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# BUCCAL FILMS IN ADVANCED DRUG DELIVERY SYSTEM

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## ABSTRACT

In developing buccal films for oromucosal drug administration ,an extensive research is being done on the design and development of novel drug delivery system in order to improve the safety ,efficacy and patient compliance in buccal film technology. This technology has involved in an advanced alternative to other conventional types of drug delivery systems, and this buccal film technology is proven for systemic delivery of active pharmaceutical ingredients(API's). Buccal films are having physiological features, so it is best suitable for local as well as systemic delivery of drugs. In comparision to other buccal films such as lozenges, wafers, gels and tablets, buccal film is smaller in size, dose and simple to use, bypassing first passing, and it increases bioavailabilty.This article provides information of mucodhesive buccal film technology and updated analysis of advantages ,disadvantages, production process, and formulation of buccal film.

## INRODUCTION

Buccal drug delivery refers to the drug administration in buccal mucosa, buccal mucosa is the best transmucosal route for local and systemic administration, and it is widely recognised where the therapeutic chemicals are absorbed from the oral mucosa which allows the medication directly in to the bloodstream and it avoids first-pass metabolism and drug degradation in gastrointestine. Oral route is most oftenly used medication administration,with low therapeutic costs and patient comport.

Buccal films are most recently created dosage form for buccal administration, buccal films are more beneficial with comparision to tablets, where it has wide surface area enables fast wetting of the film which has rapid absorption. These dosage forms are pharmacoeconomic, self-administerable with highly improved patient compliance .Buccal films are developed for treating the oral candidiasis and other fungal infections of the oral cavity, these films show greater accuracy and flexibility when compared to other dosage forms, films are flexible and elastic which provides very great comfort to the patient.

Hence, buccal films are strong enough to resist breakage caused by movements of the mouth,these films can be used at night, during sleep.Buccal films are simply placed on the tongue and the medication is released with the quick hydration by saliva then it dissolves ,the drug enters the blood stream sublingually, also they have direct access to the systemic circulation through the internal jugular vein, the drug bypasses from hepatic first pass metabolism which leads to high bioavailabilty.While comparing to other tablets the main property of buccal film is due to the large surface area of the film it will allow the rapid wetting of the film and increases the absorption of the drug.

## ANATOMY AND PHYSIOLOGY OF ORAL MUCOSA

The oral mucosal region functions as a lubricant,with less friction when the cells move with each other,and it is sticky in its nature.When compared to other areas of the oral acaless ceramindemvity the buccal and sublingual regions the mucosa is more and it is more permeable because it is having on the cells of epithelial layers outside there is a coating of mucus. This mucus is very important for mouth lubrication,mucoadhesion of the mucoadhesive drug delivery system.This speacialised mucosa, where it has both keratinized and non-keratinized layers,of the third type of mucosa. The layer of mucus plays an important role in oral lubrication as well as mucoadhesion of mucoadhesion drug delivery systems

## ADVANTAGES:

- Rapid disintegration and dissolution in the oral cavity due to wide surface area of the buccal film.
- More affordable, simpler for storage, shipping and customer service.
- Chewing is not required ,there is no possibility of choking.
- Self administration is possible.
- Good stability and good mouth feel.
- Buccal films increases the systemic bioavailability of the drugs, as it bypasses the first pass metabolism.
- Ease of transportation ,storage and consumer handling.
- Requires less excipient.
- Taste masking is possible.
- More economical.

## DISADVANTAGES

- When drug is ingested with saliva, the maximum amount of the dissolved drug is taken from the site of absorption.
- Some unfavourable effects are also there, such as tooth erosion or discolouration.
- Not permitted to eat or drink when using a traditional form of buccal drug delivery system.

## OVERVIEW OF THE MUCOADHESIVE FILM TECHNOLOGY

As we know, mucoadhesive buccal films are multilayered systems which are designed for prolonging release of the drug into oral cavity.Mucoadhesive buccal films sticks to the buccal mucosa also include mucoadhesive films which sticks or adheres to other areas of oral cavity .Also, there are other types of films like orodispersible films which is applied to the oral cavity and it is designed for quick absorption and rapid release in gastrointestinal tract.

## MUCUS AND MUCOADHESION

Mucus is secreted by salivary glands.Mucins are made up of basic units (approximately 400-500kDa) linked together by forming a 3D network,where as this network carries a negative charge by forming a cohesive gel which will bind to the buccal epithelial surface.The mucoadhesion procces will occur in two different stages like contact and consiladation.thereby the contact stage is where the mucoadhesive meets the mucus covered membrane first, here the mucus makes the material wet and then consolidation occurs. This is the process where the mucoadhesive substance is joined to the mucus membrane due to the physiochemical forces of attraction resulting in mucoadhesion.

There are various theories present in the mucoadhesion such as..

