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Review on Fast Dissolving Buccal Film: An Emergency Treatment

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Abstract:- Orally fast dissolving films (OFDFs) have been introduced in the market recently as they provide convenience and ease of use over other dosage forms such as orally disintegrating tablets. Fast-dissolving drug-delivery systems is an alternative to tablets, capsules, and syrups for paediatric and geriatric patients which rapidly disintegrate and dissolve in saliva and then easily swallowed without need of water.Mouth dissolving buccal films are advantageous particularly for pediatric, geriatric and mentally ill patients who have difficulty in swallowing conventional tablets. This approach increase therapeutic efficiency of pharmaceutical actives by avoiding hepatic first pass metabolism, deliver drug molecule in control manner, enhance absorption and improves patient compliance.

Keywords: Oral route, Fast dissolving film, pediatric and geriatric patients, rapid absorption, enhanced Bioavailability.

I. INTRODUCTION

Fast-dissolving drug-delivery systems were first developed in the late 1970s as an alternative to tablets, capsules, and syrups for paediatric and geriatric patients which rapidly disintegrate and dissolve in saliva and then easily swallowed without need of water. A film or strip can be defined as a dosage form that employs a water-dissolving polymer(generally a hydro colloid, which may be a bioadhesive polymer),which allows the dosage form to quickly hydrate, adhere, and dissolve when placed on the tongue or in the oral cavity(i.e. buccal, palatal, gingival, lingual, or sublingual) to provide rapid local or systemic drug delivery(1). These oral strips may be flexible or brittle, opaque or transparent.

Buccal mucosa is an attractive route for systemic delivery of drugs since it is relatively permeable with a rich blood supply. A drug can be easily applied and localized to the application site, and can be removed from there if necessary. Attempt has been made earlier to formulate various mucoadhesive buccal devices, including tablets, films, patches, disks, strips, ointments and gels(2).

Formulation of fast dissolving buccal film involves the application of both aesthetic and performance characteristics such as strip-forming polymers, plasticizers, active pharmaceutical ingredient, sweetening agents, saliva stimulating agent, flavoring agents, coloring agents, stabilizing and thickening agents. From the regulatory perspectives, all excipients used in the formulation of oral drug strips should be approved for use in oral pharmaceutical dosage forms. be approved for use in oral pharmaceutical dosage forms.

A. Need of Fast Dissolving Film

- Convenient dosing
- No water needed
- No risk of chocking
- Taste masking
- Enhanced stability
- Improved patient compliance
- The drug enters the systemic circulation with reduced hepatic first pass effect.
- Site specific and local action
- Availability of large surface area that leads to rapid disintegration and dissolution within oral cavity.

B. Special Features of Fast Dissolving films [4]

- Film should be thin and elegant.
- Films are available in various size and shapes.
- It should be Unobstructive.
- It should be easily adhere to the oral cavity.
- Fast disintegration without water and Rapid drug release.

C. Ideal Characteristics Of A Drug To Be Selected [5]:

- The drug should have pleasant taste.
- The drug should preferably have a minimum dose.
- The drug should have small or moderate molecular weight.
- The drug should have good stability and solubility in water and in saliva.
- It should be partially unionized at the pH of oral cavity.
- It should have the ability to permeate oral mucos.

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D. Comparison between orally fast dissolving films and oral disintegrating Tablets [6]

Orally Dissolving Films	**Oral Disintegrating Tablets**
It is a film	It is a tablet
Greater dissolution due to larger surface area	Lesser dissolution due to less surface area
Better durable than oral disintegrating tablets	Less durable as compared with oral films
More patient compliance	Less patient compliance than film
Low dose can only be incorporated	High dose can be incorporated
No risk of chocking	It has a fear of chocking

