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# A Review on Recent Inovative Rapid Mouth Dissolving Film

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**ABSTRACT:** They have advantages like administration without water, rapid onset of action on circulation and convenience of dosing. These films give rapid action on the mouth related infections. These are the solid dosage form which is thin polymeric strip incorporating and delivering pharmaceutical active ingredients and once placed within the mouth dissolves within the short period of your time without beverage or chewing. That solid dosage forms are widely used as medicaments in oral dosage form. But now a day's most of the pediatric, geriatric and dysphagia patients who finds difficulty in swallowing, the Oral Dissolving Films (ODF) is often wont to overcome such type problems. The most concept of mouth dissolving film features a valuable interest within the various fields of pharmaceutics. There are many advantages of mucoadhesive buccal drug delivery system (MBDDS) that made this a completely unique drug delivery system for the local also as systemic delivery of varied drugs. The most advantage of this drug delivery system is that it prolongs the duration of the dosage form at the location of application. The films are designed to dissolve upon contact with a wet surface, like the tongue, within a couple of seconds, meaning the buyer can take the merchandise without need for water intake. This convenience provides both a marketing advantage and increased patient compliance.

**KEYWORD:**-Mouth dissolving films, fast disintegrating, site specific, polymer, plasticizer, solvent casting, solid dispersion intraoral, tensile strength, Permeability, Bioavailability

## I. INTRODUCTION:-

**Mouth Dissolving Film**

Mouth dissolving Film (MDF) or Oral Dissolving Film (ODF) it's define as a skinny film which is putted on the tongue or the mucosal membranes instantly wet by saliva the film rapidly hydrates and adheres onto the location of application.

These also are called as a

- Oral thin film
- Buccal films / strip
- Oral strips.

A novel oral drug delivery system, mouth dissolving films were prepared supported skin patch technology. This technology is employed for dissolving a Drug in Mouth by using Saliva. A skinny layer drug film is ready and is placed on the patient's mucosal cavity where it's wetted by saliva making it adhere to the surface. Polymeric films have shown great potential in delivering medications into mouth. It's preferable for the patients who can't be swallowing or chewing other solid oral dosage form like tablet or other forms. This novel drug delivery system also can be beneficial for meeting current needs of the industry. **(1)**

As for instance Chloraseptic relief strips were the primary therapeutic oral thin films (OTF) which contained benzocaine and were used for the treatment of pharyngitis. Formulation of fast dissolving mucosal/buccal film that involves materials like strip-forming polymers, plasticizers, active pharmaceutical ingredient, sweetening agents, saliva stimulating agent, flavouring agents, colouring agents, stabilizing and thickening agents, permeation enhancers, and superdisintegrates were they're important for the preparation of these, excipients utilized in the formulation for fast dissolving film. This could be approved to be used in oral pharmaceutical dosage forms as per regulatory perspectives. **(1)**

A drug is often taken via many various routes to supply a systemic pharmacological effect. The foremost common method of drug administration is via the peroral route, during which the drug is swallowed and enters the circulation. Although, this sort of drug

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administration more accurately doing, the drug absorption the mouth itself. Generally, the mucosal DDS drugs penetrate the mucosa by simple diffusion and are carried in blood, which richly supplies the salivary glands and their ducts, into the circulation via the vena jugularis. Oral drug delivery system has lately become a preferable route of drug administration.

Oral dissolving tablets (ODTs) and oral dissolving films (ODFs) are the standard samples of mouth disintegrating drug delivery systems. These systems were developed in 1970 to function an alternate to standard dosage forms, as an example, fast disintegrating tablets and capsules for geriatrics and pediatric patients having difficulty in swallowing conventional dosage forms. A typical ODF is typically adequate to the dimensions of postage. In market place, the introduction of ODT was strongly related to counselling of patients about the acceptable administration by giving instruction like **'do not chew/do not swallow'**. However, for all of those instructions, incidents regarding chewing and swallowing were often reported. But, ODFs unbound the masses from these adverse events. [(2)]

Fast dissolving films (FDF) were initially introduced within the market as breath fresheners and private care products like care strips and soap strips like many others. However, these sorts of dosage forms are introduced within the us and European pharmaceutical markets for therapeutic benefits. Very first, quite Oral Strips (OS) were developed by the main drug company Pfizer that named was Listerine pocket packs™ and were used for mouth freshening.

