A Review on Mouth Dissolving Films

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***Abstract*—Because of its systemic effects, the oral route is the most favored and preferable way to take medicines. With its benefits in terms of bioavailability, solubility, and therapeutic efficacy, this buccal drug delivery system provides an alternative to conventional oral medications like tablets. Weight, thickness, surface pH, folding endurance, medication content, texture profile, and so forth are important formulation parameters. These oral films are made using a variety of production techniques, such as rolling, solvent casting, hot melt extrusion, and semi-solid casting. A promising platform for a variety of applications in various disorders is provided by buccal films.**

***Index Terms*—Rolling, hotmeltextrusion, solventcasting, semisolidcasting.**

I. INTRODUCTION

The most popular and patient-friendly method of administering medication is orally. Almost all patients, including adults, children, and elderly patients, take the majority of medications as pills and capsules. However, between 26 and 50 percent of patients have trouble swallowing firm gelatin capsules and tablets. Elderly and pediatric patients are among them, as are patients with mental illnesses, developmental disabilities, patients on decreased liquid intake regimens, patients who are nauseous, and travellers who might not have access to water.

Additionally, the ability of many medications is limited by relatively poor absorption, the abundance of digestive enzymes in the GI lumen and epithelium, post-absorption efflux, and first-pass metabolism by the hepatic enzymes followed by excretion.

• Transmucosal methods of drug delivery (the mucosal linings of the nasal, rectal, vaginal, ophthalmic, and oral cavities) offer clear advantages over oral administration for systemic drug delivery in order to achieve the therapeutic levels by oral route. The oral route (intraoral route) offers advantages over the traditional gastro intestinal route, the parenteral route, and the other mucosal route of drug administration. These advantages include the potential to avoid the first pass effect, the avoidance of presystemic elimination within the gastrointestinal tract, and low enzyme activity. It offers direct access to the systemic circulation, preventing the first pass impact and making administration simple, among other benefits.

Today For the systemic distribution of active pharmaceutical components for over-the-counter medications and some prescription medications, oral thin films are a tried-and-true method

- A distribution method based on transdermal patch technology was created: fast dissolving films.
- This delivery system consists of a thin film composed of polymers that is easily applied to the patient's tongue or mucosal tissue, where it quickly dissolves and disintegrates to release the drug for oral absorption.
- It offers better patient compliance, ease of handling, and a pleasant taste. [1,2]

II. BENEFITS

Increased bioavailability: Drugs can be absorbed straight through the buccal mucosa with oral films, bypassing the gastrointestinal tract and liver's initial processing. This significantly increases the bioavailability, particularly for drugs with low oral bioavailability, such as proteins, peptides, etc Fast onset of action: Compared to oral dose forms, buccal films enable faster absorption due to the buccal mucosa's incredibly adaptable structure, which causes a quicker onset of action. Increased patient compliance: Because buccal films are thin, light, and easy to use, patients find them more appealing, especially young patients and the elderly who have trouble swallowing regular oral .

Targeted local delivery: Because buccal films carry medication directly to the site of action with minimal systemic absorption, reducing side effects, they are especially useful for the local treatment of oral problems such infections, ulcers, and cancers. Versatile formulation: These films can be made to carry a variety of drugs, such as peptides, nanoparticles, and small molecules, making them useful in a variety of therapeutic contexts.[3]

III. DRAWBACKS

- It is not possible to deliver medications that are unstable at buccal pH.
- This method cannot be used to give medications that irritate the mucosa.
- Only medications with low dosage requirements can be given.
- Flavour masking: Since most medications have a bitter flavor, taste masking is necessary One of the technological challenges is dose consistency
- Oral film comes in pricy package.[4]

IV. IDEAL MOUTH-DISSOLVING FILM PROPERTIES

It includes being thin, flexible, and manageable.the films should be easy to administer, transportable, non-stick, and maintain a flat form without rolling up; they should have a pleasing mouthfeel and taste; they should disintegrate as quickly as possible; they should have a smooth, uniform surface; they should be chemically and physically stable for the duration of their shelf life; they should be affordable and simple to produce commercially. A unit film's size shouldn't be so large that it compromises patient compliance.[5]