II. MECHANISM OF ORAL THIN FILM [7]

Oral thin film

↓

Keep in mouth

↓

Disintegrate into small particles by saliva

↓

Through buccal cavity, pharynx, oesophagus, provide better absorption

↓

Quick onset of action-More bio-availability

III. CLASSIFICATION OF ORAL THIN FILM [8]

a) Flash Release wafer
b) Mucoadhesive melt-away wafer
c) Mucoadhesive sustained-release wafer

A. Three types of oral films are differentiate from each other as follows:

Type → Properties	**Flash Release wafer**	**Mucoadhesive melt-away wafer**	**Mucoadhesive sustained-release wafer**
Area (cm^2)	2-8	2-7	2-4
Thickness (µm)	20-70	50-500	50-250
Structure	Film: Single layer	Single or multilayer system	Multilayer system
Excipients	Hydrophilic polymers	Hydrophilic polymers	Low non soluble polymer
Drug Phase	Solid solutions	Solid solutions or suspension	Suspension or solid solution
Application	Tongue (upper palate)	Buccal region	Other region in oral cavity
Dissolution	Max. 60 sec.	Disintegration in few minutes	Max. 8-10 hrs.

B. Component of fast dissolving film [9]:

1) Drug (API)
2) Film Forming Polymers
3) Plasticizers
4) Sweetening Agents
5) Saliva Stimulating Agents
6) Cooling Agent
7) Flavouring Agent
8) Colouring Agent
9) Surfactants
10) Stabilizing and thickening agents

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Sr. No.	Ingredient	Amount	Role of contents	Example
1	Drug(API)	5-30%	Active pharmaceutical ingredients	Antimigrain, Antacid, Vasodilator, Antiallergic, Anti-diabetic
2	Water Soluble polymer	45%	Film forming capability	Hydroxy propyl methyl celullose, Pullulan, Maltodextrin
3	Plasticizer	0-20%	It improves the flexibility and reduces the brittleness of the film	Glycerol, ,Dibutyl Pthalate
4	Saliva Stimulating agent	2-6%	Production of saliva tofaster disintegrationt.	Citric acid, Malic acid, Ascorbic acid.
5	Surfactant	Q.S.	To reduce interfacial tension	Tween-80
6	Sweetening agent	3-6%	Tasking masking agent.	Sucrose, Dextrose, Mannitol, Aspartame, Sorbitol, fructose
7	Flavours,Colours,Fillers	Q.S.	It imparts attractiveness to film.	United State Food and Drug Administration approved

1) **Drug (API):** Variety of API can delivery through FDOTF. It is always used to have microionised API which will improves the texture of the film and allows for better dissolution. eg. Ondansetron HCL, Montelukast Sodium etc.

2) Film Forming Polymers: Water-soluble polymers are used as film formers as they provide rapid disintegration, good mouth feel and mechanical strength to the films. Water-soluble polymers film adheres to the bucosal mucosa and rapidly delivers medication into the systemic circulation. e.g. Gelatin, Hydroxyl propyl methyl cellulose, Modified starches, Hydroxyl ethyl cellulose etc.

3) Plasticizers: It is a essential ingredient of the oral films. The selection of plasticizer depends upon itscompatibility with the polymer and also the type of solvent employed in the casting of film. Itimproves the flexibility of the film and reduces the brittleness of the film. eg. Glycerol, Propylene glycol, Low molecular weight polyethylene glycols, Citratederivatives like triacetin, acetylcitrate, Phthalate derivatives likedimethyl,diethyl,dibutyl derivatives, Castor oil etc.

4) Sweetening Agents: This is used for taste masking of bitter drugs. Natural sweeteners as well as artificial sweeteners are used. Following are the sweetenerswhich are Suitable in FDF formulation:
(a) Water soluble natural sweetener: xylose, ribose, glucose, sucrose, maltose, stevioside etc.
(b) Water soluble artificial sweetener: sodium or calcium saccharin salts, cyclamate salts,acesulfame-k etc.
(c) Dipeptide based sweetener: aspartame

5) Saliva Stimulating Agents: The saliva stimulating agents are used to increase the rate of production of saliva that is helpful in the faster dissolution of the film formulations. eg. Citric acid, malic acid, lactic acid, ascorbic acid and tartaric acid etc.

