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A REVIEW ON BUCCAL FILMS: A NOVEL DRUG DELIVERY SYSTEM

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ABSTRACT

The oral cavity is an attractive site for the administration of drugs because of ease of administration. Various dosage forms like Tablets, Capsules and Liquid preparations are administered by oral route. Oral administration is the most widely used route due to its ease of ingestion, lack of pain, versatility in accommodating most of the drug type that are administered orally shows high patient compliance. Additionally, oral solid delivery systems do not require sterile conditions, making them less costly to produce. In recent years delivery of therapeutic agents through buccal mucosa has gained significant attention. There is a possibility for mucosal (local effect) and trans mucosal (systemic effect) drug administration. In first case the mucosal administration of drugs is to achieve site-specific release of drugs on the mucosa whereas in second case, trans mucosal administration involves drug administration through mucosal barrier to reach the systemic circulation.[1] This delivery route extends numerous advantages over the other delivery routes due to its rich blood supply, rapid onset of action, avoidance of the first pass metabolism as well as enzymatic degradation which results in enhanced bioavailability, increased patient compliance, and easy of self-medication.[2] Buccal Films are a solid single-unit dosage form which are made of a water dissolving polymer allows the dosage form to rapidly hydrate, adhere and dissolve when placed on the buccal region in the oral cavity to provide local or systemic drug delivery. The large surface area available in the film dosage form allows rapid wetting by saliva, dissolution and absorption of drug directly enter into the systemic circulation without undergoing first-pass hepatic

metabolism with increased bioavailability.[3]

KEYWORDS: Drug delivery, Buccal films, Enhanced bioavailability, Dysphagia.

INTRODUCTION

A buccal mucosa covers the inside of the cheek as well as an area between gums and upper and lower lips and has an average surface area of 100 cm.[2] Mucosa has a function to protect underlying tissues from mechanical and chemical damage.[4]

Buccal films first introduced in the market as breath fresheners and personal care products such as dental strips and soap strips. However, they are introduced in the United States and European pharmaceutical markets for therapeutic effect. Buccal films are most advance form of solid dosage form due to various reasons like flexibility, improved efficacy of API (Active Pharmaceutical Ingredient), dissolution and disintegration within 1 minute with the help of less amount of saliva as compared to dissolving tablet. Buccal films have the potential to allow the development of sensitive drug targets that may otherwise not be possible in tablets or liquid formulations.[5] Approximately one-third of the population, primarily the elderly and children, has swallowing difficulties, resulting in poor adherence to oral tablet drug therapy and reduced overall therapy effectiveness. A new buccal dosage form, such as buccal tablet or buccal film, has been developed that combines the benefits of ease of dosing with the convenience of dosing in the absence of water or fluid.[6]

MUCOSAL LAYERS

The oral mucosa contains following three layers of cells:

- Stratified squamous epithelium: This is the oral epithelial outermost layer. The contact between connective tissue and epithelium is known as the basement membrane.
- Lamina propria - a connective tissue presents below basement membrane.
- Sub mucous membrane - consists of the inner most layer of the oral epithelium.[7]

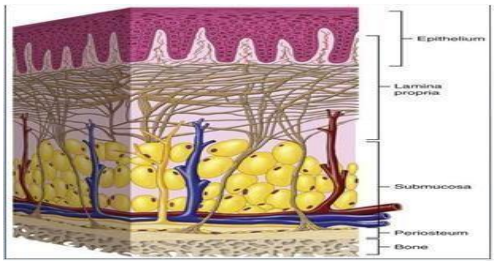

Fig. 1: Anatomy of epithelium.

In this study, oral films was designed to deliver drug through oral mucosa in order to produce fast onset of action.

