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Buccal Film - A Review on Novel Drug Delivery System

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ABSTRACT

Nowadays, requirement of design and development of novel dosage form is created to improve patient compliance, safety and efficacy. Buccal film is novel film technology which is fulfilled all these requirements. Buccal film is administered through buccal drug delivery system. Buccal film is small in size, dose, easily administered so that it is more palatable and acceptable dosage from than other buccal drug delivery system like wafers, lozenges, microparticles, gel, tablets. Buccal film is effective dosage form which improves bioavailability as it bypasses first pass metabolism. It is satisfactorily adhered to buccal layer of oral cavity so it is more convenient than other dosage form. It is cost effective, biodegradable, fast absorption, elegant, easy to handle, non irritating and no requirement of swallowing of drug henceforth it is more accepted dosage form by geriatric and pediatric patients. This article gives comprehensive review on benefits, limitations, manufacturing methods, evaluation parameters and formulation of buccal film.

Keywords- Buccal film, cost effective, effective buccoadhesion, improving patient compliance, bioavailability.

INTRODUCTION

The present article focuses on the buccoadhesive drug delivery systems depend on binding to biological surfaces that are covered by mucus. Nowadays, growing demand for patient convenience and compliance related research. Also novel method is the development of buccal films, which dissolve on the patient buccal mucosa. This drug delivery system is suitable for the drugs which passes through high first pass metabolism and is used for enhancing bioavailability with reducing dosing frequency to mouth plasma peak levels, which in turn minimize adverse side effects. It is also make cost effective and effective in geriatric and pediatric patients. In addition, films have improved patient compliance due to their small size and reduced thickness, compared for example to lozenges and tablets. Films as dosage forms have gained importance in the pharmaceutical industry as novel, patient friendly, convenient products. Currently, buccal film is come under focus. This dosage form is less friable than most commercialized orally disintegrating tablets, which usually require special packaging. Mucoadhesive buccal films share some of these advantages. In addition, as muco-adhesion implies attachment to the buccal mucosa, films can be formulated to exhibit a systemic or local action. Many mucoadhesive buccal films have been formulated to release drug locally in order to treat fungal infections in the oral cavity such as oral candidiasis. speaking, bioadhesion is an term which broadly includes adhesive interactions with any biological or biologically derived substance and mucoadhesion is used when the bond is formed with a mucosal surface. However, buccal films have greatest challenge to develop high quality which is also necessities to constant evaluation and understanding performance. [1, 2]

Buccal Mucosa

In Novel drug delivery system, oral route is conceivably the most suggested to the patient and the clinician alike. However, oral administration of drugs has limitations such as hepatic first pass metabolism and enzymatic degradation within the GI tract, that inhibit oral administration of certain classes of drugs particularly peptides and proteins. As a result, other absorptive mucosae are considered as possible sites for drug administration. Transmucosal routes of drug delivery (i.e., the mucosal linings of the nasal, rectal, vaginal, ocular, and oral cavity) propose distinct advantages over peroral administration for systemic drug delivery. Due to this advantages include possible bypass of first pass effect, avoidance of presystemic elimination within the GI tract, and, depending on the particular drug, a better enzymatic flora for drug absorption. [3] Oral mucosal drug delivery system is divided into two classes, buccal and sublingual in which buccal cavity is extensively applicable for drug administration through mucosa in case of sublingual route mostly useful for fastest onset of action as in the case of Angina pectoris. Buccal mucosa lines the inner cheek. [4]

Inside the oral mucosal cavity, delivery of drugs is classified into three categories: [5]

1. Sublingual Delivery
2. Buccal Delivery
3. Local Delivery

Anatomy of Oral Cavity

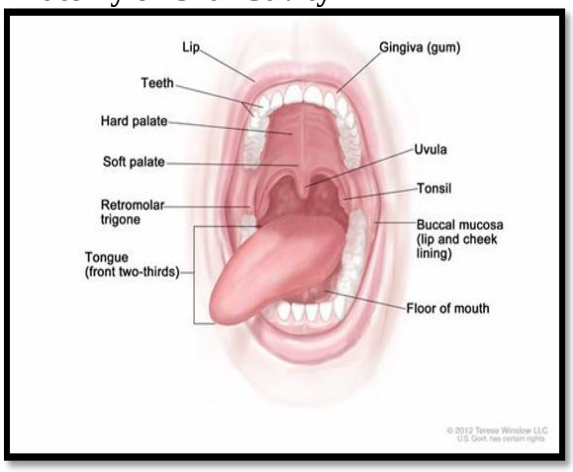

Figure 1. Mucosal region of mouth [33]