Oral mouth dissolving films are mainly preferred for paralysis, mental disturbance and dysphagia patients who cannot swallow large quantities of water. There are common drugs which are available within the sort of films for antiulcer, anti-asthmatics, antitussives, expectorants, antihistamines and Non-Steroidal Anti-Inflammatory Drugs. (2)MDF possesses popularity thanks to its availability in various size and shape; MDFs are intended or disintegrate or dissolve within seconds. MDFs offer fast, accurate dosing for a secure, efficacious format that's convenient and portable, without the necessity for water or measuring devices. MDFs are typically disintegrated on a patient's tongue during a matter of seconds for the rapid release of 1 or more APIs. [(3)]

Drug are often loaded up to one dose maximum 30 mg. Fast mouth dissolving films (FMDFs) are the foremost innovative advanced sort of solid oral dosage form thanks to their flexibility and luxury for a administration. Most of the drugs are taken orally within the sort of tablets, capsules, strips etc by all patients including adult, pediatric and geriatric patients who cannot swallow the solid dosage form. [(4)]

Systemic absorption of drug is based on factor such as route of administration for a drug and dosage of drug and contain in formulation. Parenteral administration has main disadvantage is requires strict aseptic procedures for preparation. That route gives pain at the site of injection. The route of administration of drug may it is oral route that is most effective, non-invasive, adaptable, and acceptable route. Oral route has good therapeutic efficacy, cheap in cost and give good patient compliance. Form of oral cavity, the delivery of drug may be by intraoral sublingual, intraoral buccal and peroral etc. Intraoral sublingual is different administration method through the mucosa of mouth below the tongue. Intraoral buccal, it is passage through the mucosa of cheeks and peroral is passage through the mouth to the gastrointestinal tract (GI tract). [(5)]

**OBJECTIVES:-**

The main objectives were to develop the speedy mouth dissolving film system are as follow:

- Provide the higher bioavailability
- Quick onset action
- Improve patient compliance
- Rapid dissolution of drug and absorption
- Avoid initial pass metabolism
- That designed like no or lowest residual in mouth

**ADVANTAGES [(2, 4)]**

The advantages of quick dissolving films are-

- There isn't any water required.
- Convenient and correct dosing,
- Less chance of chocking.
- Though there are some drawbacks like oral dissolving films are wetness sensitive.
- High dose can't be given in oral film and simply breakable.
- Administered while not water, anywhere, any time. & Dose accuracy.
- Due to larger extent, provides speedy disintegration and dissolution within the mouth.
- Acidic surroundings of abdomen will be avoided.
- Site specific action and native action.

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- Stable for extended length of your time, since the drug remains in solid indefinite quantity kind until it's consumed.
- Flexible and moveable in nature thus provides ease in transportation throughout shopper handling and storage.
- Suitable for geriatric and medicine patients, World Health Organization expertise difficulties in swallowing, unstable, the developmentally disable and therefore the patients World Health Organization are un-cooperative, or are on reduced liquid intake or are queasy.
- Beneficial in ill, acute pain, allergic attack or coughing, wherever speedy onset of action is needed.
- The oral or buccal tissue layer being extremely vascularized, medicine gets absorbed directly and enters the circulation while not undergoing first-pass viscus metabolism.
- The organ and buccal delivery of a drug via film has the potential to boost the onset of action, lower the dosing, and enhance the effectualness and safety profile of the medicine.
- Provide new business chance like product differentiation, product promotion and patent extension.

**DISADVANTAGES** [4]

- It is absorptive in nature thus it should be unbroken in dry places.
- Packaging of films needs special equipment's and it's tough to pack.
- High can't be incorporated into the oral film.
- Eating and drinking might become restricted.
- Mouth Dissolving film are wetness sensitive.

**FORMULATION** [6]

| SR NO. | INGREDIENTS | AMOUNT (% w/w) |
|---|---|---|
| **1.** | Drug | 1-30% |
| **2.** | Film forming polymer | 40-50% |
| **3.** | Plasticizer | 0-20% |
| **4.** | Saliva stimulating agent | 2-6% |
| **5.** | Sweetening agent | 3-6% |
| **6.** | Flavouring agent | q.s. |
| **7.** | Surfactant | q.s. |
| **8.** | Colours/ filler | q.s. |

**Table no.2**

**IDEAL CHARACTERISTICS OF APPROPRIATE DRUG CANDIDATE :-** [7, 8]

- The drug ought to have pleasant style.
- Dose ought to be low as potential.
- The medicine with smaller and moderate mass square measure preferred.
- Good stability in water and secretion.
- It ought to be part unionized at the pH of rimaoris.
- It ought to have the power to permeate oral membrane tissue.
- The drug to be incorporated ought to have low dose up to forty mg.
- The drug ought to have smaller and moderate mass.
- The drug ought to have smart stability and solubility in water yet as secretion.
- It ought to be part unionized at the pH of rimaoris.
- It ought to have ability to permeate the oral membrane tissue.

