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A Review On: Mouth Dissolving Film

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ABSTRACT

Mouth Dissolving Film is the solid oral drug delivery system, in which water soluble polymer involve to disintegrate film into mouth fastly. Mouth dissolving film keep into mouth it rapidly disintegrate into mouth absorb via mouth and directly reach into systemic circulation via avoiding first pass metabolism. Basically those drug irritate to gastro intestinal tract, suffering from first pass metabolism, having less dose and shows sufficient water solubility eligible for preparation of mouth dissolving film. To make mouth dissolving film mostly anti-inflammatory, antiemetic, anti-allergic, antihypertensive and anti-epileptic drug used. In this article we have given drug eligibility criteria for making film, Formulation aspect, advantages, method of preparation and Evaluation parameter for mouth dissolving film. Briefly explain studies on drug along polymer and for disease.

I. INTRODUCTION

At present situation formulation research modified in such way that, drug targeting to different site via various targeting drug delivery system. Instead of developing generic molecule formulator prefer new drug delivery system and avoiding tedious molecule development process. Oral drug delivery is mostly preferred drug delivery and commonly used drug delivery system there are certain advantages like dose uniformity, self use and stable delivery.(1) Oral thin film was first develop in 1970 as a novel dosage form and film were launched in 2004 for systemic drug delivery.(2) Fast dissolving oral disintegrating film in advance form which instant drug release from dosage form (within 1 min) and rapid absorb via mouth as a result quick reach into blood circulation hence maximum bioavailability is been achieved.

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There are criteria to incorporate API into film like drug should have low molecular weight, less dose, should not be bitter, it should be absorb via mouth. Then only we can formulate oral thin film. Most commonly thin film having the area 2*2 cm^2, due to more surface area is help to dissolve or disintegrate easily and within less time it reach into systemic circulation.(3) Oral thin film contain some water soluble polymer, saliva stimulating agent, sweetener and plasticizer. Some hydrophilic polymer form matrix so within that matrix incorporate drug when it come in contact with saliva it will quickly disintegrate and absorb fastly.(2) Polymer plays an important role while making film some synthetic polymer like HPMC, HPMCE-15, HPMCE-5, PVA and Natural like Pullulan is used. Sweetener is used to mask bitter taste ex. Sodium Saccharin, Sucralose. Plasticizers is used to maintain flexibility and elastic nature of film Ex. PEG-400, Tween-80.

The disease like allergy, hypertension, angina, epilepsy, severe pain dominantly treat by using film mostly commonly used in pediatrics, Geriatrics, Bedridden patient. Those drug shows first pass metabolism, gastric irritation, having less dose and less molecular weight it will be eligible for making film formulation.(3)(4) Generally 45% w/w of polymer used based on total weight of film concentration of polymer decide transparency of film. High amount of polymer leads to thickness of film as a result more time take for disintegration it means more time required for dissolution and bioavailability.

Selection of Drug Candidate for MDF

While selecting drug candidate for mouth dissolving, some characteristics of drug molecule should be keep into the consideration. Molecular weight of drug should be low so it easily cross the membrane. Drug should have lose upto 40 mg. if more dose of drug then there may be chances of crystallization of drug into the film. Drug should not be bitter, should not cause irritation to mucosa, drug does not show adverse effect like discoloration of teeth. In most of film formulation drug should be BCS class 1 because high solubility and High permeability. Due to sufficient solubility in water, helps to easily dissolve in the water soluble polymer and also improve the permeation. Most of the NSAID cause gastric irritation so such kind of drug candidate eligible for the film formulation. The drug mostly used for immediate action in that Mouth dissolving film approach used.(5)(6)

Formulation of Mouth Dissolving Film

1. API

Selection of API in the film formulation very critical task. Because capacity of drug loading into the film is very low. So upto 40 mg API can load into the film. Drug should not be irritant, bitter. Most commonly, the drug which cause gastric irritation and first pass metabolism eligible for film formulation. Drug should have sufficient water solubility and permeability means belong from BCS Class 1 Drugs.(7)

2. Film forming polymer

Mainly water soluble polymer used in preparation of film. Concentration of polymer plays important role while making film formulation. If the concentration of polymer is more in that case it take more time for dissolution purpose. Ultimately thickness of film also be more. Concentation of polymer also plays role in the folding endurance of film, low concentration leads to the minimum folding endurance as a result very easily film breaking capacity which folding of film. There are

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two type of polymer used natural and synthetic polymer. Natural Polymer Include Pullulan, Gelatin, guar gum, xanthan gum. Synthetic polymer Include Hydroxyl propyl methyl cellulose (HPMC), Modified starches, PVPK30, PVA etc. HPMC E3/E5/E6/E15.(8)

