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A MINI REVIEW ON BUCCAL FILMS:AN INNOVATIVE DOSAGE FORM

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ABSTRACT:

Objectives: Buccal drug delivery refers to the delivery of drugs through the buccal mucosal membrane lining of the oral cavity. For geriatric,pediatric patients who undergo difficulties in swallowingoral solid dosage formsthis buccal film is a better alternative.These avoid first-pass metabolism and it is cost-effective. It enhances the efficacy of API in the oral cavity. In the current review we proposed to give information of the advantages, limitations,uses, composition, method of preparation and evaluation of buccal films.

Conclusion: Buccal filmsare most acceptable and palatable dosage forms.

Keywords: Biodegradable, polymers, adhesive, effective, compliance.

INTRODUCTION:

Buccalfilms are the most recently developeddosage formforbuccal administration.They are semi-solid dosage forms which are placed on buccal region and allowed to dissolve.After administration they enter directly into systematic circulation. They rapidly gained acceptance as new route of drug administration due to improved safety, enhanced onset of action.Buccal film is an elegant and effective dosage form with enhanced bioavailability when compared to other buccal dosage forms such as buccal tablets, lozenges, wafers etc., as it by-passes the hepatic first-pass metabolism. They dissolve in the patient's buccal mucosa. The site of drug administration in oral-mucosa is subdivided into buccal and sublingual mucosa.

Buccal film is prepared using hydrophilic polymer that rapidly dissolves on thetongue or buccal cavity.They are preferred rather than buccal tabletbecause of their comfort and flexibility. It provides direct entry of a drug into systematic circulation through the jugular vein which there by avoiding first-pass hepatic metabolism.

Fig.1: Buccal film

Some of the ideal characteristics of buccal films areall degradation products and polymers should not be toxic,poisonousand irritant and must be free from impurities. They should have good spreadability,swelling,wetting,solubility,biodegradability,viscoelasticpropertiesandbiocompatible pH range. It should have an appropriate shelf life without decomposition on storage. It should adhere quickly to the buccal mucosa and should have good mechanical strength.It should have adequate patient compliance without obstructing normal functioning such as talking, eating, and drinking. Dose should be lower than 20mg with low molecular weight.

ADVANTAGES

Buccal films has several advantages such as availability in various sizes and shapes, ease of handling and transportation, fast dissolution, accurate dose administration,enhanced stability and safety and they avoid the first-pass metabolism.

DISADVANTAGES

Buccal films along with advantages it has a few disadvantages such as barrier properties of the oral mucosa, restriction of drinking and eating, drugs with a lower dose requirement can be administered, dilution of drug and swallowing of the formulation due to vigorous secretion of saliva and they are moisture sensitive.

COMPOSITION

Active ingredients:The buccal film technology has the potential for delivery of variety of APIs. Active pharmaceutical substances can be from any Biopharmaceutical Classification System (BCS) class of pharmaceutically active substances that can be given either orally or even by buccal mucosa. To make a successful and effective formulation the drug to be administered should beless than20mg.

Plasticizers: Plasticizers are very important for the formulation of a buccal drug delivery system. They help by improving the mechanical properties of the buccal film which includes tensile strength, elongation of the films.Examples includeglycerol, castor oil, tri-citrate, acetyl tri-ethyl-citrate, and other citrate esters

Sweetening agents: Sweeteners play an important role in the pharmaceutical preparations which have an aim of either disintegrating or dissoluting in the mouth. The natural sources of sweeteners aresucrose, dextrose, fructose, glucose, liquid glucose, and iso-maltose.

Surfactants: Surfactants are utilized as solubilizing or wetting or dispersing agents with the aim that the film gets melted within seconds and liberate the active agent instantly. Surfactants also enhance the solubility of poorly soluble drugs in fast-dissolving buccal films. Examples include polaxamer407, sodium lauryl sulfate, benzalkonium chloride, tweens, and spans.

Flavoring agents:Flavoring agents are used to providing flavor to the product which is also a factor of patient compliance. Peppermint oil, cinnamon oil, spearmint oil, and oil of nutmeg are examples of flavor oils, whereas vanilla, cocoa, coffee, chocolate, and citrus are fruity flavors derived from fruits.

Saliva stimulating agents: The main aim of saliva stimulating agent is to increase the production of saliva and help dissolve the buccal film faster. The concentrations in which they are used ranges from 2% to 6%.

Polymers: Polymers are within easy reach for the production of fast dissolving buccal films. The polymers can be used exclusively or in conjunction to give the required film properties. The film procured should be strong enough to withstand any damage while handling or during transportation. The many polymers employed in production fast-dissolving films includecellulose or cellulose derivatives, pullulan, gelatin, hydroxyl propyl methyl cellulose (HPMC), hydroxyl ethyl cellulose (HEC), hydroxyl propyl cellulose (HPC), polyvinyl pyrrolidone (PVP), carboxymethyl cellulose (CMC), polyvinyl alcohol (PVA), sodium alginate, xanthine gum, tragacanth gum, guar gum, acacia gum.