**THREE TYPES OF ORAL FILMS ARE DIFFERENTIATED FROM EACH OTHER** [9]

| Properties | Flash release | Muco-adhesive melt away wafers | Muco-adhesive sustained wafers |
|---|---|---|---|
| **Area($cm^2$)** | 2-8 | 2-7 | 2-4 |
| **Thickness** | 20-70 | 50-500 | 50-250 |

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| | | | |
|---|---|---|---|
| **Structure** | Single layer system | Single or multilayer | Multilayer system |
| **Excipients** | Soluble hydrophilic polymer | Soluble hydrophilic polymer | Low/non-soluble polymer |
| **Drug phase** | Solid solution | Solid solution or suspended solution | Suspension and/or solid solution |
| **Dissolution** | 60 sec | Few min | Max8-10 hrs |
| **Application** | Tongue | Gingival or buccal region | Gingival (other region in oral cavity) |

**Table no. 3**

**COMPOSITION FOR MOUTH DISSOLVING FILM [2, 3, 4, 10, 11, 27, 28]**

**Active pharmaceutical ingredients (API):**

Have associate degree API containing answer or suspension, taken it on a carrier and allowed onto it. Then keep it to drying for a few amounts then finally cut it in applicable dimensions. Several categories of medication are often incorporated into ODFs e.g., anti-histamine, anti-diarrheal, anti-depressants, vasodilators, anti-asthmatic, anti-emetic, etc. For style masking antiemetic drug can even be incorporated into ODFs. Some common samples of medicine incorporated into ODFs ar salbutamol salt, rizatriptan salt, calcium blocker ondansetron, Hexadrol, rofecoxib, cetirizine, alkaloid, tianeptine metal, nonsteroidal anti-inflammatory, etc. From the assorted categories associate degree API that may be developed into MDFs some examples ar anti-emetic, neuroleptics, anti-hypertensive, analgesics, anxiolytics, diuretics, anti-tussives, opposing Alzheimer's, and Parkinsonism agents.

**The ideal characteristics of associate degree API to be elite in MDF [8]**

- Taste of API –should be pleasant.
- The API dose –should up to forty mg.
- The relative molecular mass – ought to be ideally smaller.
- In mouth (fluid) gift -should be stable
- Should be moderately unionized in rimaoris fluid.
- Should have porosity through membrane tissue.

**Polymers:**

The selection of polymers that plays an important role for the winning formulation of Oral Dissolving Films, for the formulate of ODF they'll be either used alone or among the mix with different polymers/co-polymers. The principle of the ODF's depends on the Concentration and nature of the polymers, usually forty fifth is that the best concentration of the compound for the preparation of ODF. The normally used polymers their examples like HPMC K5, CMC, PVP K90, pectin, metal alginate, HPC. HPMC is well-tried to be a much better compound than others.

**Ex: Pullulan, Gelatin, metal Alginate, Pectin, Rosin, Starch, Chitosan etc…**

**Water Soluble Polymers:**

Water- soluble polymers that are used as film formers. The employment of film forming polymers in dissoluble films has attracted considerable attention bound medical and nutraceutical application. The soluble polymers have a speedy disintegration, smart mouth feel and mechanical properties to the films. The disintegration rate of the compounds is reciprocally proportional to the relative molecular mass of polymer film bases. variety of the water soluble polymers used as film former are HPMC E-3 and K-3, methyl radical polysaccharide A-3, A-6 and A-15, Pullulan, carboxmethylcellulose ecekol thirty, Polyvinylpyrollidone PVP K-90, Pectin, Gelatine, metal Alginate, Hdroxypropylcellulose, Polyvinyl alcohol, Maltodextrin and eudragit-RD. Novel film forming compound could also be a Polymerized rosin. Pullulan is obtained from natural origin, thus does not need chemical modification. Compound ought to be: Non incompatible, Non toxic and empty leachable impurities. Good spreading property and wetting property.

