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BUCCAL FILM: AN UPDATED OVERVIEW

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Abstract: *In order to increase safety, efficacy, and patient compliance, substantial research is being done today on the design and development of novel drug delivery systems. Buccal film technology is one such distribution method. This technology has become a cutting-edge replacement for more traditional sorts of drug delivery systems. Through a buccal drug administration device, buccal film is delivered. In comparison to other buccal drug delivery systems such wafers, lozenges, microparticles, gel, and tablets, buccal film is smaller in size, dose, and is simple to apply, making it a more palatable and acceptable dosage form. Bypassing first pass metabolism, buccal film is a potent dose form that increases bioavailability. This page provides an updated analysis of the advantages, restrictions, production processes, test criteria, and formulation of buccal film.*

Key Words: *Buccal film, Bucco adhesion, improving patient compliance, bioavailability, oral cavity.*

1. INTRODUCTION :

There are numerous ways to give drugs to the body, including transdermal, transmucosal, parenteral, oral, and parenteral [1]. When comparing different medication delivery methods, transmucosal drug delivery has clear advantages over oral administration in terms of systemic impact. Buccal mucosa is the best transmucosal route for local and systemic medication administration among the available options [2,3]. It is widely recognised that therapeutic chemicals absorbed from the oral mucosa allow for a direct entry of the medication into the bloodstream, avoiding first-pass hepatic metabolism and gastrointestinal drug degradation, both of which are connected to peroral administration[4-6]. The most often used route for medication administration is the oral route[7]. Low therapeutic costs and patient comfort make the oral route a favourite Due to pain evasion and adaptability, oral dose forms make for more than 70% of commercially available drugs[8].

The most recently created dosage form for buccal administration is buccal films. In terms of comfort and flexibility, buccal film may be favoured over buccal tablets. The pharmaceutical industry has increased its focus on films as dosage forms since they are cutting-edge, patient-friendly, and practical. Buccal film is the current topic of discussion. Compared to the majority of commercially available orally disintegrating tablets, which typically require special packaging, this dosage form is less friable[9,10].

Additionally, these dose forms are pharmacoeconomic, self-administerable, and have improved patient compliance[11,12]. The treatment of oral candidiasis and other fungal infections of the oral cavity has led to the development of numerous mucoadhesive buccal films that deliver medication locally. The development of dosage forms as a result of changes in oral drug administration included the transition from conventional solid dosage forms to variable release tablets/capsules, oral dispersible tablets, and ultimately the creation of fast mouth dissolving films (MDFs) [13]. MDFS are extremely thin films that are virtually exactly the size and form of postage stamps. They are simply placed on the tongue, where they quickly become hydrated by saliva and release the medication. The three main regions—the US, the EU, and Japan—have all approved MDFs for prescription use. These films appear to have a major market advantage over other oral dose forms that contain the same pharmacological active ingredients[14].

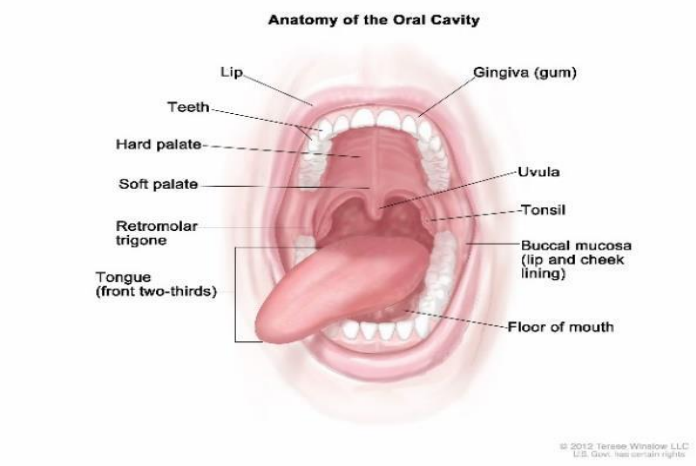

Figure :1 Anatomy of oral cavity.