V. BUCCAL FILM

One or more polymer films or layers containing the medication and/or additional excipients make up buccal film, a non-dissolving thin matrix modified release dosage form. For regulated medication release into the oral cavity, gingiva, or mucosa (unidirectional release), or both (bidirectional release), the film may have a mucoadhesive polymer layer that adheres to the teeth, gingiva, or oral mucosa After a predetermined amount of time, the patch is taken out of the mouth and thrown away. Buccal medication administration has a number of clear advantages over other systemic impact paths.[6]

VI. BUCCAL ABSORPTION MECHANISM

The mechanism of buccal medication absorption is primarily controlled by concentration gradients and involves the passive diffusion of nonionized species across the intercellular spaces of the epithelium The passive movement of nonionic species across the buccal cavity's lipid membrane is the main mode of transport. The buccal mucosa is seen as a lipoidal barrier to drug passage, similar to many other mucosal membranes; the more lipophilic the drug molecule, the quicker it is absorbed. The first order rate process provides a sufficient description of the kinetics of drug absorption through the buccal mucosa.[6]

VII. MECHANISM OF BUCCAL ABSORPTION FLOW DIAGRAM

Mechanism [6]
Oral thin film kept in mouth
Disintegrate into smaller particles by saliva
Through buccal cavity, pharynx, oesophagus provides better absorption.
Quick onset of action -more bioavailability.
Choosing a medication candidate for the mouth-dissolving film: It's crucial to take into account the medication candidate's taste, irritability, allergenicity, and any negative effects like tooth discoloration or erosion before choosing mouth dissolving film as a drug administration method. The drug should be sufficiently soluble in water and absorbable through the mouth. Water-soluble polymers should be used to increase the solubility of medications that are poorly soluble. fast commencement of action due to fast disintegration within the oral cavity and, consequently, rapid absorption through gut can be a motivating reason in the selection of mouth dissolving film as dosage forms, even if the drug has little or no intraoral absorption.

VIII. PRODUCTION TECHNIQUES

- Solvent casting method: A homogeneous solution is created by dissolving water-soluble polymers. Small amounts of water are used to dissolve the medication and other water-soluble

ingredients. Both solutions are combined while being constantly stirred. By using a vacuum, trapped air bubbles are eliminated. The resultant solution is poured onto an untreated surface. chopped into pieces and allowed to dry. [8]

- Hot melt extrusion: In this process, an extruder screw heats and homogenizes the dry film materials until they are molten and combined. The extrudate is pressed into the required film shape by forcing the melted material through a flat extrusion die. When the material is still hot and flexible, elongation rollers can alter the film's thickness and strength. After cooling, the extruded film is cut and packaged. [8]
- Semi-solid casting process:It involves making a solution of a water-soluble film-forming polymer. The acid-insoluble polymer solution is mixed with the resultant solution. The right amount of plasticizer is applied to achieve the desired gel mass. Finally, heat-controlled drums are used to cast the gel mass into the films or ribbons. The ideal film thickness is between 0.015 and 0.05 inches. It is recommended that the ratio of film-forming polymer to acid-insoluble polymer be 1:4. [8]

IX. ROLLING METHOD

This technique creates the film by first preparing the premix, then adding the active ingredient, and finally forming the film. Make a premix using polar solvent, film-forming polymer, and additional ingredients (apart from a medication). Fill the master batch feed tank with premix. Deliver it to one or both of the first and second mixers using a first metering pump and control valve. Add the necessary quantity of medication to the preferred mixer. To create a consistent matrix, blend the medication with the master batch premix. Then, using the second metering pumps, a predetermined volume of uniform matrix is put into the pan. The film is at last developed on the substrate before being removed by the support roller. After that, controlled bottom drying is used to dry the wet film. Water and water-alcohol mixtures are the most common solvents employed. [8]

Solid dispersion extrusion:

The dispersion of an active substance in a solid state in a passive carrier with an amorphous hydrophilic polymer present is referred to as solid dispersion. The medication is first dissolved in an appropriate liquid solvent, and then this solution is added to a polyethylene glycol melt that is below 70 ˚ C without the liquid solvent being removed. In order to create a film, the solids are eventually distributed and run through the dies.[6]

Evaluation of Fast dissolving films:

Physical parameters [8]:

Mechanical parameters:

- Dryness /Tack test
- Tensile strength
- Percentage elongation
- Youngs modulus
- Tear resistance
- Folding endurance

Other physical parameters:

- Appearance
- Thickness
- Weight variation
- Contact angle
- Transparency
- Moisture content

Chemical parameters

- Surface ph test
- Disintegration time
- In vitro dissolution test
- Thermal analysis
- Crystallinity
- Assay /content uniformity