3. Saliva Stimulating Agent

These are the agent which responsible for the production of saliva. When we keep film into the mouth so for the dissolution purpose we need saliva therefore adding of the saliva stimulating agent into the formulation. If more amount of the saliva in the mouth then film dissolve easily and very less time. The basically used saliva stimulating agent include Citric acid, tartaric acid, ascorbic acid ,lactic acid and malic acid. (9)

4. Plasticizer

Plasticizer plays an important role in to give flexibility to film. For the formulation purpose flexibility, tensile strength, elongation is very necessary so with adding of plasticizer we can get all this properties in the film. Concentration of plasticizer also impact on the film formulation like more amount of plasticizer in the film leads to turbidity to the film. Commonly used plasticizer include Tween 80, PEG-400.(10)

5. Colouring Agent

Colouring agent agent colour to the film. In some the cases some problem observed like bubble entrapment and transparency donot maintain so in such kind of cases we can add colouring agent. Most commonly used colouring agent include FDC approved natural coloring agents and natural juice. (11)

6. Sweetener

Sweetener is added in the formulation for the purpose of sweetening effect to the formulation. Some of drug having very bitter in taste so in that case we are adding sweetener. Most commonly used sweetener include Sodium Saccharin, Mannitol, Aspartame, Neotame.(9)

Marketed Product of Film (12)

Product	Manufacture	API	Strength
Donezepil	Labtec GmbH	Donezepil HCl	5/10
Theraflu	Novartis	Dextromethorphan HBr	15
Orajel	Del	Menthol/Pectin	2/30
Ondansteron	Labtec GmbH	Ondansetron	4/8
Suppress	InnoZen	Menthol	2.5
Triaminic	Novartis	Diphenhydramine HCl	12.5
Chloraseptic	Prestige	Benzocaine/Menthol	3/3
Sudafed	Pfizer	Phenylephrine HCl	10

Method of Preparation of Mouth Dissolving Film

1. Solvent Casting Method

In this method dissolve water soluble polymer (Like HPMC E5,E15) in water. Stir the soluble till completely soluble and make transparent solution. In another beaker dissolve drug into the water stir the solution till completely soluble. In another beaker dissolve remaining excipient like preservative, sweetener, flavor into the water. At the end mix polymer solution into the excipient solution and sonicate for 10 min. finally drug solution add into the above solution and sonicate the solution for 10 min to remove entrapped air bubble. After that pour the solution into the petri plate dish and keep into the hot air over for 24 hr at 30˚C. (13)

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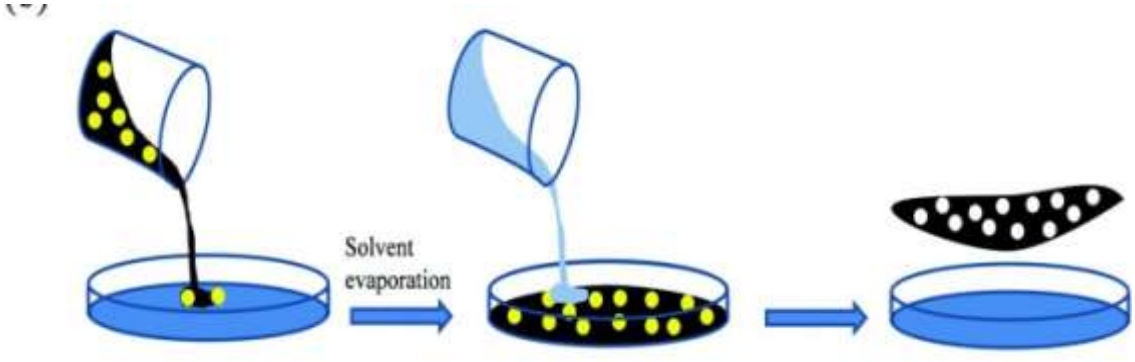
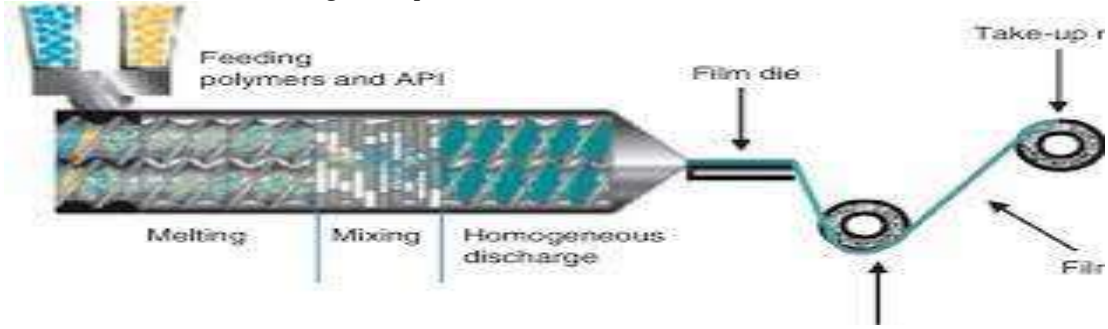
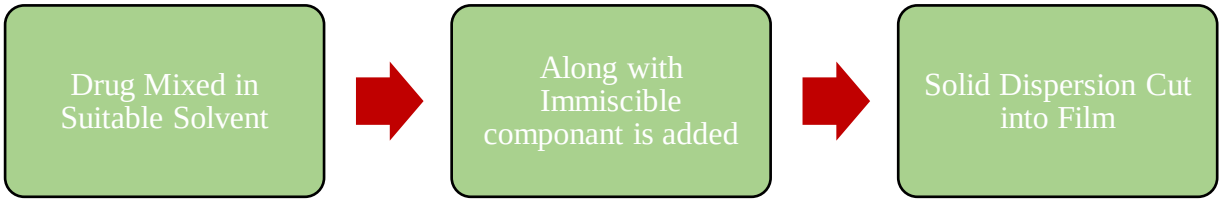