The fundamental benefit of the buccal film is that, in comparison to tablets, its wide surface area enables fast wetting of the film, which speeds up drug absorption [15]. The buccal mucosa has an abundant blood supply, making it an ideal and quick location for medication absorption [16]. However, buccal films face the greatest obstacle in producing high-quality work, which is also necessary for ongoing assessment and comprehension of performance.

2. ANATOMY AND PHYSIOLOGY OF ORAL MUCOSA

The oral mucosal region is sticky by nature and functions as a lubricant, reducing friction as the cells move in relation to one another. (Four areas have been employed for medication administration: the buccal cavity, the lingual region, the palate, and the gingival region. The buccal route is the one of the four sites listed above that is most frequently employed for medication administration.) The buccal mucosa is the term for the anatomic location for medication delivery located between the cheek and gingiva [17]. The basement membrane, lamina propria, stratified squamous epithelium, and sub mucosa make up the oral mucosa's outermost and innermost layers, respectively. Because the epithelium in the buccal, sublingual, and soft palate regions is not keratinized, it lacks the ceramides and acylceramides that are thought to serve as a barrier function [18]. When compared to other areas of the oral cavity, the buccal and sublingual region's mucosa is more permeable because it contains far less ceramidem [19]. In contrast, the non-cornified surface epithelium covering the remainder of the areas, such as the lips, cheeks, mouth floor, and soft palate, gives the lining mucosa its suppleness. It can be divided into basal, prickle-cell, intermediate, and superficial layers. The specialised mucosa, which has both keratinized and non-keratinized layers, is the third type of mucosa[20].

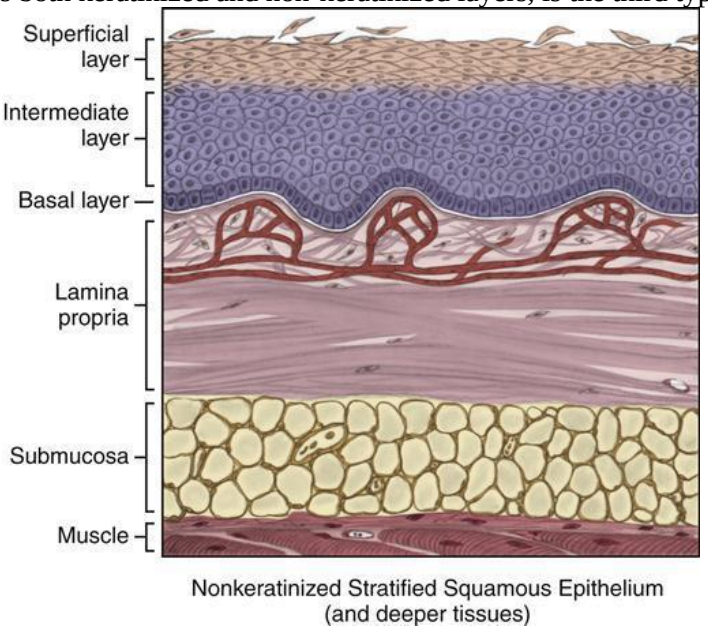

Figure : 2 Structure of oral mucosa.

On the cell's epithelial layer's outside, there is a coating of mucus. This is crucial for mouth lubrication, mucoadhesion of mucoadhesive drug delivery systems, and cell-to-cell adhesion. It is appropriate to position the retentive system in the buccal area since it has a smooth, immobile surface [21].

3. ADVANTAGES:

- Since swallowing or chewing are not required, there is no possibility of choking.
- More affordable, simpler for storage, shipping, and customer service.
- Good bioavailability and a quick commencement of effect.
- Because there is no contact between the medicine and the GI tract or acidic environments, the drug is preserved from degradation.
- Easy administration of buccal film for patients with physical disabilities, the elderly, and children.
- Rapid disintegration and dissolution in the oral cavity due to the wide surface area of the buccal film.[22]

4. DISADVANTAGES:

- Drug concentration is low when there is buccal film in the mouth cavity because salivating dilutes medications at the site of absorption.
- When a drug is ingested with saliva, the maximum amount of the dissolved or released drug is taken from the site of absorption, increasing the probability that the delivery system will be swallowed as well.
- It's possible that a drug's flavour, tongue irritability, or allergy will manifest.
- There are some unfavourable effects as well, such as tooth erosion or discolouration.
- When using a traditional form of buccal drug delivery system, it is not permitted to eat, drink, or in certain cases, converse at the same time[23].

