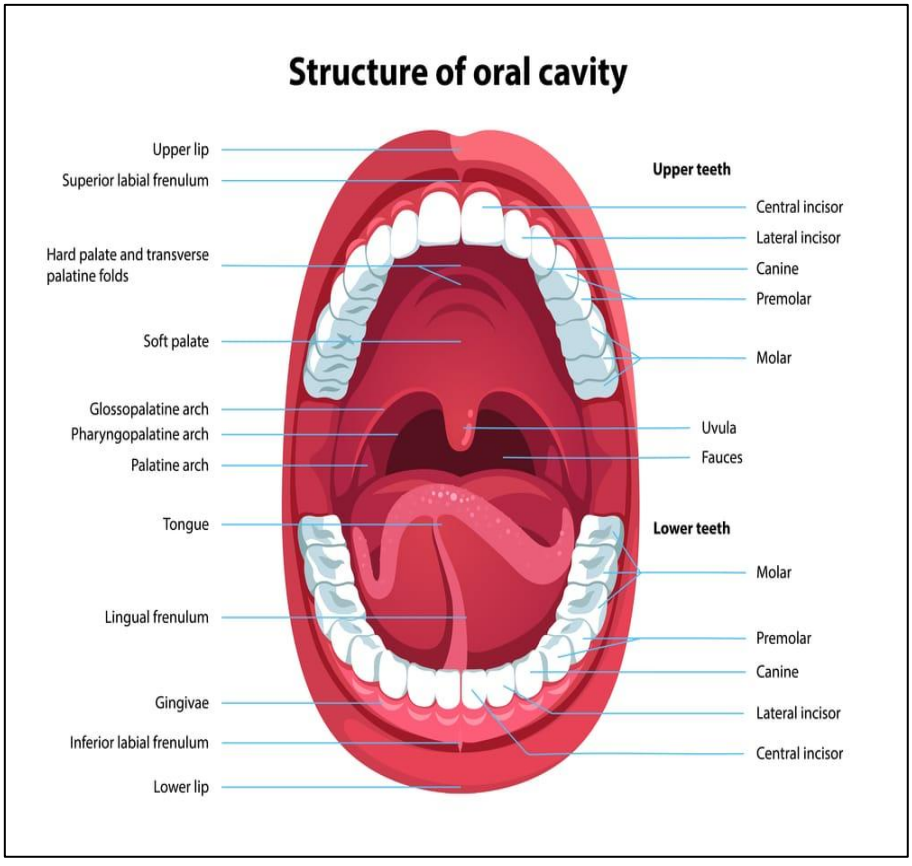

Fig.1: Anatomy & Physiology of Oral Mucosa

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ADVANTAGES:

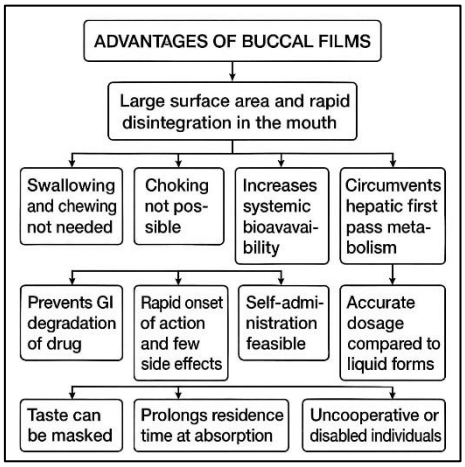

Fig.2: Advantages [11]

DISADVANTAGES:

- Risk of involuntary swallowing or dislodgement of the film.
- Dilution and removal of drug due to continuous saliva secretion and swallowing.
- Barrier properties of the oral mucosa limit drug permeability.
- Restriction on drinking and eating during film application.[12]
- Limited drug load capacity due to small surface area.
- Suitable mainly for drugs with low dose requirements.[13]
- Potential discomfort or irritation in the oral cavity.[14]

FORMULATION:

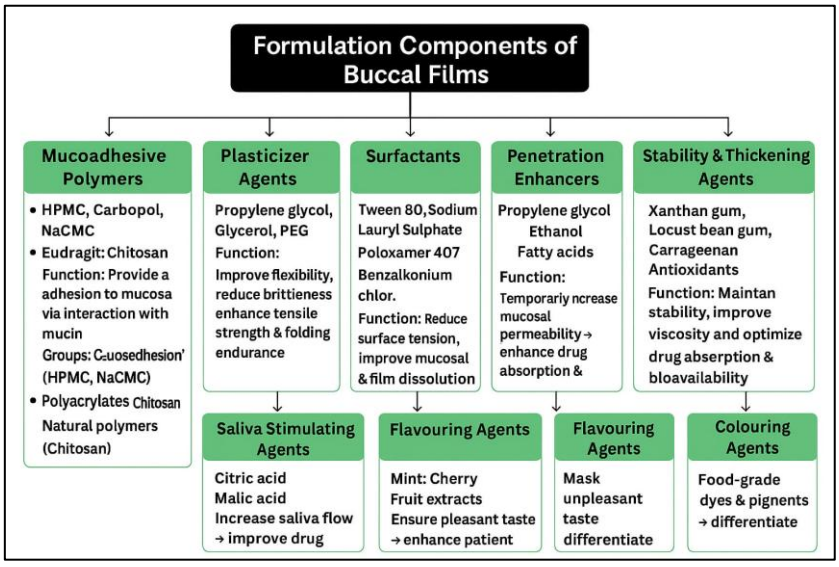

Fig.3: Formulation components of Buccal film [15-19]