1.Wetting theory

2. Electrostatic theory

3. Diffusion theory

4. Adsorption theory

5.Fracture theory

## FACTORS AFFECTING MUCOADHESION

- Polymeric factors
- Environmental factors
- Physiological factors

| Polymeric Factors | Environtmental Factors | Physiological Factors |
|---|---|---|
| -Flexibility<br>-Molecular Weight<br>-Hydrogen Bonding<br>-Charge<br>-Concentration<br>-Hydration Properties | -Application Pressure<br>-Initial contact time<br>-Wetting<br>Polymeric-Mucin<br>interface pH | -Mucin turnover<br>-Tissue movement<br>-Mucosal movement<br>-Disease state |

**MANUFACTURING METHODS :**

The following process can be used to manufacture the buccal film.

1.Solvent casting method

2. Hot melt extrusion method

3.Direct milling method.

**1.SOLVENT CASTING :** This technique is most widely used in preparing buccal films, hence it is simple in process and low in cost. Firstly, 'casting solution' is prepared by dissolving water soluble ingredients to form homogenous viscous solution and then dissolving the API and other excipients.After the solution is dried, the films are cutted in specific dimensions with final dosage form to the desired dosage.

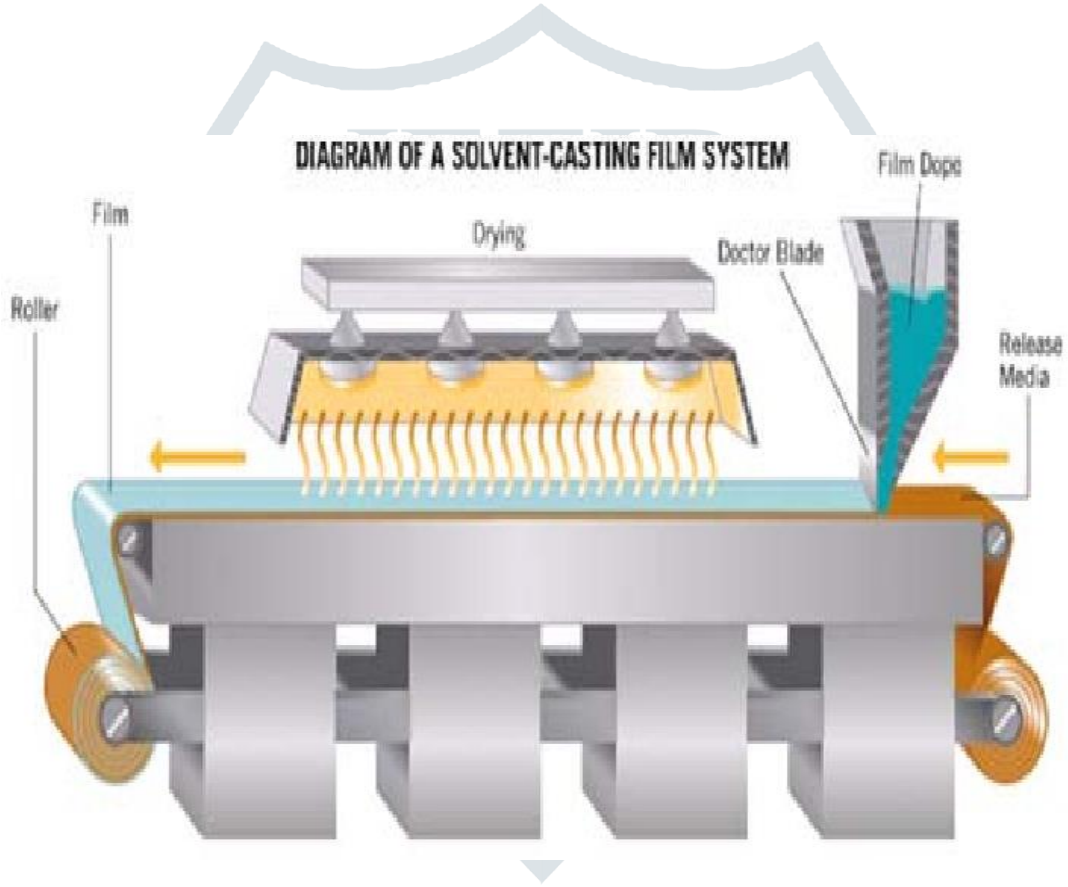



Figure : 1 Solvent casting method

**HOT MELT EXTRUSION TECHNIQUE**:

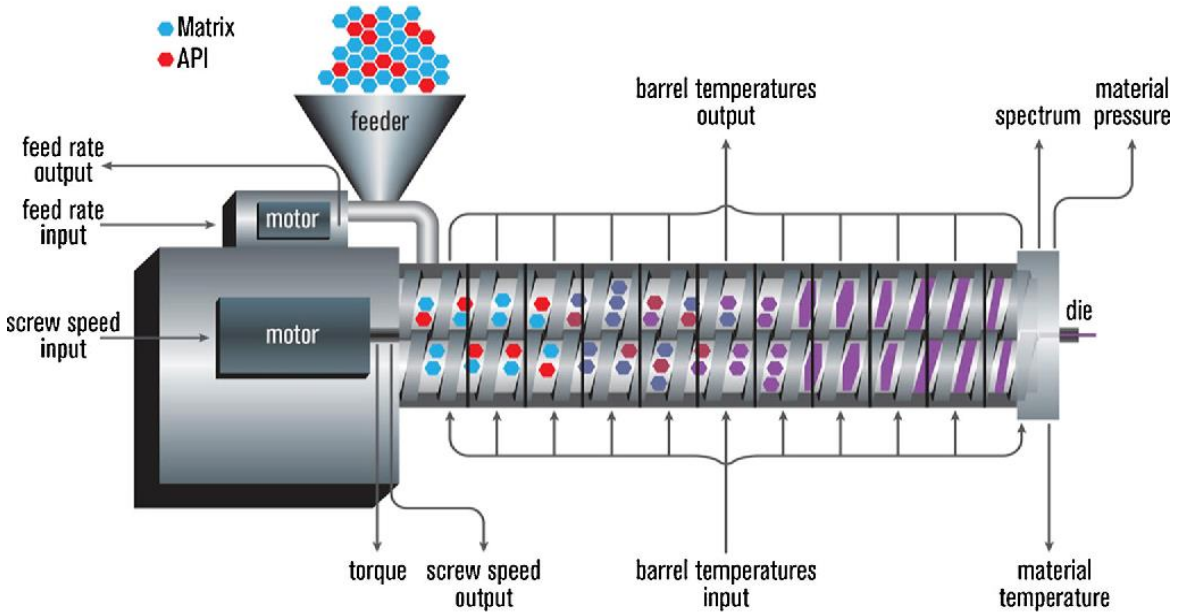
Hot melt extrusion equipment consists of an extruder, auxiliary equipment for the extruder, down stem processing equipment, and other monitering tools.

Steps involved in Hot melt extrusion method:

Step1:The drug is mixed with the carriers in solid form.

Step2:Extruder which are having heaters will melt the mixture.

Step3:Finally the melted mixture is shaped in the form of films.




## DIRECT MILLNG METHOD:

This method is also known as solvent free method.In this method drugs and excipients are mixed without presence of lipid by direct milling or kneading.After completing the mixing procces the material which is formed is then rolled on a release liner until the desired thickness is formed.This method is usually preffered because it avoid possibility of residual solvent and prevents associated solvent-related health issues.

## CHARECTERIZATION OF BUCCAL FILMS:

### Weight and thickness of film:

The film of each formulation is taken and weighed individually on a digital weighing balance for determining the weight of the film.The average weights are calculated. Similarly the films are measured by using micrometer screw guage at three different places and then the mean value is calculated.