METHODS OF PREPARATION OF BUCCAL FILMS

Solvent casting method

Preparethe casting solution(API, polymer, distilled water). Deaerate this solution. Transfer the appropriate volume of solution into the mould. Then dry the transferred casting solution. Cut the final dosage form into shapes.

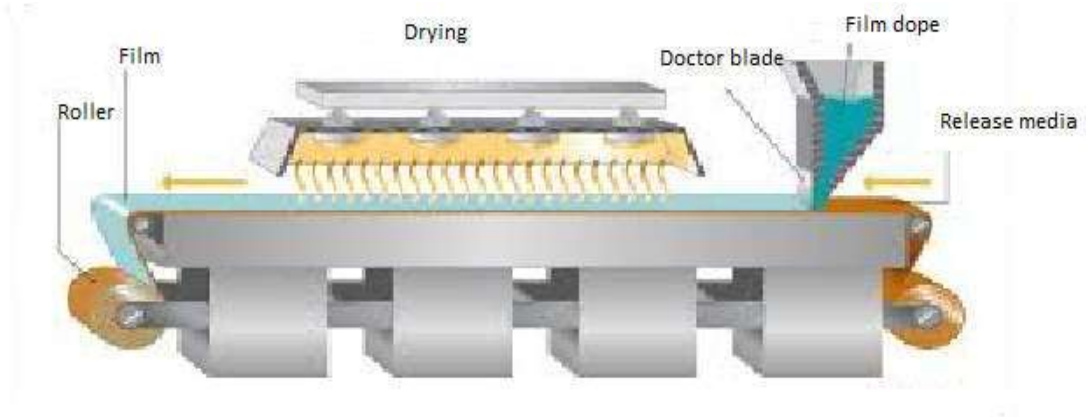

Fig 2: Solvent casting method diagram

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.

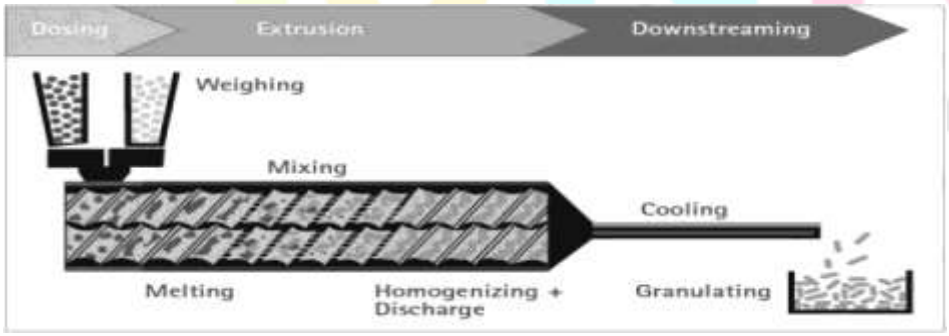

Fig 3: Hot Melt Extrusion method diagram

Solid dispersion method:

Dispersing one or more active ingredients in an inert carrier in a solid state.(in presence of amorphous hydrophilic polymers) is known as solid dispersion. Drug is dissolved in a liquid solvent.Then incorporate this solution into a melt of polyethylene glycol below $70^{O}C$. Obtained solid dispersions are shaped into films by means of dies.

EVALUATION

Weight of the film: Buccal film is weighed by calibrated weighing balance. Individual weight of each film is calculated. Average weight is calculated and compared with standard.

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.

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 section area of fractured film from following equation.

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 2hours 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.

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.

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

PercentageMoisture Loss = (Initial weight-final weight)/Initial weight ×100

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**.**

***in-vitro* disintegration:** It is determined visually in a petri plate 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.

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

Swelling index: The initial weight of the film is determined using a digital balance (W_0). 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 (W_t) at predetermined time intervals for 5 min. The percentage of swelling (% S) is calculated using the following formula

$$\% S = (W_t - W_O)/W_o \times 100$$

Where W_t is the weight of swollen patch after time t, W_0 is the initial weight of patch at t=0.

USES

Buccal films has following uses such as rapid disintegration and dissolution, no need of chewing or swallowing, they increase the systemic bioavailability of the drugs, as it bypasses the hepatic first pass metabolism, drug can be protected from degradation by GI enzymes and the acidic environment, rapid onset of action and minimum side effects, self-administrationand taste masking possible,accurate dosing compared to liquid dosage forms, prolongs the residence time of the dosage form at the site of absorption, hence increases the bioavailability.

CONCLUSION

This is to concludethat buccal film is most acceptable, palatable dosage form. It avoids first pass metabolism and also enhance bioavailability of drug when compared to 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. They are available in low cost and no irritancy in oral cavity. They have good mucoadhesiveproperty and rapid onset of actionwhich enhances safety, efficacy and stability of drug. That is why these are considered as most successful and safe dosage form for all age group patients.

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AUTHORS CONTRIBUTIONS

The literature search, manuscript framing, preparation, design and drafting the article is done by B.Divya.Reviewing it critically for important intellectual content and final editing of the manuscript is done by R.Shireesh Kiran.

CONFLICT OF INTERESTS

The authors have declared no conflicts of interests.

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