



A Review on Quick Release mouth Dissolving film as a Convenient Dosage form for Oral delivery

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ABSTRACT

For the preceding two decades, there has been a heightened demand for more patient-compliant dosage forms. Modern progresses in the technology have offered viable dosage substitutions from oral route for pediatrics, geriatric, bedridden, nauseous or noncompliant patients. Buccal drug delivery has newly become a chief route of drug administration. Numerous bio-adhesive mucosal dosage forms have been established, which includes adhesive tablets, gels, ointments, patches and more recently the usage of polymeric films for buccal delivery, also identified as mouth dissolving films. Due to fast dissolution it afford sooner onset of action, sidestepping the first pass metabolism, dropping gastric degradation and metabolism of drugs and thus enhance their oral bioavailability. These properties of oral films with patient convenience and compliance made prevalent and accepted dosage form for pediatric and geriatric as well as adult residents. The present review offers up to date review in fast dissolving oral films so investigators can easily track various technologies/research in design and development of oral fast dissolving film.

Keywords: Mouth dissolving film, Hydrophilic polymers, Formulation consideration, Manufacturing techniques, Evaluation parameters.

INTRODUCTION

Diversities of the medicinal inventions are there in the arcade which embraces active components as well as Excipients to create a biocompatible curative product. Pharmaceutical inventions like tablet, capsules, syrups, ointments are extensively acknowledged and believed globally. Therapeutic efficacy of the drug has a prodigious impression on the drug conveyance system. Out of all drug delivery system, oral route is most favored route as they are stress-free to administer, charge effective and suitable to use ¹. The difficulty ascends in the aged, pediatric, bed ridden, non-compliance and wozy patient because of difficulty in swallowing the conservative oral formulations. Throughout the population, 50% of the population was exaggerated by this problem which grades in unproductive therapy ². Magnitude of the dosage form, palate and surface form were the mutual criticism concerning the oral dosage form. Travelling patients also agonized from the problem of taking oral dosage form because of un approach ability of water ³.

History of Fast Dissolving Oral Films

Fast dissolving oral films was first familiarized by North America in 1970 ⁴. At that period, the oral films were introduced as mouth fresheners and personnel care merchandises. Pfizer was the founder designer of fast dissolving films who entitled it as Listerine® pocket packs™ and it was used as a breath freshener. However, European markets and United States promptly framed fast dissolving films ⁵. At this moment there are 15 companies which formulating oral fast dissolving films by

ever-changing from formulation of tablet dosage form. The report ascertains that Lab tec GmbH, APR settled a unique technology for the formulation of oral fast dissolving films. In the preceding few years, oral strips get admiration in the breath freshening by rapidly dissolves to discharge minty flavor. Pharmaceutical companies are now making these oral strips as over the counter and prescription pharmaceuticals ⁶.

Mechanism of Absorption through Oral Mucosa

For passive drug transference, around two penetration passage ways through the oral mucosa which are Trans cellular (intracellular, passing through the cell) and Para cellular (intercellular, passing around the cell). Drug fragment can use together of the track concurrently however one track is favored over the former depending upon physicochemical possessions of the drug. Cell membrane is lipophilic in nature and has trouble in permeation of hydrophilic solutes because of low partition coefficient. The lipophilic compounds are having little solubility in passive transport system because of the intercellular places which actions as an obstacle to permeation. Meanwhile the oral epithelium is stratified and solute permeation is conveyed by the amalgamation of these two itineraries. Hence, the route which has fewer amount of prevention to passage is favored over the other for permeation through oral mucosa ⁷.

Special Features of Mouth Dissolving Film

- ❖ Tinny sophisticated film
- ❖ Decent mucoadhesion



- ❖ Accessible in numerous form and extent
- ❖ Stress-free for administration
- ❖ No prerequisite of water to swallow
- ❖ Debaunched dissolution and disintegration
- ❖ Prompt drug freedom
- ❖ Elude obnoxious perception of the drug
- ❖ Possibility of clogging and asphyxia throughout oral administration is evaded.
- ❖ Circumvent first pass result
- ❖ Leave least or no remainder later the administration.
- ❖ Afford benefit of liquefied medication in the form of solid preparation⁸⁻¹¹.