**Ex: Poly ((meth) acrylic) acid and its co-polymers, poly vinyl alcohol or Substituted polysaccharide like hydoxyethylcellulose**

**Film forming compound (40-50%):**

In order to arrange a flick formulation that is soluble and excipients or compound should be water soluble with low relative molecular mass and glorious film forming capability. The compound that is to be used ought to be non-toxic, non-irritant and empty leachable impurities. It ought to have smart wetting and unfold ability property. It ought

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to exhibit comfortable peel, shear and lastingnesss. It ought to be without delay on the market and cannot be terribly dear. Variety of the samples of appropriate polymers which can be incorporated among the;

**Ex: Polyvinylpyrollidone (PVP), acrylates, acrylamides, its co-polymers, FDFs ar HPMC, CMC, Gelatin, Pullulan, etc...**

**Hydrophilic polymer/film formers:-**

Hydrophilic Polymers Contain Polar or charged purposeful teams, ripping them soluble in water. Among this section, most hydrophilic polymers classified by the chemistry of their structure. Properties of compound play an enormous role in disintegration time of film.

**Ex. soluble polymers/film formers are hydroxypropylmethyl cellulose, methylcellulose, pullulan, cellulose, polyvinyl pyrrolidone, etc.**
**Ex. of novel film former is polymerized rosin. Polyacrylamide, polyurethanes, poly-(hydroxyethyl methacrylamide) or poly (ethylene glycol derivatives etc…**

**Ideal properties of the polymers utilized within the oral film [(2)]**

- Polymers ought to be nontoxic, non- bother and non-bitter.
- Polymers ought to be tasteless.
- Should be empty leachable impurities.
- Should be cheap and without delay on the market.
- Should not be associate degree obstacle among the disintegration time.
- Should have smart wetting and spreadibility property.
- Should exhibit comfortable peel, shear and enduringness.
- Should not cause secondary infection among the mouth and can have comfortable period.

**Plasticizers**

The properties of plasticizers like lastingness and elongation are directly associated with the concentration of the plasticizers, for the preparation of ODF the concentration of plasticizer that range is from 0-20% w/w. Formulation considerations (plasticizer, etc.) are reported as important factors affecting mechanical properties of films. The mechanical properties such as lastingness and Elongation to the films has also been improved by the addition of plasticizers.

**Ex: glycerol, polyethylene glycol, triethyl citrate.**

**Some important criteria for the plasticizers:**

- Used in 1-20 %w/w of the dry polymer weight. Their concentration may affect these properties.
- The commonly used plasticizers are glycerol, diethyl, diethyl and dibutylpthalate, citrate derivatives like tributyl, triethyl citrate, polyethylene glycol, and purgative, etc.
- Various study administered in several plasticizer to review their effect on gelatine strips which ends up observed that malic acid was found to raised plasticizer in comparison to acid, monounsaturated fatty acid and hydroxy acid because it wasn't crystallize out when the film was dried.
- Low relative molecular mass of polyethylene glycol was found to raise plasticizer than high M.W polyethylene glycol.
- Maltodextrin also can be plasticized and converted into oral dissolving film with incorporation of glycerin and propanediol as plasticizer within the concentration range of 16–20%w/w, and located to be more advantageous by using glycerin over propanediol because it shows miscibility.
- It avoids breakability of films. It should are compatible with other ingredients. Some excipients are like polyethylene glycol, phthalate, citrate derivatives, and purgative.
- Surfactants are used as solubilising or wetting or dispersing agent in formulation in order that the film gets dissolved within seconds and releases active quickly.
- Some commonly used surfactants are like Sodium lauryl sulphate, Benzalkonium chloride, Tweens etc. most vital surfactant is Polaxamer 407 that's used as solubilizing, wetting and dispersing agent. They act as wetting, dispersing, or solubilizing agents.

**Ex: poloxamer, sodium lauryl sulphate, and tweens.**

**Saliva Stimulating Agents:-**

Saliva stimulating agents is employed to extend the speed of production of saliva that might aid within the faster disintegration of the rapid dissolving films. Generally acids which are utilized in the preparation of food are often used as salivary stimulants like acid, Malic acid, carboxylic acid, vitamin C and hydroxy acid. These are useful to reinforce the saliva creation within the mouth that provides quick disintegration. Ex: tartaric, lactic, malic, ascorbic, and citric.