Oral cavity is includes lips, cheeks, hard palate, soft palate and floor of mouth (figure1). The oral cavity consists of two regions. Outer oral vestibule, which is bounded by cheeks, lips, teeth and gingival (gums). Oral cavity proper, which extends from teeth and gums back to the fauces (which lead to pharynx) with the roof comprising the hard and soft palate. The tongue projects from the floor of the cavity. [6]

The oral cavity can be divided into specific areas, including:

- Gingiva
- Hard palate
- Soft palate
- Tonsil
- Tongue

Structure of Oral Mucosa

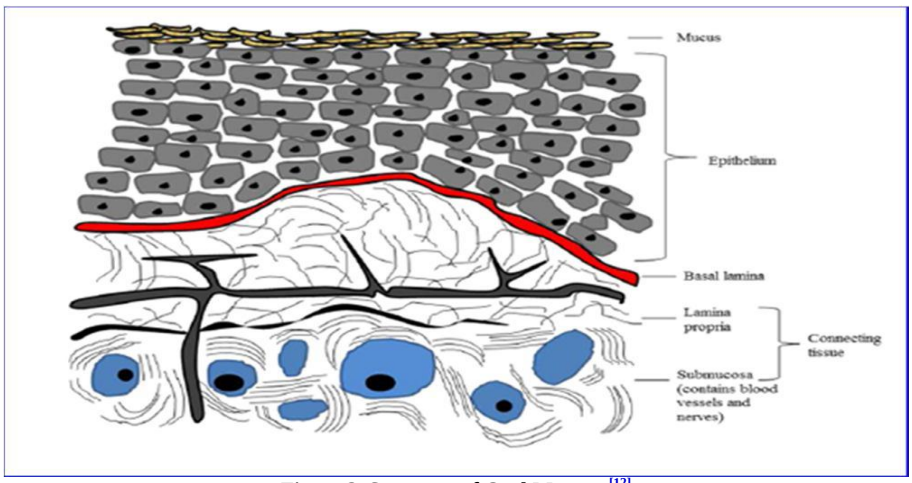

Figure 2. Structure of Oral Mucosa [12]

The main difference between the oral mucosa and skin as compared to the gastrointestinal (GI) tract lining lies in the organization of the different epithelia. Whereas the second has a single layer of cells forming the simple epithelium, the skin and the oral cavity have several layers of cells with various degrees of differentiation. Inside the oral cavity, the masticatory mucosa has a keratinized or cornified epithelium, and covers the stress-enduring regions such as the gingival and the hard palate, given that chemical resistance and mechanical strength. It is divided into four layers: keratinized, granular, prickle-cell, and basal layer (Figure 2). The lining mucosa is provide elasticity, in difference, is included of non-cornified surface epithelium covering the rest of the regions including the lips, cheeks, floor of the mouth, and soft palate. It can be classified into superficial, intermediate, prickle-cell, and basal layers. The third type of mucosa is the specialized mucosa consisting of both keratinized and non-keratinized layers. It is controlled to the dorsal surface of the tongue. The intercellular spaces contain water, lipids, and proteins. [4]

Permeability

It is found that the permeability of the buccal mucosa is 4-4000 times greater than that of the skin. As investigative by the wide range in this reported value, there are considerable differences in permeability between different regions of the oral cavity because of the diverse structures and functions of the different oral mucosae. The permeability of the oral mucosae is greater in buccal than sublingual. This is depend on the relative thickness and degree of keratinization of these tissues, with the sublingual mucosa being relatively thin and nonkeratinized, the buccal thicker and non-keratinized, and the palatal intermediate in thickness but keratinized. Nowadays, it is believed that the permeability barrier in the oral mucosa is a result of intercellular material derived from the so-called 'membrane coating granules' (MCG). This barrier consists in the outermost 200μm of the superficial layer. Permeation studies are done by using a number of very large molecular weight tracers, like as horseradish peroxidase and lanthanum nitrate. When applied to the outer surface of the epithelium, these tracers penetrate only through outermost layer or two of cells. When applied to the submucosal surface, they permeate up to, but not into, the outermost cell layers of the epithelium. As per results, it seems clear that flattened surface cell layers present the main barrier to permeation, while the more isodiametric cell layers are relatively permeable. [7]