Limitations of Mouth Dissolving Film

- ❖ Drugs which are insecure at buccal pH cannot appropriate.
- ❖ Drugs which annoy the oral mucosa can't be proper for administration by this itinerary.
- ❖ High dose range is not allowed for this dosage form.
- ❖ Most of the drug have bitter taste and need taste masking.
- ❖ Oral films require special packaging because of its fragile nature.
- ❖ Dose uniformity is critical challenge.
- ❖ Oral films are moisture sensitive.
- ❖ This site of administration is not suitable for sustained release dosage form.
- ❖ This type of administration interferes with talking, drinking and eating¹²⁻¹⁵.

Selection Criteria of Drug

- ❖ It should have agreeable perception.
- ❖ Beneficial dose of the drug has a duty to not more than 40mg.
- ❖ The drug should have stumpy molecular weight and mass.
- ❖ The drug had better solubility in water and saliva.
- ❖ It ought to be incompletely ionized at pH of buccal cavity.
- ❖ The drug has a duty to reveal least sympathy to ecological conditions.
- ❖ It should have the talent to pervade the oral mucosa¹⁶.

Selection Criteria of Polymer

- ❖ The polymer should be non-toxic, non-irritant.
- ❖ It should having good wetting ability and spread ability.
- ❖ Polymer should have sufficient peel and tensile strength.
- ❖ The polymer should not very expensive.
- ❖ It should be easily available.
- ❖ It should not retard disintegration time of the film.
- ❖ Polymer should be tasteless.
- ❖ Molecular weight of the polymer should not be greater¹⁷⁻¹⁹.

Formulation Consideration of Mouth Dissolving Films

The constituents who include in the design of mouth dissolving films are as follow.

- ❖ Active pharmaceutical ingredients
- ❖ Film forming agent
- ❖ Sweetening agent
- ❖ Saliva stimulating agent
- ❖ Flavoring agent
- ❖ Coloring agent

We will deliberate about each ingredient one by one.

Active pharmaceutical ingredients

Drug fragment is the chief element of the film and it covers 1-25% of the film. Numerous categories of active components can be used for the preparation of mouth dissolving film. Lesser dose molecules are the greatest to be merged in the oral films. It is obligatory to cover the acrimonious taste of the drug when the drug is having bitter taste. A number of class of the drug can be incorporated which are antiulcer (omeprazole), antihistamine (salbutamol sulphate), anti-tussives, expectorants and NSAID's^{20, 21}.

Film forming polymer

Hydrophilic and biocompatible polymers are the mainstay of the oral films⁴². The extent of the polymer illustrates the robustness of the film. Polymers used in the formulation are having the prominence for such variety of formulation. The properties like robustness, folding and disintegration time are contingent on the concentration of polymers added into the formulation. Usually 45% w/w of the polymer is used as compared to total mass of the film. The polymers which are having the hydrophilic property are suited for this formulation⁴³.

Examples: HPMC E3, E5 and E15, pullulan, sodium alginate etc.