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**Flavouring Agents:-**

Flavouring agent are the agents who are added in to the preparation of ODF for mask the unpleasant taste of the drug; the concentration of flavour depends upon its strength and nature. The FDA approved flavours can be used for the formulation, the mostly used flavouring agents are liquorice, mint and sucralose. The acceptance of an orally disintegrating or dissolving formulation by an individual depends on the flavour quality which is observed in first few seconds after the product has been consumed and the after taste of the formulation which lasts for at least about 10min. The selection of flavour depends on the type of drug to be incorporated in the formulation. The geriatric peoples like mint or orange flavours, while younger generation peoples like flavours such as fruit punch, raspberry etc. Flavouring agents can be selected from synthetic flavour like oils, oleo resins, extract derived from various parts of the plants like leaves, fruits and flowers. Flavours can be used alone or in combination for the preparation of ODFs.

**Ex. Peppermint oil, cinnamon oil, spearmint oil, oil of nutmeg, flavouring oils.**
**Vanilla, cocoa, coffee, chocolate and citrus are fruity flavour.**
**Apple, raspberry, cherry, pineapple is few examples of fruit essence type.**

**Sweetening Agents**

Sweeteners became a crucial a part of the formulation that disintegrate or dissolve within the mouth. Both natural also as artificial sweeteners are often utilized in the formulation of those fast dissolving films. Polyhydric alcohols like Sorbitol, Mannitol, and Isomalt are often utilized in combination as they supply good mouth feel and cooling sensation. However, use of natural sugars should be restricted in people that are on diet or in diabetic patients. Thanks to this reason, the synthetic sweeteners have gained more popularity in food and pharmaceutical preparations. Saccharin, Cyclamate and Aspartame are the synthetic sweeteners. Sweeteners became a crucial a part of the food products also as pharmaceutical products intended to be disintegrated or dissolved within the mouth. Natural sweeteners also as artificial sweeteners are wont to improve the palatability of the mouth dissolving formulations. Some suitable sweeteners include:

- Water soluble natural sweetener: xylose, ribose, glucose, sucrose, maltose, stevioside etc.
- Water soluble artificial sweetener: sodium or calcium saccharin salts, acesulfame-K etc.
- Dipeptide based sweetener: aspartame.

Colouring Agents are full range of colours is out there, including FD&C colours, EU Colours, Natural Colours. Some saliva stimulating agents can also be added to reinforce the disintegration and to urge rapid release. a number of these agents are acid, hydroxy acid, malic acid, vitamin C and carboxylic acid.

**List of marketed films containing API** [12, 13]

| Product | Company | API | Use |
|---|---|---|---|
| **Benadryl** | Pfizer | Diphenylhydramine | Cough & allergy |
| **Listerine pocketpak** | Pfizer | Menthol | Mouth freshner |
| **Orafilm** | Apothecus | Benzocaine | Pain relieving strips |
| **Spiderman** | Aquafilm | Vitamin | Vitamin supplement |
| **Theraflu** | Novartis | Diphenhydramine HCL | Cough supplement |
| **Triaminic** | Novartis | Dextromethorphan | Cold/allergy |
| **Sudafed** | Pfizer | Phenylephrine | Nasal decongestant |

**Table no.4**

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**FORMULATION ASPECTS & METHOD OF PREPARATION:-**

**MANUFACTURING PROCESS: -** [2, 3, 4, 10, 11, 14]

There square measure some strategies throughout that oral dissolving films square measure usually ready, every of the strategies square measure represented below;

i. Preparation of film mistreatment, solvent casting technique
ii. Solid casting
iii. Hot soften extrusion
iv. Solid dispersion extrusion
v. Rolling technique Solvent Casting technique

**Solvent casting Method:-**

It is one in every of the usually used strategies for the formulation of film. It is ready for treatment of water soluble polymers, excipients and drug. Due to the appliance of high shear force a regular mixture is created (Fig 1). The solution obtained is poured into foil unfold with coating knife to induce uniform thickness. In solvent casting technique water soluble polymers square measure dissolved in water and thus the drug aboard alternative excipients is dissolved in appropriate solvent then each the solutions square measure mixed and stirred and eventually casted in to the Petri plates, dried and cut in to uniform dimensions.