5. FORMULATION:

- **Active pharmaceutical ingredient [APIs]**

The buccal film can typically contain active medicinal components ranging from 5% w/w to 30% w/w. APIs that are water soluble can be found in the buccal film in a dissolved condition or as a solid solution. The water-insoluble medications are evenly distributed throughout the film. This entails mixing water-insoluble molecules into water-miscible polymers, or complexing the medication with different cyclodextrins to increase its solubility. APIs can also be added as milled, micronized, or in the form of nano crystals or particles, depending on the intended release profile.

- **Mucoadhesive polymers:**

Depending on the type of formulation, polymers with various qualities must be taken into account. Depending on the dosage type, many scenarios for buccal muco-adhesion are feasible. Hydrophilic polymers and hydrogels are the two basic categories for mucoadhesive polymers. Polyvinyl alcohol [PVA], sodium carboxy methylcellulose [NaCMC], hydroxyl propyl methyl cellulose [HPMC], hydroxyl ethyl cellulose, and hydroxypropyl cellulose [HPC] are the hydrophilic polymers that are most frequently utilised in buccal dry or partially hydrated dosage forms. Anionic polymers like carbopol and polyacrylates, cationic polymers like chitosan, non-ionic polymers like eudragit analogues, and elastomers are all used to make hydrogels.

- **Plasticizers**

It is a component that the oral films must have. The choice of plasticizer is influenced by the polymer's compatibility as well as the type of solvent employed in the casting of the film. It lessens the brittleness of the film and increases its flexibility. They are utilised in concentrations ranging from 1 to 20% by weight of dry polymer. Glycerol, propylene glycol, low molecular weight polyethylene glycols, citrate derivatives such as triacetin and acetyl citrate, phthalate derivatives such as dimethyl and dibutyl derivatives, castor oil, etc. are some examples[24].

- **Sweetening agents**

Sweeteners have emerged as crucial excipients in oral medication delivery systems. In the case of the paediatric group, the sweet flavour in the formulation is particularly significant. Both natural and artificial sweeteners are used to increase the mouth-feel of mouth-dissolving formulations. Sucrose, dextrose, fructose, glucose, liquid glucose, and maltose are some examples of natural sweeteners. When compared to sucrose and dextrose, fructose's sweetness is more quickly tasted in the mouth. If the dose form is intended for diabetic people, artificial sweeteners should be utilised. The first generation of artificial sweeteners includes saccharin, cyclamate, and aspartame. The second generation includes acesulfame-K, sucralose, alitame, and neotame.

- **Saliva stimulating agent**

In general, acids that are employed in food preparation can be used to stimulate salivary glands. Utilizing saliva stimulating chemicals has the goal of increasing saliva production, which will help hasten the breakdown of formulations for rapid dissolving films. Among the few instances of salivary stimulants, citric acid is the most popular. Other examples include malic, lactic, ascorbic, tartaric, and malic acids. Between 2 and 6% w/w of the film's weight, these chemicals are used alone or in combination.

- **Flavoring agents**

When it comes to oral dissolving systems, flavouring ingredients are crucial. The initial flavour quality, which is noticed in the first few seconds after the product has been consumed, and the aftertaste of the formulation, which lasts for at least roughly 10 minutes, determine whether a patient would accept the oral disintegrating formulation. Examples of taste oils include peppermint, cinnamon, spearmint, and nutmeg oils, whereas fruity flavours include vanilla, cocoa, coffee, chocolate, and citrus. Some examples of the fruit essence category are apple, raspberry, cherry, and pineapple. You can use flavours individually or in combination. The type and strength of the flavour determine how much flavour is required to cover up the taste. In the formulations for buccal films, tastes should ideally be included up to 10% by weight. Cooling agents like monomethyl succinate can be added to products to increase flavour intensity and improve mouthfeel.