Table 1: Formulations of mouth dissolving films

Sr. No.	Name of Drug	Film forming polymers used	Plasticizers used	Solvents used	References
1	Nicotine di picrate	HPMC	Glycerin, PEG 400	Distilled water	22
2	Atomoxetine hydrochloride	HPMC E5	Propylene glycol	Ethanol, Water	23
3	Chlorpromazine	PVA, HPMC E5, HPMC E15,	Propylene glycol	Distilled water	24
4	Tramadol hydrochloride	HPMC E5, HPMC E6,	Polyethylene glycol 400	Distilled water	25
5	Amlodipine besylate	HPMC E3, E5, E15, Microcrystalline cellulose	PEG 400, PVP, SLS	Distilled water, Methanol	26
6	Donepezil hydrochloride	Sodium alginate, PVP, Guar gum, Cross povidone, Cross Carmelose sodium, Sodium Starch glycolate	Glycerin	Distilled water	27
7	Acetaminophen	HPMC A5, E5, E15,	Polyethylene glycol 400	Distilled water	28
8	Aprepitant	Pullulan	Polyethylene glycol 400	Distilled water	29
9	Diazepam	HPMC E3, E5, E15	Polyethylene glycol 400, Propylene glycol	Methanol and Dichloromethane	30
10	Dicyclomine hydrochloride	PVA, HPMC E15, HMPC E50:Eudragit HPMC-15:PVA	Polyethylene glycol 400	Distilled water, Ethanol	31
11	Etoricoxib	HPMC 15 cps	Glycerin	Distilled water	32
12	Losartan potassium	HPMC 5 cps, Na-Carboxy methyl cellulose, Na-Alginate, Gelatin	Glycerol	Distilled water, Methanol	33
13	Olanzapine	HPMC E5, Na-CMC	PEG 400, Glycerin	Ethanol 95%, Acetone	34
14	Ondansetron hydrochloride	HPMC E5, Taro gum,	Glycerin	Distilled water	35
15	Promethazine hydrochloride	HPMC E 15	Polyethylene glycol 400	Distilled water	36
16	Rofecoxib	HPMC E15, Polyvinyl alcohol	Glycerin, Polysorbate 80	Distilled water, Ethanol	37
17	Sumatriptan succinate	HPMC E5, E15, Polyvinyl alcohol	Polyethylene glycol 400	Distilled water, Methanol	38
18	Tadalafil	HPMC E5, E15	Polyethylene glycol 400, Propylene glycol	Distilled water	39
19	Meloxicam	HPMC E6,	Polyethylene glycol 400,	Distilled water	40
20	Valsartan	HPMC E5, E50, K4M	Propylene glycol	Distilled water	41

HPMC

HPMC is shortened as Hydroxypropyl Methyl Cellulose. HPMC is a kind of non-ionic cellulose mixed ether. It is a multi-functional polymer used in the pharmaceutical inventions as a thickener, dispersants, emulsifier and film forming agent. It is odorless, tasteless and non-toxic white powder can be dissolved in cold water to precede transparent viscous solution. As film forming polymer in the grounding of oral thin films, it progresses the dissolution proportion of the drugs. HPMC is having good water preservation property and evade cracking of the film. Various grades of HPMC are available in market which is given below⁴⁴.

Table 2: Pharmaceutical grades of HPMC⁴⁵

Type	Viscosity	Remark
E5	4-5.5	2910(E)
E6	5.6-7.0	
E15	12.1-18.0	
E4M	3000-5000	2208(E)
K100	91-120	
K4M	3000-5000	
K100M	80000-120000	

Pullulan

Pullulan is extracellular polysaccharide created by the fungus *Aureobasidium pullulans*, used in food and pharmaceutical industries. It is speedily dissolve in water to form a stable, tacky solution that does not gel. Its solubility can be amended by esterification, etherification or cross linking to make more advantageous formulations. Pullulan solution conveys high asset to paper and wood and stick to inorganic substances such as wood, glass and metal when smeared and dried out. Pullulan comprehending oral thin films dissolves speedily in warm or cold water three times quicker than PVA films. These films are heat stable and do not misplace its flexibility and elasticity⁴⁶.

Sodium Alginate

Sodium alginate gradually soluble in cold water form viscous or colloidal solution. It is insoluble in alcohol and hydro-alcoholic solutions in which alcoholic content is superior to 30% by weight. It is ordinarily used in the formation of mouth dissolving film as a ordinary film former. It has a greater struggle of moisture. It is used as a thickener and emulsifier in a number of preparations⁴⁷.

Plasticizer

Plasticizer acts as a chief building block for the preparation of fast dissolving film after the film forming polymer. It organizes 40% of the aggregate weightiness of the film. It supports to progress the elasticity of the oral film and also diminishes the breakability⁴⁸. The mechanical properties of the film are exaggerated by this polymer. Mechanical properties like tensile strength as well as elongation of the film are upgraded by the accumulation of plasticizer⁴⁹.

Examples: Glycerol, Dibutyl phthalate and polyethylene glycols etc.