Role of Saliva

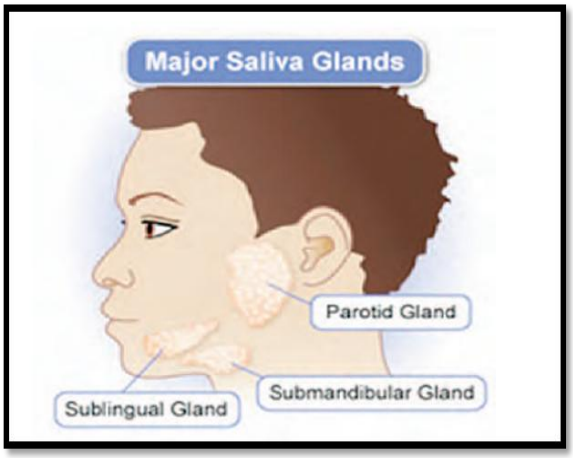

Figure 3. Salivary glands [8]

Salivary fluid is an exocrine secretion consisting of approximately 99% water, containing a variety of electrolytes (sodium, potassium, calcium, chloride, magnesium, bicarbonate, phosphate) and proteins, represented by enzymes, immunoglobulins and other antimicrobial factors, mucosal glycoproteins, traces of albumin and some polypeptides and oligopeptides of importance to oral health. [3, 8]

Functions of Saliva

- Buffer Capacity
- Dilution and Cleaning
- Integrity of Tooth Enamel
- Protection and Lubrication
- Digestion
- Dilution and Cleaning
- Buffer Capacity

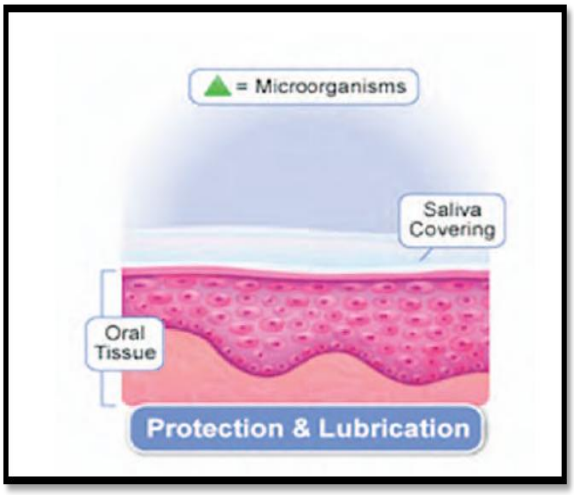

Figure 4. Role of Saliva [8]

Role of mucus

Mucus is negatively charged and contains large glycoproteins termed mucins. Mucin consists of a protein core, rich in O-glycosylated serine and threonine, containing many helix-breaking proline residues. The pH of Saliva is 5.8-7.4. [4]

Functions of Mucus [9, 10]

- Protective in nature due to hydrophobicity.
- Cell- cell adhesion
- Lubrication
- Bioadhesion of mucoadhesive drug delivery system

Buccal Drug Delivery System

Buccal controlled drug delivery system has been developed as the oral cavity provides potential sites for drug delivery. It is bypasses acid hydrolysis and first pass metabolism. Continuous secretion of saliva is affect drug release through buccal film. The mucin film exists in oral mucosa offers an opportunity to develop mucoadhesive system, which retain at absorption site for prolonged time by mucoadhesion. The close contact with absorption membrane causes more absorption of the drug. The pH of buccal cavity does not cause any problem to the drug with the right dosage form design and formulation. The permeability and the local environment of the buccal mucosa can be controlled and manipulated in order to accommodate drug permeation. [11]

Novel buccal dosage forms

The novel buccal dosage forms consist of buccal adhesive tablets, patches, films, semisolids (ointments and gels) and powders.