- **Cooling Agent**

Monomethyl succinate is utilised as a cooling agent, which contributes to enhancing the mouthfeel and flavour intensity of the film. In addition to tastes, other cooling agents including WS3, WS23, and Utracoll II can be used[25].

- **Flavoring Agent**

It has been found that flavouring agents significantly influence how much people like a food. The initial flavour quality, which is noticed in the first few seconds after the product has been consumed, and the aftertaste of the formulation, which lasts for at least roughly 10 minutes, determine whether a patient would accept the oral disintegrating formulation. For the purpose of choosing a flavouring ingredient, synthetic flavour oils, oleo resins, and extract from various plant components such as leaves, fruits, and flowers are employed. The amount of flavouring ingredient required to disguise a flavour depends on the intensity of the flavouring agent. In the formulations for buccal films, tastes should ideally be included up to 10% by weight. Cooling chemicals like monomethyl succinate can be added to products to increase the mouth-feel effect and flavour intensity.

- **Coloring Agent**

When some of the formulation ingredients or medications are present in insoluble or suspension form, pigments such titanium dioxide or FD&C approved colouring additives are used (not exceeding concentration levels of 1%w/w) in buccal film formulation [9,25].

6. MANUFACTURING METHODS

The buccal film manufacturing process includes the following techniques.

- Solvent casting technique
- Hot melt extrusion technique
- Direct milling method.

- **Solvent Casting Method**

The necessary amount of polymer is added and dissolved in distilled water when using the solvent casting process. A little amount of the active medicinal component has been added to this solution. The solution is amended with plasticizer and thoroughly mixed. The solution is then cast onto a baking plate and dried in a hot air oven at 400C. Once it had dried, cut it out of the petri dish with a knife and left it in the desiccator for 24 hours. Cut moving forward in the desired size and form. Steps in the solvent casting process [29].

Step 1: Make the casting solution.
Step 2: Deaeration of the solution.
Step 3: Pour the right amount of solution into the mould.
Step 4: The casting solution is dried.
Step 5: Cutting the final dose form to the desired dosage [26, 27].

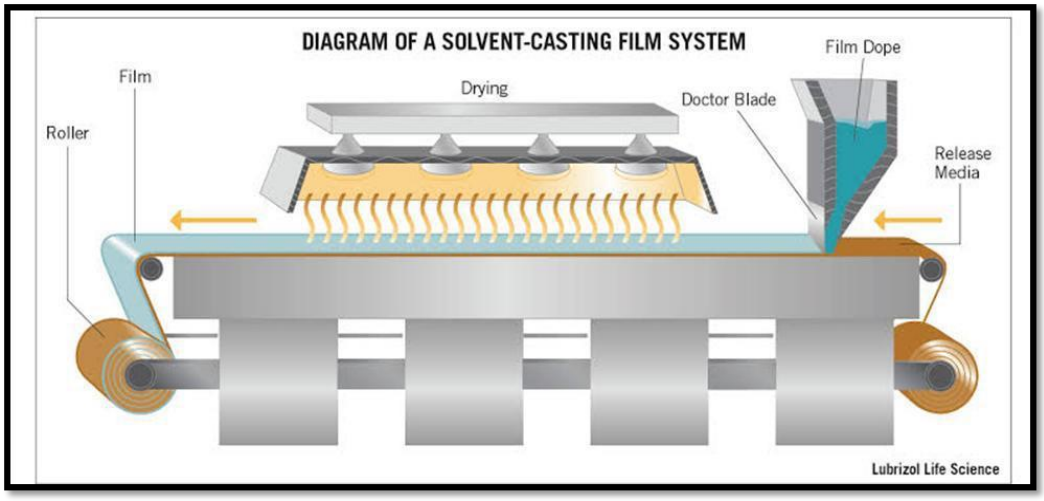

Figure: 3 Solvent casting method.