Release mechanism involved: The solid single-unit dosage form which are made of water dissolving polymer, allows the dosage form to rapidly, hydrate, adhere and dissolve when placed on buccal region in the oral cavity to provide local or systemic drug delivery. The large surface area available in the film dosage form allows rapid wetting by saliva, quick disintegration, dissolution and absorption of drug directly enter into the systemic circulation without undergoing first-pass hepatic metabolism with increased bioavailability. In such cases bioavailability of drug is significantly greater than those observed from conventional tablet dosage form.[8]

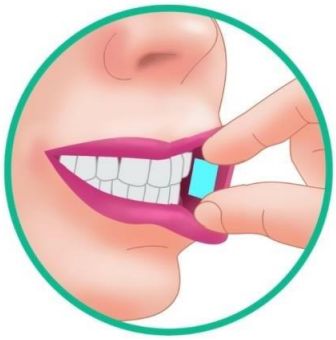

Fig. 2: Pictorial representation of administering an Buccal films inside the mouth cavity.

Criteria for Buccal Films[9]

- Thin elegant films are available in sizes and shapes.
- Un-obstructive in nature.
- Quick disintegration and rapid drug release.
- It should dissolve or crumble in the mouth in a matter of seconds, eliminating the need for water when swallowing.
- The film should impact a pleasant after taste.
- Suitable for use with agents that disguise tastes.
- Minimize or eliminate residue in the mouth.

Table No. 1: Composition of buccal films.

Sl. No	Composition of films	Quantity
1	Active pharmaceutical agent	1-25%
2	Film-forming polymer	40-50%
3	Plasticizer	0-20%
4	Saliva stimulating agent	2-6%

5	Sweetening agent	3-6%
6	Flavouring agent	10%
7	Colouring agent	1%

Manufacturing Methods

Buccal films can be made using the following processes.

1. Solvent casting
2. Semi solid casting
3. Hot melt extrusion
4. Solid dispersion extrusion
5. Rolling method.

1. Solvent Casting

The buccal films are prepared by dissolving strip forming agents, plasticizer and saliva stimulating agent in the distilled water, then solution is continuous stirred on magnetic stirrer and kept for 1 hour to remove all the air bubbles entrapped. Meanwhile, in the separate container remaining water soluble excipients i.e. sweetening agent, disintegrating agent, saliva stimulating agent, flavor and drug are dissolved with constant stirring. When the stirring is over both the solutions are mixed together with stirring for another1hon magnetic stirrer. Then keep the solution stationary for 1 hour to let the foams settle down. The resulting formulation is casted on a suitable platform and is dried to form a film. The film is preferably air-dried or dried under oven then the film is carefully removed.[10]

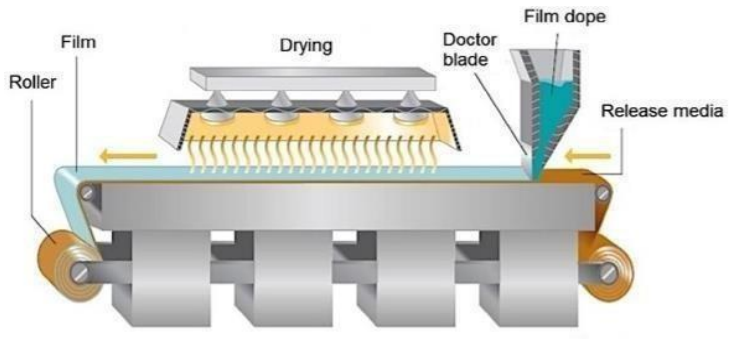

Fig. No. 3: A Solvent casting film system.

2. Semi-solid casting technique

In the semisolid-casting method, a solution of the water-soluble, film-forming polymer is prepared. The resulting solution is added to a solution of acid insoluble polymer (e.g., cellulose acetate phthalate and cellulose acetate butyrate), which is previously prepared in

ammonium or sodium hydroxide. The appropriate amount of plasticizer is added to obtain a gel mass. The prepared gel mass is cast into films or ribbons using a controlled heat source. The thickness of the film is controlled between 0.015–0.05 in.[11]

3. Hot melt extrusion method

The drug is first mixed with carriers in solid form in the hot melt extrusion method. The mixture is then melted by an extruder equipped with heaters. Finally, the dies shape the melt into films. There are some advantages to using hot melt extrusion.

a. A reduction in the number of operational units
b. Better content uniformity
c. An anhydrous process.[12]