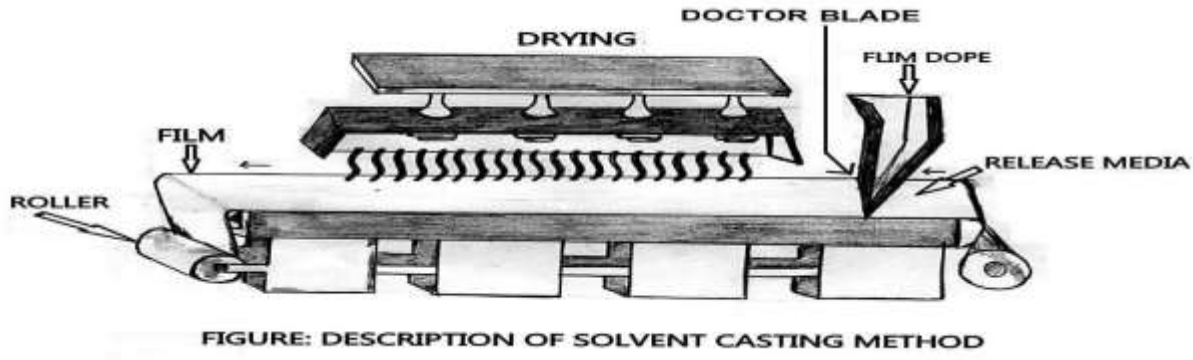


**Fig: 1 Solvent casting Methods**

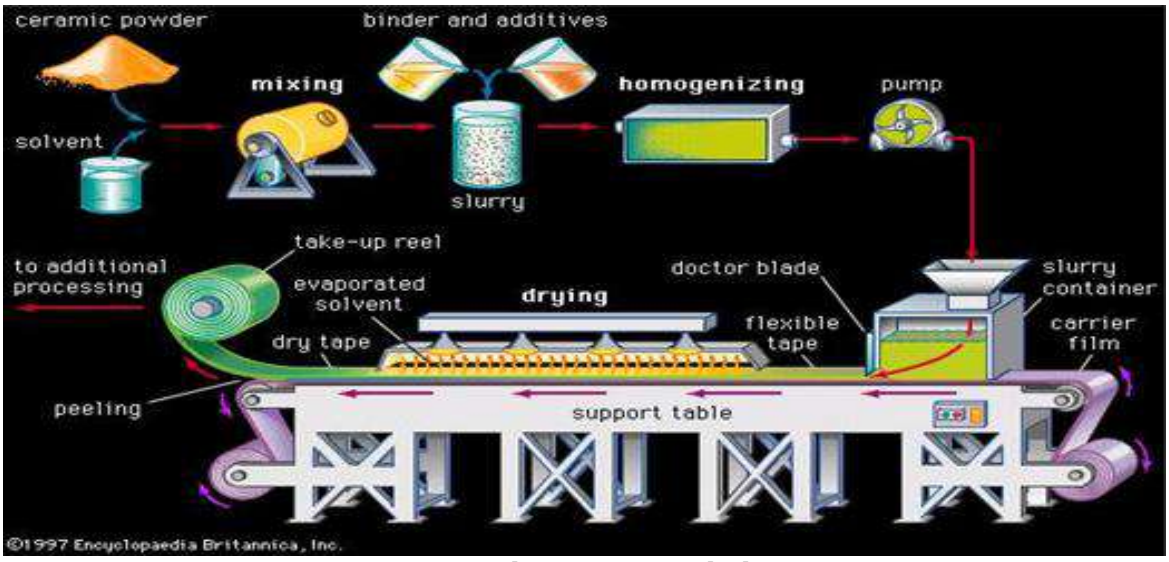


**Fig: 2 Solvent casting Methods**

**Semisolid casting method:**

In solid casting methodology first off a solution of soluble film forming chemical compound is prepared. The ensuing answer is supplemental to a solution of acid insoluble chemical compound (e.g. ester phthalate, ester butyrate), that was ready in ammonium ion or hydroxide. Then applicable quantity of plasticiser

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is supplemental so as that a gel mass is obtained. Finally the gel mass is casted in to the films or ribbons exploitation heat controlled drums. The thickness of the film is concerning zero.015-0.05 inches. The quantitative relation of the acid insoluble chemical compound to film forming chemical compound ought to be 1:4.

**Hot soften Extrusion (HME):-**

In hot soften extrusion methodology first off the drug is mixed with carriers in solid kind. Then the extruder having heaters melts the mixture. Finally the soften is created in to films by the dies. There are bound edges of hot soften extrusion.

Advantages of hot soften extrusion for film formation includes:-

- No demand on the squeezability of the active ingredients.
- More uniform dispersion of the fine particles because of intense intermixture and agitation inflicting suspended drug particles to deaggregate inside the liquefied chemical compound.
- The bioavailability of the drug substance may be improved once its spread at the molecular level in hot softens extruded indefinite quantity forms.