2. Hot melt extrusion

Hot melt extrusion technique involve shaping of polymer. In this method polymer substance and drug molecule allow in the high temperature. Due to high temperature solid convert into molten state which on further give shape to the solid material and finally converted into the film. This method do not any kind of solvent system as like solvent casting method, its solvent free method. But if the drug or polymer is thermoliable so we cannot proceed with this method.(8)



3. Solid Dispersion Method (14)



4. Semi Solid Casting Method

In this method water soluble polymeric film is prepared then the polymeric solution is added to acid insoluble polymeric solution .The sufficient quantity of plasticizers is added to obtain gel, the gel is casted into plate by required thickness. The acid insoluble polymer and water soluble polymeric solution should be in the ratio1:4(15)

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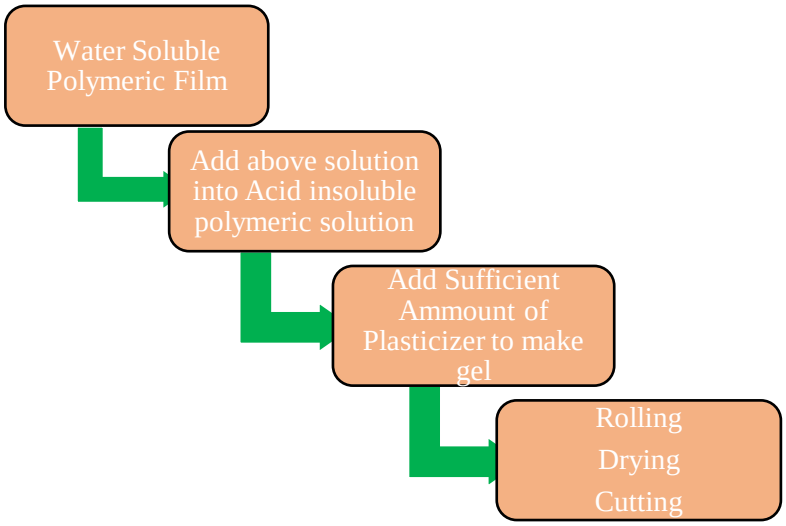

5. Rolling Method

In this method , 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 cut in to desired shapes and sizes. (16)

Mouth Dissolving Film Studies on Drug & Polymer

Sr.No	Name of Drug	Name of Polymer	Use	Reference
1	MONTELUKAST SODIUM	HPMC, PVA, SSG	asthma	(17)
2	Losartan potassium	HPMC, NA-CMC, Gelatin, Na Alginate	hypertension	(18)
3	RIZATRIPTAN BENZOATE	HPMC E5 & 15, Pullulan gum	arthritis, primary dysmenorrhea,	(19)
4	Amlodipine Besylate	HPMC E3, E5, E15.	hypertension and angina pectoris	(20)
5	Diazepam	HPMC E3, E5, E15	antiepileptic	(21)
6	domperidone	B Cyclodextrin, HPMC E15	antiemetic	(22)
7	ROFECOXIB	HPMC	osteoarthritis and dental pain	(23)
8	PROPRANOLOL HCL	HPMC E15	Hypertension	(24)
9	Lercanidipine HCl	HPMC E5, E15 and PVA	hypertension and angina pectoris	(25)
10	Zolmitriptan	sodium alginate, xanthan gum and sodium starch glycolate, guar gum.	migraine	(26)
11	Sumatriptan Succinate	HPMC E5, E15, PVP K30	migraine	(27)
12	Aceclofenac	Cyclodextrin, HPMC E5 &HPMC E15LV	Anti-inflammatory	(28)
13	KETOROLAC TROMETHAMINE	PVP, HPMC E15 LV	Pain management	(29)
14	TRAMADOL HYDROCHLORIDE	Pullulan, HPMC E5, HPMC E15, HPMC E6 and Sodium Alginate	Pain management	(30)(31)
15	Meloxicam	PVP	anti-inflammatory	(32)
16	PARACETAMOL	HPMC, SLS	Antipyretic	(33)
17	Levocetirizine	hydroxyl propyl β-	antihistamine	(34)