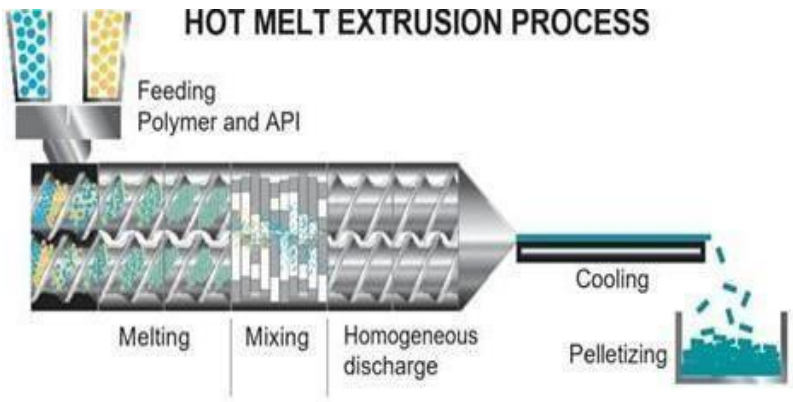

Fig. No. 4: Hot melt extrusion process.

4. Solid Dispersion Extrusion

Solid dispersion extrusion use HME- like method. One or more API is dispersed in an inert carrier in solid state in the presence of amorphous hydrophilic polymers. The immiscible components are then extruded with the drug, forming solid dispersions that finally shaped into films by dies.[13]

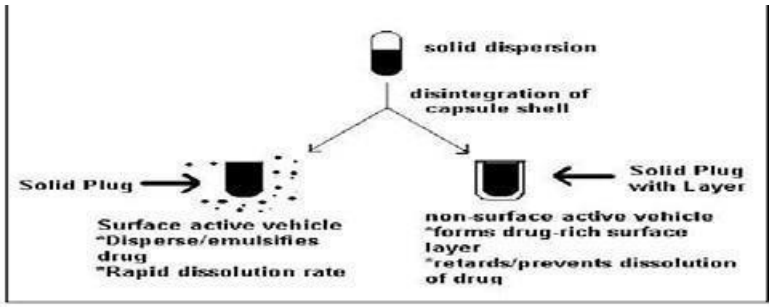

Fig. No. 5: Solid dispersion extrusion process.

4. Rolling method

In the first instance, a pre-blend is made with foil packaging, polar dissolvable polymers and other additional medications. In the pre-blend, add the appropriate amount of medication. The medication is pre-mixed to create a stable grid. The mixture collected is provided for in the roller. The film is shaped and extracted by a roller aid. Using managed base drying is then dried wet film. The film is divided into the size and type necessary. The drum should be rolling with different rheological characteristics.[14]

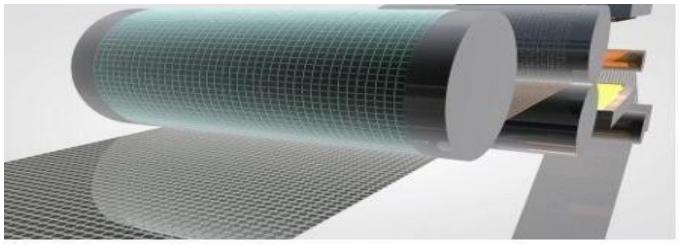

Fig. No. 6: Rolling method.

ADVANTAGES OF FILMS[15]

- Ease of administration to patients who refuse to swallow a tablet, such as pediatric, geriatric and psychiatric patients.
- Convenience and accuracy in drug administration when compared to liquid formulations.
- Water is not required for swallowing the dosage form, which is a useful feature for patients who are on the go and do not have easy access to water.
- The good mouth feel property helps to change the basic perception of medication as a "bitter pill,", especially in pediatric patients.
- Rapid dissolution and absorption of the medication, resulting in a rapid onset of action.
- Some drugs are absorbed from the mouth, pharynx and oesophagus as saliva passes down into the stomach, increasing drug bioavailability.
- It offers the benefits of liquid formulations in the form of solid dosage form.

DISADVANTAGES OF FILMS[16,17]

- It is not possible to deliver medication that irritate the mucosa or are unstable at buccal Ph by using this route.
- Only drugs required in lower dose can be delivered through this dosage form.
- Most drugs have bitter taste masking is highly recommended.
- It shows fragile and granular property affecting its appearance.