A. Buccal mucoadhesive tablets

Buccal mucoadhesive tablets are dry dosage forms which gets moistened when come in contact with buccal mucosa. Example: a double layer tablet, consisting of adhesive matrix layer of HPC and polyacrylic acid with an inner core of cocoa butter containing insulin and a penetration enhancer (sodium glycocholate).

B. Patches and Films

Buccal patches consists of two laminates, with an aqueous solution of the adhesive polymer being cast onto an impermeable backing sheet, which is then cut into the desired oval shape.

C. Semisolid Preparations (Ointments and Gels)

Bioadhesive gels or ointments have not patient acceptability as like other solid bioadhesive dosage forms, and most of the dosage forms are used only for localized drug therapy within the oral cavity.

D. Powders

HPC and beclomethasone in powder form when sprayed on to the oral mucosa of rats, a significant increase in the residence time relative to an oral solution is seen, and 2.5% of beclomethasone is retained on buccal mucosa for over 4 hrs. [12]

Buccal film

Figure 5. Buccal Film [34]

Buccal film is a non dissolving thin matrix modified release dosage form composed of one or more polymer films or layers containing the drug and/or other excipients. The film may contain a mucoadhesive polymer layer which bonds to the oral mucosa, gingiva, or teeth for controlled release of the drug into the oral mucosa (unidirectional release), oral cavity (unidirectional release), or both (bidirectional release). The patch is removed from the mouth and disposed of after a specified time. [13]

Advantages of Buccal Film

- No risk of chocking.
- No need of chewing and swallowing.
- Rapid onset of action and minimum side effects.
- Accurate dosing compared to liquid dosage form.
- Taste masking is possible.
- Good mouth feel and good stability.
- Requires less excipient.
- Ease of transportation, storage and consumer handling.
- More Economical
- Ease of administration to pediatric, geriatric patients. Also to patients who are mentally retarded, disabled or non cooperative.
- Prolongs residence time of dosage form at site of absorption. So improves bioavailability.
- Drug can be protected from degradation in GI tract and acidic environment.
- Buccal film has large surface area that leads rapid disintegration and dissolution in oral cavity. [14]

Disadvantages of Buccal Film

- Saliva is continuously secreted into the oral cavity diluting drugs at the site of absorption resulting in low drug concentrations at the surface of the absorbing membrane. Instinctively swallowing of saliva results in a maximum part of dissolved or suspended released drug being removed from the site of absorption. Moreover, there is risk that the delivery system itself would be swallowed.
- Drug characteristics can make boundary for use of the oral cavity as a site for drug delivery. Taste, irritancy, allergy and adverse properties such as discoloration or erosion of the teeth can limit the drug candidate list for buccal route. Conventional type of buccal drug delivery systems did not allow the patient to concomitantly eat, drink or in some during talk. [6]

Formulation aspects for Buccal Film

Active Pharmaceutical Ingredient

Active pharmaceutical substance can be from any class of pharmaceutically active substances that can be administered orally or through the buccal mucosa. Like antiulcers, antiasthmatics, antitussive, antihistaminic, antiepileptic, expectorants, antianginal etc. For the effective formulation, dose of drug should be in mgs (less than 20 mg/day). Usually 5%w/w to 30%w/w of active pharmaceutical ingredients can be incorporated in buccal film. High dosage of molecules is difficult to incorporate into film. [1]

Ideal Characteristics of Drug to be selected:- [15]

- No Bitter Taste
- Dose lower than 20mg.
- Low molecular weight
- Good stability in water and saliva.
- Ability to permeate oral mucosal tissue

Mucoadhesive agents

Different situations for buccal mucoadhesion are possible depending on the dosage form. In the case of dry or partially hydrated formulations, polymer hydration and swelling properties probably play the main role. The polymer hydration and consequently the mucus dehydration could cause enhance in mucouscohesive characteristics that support mucoadhesion. Swelling should help polymer chain flexibility and interpenetration between polymer and mucin chains. The spreading coefficient and the capability to form

physical or chemical bonds with mucin increase when fully hydrated dosage forms. So that depending on the type of formulation, polymers with different characteristics have to be considered. The polymers most commonly used in buccal dry or partially hydrated dosage forms include polyacrylic acid (PAA), polyvinyl alcohol (PVA), sodium carboxymethyl cellulose (NaCMC), hydroxypropyl methyl-cellulose (HPMC), hydroxyethyl cellulose (HEC), hydroxypropyl cellulose (HPC) and sodium alginate.