MANUFACTURING METHODS:

1.Solvent Casting Method:

a. Water-soluble polymers dissolved in water or appropriate solvent to make viscous solution; API and excipients dissolved in compatible solvent; mixed to form homogeneous blend; cast onto flat surface and dried to form film; film cut to desired size.

b. Widely used for heat- and light-sensitive APIs because it uses lower temperatures.

c. Industrial solvent casting offers better control on film thickness and concentration.

d. Produces immediate release films with high absorption rate.

e. Limitations include drug recrystallization and difficulty in dose uniformity.[20]

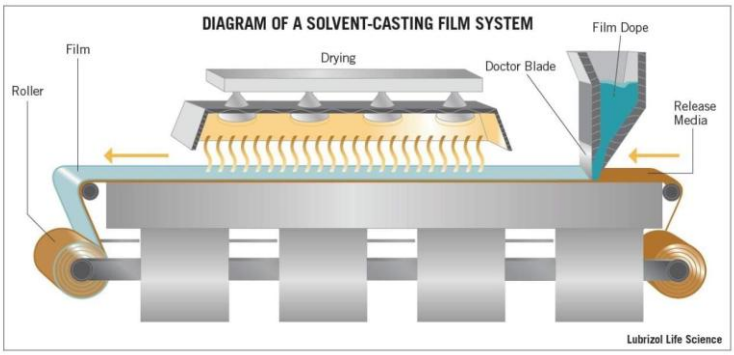

Fig.4: Solvent casting film system

2.Hot-Melt Extrusion Method:

a. Dry ingredients including API and excipients blended and fed to extruder; heated and melted; molten mass extruded through flat die forming thin film; film cooled and cut.

b. Solvent-free continuous process suitable for thermally stable APIs.

c. Allows control over drug release by modifying polymer molecular weight and plasticizer concentration.

d. Used for mucoadhesive films with good mechanical properties and potential for multilayer and gastroretentive films.

e. Preserves enzyme activity in biologics.[21]

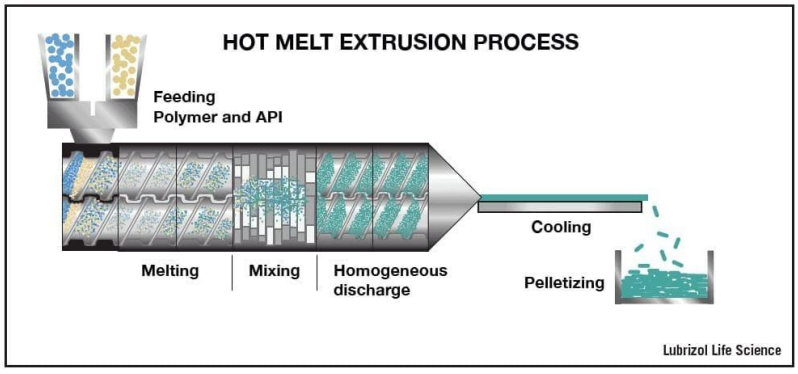

Fig.5: Hot melt extrusion process

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3.Direct milling method:

a. It is a solvent-free technique where drugs and excipients are mixed without the presence of solvent or lipid, typically by direct milling or kneading.

b. The mixture is then rolled on a release liner until the desired film thickness is achieved.

c. This method avoids residual solvent issues and related health risks, making it preferred for safer production.

d. The thickness of the film plays an important role in drug administration and absorption.[22]

EVALUATION PARAMETERS:

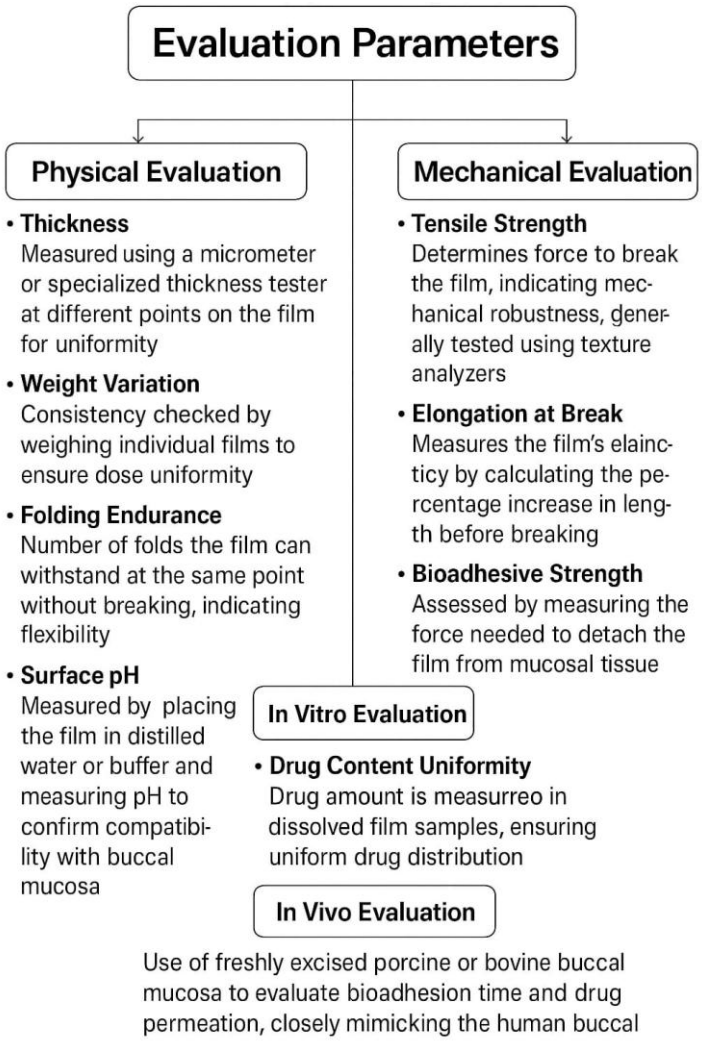

Fig.6 Evaluation parameters of buccal film [23-24]

FACTORS AFFECTING IN MUCOADHESIVE AND DRUG RELEASE:

A. Polymer Molecular Weight and Crosslinking in Buccal Films: The molecular weight of polymers used in buccal films is a critical factor for muco-adhesion. Higher molecular weight polymers generally provide stronger mucoadhesive forces due to increased chain entanglement with mucin glycoproteins in the mucus layer, enhancing the residence time of the film on the buccal mucosa. However, excessively high molecular weights may reduce polymer flexibility and hinder intimate contact with the mucosal surface.

B. Hydration Rate: Hydration of buccal films upon contact with saliva or mucosal fluids is essential for muco-adhesion. Hydration allows polymers to swell, increasing the surface area and exposing adhesive sites for interaction with mucin. Controlled hydration enables structural integrity while facilitating drug diffusion and release.

C. Drug–Polymer Interactions: Drug-polymer interactions directly affect both the adhesion properties and the release profile of drugs from buccal films. These interactions include hydrogen bonding, electrostatic interaction, and Vander Waals forces between drug molecules and functional groups on the polymer chains. [4,25]

RECENT ADVANTAGES & FUTURE PROSPECTIVE:

Recent Advantages of Buccal Films: Buccal films are thin mucoadhesive layers designed for placement on the inner cheek to release medication directly into the bloodstream through the oral mucosa.

Their key recent advantages include:

1.Bypassing first-pass metabolism by the liver, leading to improved bioavailability of drugs that are otherwise degraded in the gastrointestinal tract.[26]

2.Patient compliance, especially for paediatric, geriatric, and dysphagic populations, due to the ease of administration, portability, and taste masking capability.[17]

3.Non-invasive systemic delivery for peptides, proteins, and small molecules positioning them as alternatives to oral and parenteral routes.[2]

4.Rapid onset of action and better therapeutic efficiency, making them suitable for emergency and chronic use.

5.Cost-efficiency and stability, since these films are manufactured using solvent casting or hot-melt extrusion with polymers like HPMC, PVA, and pullulan.[27]

Future prospect:

1.Integration of nanomedicine: nanoparticles within buccal films enhance permeability and drug retention time.

2.Smart polymers: the use of bio-responsive and thiolate polymers offers controlled, targeted, and prolonged muco-adhesion.

3.Regulatory advancements: improved international guidance for testing mucoadhesive strength, tensile properties, and in vitro–in vivo correlations are facilitating faster approvals.[2]

4.3D Printing of Buccal Films: advanced additive manufacturing techniques now enable precise dose personalization and reproducibility.[28]

5.Expansion to biologics: potential for delivering vaccines, enzymes, and monoclonal antibodies through thin-film carriers.[29]

CONCLUSION:

Buccal films are a novel, patient-friendly method of drug delivery that can be used as a substitute for traditional parenteral and oral routes. Improved bioavailability and a quicker onset of treatment are the outcomes of their ability to avoid the gastrointestinal system and hepatic first-pass metabolism. Chitosan, sodium carboxymethylcellulose, and hydroxypropyl cellulose are examples of mucoadhesive polymers that are essential for preserving adhesion, regulating drug release, and lengthening mucosal residence time. Each of the manufacturing processes solvent casting, hot-melt extrusion, and direct milling offers special benefits for creating stable, flexible films that can be used in formulations for both immediate and sustained release. Research is still being conducted to improve formulation parameters in order to maximize film performance, despite obstacles such as mucosal irritation, salivary dilution, and limited drug loading capacity.

The delivery of complex biologics and personalized therapy are made possible by the integration of cutting-edge technologies like 3D printing, smart bio-responsive polymers, and nanocarriers. Mucoadhesive buccal films have the potential to soon become a common platform for systemic and local drug delivery applications thanks to better mechanistic understanding and regulatory guidance.[30]

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