Saliva stimulating agent

The frequency of the creation of the saliva in the oral cavity is amplified by the saliva stimulating agent. It is having the advantage that it raises the disintegration of the film afterward positioned into the oral cavity. Customarily acids are used as saliva stimulating agents⁵⁰.

Examples: - Citric acid, malic acid, lactic acid and ascorbic acid etc.

Colors, flavors and sweeteners

FD & C sanctioned coloring agents are used for manufacturing of the oral films. Some of the colors added into the formulations are titanium dioxide, silicon dioxide etc⁵¹.

Flavors are added for fragrance hiding and to upsurge the demand of the film. This is a chief issue for pediatric patients. Peppermint oil and cinnamon oil are the common example of the flavors employed in the pharmaceutical preparations⁵².

Mostly 3-6% w/w of the sweetener is added into the formulation. Sweeteners are auxiliary for the purpose of enlightening the tastiness of the dosage form. Mostly employed sweeteners are saccharin, cyclamate, aspartame and sucralose etc⁵³.

Methods of the Preparation of Mouth Dissolving Film

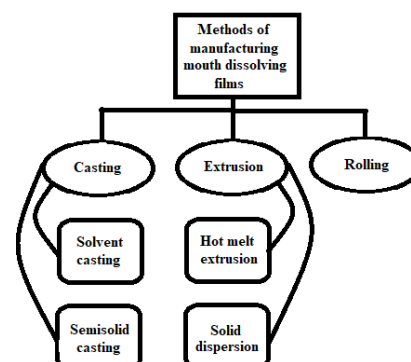


Figure 1: Conventional approaches for manufacturing mouth dissolving films.

Solvent casting method

Further most favored direction for the preparation of mouth dissolving film is solvent casting method. In this manner, water soluble constituents are liquefied to form the perfect gummy solution. Active constituents and other agents are liquefied in lesser volumes of solution and then shared with the bulk. Confiscate entrapped air by caring the solution overnight. Resulted solution is casted as film and dried out. At last, cut it into the pieces of the preferred sizes.

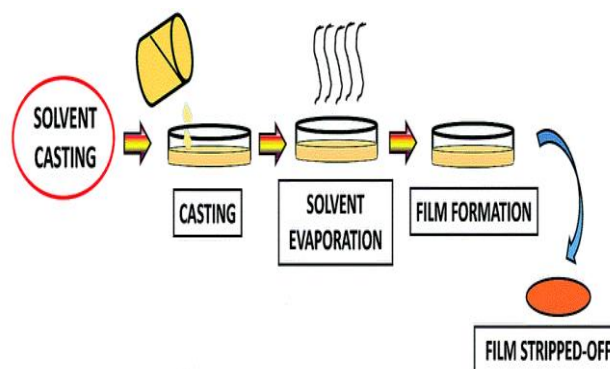


Figure 2: Diagram for solvent casting technique

Semisolid casting method

In this practice, water soluble film forming solution is organized and the consequential solution is added to a solution of acid insoluble polymer (cellulose acetate phthalate) which was prepared in ammonium hydroxide. The suitable quantity of plasticizer is added so that a gel mass is achieved. The resultant solution is casted into the film by consuming heat controlled drums. The proportion of acid insoluble polymer to film forming polymer had better be 1:4.

Hot melt extrusion method

In this scheme, parched constituents are heated as well as homogenized by action of extruder till they are mixed. The igneous material is enforced over and done with flat extrusion die that authorize the material into the favored film shape. Due to hot nature of the material, thickness and strength of the film is exaggerated. The resulted film is cooled, cut and then packed.

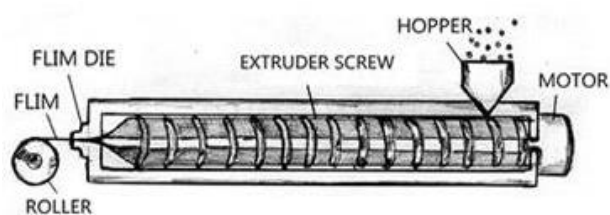


FIGURE: HOT MELT EXTRUSION

Figure 3: Hot melt extrusion method

Solid dispersion extrusion

Solid dispersion is organized by extruding the immiscible constituents by way of the drug. As a final point solid dispersions are fashioned into the films by means of the dies.