Their peculiarity depends in the mucoadhesion mechanism: such substances are able to identify and bind some specific sugar residues on mucosal surface without altering the structure of the recognized ligand. [1]

Plasticizers

It is a necessary ingredient of the oral films. The selection of plasticizer depends upon its compatibility with the polymer and also the type of solvent used in the casting of film. It improves the flexibility of the film and reduces the brittleness of the film. They are used in the concentration of 1 - 20%w/w of dry polymer weight. Examples include: Glycerol, Propylene glycol, Low molecular weight polyethylene glycols, Citrate derivatives like triacetin, acetylcitrate, Phthalate derivatives like dimethyl, diethyl, dibutyl derivatives, Castor oil etc. [15]

Sweetening Agents

Sweetening agents are important in food and all pharmaceutical products which are disintegrate or dissolved in oral cavity. The standard source of sweetener is sucrose, dextrose, fructose, glucose, liquid glucose and maltose. The sweetness of fructose is accepted rapidly in the mouth as compared to sucrose and dextrose. But use of natural sweeteners has major issue to diabetic patients. Due to this reason, intake of the artificial sweeteners has more popularity in food and pharmaceutical preparations. Saccharin, cyclamate and aspartame are the first generation of the artificial sweeteners followed by acesulfame-K, sucralose, alitame and neotame which fall under the second generation artificial sweeteners. [1]

Saliva Stimulating Agents

Addition of this agent in formulation is important because it increase rate of production of saliva so that film undergoes fast disintegration and rapid dissolution takes at buccal cavity. Usually acids which are used in the preparation of food can be utilized as salivary stimulants. Citric acid, malic acid, lactic acid, ascorbic acid and tartaric acid are the few examples of salivary stimulants, citric acid being the most preferred amongst them. These agents are used individually or in combination between 2 to 6%w/w of weight of the film. [1]

Cooling Agent

Monomethyl succinate is used as cooling agents which helps to improve the flavour strength and to improve the mouth-feel effect of the film. Other cooling agents such as WS3, WS23 and Utracoll II can also be used in conjunction with flavors. [16]

Flavoring Agent

It was observed that flavoring agent plays a major role in the taste fondness. Synthetic flavor oils, oleo resins, extract derived from various parts of the plants like leaves, fruits and flowers are used for selection of flavoring agent. Depending of flavoring agents strength, need of amount of flavoring agent to m mask taste. [16]

Coloring Agent

Pigments like as Titanium dioxide or FD&C approved colouring agents are incorporated (not exceeding concentration levels of 1%w/w) in buccal film formulation when some of the formulation ingredients or drugs are present in insoluble or suspension form. [1, 16]

Surfactants

Surfactants are used as solubilising or wetting agent. Film gets dissolved rapidly within seconds by use of surfactant and immediately drug is released. Solubility of poorly soluble drugs in buccal can be improved by using surfactant. For examples are Polaxamer 407, sodium lauryl sulphate, benzalkonium chloride, benzethonium chloride, tweens and spans etc. [16]

Stabilizing and thickening agents

Addition of stabilizing and thickening agents are important to improve the viscosity and consistency of dispersion or solution of the film preparation before casting. Natural gums like xanthan gum, locust bean gum, carragenan and cellulosic derivatives are few examples of stabilizing and thickening agents. They are used in the concentration up to 5%w/w. [16]

Manufacturing methods of Buccal film

Buccal film formulation is mainly prepared by following three methods

1. Solvent Casting Method
2. Hot Melt Extrusion Method
3. Direct Milling Method

Solvent Casting Method

In solvent casting method, required quantity of polymer is added and dissolved in distilled water. Active pharmaceutical ingredient in small quantity added in this solution. Plasticizer is added in solution and stirred well. Solution is then casted on petridish and kept in hot air oven for drying at 40^0C. After drying removed it from petriplate by cutting with blade and allowed to keep in desicator for 24hours. Henceforth cut in required size and shape.