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	dihydrochloride	cyclodextrin, Xanthum gum , pullulan	drug	
18	METOPROLOL TARTRATE	HPMC E5	hypertension , angina pectoris and arrhythmia	(35)
19	Amphotericin B	Maltodextrin, Avicel 200	Antifungal	(36)
20	Dicyclomine	HPMC PVA	antispasmodic	(37)
21	Phenobarbital	METHOCEL- E 15, HPC(LV), SSG, Croscarmellose sodium.	Treatment of Epilepsy	(38)
22	Piroxicam	β-cyclodextrin, sodium CMC, chitosan, crospovidone, sodium starch glycolate	NSAID	(3)

Evaluation

1. Appearance, Size, Shape and Thickness

Thickness of film decide the dissolution rate, if the film thick then dissolution rate will be less and vice varsa. Thickness of determine 5 different location of film and then calculate the mean.(39) Thickness of film check by using Digital Vernier Caliper(40), Micrometer Screw Guage and Dial Guage Tester(41).

2. Weight Variation

Weight variation plays an Important role to maintain dose uniformity of each film. Cut film 2*2 cm^2 and check weight of film by using Digital analytical Balance. Weight of three film measure and take mean. This test also usefull to ensure that film contain proper amount of drug and Exipient.(40)(39)(23)

3. Folding Endurance

Initially film were cut, then film fold into repeated time at same point until break. The number of time film folding until break is called Folding Endurance Value. Typical value for folding endurance is between 100-150.(42)(43)(8)(15)(26)

4. Swelling Properties

By using the simulated saliva solution calculating swelling properties. Cut the film and take weight of every film and placed into stainless still wire mesh. Mesh dissolve in 15 ml of medium and then calculate initial weight and final weight of film. (42)(8)(44)(45)

$$\text{Degree of Swelling} = \frac{\text{Final wt} - \text{Initial wt}}{\text{Initial wt}} * 100$$

5. Tensile Strength

This test is used to determine mechanical properties of film.(44) Tensile strength basically depends on the concentration of polymer used in the formulation. It can be determine using texture analyser(26) and Digital tensile tester.(23) Tensile strength means maximum stress applied at which film break. It can be calculate by using following formula (45)

$$\text{Tensile Strength} = \frac{\text{Load at Failure}}{\text{Strip Thikness} * \text{Strip Width}} * 100$$

6. Drug Content

Cut film into 2*2 cm. dissolve the film into the 10 ml Phosphate buffer 6.8 Ph. Take absorbance of film in respective wavelength. Obtain absorbance put into calibration curve and determine the content of drug available in the film.(19)

7. Surface PH

Surface PH of film det ermine by using buffer. Take a petri dish to it add cut film o that film add 0.5 ml buffer solution and check ph by using digital Ph meter.(46)

8. In Vitro Disintegration

Cut the film according to the dose required in the film. Take 10 ml of Phosphate buffer 6.8 Ph to it add film. Note the time, required to disintegrate film in buffer solution.(21)

9. In Vitro Dissolution Study

In vitro dissolution carried out on USP Paddle dissolution test apparatus. Initially prepared 6.8 Ph phosphate buffer, 900 ml buffer solution add into jar. Set temperature 37 ˚C and RPM 50. Add film into Jar, withdraw 5 ml sample from jar for each 1 min. add fresh 5 ml phosphate buffer into jar to maintain sink condition. Take 6 reading from dissolution apparatus and finally calculate CDR by using UV Spectroscopy.(22)

10. Burst Strength

The force required to break or rupture the film is called burst strength. It indicate the flexibility of film(47)

11. Stability Study

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Stability study basically focus on effect of temperature and humidity on film. For the stability purpose initially sample pack into the aluminium foil and thereafter subjected for 40˚C and 75% RH. Sample withdraw after 3 month and 6 month, check its Drug content by using UV Spectroscopy and physical appearance. If its look good then it pass the test.(16)

II. CONCLUSION

Fast dissolving films are the novel approach in oral drug delivery systems. Oral fast dissolving films have emerged as revolutionary trend and extensive research activities involving various categories of drug are going on in this field. This formulation overcome problem which is facing other solid formulation. Patient compliance for this formulation more in geriatrics and paediatrics. In most of severe case it can use because just keep into the mouth within few minute it will disintegrate and reach into blood circulation. So it can be concluded that the oral films with so many advantages and high patient compliance have glowing futuristic opportunities.

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