Producing skinny films for transdermic / transmucosal drug delivery and wound care is via film casting from binary compound or organic solvents. The recent soften extrusion method has recently gained acceptance inside the pharmaceutical business. Building on data from the business, formulators will squeeze out combos of medication, polymers, and plasticizers into numerous final forms to comprehend desired drug unleash profiles.

The benefits of exploitation HME over ancient process techniques include:

- Fewer unit operations
- Better content uniformity
- An anhydrous method
- A dispersion mechanism for poorly soluble medicine
- A low energy various to high-shear granulation
- Fewer intervals compared with conventional wet granulation.

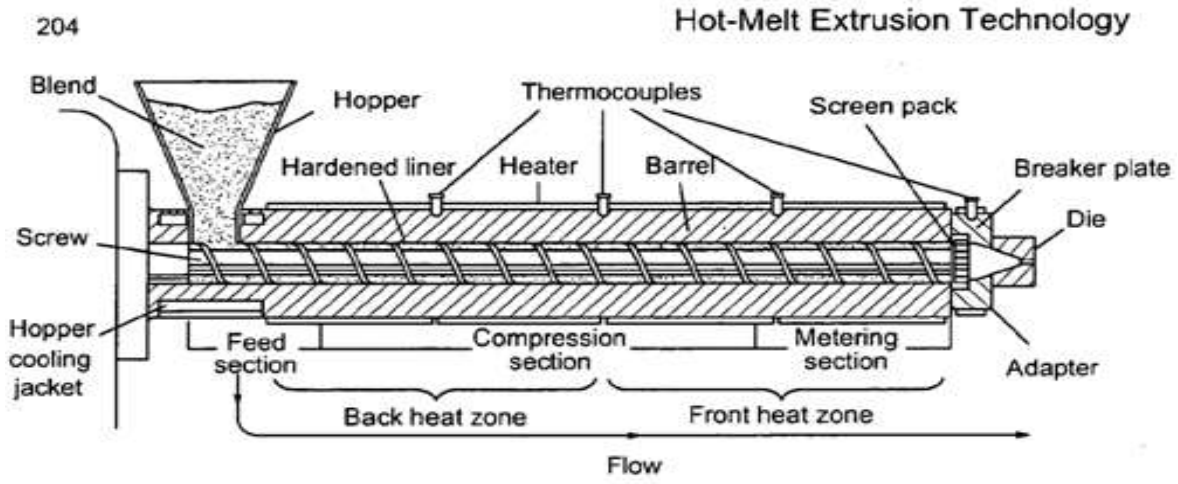


**Fig: 3 Hot Extrusion Technology**

**Solid Dispersion Extrusion**

In this methodology immiscible elements are create with drug then solid dispersions are ready. Finally the solid dispersions are formed in to films by suggests that of dies. Throughout this methodology immiscible elements are create with drug then solid dispersions are ready. Finally the solid dispersions are formed in to films by suggests that of dies. Rolling methodology: In rolling method a solution or suspension containing drug is rolled on a carrier. The solvent is very 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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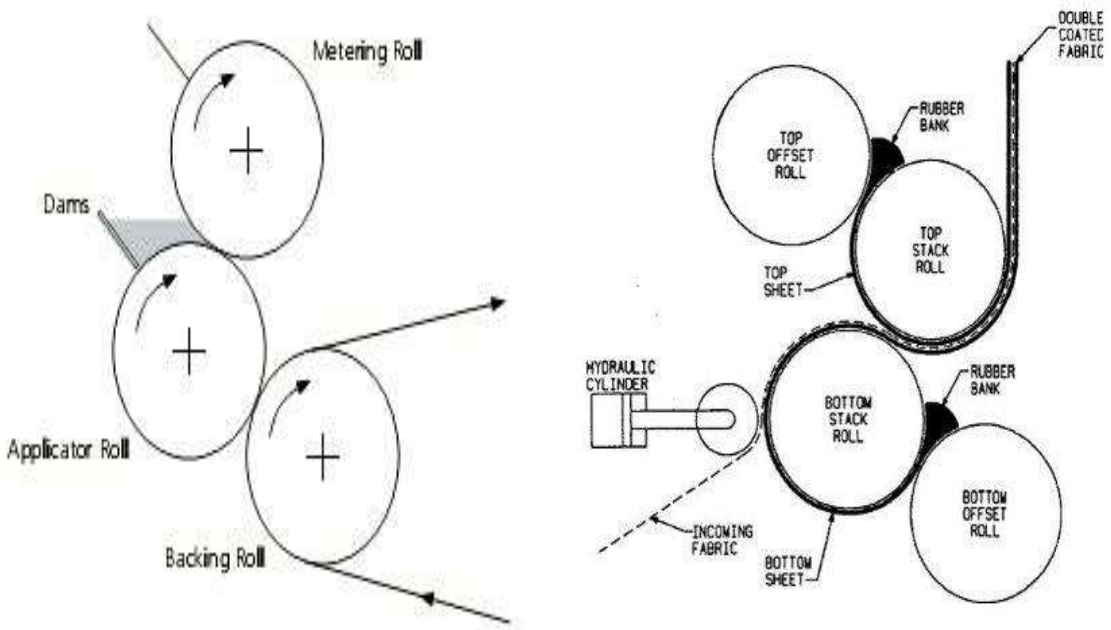