### Surface pH of films:

The film is allowed to swell on the surface of agar plate for two hours then the pH paper should be placed on the surface of the film where it is swollen and the mean is calculated with three readings.

### Swelling Index:

After the original weight and diameter have been determined the samples are kept in the agar plate in an incubator at temperature 37 $\pm 0.2°$ for swelling.Three film weight (n=3) are calculated at various time intervals.

The percent swelling is calculated by using following equation:

Percent swelling (%S) $=[Xt\text{-}X_o/X_o]\times 100$

Where,

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

$X_o$=The initial film weight at zero time

**Folding endurance:**

The folding endurance is performed by folding the film repeatedly at the same spot until it breaks and the value is determined by noting down the no.of times of the film until it breaks.

For all of the formulations, dissolving tests are conducted using a USP dissolution apparatus rotating at a constant speed Moisture content:

The films are weighed separately and maintained at room temperature for 24hours in desiccators with calicium chloride.After 24hrs the films are weighed again until the steady value is displayed.To calculate the %moisture content following formula is used,

%Moisture content=[initial weight-final weight]×100

**Drug content:**

The film should be kept in 4.5 acetate buffer solution ,then it is stirred for 24hours in orbital shaker.Then the solution is filtered, and the obtained solution is diluted and observed under UV spectroscopy at 244nm.

The average and standard deviation of drug content for three films are taken and observed.

**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.

**Conclusion:**

The buccal film is the most precise and palatable dose from where it exibits high absorption and avoids the hepatic first pass metabolism.This technique is more innovative and very promising and beneficial to all age people,especially those who are having trouble in swallowing.Comparing to conventional dosage forms buccal films are having many advantages and also it has low cost of production. This technology offers a useful tool for maintaining the medicinal and financial worth of pharmaceuticals.

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