Rolling method

The drug comprehending solution is roll along on a carrier. Customarily water or fusion of water and alcohol is used as a vehicle. The film is dried out into the rollers and cut into the chosen sizes⁵⁴⁻⁵⁷.

Evaluation of Mouth Dissolving Films

Organoleptic evaluation

Color, odor and taste were assessed as an organoleptic property.

Physical appearance and surface texture

Corporeal form was tested by optical scrutiny and outward smoothness was evaluated by way of touch or responsiveness of the film.

Thickness

It was measured through digital vernier caliper with least count of 0.01mm at three altered spots of the film at that moment middling of them was to be deliberated.

Weight variation

Drug content uniformity is straightly concern with the thickness of the drug subsequently it is obligatory to ascertain uniformity in the thickness of the film. It was measured by the micrometer screw gauge or vernier caliper at three unlike spots of the film and the mediocre of the film is to be taken.

Tensile strength

It is nothing but the maximum stress applied to the point at which the strip specimen disrupts.

$$\text{Tensile strength} = \frac{\text{Load at failure} \times 100}{\text{Strip thickness} \times \text{Strip width}}$$

Percent elongation

As soon as stress is applied, a strip model expands and this is mentioned to a strain. A strain is ultimately the deformation of the strip divided by means of the original dimension of the sample.

$$\text{Percent elongation} = \frac{(L - L_0) \times 100}{L_0}$$

Where L was the Final length and L₀ was initial length.

Principally, elongation of the strip improves as the plasticizer content upsurges.

Folding endurance

It is determined by the continual folding of the strip at the identical point till the strip disrupts. The figure of folding deprived of breaking is deliberated as folding endurance value.

Surface pH

The films were permissible to swell in secure petri plate at room temperature for 30 minutes in 1 ml of distilled water. Solution was positioned underneath the digital pH meter to conclude the surface pH.

Disintegration time

It elaborates knowledge about the disintegration physiognomies of the film. The obligatory size of the film was positioned in a beaker encompassing 25 ml of pH 6.8 simulated salivary fluids. The time taken by the film to disrupt and liquefied into the fluid is to be measured as in vitro disintegration time.

In vitro dissolution studies

This learning for altogether the consignments of the film was accomplished for five minutes and every single film was positioned with the assistance of forceps in a 50 ml glass beaker covering 30 ml of simulated salivary fluid pH 6.8. Dissolution medium was reserved at 30 °C ± 0.5 °C and magnetic stirrer was rotated at 50 rpm. The sample (5 ml) was withdrawn at 15 seconds, 30 seconds, 1, 2, 3, 4, 5 minutes and switched with renewed simulated salivary fluid pH 6.8. The models were scrutinized for the drug released using UV visible spectrophotometer.

Drug content

It can be experienced by the UV Visible spectrophotometer. Films of every consignment was located in different 100 ml volumetric flask and can be liquefied using the pH buffer and bulk was made up to 100 ml. 5 ml of sample was withdrawn and shifted to 10 ml volumetric flask and bulk was made up to 10 ml. The absorbance of the resultant solution is measured in contradiction of blank in UV spectrophotometer. The percentage drug content was determined using the standard graph. The mean and standard deviations were premeditated⁵⁸⁻⁶¹.

CONCLUSION

Recently Fast dissolving films have multiplied admiration as dosage forms for the mouth fresheners. In the intervening time pharmaceutical industries have renowned their prospective for delivering curative products and have thrown several products for the OTC market by consuming this technology. Mouth dissolving films are a very appropriate dosage form for youngsters and the elderly, as they are relaxed to swallow and encompass no possibility of choking. Mouth dissolving films have superior patient agreement and may advance biopharmaceutical properties, improve usefulness and better safety, compared with unadventurous oral dosage forms. The main downside is with drug loading. Drug loading is generally narrow to roughly 40 mg. This problem can be unraveled by increasing the thickness of the film, but that in turn may increase the disintegration and dissolution time. Due to nonexistence of standard methodology for preparation and analysis products existence in the market is limited.

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