6) Cooling Agent: Monomethyl succinate is used as Cooling agents which helps to improve the flavour strength and to enhance the mouth-feel effect of the product. Other cooling agents like WS3, WS23and Utracoll II can also be used in conjunction with flavours.

7) Flavouring Agent: The acceptance of oral disintegrating films depends on flavoring agent. Selection of drug is depend on type of drug in the formulation. eg. Peppermintoil, cinnamon oil etc.

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8) Colouring Agent: Titanium dioxide or FD&C approved colouring agents are incorporated (not exceeding concentration levels of 1%w/w) in FDF formulation when some of the formulation ingredients or drugs are present in insoluble or suspension form

9) Surfactants: Surfactants are used as wetting or dispersing agent. By the use of surfactant the film gets dissolved within seconds and release active agent immediately. Solubility of poorly soluble drugs in fast dissolving oral films can be improved by using surfactant. eg. polaxamer 407, benzalkonium chloride, tweens and spans etc.

10) Stabilizing and thickening agents: Generally, to improve the viscosity and consistency of dispersion or solution of the filmpreparation the stabilizing and thickening agents are employed before casting. Natural gumslike xanthan gum, locust bean gum, carragenan and cellulosic derivatives are few examplesof stabilizing and thickening agents.

IV. METHODS OF PREPARATION [10]

One or combination of the following process can be used to manufacture the mouth dissolving films:

1) Solvent casting method:

In solvent casting method water soluble polymers are dissolved in water and the drug along with other excipients is dissolved in suitable solvent then both the solutions are mixed and stirred and finally casted in to the petri plate dried and cut in to uniform dimensions

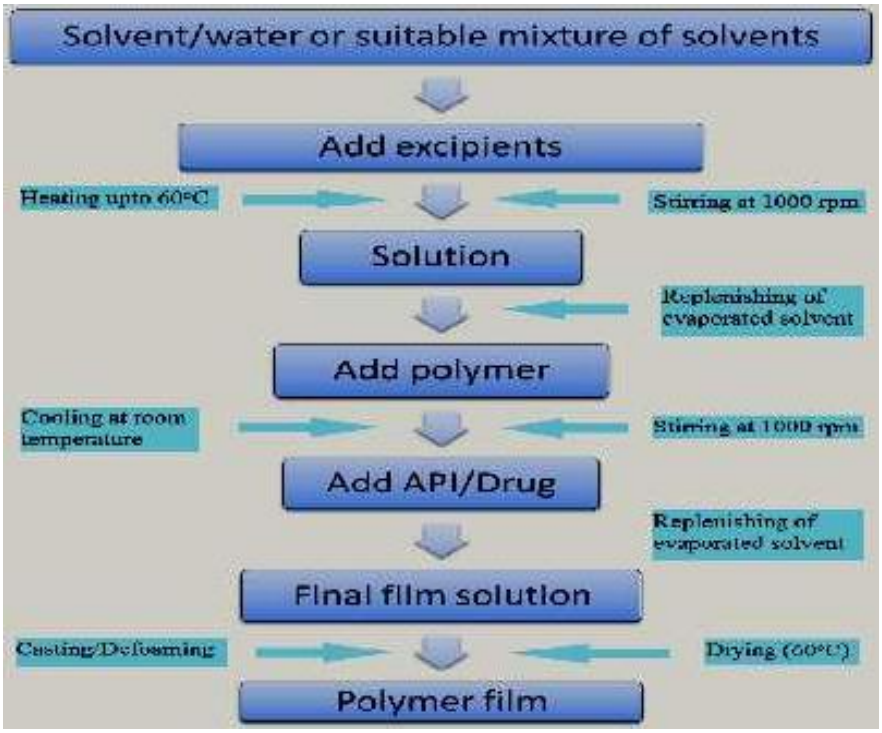

Fig 1. Steps involved in Solvent casting method.