Steps involved in Solvent Casting Method

Step 1: Preparation of casting solution

Step 2: Deaeration of solution

Step 3: Transfer of appropriate volume of solution into the mould

Step 4: Drying the casting solution

Step 5: Cutting the final dosage form to contain desired amount of drug. [17, 18]

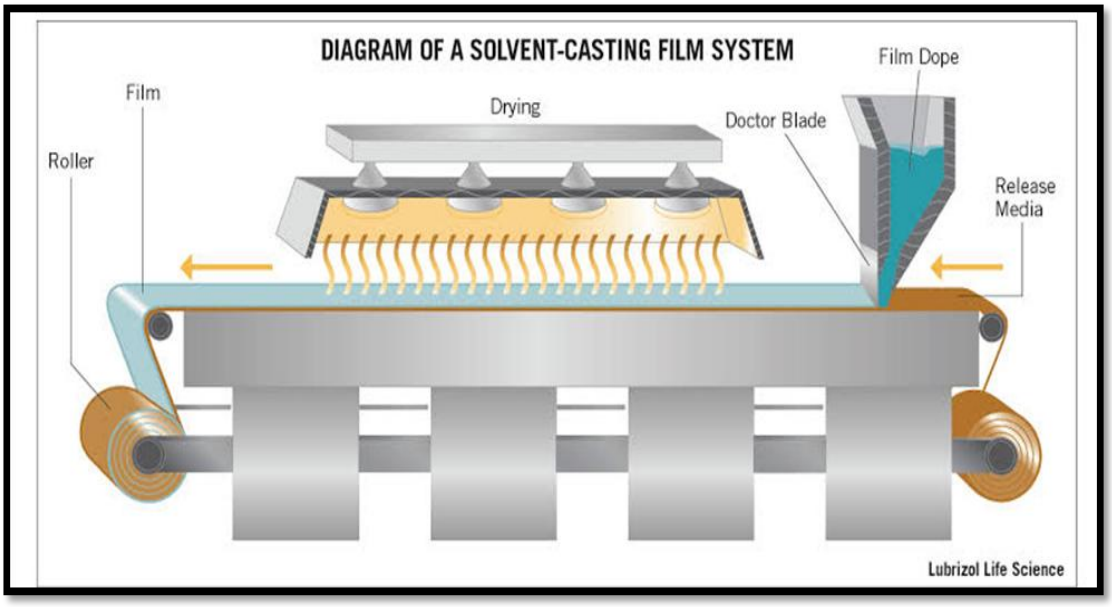

Figure 6. Solvent casting method [33]

Hot Melt Extrusion Method

In hot melt extrusion method mixture of drug and other excipients is molten. Then forced through orifice to yield a more homogenous material in different shapes like granules, tablets, or films. It is used for transdermal drug delivery System. [13, 17]

Steps involved in Hot Melt Extrusion Method

Step 1: The drug is mixed with carriers in solid form
Step 2: Extruder having heaters melts the mixture
Step 3: Finally the melted mixture is shaped in films by the dies