- **Hot melt extrusion technique**

This procedure makes use of a hot melt extruder. In this method, a polymer is heated and then shaped into a film. A mixture of dry pharmaceutical materials, including API, is added to the hopper, transported, mixed, and heated before being extruded out in molten form by the extruder. The film is cast using the molten mass that has now solidified. The casting and drying process is a crucial step [26,28].

Table 1:

S.no	Ingredients	Quantity
1	API	5-30%(w/w)
2	Mucoadhesive polymer	45%(w/w)
3	Plasticizers	0-20%(w/w)
4	Sweetening agents	3-6%(w/w)
5	Saliva stimulating agents	2-6%(w/w)
6	Colors and Flavors	Q.S

Steps involved in Hot Melt Extrusion Method

Step 1: First, the medication is combined with solid carriers.
Step 2: A heater-equipped extruder melts the mixture.
Step 3: Using dies, the melted substance is finally moulded into films.

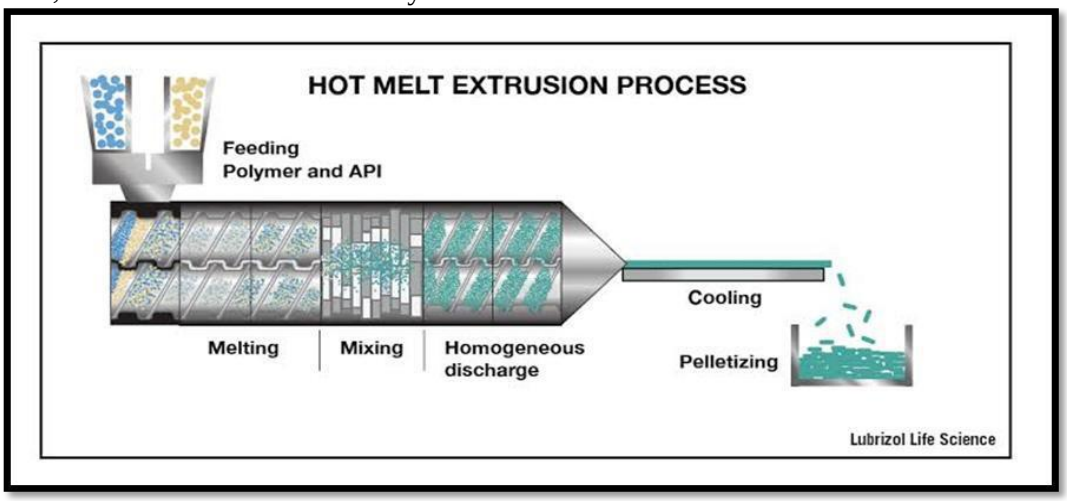

Figure: 4 Hot melt extrusion process.

- **Direct Milling Method**

This technique doesn't use any solvents. Using either direct grinding or kneading, the medicine and excipients are combined in this manner without the use of fluids. The finished product is then rolled till it reaches the desired thickness

on a release liner. This approach is typically recommended because there is zero chance of leftover solvent and zero correlation with any health issues associated to solvents[26,28].

7. EVALUATION METHODS:

The buccal films are evaluated by

- **Weight and thickness of the film:**

Three films of each formulation are taken and weighed separately on a digital balance for the purpose of determining the film weight. Weight averages are computed. Similar to this, three films of each formulation were collected, and the thickness of each film was measured using a micrometre screw gauge three distinct locations, with the mean value being determined [30,31].

- **Surface pH of films**

Three films of each formulation are allowed to swell on the surface of an agar plate for two hours in order to measure the surface pH. A pH paper should be placed on the surface of the swollen region in order to measure the surface pH. Three readings are required to calculate the mean [32].

- **Swelling index**

The samples are allowed to expand on the surface of an agar plate that is kept in an incubator that is kept at a temperature of 37 0.2 oC after the original film weight and diameter have been determined. Three films' weights (n=3) are calculated at various time intervals (1-5 h).

The percent swelling, % S is to be calculated using the following equation:

Percent swelling [% S] = [Xt–Xo/Xo] ×100,

Where,

Xt=The weight of the swollen film after time t, x

Xo=The initial film weight at zero time [33,34].