- Special packaging is required to ensure stability and safety of product.

Evaluation Parameters

1. Thickness

The patch's thickness was measured using a digital Vernier Calliper with a minimum count of 0.01mm at various locations on the film. The patch's thickness was measured at three different locations, and an average and standard deviation were calculated.[16]

2. Weight variation

Weight variation of the films was determined by weighing three films of (2cm x 2cm) individually, from each batch of the formulation and the average weight was calculated. An Electronic balance was used for this purpose. The individual weight should not deviate significantly from the average weight.[17]

3. Folding endurance

Folding endurance was determined by repeated folding of the film at the same place till the strip breaks. The number of times the film is folded without breaking was computed as the folding endurance value.[18]

4. Tensile strength

Tensile strength is the maximum stress applied to a point at which the strip specimen breaks. It is calculated by the applied load at rupture divided by the cross-sectional area of the strip as given in the equation below.[19]

$$\text{Tensile strength} = \frac{Load\ at\ breakage}{Strip\ thickness \times Strip\ width}$$

5. Percentage elongation

Strain is the term used to describe how much a material extends when subjected to stress. In essence, strain is the film's distortion divided by the substrate's initial dimension. In general, The longer the film, the more plasticizer there is in it.[20] The formula used to calculate it is

$$\%\ \text{Elongation} = \frac{Strip's\ length\ increase}{Initial\ length\ of\ strip} \times 100$$

6. Drug content uniformity

The film (2cm x 2cm) was cut at three different places with nominal drug content. Each film was dissolved in 100ml of phosphate buffer pH 6.8 (stimulated saliva fluid) for 20 minutes with continuous shaking to obtain a homogenous solution. 10ml of the above solution was

filtered to remove polymer residues if any and the filtrate obtained was made up to 100ml with phosphate buffer pH 6.8 in a volumetric flask and the absorbance was measured using UV visible spectrophotometer.[21]

7. Surface pH

A 4 cm^2 part of the film was cut, and it was placed in distilled water for an hour in a glass tube to swell to measure the surface pH of the film. The combined glass electrode of the pH meter was then brought close to the film's surface, and it was given a minute to acclimatize before measuring the surface pH. The average values of the three replicated experiments were recorded.[22]

8. *In-vitro* release study Dissolution studies

were carried out in a USP dissolution apparatus using 900ml of dissolution medium at 37± 0.5°C, and a rotation speed of 50 rpm was used. An aliquot of sample was periodically withdrawn and replaced with fresh medium. The samples were filtered through whatman filter paper and analyzed spectrophotometrically.[23]

CONCLUSION

Buccal Films represent a significant advancement in pharmaceutical drug delivery, offering enhanced patient compliance, rapid disintegration, and improved bioavailability. Designed to address the needs of populations with dysphagia, including pediatric, geriatric, and psychiatric patients, Buccal films provide a convenient, water-free administration route while reducing the risk of choking. The formulation of Buccal films incorporates a range of polymers, plasticizers, taste-masking agents, and surfactants, ensuring stability, efficacy, and patient acceptability. Their formulation, manufacturing advancements, and innovative drug delivery technologies have expanded their therapeutic applications. Despite some limitations, ongoing research continues to enhance their stability, drug-loading capacity, and patient acceptance, making Buccal films a promising dosage form in modern pharmaceuticals.

The article also presents a thorough evaluation of manufacturing techniques such as solvent casting, hot melt extrusion, and rolling methods. Solvent casting remains the most commonly used due to its simplicity and reproducibility. However, hot melt extrusion and solid dispersion methods are gaining prominence for their ability to improve drug solubility and content uniformity.

Despite their numerous advantages, Buccal films face certain drawbacks. Drugs that irritate

the mucosa, require high doses, or are unstable at buccal pH are not suitable for this delivery system. Additionally, the films are fragile and require special packaging, increasing production costs.

Future prospects for Buccal films include expanding their use for systemic therapies, vaccines, and macromolecules like peptides and proteins. Advancements in nanotechnology, muco adhesive agents, and smart polymers may overcome existing limitations and further broaden the therapeutic scope of this novel drug delivery system.

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