In vivo test using electronic tongue tester

Another test:

- Dsc
- Xray diffraction
- FT-IR study

Sr.no	Name of ingredient	Uses	Amount	Example
1.	Drug	Therapeutic activity	5-30 % w/w	All drugs are suitable
2.	Polymers	Ability to form film	45% w/w	Hpmc
3.	Plasticizer	Increase flexibility of film	0-20 % w/w	Glycerol, Polyethylene glycol
4.	Surfactant	Solubilizing agent and wetting agent	9.5% w/w	Tween 80, sls
5.	Sweetening agent	Enhance the palatability	3-6 %w/w	Saccharine, Aspartame
6.	Saliva stimulating agent	Increase saliva stimulation	2-6 % w/w	Citric acid
7.	Flavours	To mask the odour of the drug	Should not exceed 1 %w/w	Menthol
8.	Colors	To give elegancy to film	Should not exceed 1 % w/w	Titanium dioxide

Table No 1. Composition Of Formulation

BCS CLASS 1 HIGH SOLUBILITY HIGH PERMEABILITY	BCS CLASS 2 LOW SOLUBILITY HIGH PERMEABILITY
BCS CLASS 3 HIGH SOLUBILITY LOW PERMEABILITY	BCS CLASS 4 LOW SOLUBILITY LOW PERMEABILITY

Table No 2. Bcs Classification

Name of the polymer	source
Pullulan	Natural
Gelatin	Natural
Sodium alginate	Natural
Pectin	Natural
Rosin	Natural
Starch	Natural
Maltodextrin	Natural
Chitosan	Natural
Gum careegnan	Natural
Hydroxy propyl methyl cellulose	Synthetic
Hydroxy propyl cellulose	Synthetic
Polyethylene oxide	Synthetic
Kollicoat	Synthetic
Polyvinyl alcohol	Synthetic
Poly vinyl pyrollidone	Synthetic

Table No 3. Different Polymers

Zolmitriptan [9]	pullulan	Peg 400	Sodium saccharine
Telmisartan [10]	Hpmc	Propylene glycol	Mannitol
Montelukast sodium [11]	pullulan	Peg 400	Mannitol
Domperidone [12]	Pullulan	Peg 400	Sodium saccharine
Midazolam [13]	Pullulan	Peg 400	Aspartame
Metoprolol succinate [14]	Hpmc /pva	Peg 300	_
Miconazole [15]	Chitosan	Propylene glycol/peg 400	_
Ondansetron [16]	Hpmc K4M/Carbopol 934 p	Propylene glycol	Aspartame
Clobazam [17]	Pva	Peg 400	D-Mannitol
Telmisartan [18]	Hpmc E 5/pullulan	Glycerine	Aspartame
Triamcinolone acetonide [19]	Hpmc/pva/peg 4000/cmc/chitosan/starch/gelatin/pectin	Peg 400/Glycerine	Sodium saccharin
Furosemide [20]	Pullulan /lepidum sativum	Glycerol	Sucralose

Table No 4. Excipients Used in the Formulation of Oral Dissolving Films

Scientist	Method	Drug and its components for film
Vipul d Prajapati etal	Solvent casting method	Zolmitriptan, pullulan, glycerin, polyethyleneglycol400, sucralose Mint and distilled water.
Ajinkya M bhagurkar etal	Hot melt extrusion	Salbutamol sulphate,klucelhydroxypropylcellulose (hpc) ef,benecelhydroxypropylmethylcellulose (hpmc) k-15 M and peg 4500.
Marko kristic etal	Electro spinning and solution casting	Carvedilol,polysorbate 80, polyethylene oxide,ethanol and deionized water.
V.A. Goana sanchez etal	Electrospraying	Zein,glycerol,ethanol 96 %etc
Singh etal	Semi solid casting	Cariprazine,hpmc k4m,peg 400.