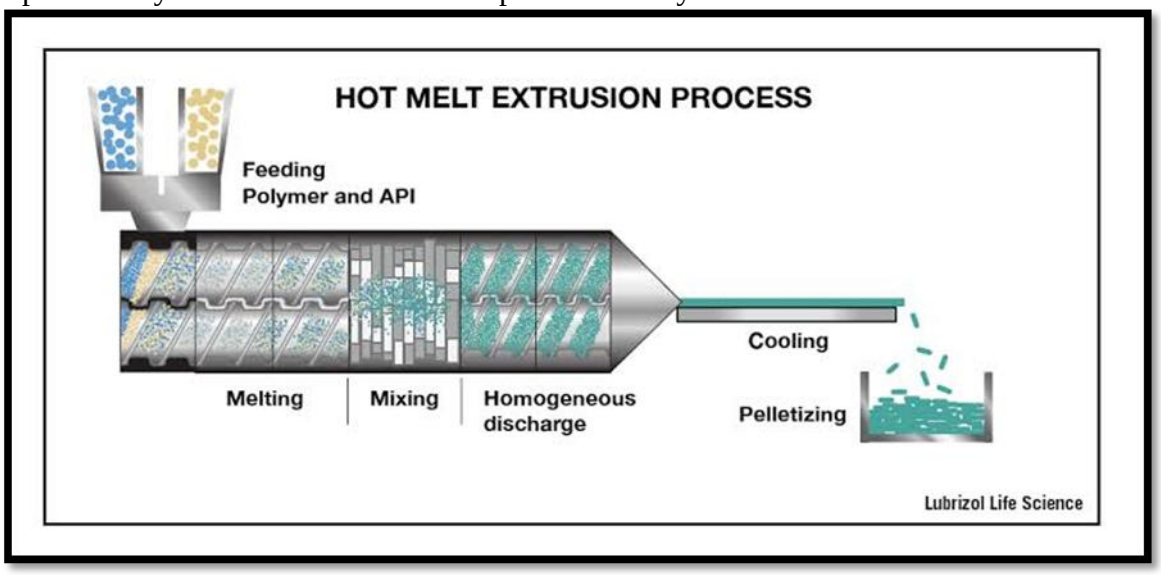

Figure 7. Hot Melt Extrusion Process [33]

Table 1. Advantages and Disadvantages of Hot Melt Extrusion Method.

Advantages	Disadvantages
• Fewer operation units • Better content uniformity • An anhydrous process	• Thermal process creates stability problem. • Flow properties of polymer are important to processing. • Limited numbers of polymers are available.

3. Direct Milling Method

This method is solvent free method. In this method, drug and excipients are mixed without presence of liquid by direct milling or by kneading. Then resulting material is rolled on release liner til the required thickness is obtained. This method is usually preffered because of there is no possibility of residual solvent and no any association of solvent related health issue**.** [17, 13]

Evaluation Parameters of Buccal film

Weight of the film

Buccal film is weighed by calibrated weighing balance. Individual weight of each film is calculated. Average weight is calculated and analyzed weight of film. [19]

Thickness

Thickness of buccal film is evaluated by calibrated micrometer screw gauge. The thickness is measured at five different points of the film and means value is calculated. This is done to ensure the uniformity in the thickness of the film as it is directly correlated with accuracy of dose in the film and supports the reproducibility of the method used for the formulation. [20]

Tensile strength

The tensile strength is the property of the film that requires a load to cause load deformation failure of film. Film strips in special dimension is held between two clamps positioned at a specific distance. Tensile strength is calculated by applying load at rupture and cross sectional area of fractured film from following equation. [21]

Tensile strength (N/mm^2) = breaking force (N)/ cross sectional area of sample (mm^2)

Surface pH of the film

The films are allowed to swell by keeping them in contact with 1 ml of distilled water for 2 h at room temperature, and pH is noted down by bringing the electrode in contact with the surface of the film, allowing it to equilibrate for 1 min. [22]

Folding endurance

Folding endurance is to be determined by repeatedly folding the film at the same place, until it breaks. The number of times, the film could be folded at the same place without breaking gives the value of folding endurance. [14]

Percentage moisture loss

This is used to check integrity of films. Film is cut out and then takes weight. After it is keep in desicator containing fuse anhydrous calcium chloride. After 72 hours it is removed and weighted. Average percentage moisture loss is calculated by below formula. [9]

Percentage Moisture Loss = (Intial weight-film weight)×100/Initial weight

Drug Content uniformity

Buccal film is dissolved in 100 ml of pH 6.8 buffer separately and mixture is suitably diluted. The amount of drug in film is measured absorbance spectrophotometrically at 242 nm. The average drug content is calculated. [23]

In vitro disintegration time

It is determined visually in a petr iplate containing 2 ml distilled water with swirling every 10 seconds. The time at which film started to break or disintegrate is recorded as the in vitro disintegration time. [24]

In vitro dissolution study

An in vitro dissolution study is carried out using USP type II apparatus (Basket type apparatus). pH 6.8 buffer (50 mL) is used as a dissolution medium at 50 rpm speed and 37^0C temperature. At specific time intervals, 1 ml samples were withdrawn and replaced with the equal quantity of fresh dissolution medium. Buccal films are filtered through 0.45 µm Whatman filter paper, and analyzed spectrophotometrically at λmax of active pharmaceutical ingredient. [25, 26]

Dissolution kinetics study

It is done by determining the best fit mathematical model for formulations.

R and k values for different mathematical models are determined putting the dissolution data in respective mathematical models. The model for which the R value is the highest that model is considered as the best fit model for the concerned formulation. The n value for the best fit model is recorded and it is used to determine the fickian or non-fickian diffusion pattern the formulation follows. [27]

A. Zero-order kinetic:

$Q_t = Qo + k_0t$

Where, Qt is amount of drug release at time t

K_0 is zero order release rate constant.