2) Semisolid casting:

In semisolid casting method firstly a solution of water-soluble film forming polymer is prepared. The resulting solution is added to a solution of acid insoluble polymer (e.g. cellulose acetate phthalate, cellulose acetate butyrate), which was prepared in ammonium or sodium hydroxide. Then appropriate amount of plasticizer is added so that a gel mass is obtained. Finally the gel mass is casted in to the films or ribbons using heat controlled drums. The thickness of the film is about 0.015-0.05 inches.

3) Hot melt extrusion:

In hot melt extrusion method firstly the drug is mixed with carriers in solid form. Then the extruder having heaters melts the mixture. Finally the melt is shaped in to films by the dies. There are certain benefits of hot melt extrusion.

- Fewer operation units
- Better content uniformity
- An anhydrous process

4) Solid dispersion extrusion:

In this method immiscible components are extrude with drug and then solid dispersions are prepared. Finally the solid dispersions are shaped in to films by means of dies.

5) Rolling Method:

In rolling method a solution or suspension containing drug is rolled on a carrier. The solvent is mainly water and mixture of water and alcohol. The film is dried on the rollers and cutted in to desired shapes and sizes.

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V. COMMERCIAL THIN FILM ORAL DOSAGE FORM PRODUCTS[11]

Product	Manufacturer	Active Pharmaceutical Agent	Strength (mg)
Triaminic	Novartis	Dextromethorphan HBr	7.5
Triaminic	Novartis	Diphenhydramine HCl	12.5
Theraflu	Novartis	Dextromethorphan HBr	15
Gas-X	Novartis	Simethicone	62.5
Sudafed	Pfizer	Phenylephrine HCl	10
Benadryl	Pfizer	Diphenhydramine HCl	12.5
Chloraseptic	Prestige	Benzocaine Menthol	3/3
Suppress	InnoZen	Menthol	2.5
Orajel	Del	Menthol/Pectin	2/30
Listerine	Pfizer	Cool mint	-

VI. PATENTED TECHNOLOGIES OF FAST DISSOLVING ORAL FILMS

A. XGel[12]

XGel film technology is developed by BioProgress which causes a revolution in the product offerings and manufacturing methods which is now available to the pharmaceutical industry. These films may be coloured or printed during manufacture for branding and coding which is quite helpful in product identification and also developed for non-ingestible applications such as cosmetic, ostomy pouches, sanitary and healthcare pouches . These films enhance the stability of product.

B. Soluleaves [12]:

In this technology, the film on coming in contact with saliva releases its active ingredients, during this film adhere to the mucous membrane in order to release the drug slowly in 15 min. This method is useful for those who have difficulty in swallowing conventional tablets. This technology is applied to flavoured products such as mouth fresheners, confectionery and vitamins

C. Wafertab [13]

Wafertab is a drug delivery system which incorporates pharmaceutically active ingredients into an ingestible film strip. When film came in contact with saliva it provides rapid dissolution and release of active ingredient. The Wafertab film strip can also be flavoured for additionally improved taste masking. The active ingredient is integrated into the body of a fused.

D. Foamburst [13]

Foamburst is a new patent granted in September 2004 which is for capsules made of formed film. During production an inert gas is blown into the film, results in a film with honeycomb structure as a capsule which dissolve rapidly and causing a melt-in-the mouth sensation. The void in the film may be gas-filled, empty or filled with other materials to produce specific taste burst characteristics or deliver active drugs.

VII. CONCLUSION

From the above, this can be concluded that fast dissolving films have proved as beneficial innovative tool for all groups of population or all groups of patients that having problem of swallowing .Fast dissolving films play vital role when quick onset of action is required .Pharmaceutical Industries also recognized the potential of fast dissolving film and also launched several products. Gaining importance as they are idea l dosage form for use in young children, as well as geriatric patients.

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