Table No 5. Recent Trends

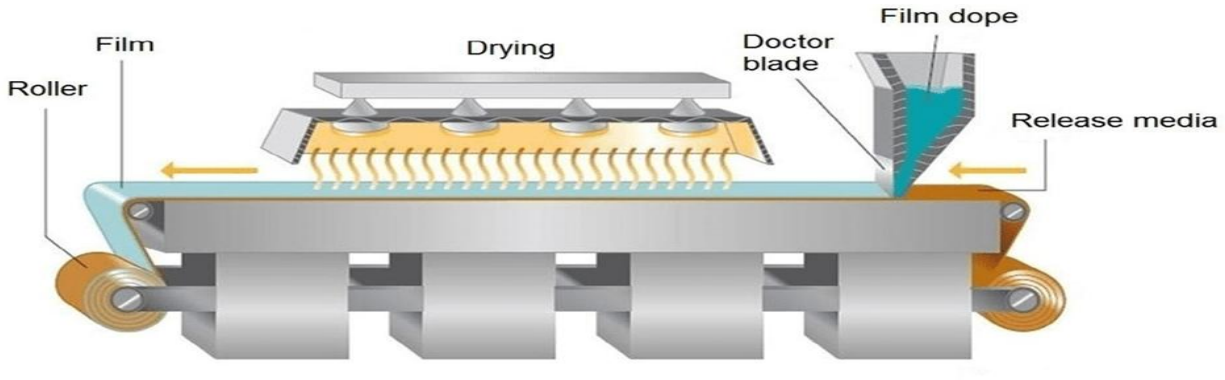

Fig No 1. Solvent Casting Method

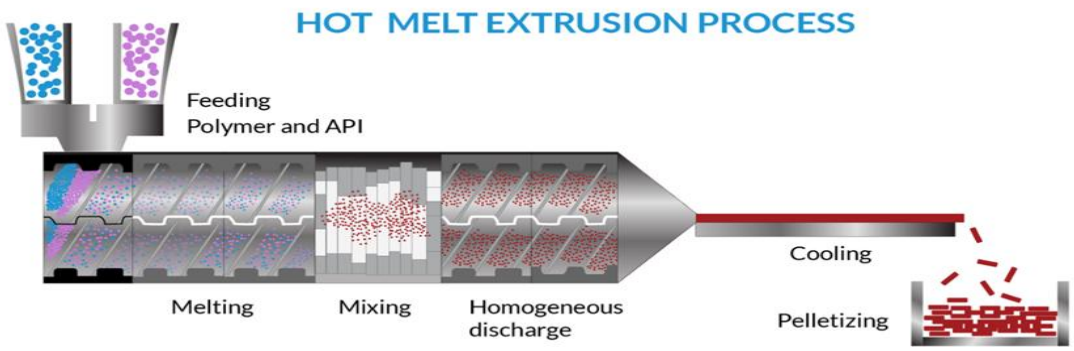

Fig No 2.Hot Melt Extrusion

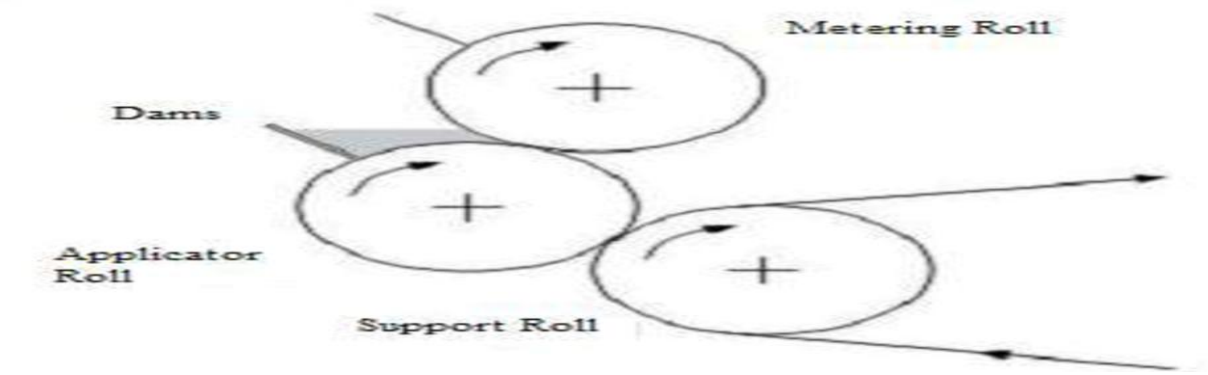

Fig No 3. Rolling Method

X. CONCLUSION

In conclusion, there are a number of benefits to using oral thin film for medication delivery. Since odf are easy to swallow and pose no choking hazard, they are an excellent dose form for both youngsters and the elderly.they usually consist of film forming polymers, plasticizers and additional excipients. For instance, in order to enhance flavor.The limited medication load is the primary drawback of odf. In due of its affordability, the solvent casting method is frequently used to create Odf.

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