Q_0 is amount of drug present initially at t = 0

B. First-order kinetic:

$\ln (100 - Q) = \ln Q_0 - k_1t$

Where, Q = amount of drug release at time t

Q_0 = amount of drug present initially

K_1 = first order release rate constant

C. Higuchi equation

$Q = k_H\ t1/2$

Where, Q = amount of drug release at time t

K_H = Higuchi dissolution constant

Swelling index

The initial weight of the film is determined using a digital balance (W0). Then the films are allowed to swell on the surface of petri plate and kept in an incubator maintained at 37 °C. Weight of the swollen film is determined (Wt) at predetermined time intervals for 5 min. The percentage of swelling (% S) is calculated using the following equation. [28]

% S= (Wt-Wo)*100 /Wo

Where **Wt** is the weight of swollen patch after time t, $\mathbf{W_0}$ is the initial weight of patch at t=0.

Ex-vivo diffusion study

For in vitro release study, goat buccal mucosa membrane is used as a barrier membrane with Phosphate buffer (pH 6.8) as a medium. Drug release from film is

evaluated by Franz diffusion cell. Buccal mucosa membrane is mounted between the donor and receptors compartments. The film is placed on the mucosal membrane. The diffusion cell is placed in simulated saliva maintained at 37±2°C.The receptor compartment is filled with 50 mL phosphate buffer (pH 6.8) and hydrodynamics is maintained by stirring with a magnetic bead at 50 rpm. 1 mL sample is withdrawn and replaced with 1 mL fresh medium to maintain the sink condition. The samples are analyzed by U.V. spectrophotometer at specific wavelength. [29, 30]

Stability study

Stability of a pharmaceutical product may be defined as the capability of a particular formulation, in a specific container / closure system, to remain within its physical, chemical, microbiological, therapeutic and toxicological specifications. The stability of all the formulations was carried out at different temperatures as per ICH guidelines. [31]

Stability study is carried out storage conditions; one was normal room conditions at 40^0C/75% RH for 6 months and another at 30^0C/75% for 24 to 36month. Film is packed in packing material like aluminum foil and then evaluated for the DSC, FTIR, Folding endurance, disintegration time, drug content and in vitro drug release. [32]

Future Aspects of Buccal film

Buccoadhesive buccal films can be incorporated potent drug which fulfilled criteria for buccal film as drug delivery system. [17]

- We can evaluate the dissolution of buccal film for drug release profile studies.
- We can examine in-vivo studies for the prepared buccal film.
- We can perform the stability study for buccal film.

FDA Approved Buccal films

Table 2. List of FDA Approved Buccal Films. [21]

Drug	Year of Approved	Company	Use
Suboxone	31/08/2010	Reckitt Benckiser Pharmaceutical Inc.	Psychological support and patient counseling.
Zuplenz	January 2010	PharmFilm technology	Prevention of nausea and vomiting before and after of Cancer Chemotherapy
Ondansetron	23/03/2010	APR Applied Pharma Research s.a. and Labtec	Prevention of nausea and vomiting before and after of Cancer Chemotherapy .and radiotherapy.
Zelapar	October 2005	Valent Pharmaceuticals International Inc.	Parkinson's Disease.

CONCLUSION

The present review concluded that buccal film is most acceptable, palatable dosage form. It is bypasses first pass metabolism and also enhance bioavailability of active molecule due to its specific characteristic features than other novel buccal drug delivery system. Buccal film is an innovative dosage because of its wide range of advantages to geriatric, pediatric as well as patients having swallowing issues. Buccal film is novel approach for replacement of conventional dosage form as buccal film is available in low cost and no irritancy in oral cavity. Buccal film is promising area for continued research with the aim of systematic delivery of orally inefficient drugs. It is feasible and alternative source for non invasive delivery of potent peptide and protein drug molecules. As buccal films have good buccoadhesive property, it gives rapid onset of action. Buccal film is buccoadhesive drug delivery system which enhances safety, efficacy and stability of active pharmaceutical ingredient. Buccal film is novel technology due to its better option to optimize therapeutic efficacy.

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