- **Folding endurance**

Utilizing a sharp blade, three films of each composition are cut to the necessary size. The test for folding endurance involves repeatedly folding the film in the same spot until it breaks. The value of folding endurance is determined by how many times the film could be folded in the same location without breaking [35].

- **Moisture content**

The produced films need to be weighed separately and maintained at room temperature in desiccators with calcium chloride for 24 hours. After a predetermined amount of time, the films must be weighed again until they display a steady weight. The following formula should be used to compute the % moisture content[36] .

% Moisture content=[Initial weight–Final weight/Final weight]×100.

- ***In-vitro* residence time**

Using an IP disintegration system and 900 mL of the disintegration liquid kept at 37 2°C, the in vitro residence time is calculated. Each of the 3 cm long segments of rat intestinal mucosa must be adhered with glue to the surface of a glass slab before being vertically fastened to the equipment. Each formulation's three mucoadhesive films are moistened on one surface before becoming in touch with the mucosal membrane. The glass slab is permitted to move up and down while being anchored vertically to the device. At its lowest and tallest points, the film is totally submerged in the buffer solution. It is important to keep track of how long it takes for the film to completely erode or separate from the mucosal surface [37].

- **Drug Content uniformity**

Buccal film is separately dissolved in 100 ml of pH 6.8 buffer, and the combination is then appropriately diluted. Spectrophotometric absorbance measurement at 242 nm is used to determine the amount of medication in the film. It's computed what the typical drug content is[38].

- **Surface characterization studies**

At 6000 X magnification, a scanning electron photomicrograph of the film was taken. The drug-containing film that has been created is checked for a clear, colourless surface. When comparing the photomicrographs of the drug-containing and blank films, it is determined if the drug is evenly dispersed throughout the film in an amorphous form [39].

- ***In-vitro* dissolution studies**

For all of the formulations, dissolving tests are conducted using a USP dissolution apparatus rotating at a constant speed of 50 rpm with 900 mL of the dissolution medium. For each test, a piece of drug film is used. At regular intervals,

an aliquot of the sample is periodically removed and replaced with new dissolving medium. At a specific nm, the sample is spectrophotometrically evaluated [40,42].

- **Organoleptic evaluation**

The prepared buccal film should possess the desired features of sweetness and flavor, which is acceptable to a large mass of population. Controlled human taste panels are used for psychophysical evaluation of the product. In-vitro methods of utilizing taste sensors, specially designed electronic tongue measurement devices can be used for this purpose [43,44].

Table :2 FDA APPROVED DRUGS

Drug	Year of Approved	Company	Use
Suboxone	31/08/2010	Reckitt Benckiser pharmaceutical Inc.	Psychological support and patient counselling.
Zuplenz	January 2010	Pharm Film technology	Prevention of nausea and vomiting before and after of cancer chemotherapy.
Ondansetron	23/03/2010	APR Applied pharma Research s.a and Lab tec	Prevention of nausea and vomiting before and after cancer chemotherapy and radiotherapy .
Zelapar	October 2005	Valent pharmaceuticals International Inc.	Parkinson's Disease[45].

8. APPLICATIONS:

- ❖ It is feasible to create multilayer drug films, which is an emerging field with direct application. It is possible to mix two or more medications into one format, with the dissolving rates of the layers being the same or different.
- ❖ The formulation of the films allows for a range in the amount of time it takes for the medications to dissolve, from minutes to hours.
- ❖ Films function as gastro retentive dosage forms; their breakdown may be prompted by the pH or enzyme secretions of the gastro intestinal tract and may be utilised to treat problems of the gastro intestinal system.

9. CONCLUSION:

According to the results of the current review, the buccal film is the most precise and palatable dose form since it avoids the hepatic first pass effect and exhibits high absorption. This is the most innovative and promising technology that benefits people of all ages, especially children and the elderly as well as those who have trouble swallowing. Due to its advantages over conventional dosage forms and their low cost of production, buccal films can take the place of conventional dosage forms, including rapid disintegrating tablets. This technology offers a useful tool for maintaining the medicinal and financial worth of pharmaceuticals.

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