**Fig: 4 Rolling Method**

**MECHANISMS:-**

Oral thin film

⇩

Kept in mouth

⇩

Disintegrate into small particles by saliva

⇩

Through buccal cavity, pharynx, oesophagus provides better absorption

⇩

Quick onset of action- more bioavailability

**PHYSICO - MECHANICAL PROPERTIES OF FILM** [2, 3, 4, 10, 11]

**Tensile strength:**

It is outlined as a result of the purpose at that the film breaks due to the appliance of most stress. This check is carried to figure out the mechanical strength of the ODF. The permanency is commonly calculated by the equation.

Tensile strength = (failure load/strip thickness ×width of strip) ×100

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**Folding endurance:-**

Within the folding endurance check the folding of the strip is run till the strip breaks at a same purpose. The folding endurance is that the live of total range of folding of the film while not breaking.

**Young's modulus:-**

It had been initial administered by Giordano riccati it is also known as as a result of the elastic modulus; it is the live of rigidity of the film and is outlined as a result of the magnitude relation of stress applied to cause elastic deformation of the film.

Young's modulus=Slope×100/ thickness of film × Crosshead speed

**Tear resistance:-**

It's outlined as a result of the most force that is needed to tear the film. The speed of loading recruit is a pair of in/min. that is planned to figure out the magnitude of force needed to initiate tearing among the film specimen.

**Percentage elongation:**

The film elongates as a result of the concentration of the softener will increase, the film extends or stretches once the force is applied, and its known as strain. The strain is that the bending of the film to the primary sample dimensions.

**Disintegration time:**

The disintegration time of oral dissolving film ranges from five to thirty seconds. principally tho' there isn't any official technique obtainable for crucial disintegrating of oral dissolving films. 2 ways area unit administered for crucial the disintegration time of the film as follows.

**Slide frame:**

During this technique the film is clamped into slide frame once dropping a drop of water on the film.

**EVALUATION PARAMETERS :-** [3, 4, 10, 11]

**Appearance/Organoleptic evaluation:-**

All ready films were checked for his or her appearances either they are clear or opaque. C**olor** could also be vital means of significant suggests that of identification for many pharmaceutical products and is to boot important for client acceptance. The colour of the merchandise should be uniform among indefinite quantity kind. **Odour** is to boot necessary for patients acceptance of oral indefinite quantity forms and will give a symbol of the quality of oral films as a result of the presence of AN odour throughout a batch might indicate a stability downside. **Taste** is to boot essential issue for the customer acceptance.Taste preference is subjective and thus the management of style among the assembly of oral soluble films relies on the presence or absence of such style.

**Thickness:-**

Thickness of the film is measured exploitation Micrometer Screw Gauge at completely different locations. Outcome is determined by taking the mean of half dozen readings. Thickness of the film ranges from 1-10 millimetre. Thickness of the ready film was measured by micrometer screw gauge at completely different strategic locations. Usually this can be typically essential to see uniformity among the thickness of the film as this is often directly related to the accuracy of dose among the strip.

**Weight Variation:-**

All batches were evaluated for its weight variation and thickness. Weight variation is evaluated by using balance and Avg. weigh is calculated. Weighing each film, and then, the typical weight of the films is subtracted from the individual film weight.

**Mechanical Properties:-**

Mechanical properties like lastingness, % Elongation, and Folding Endurance were evaluated.

**Tensile Strength**

It was measured using Tensiometer. The films of size 2×2 $cm^2$ and free of physical imperfections were placed between two clamps held 10 mm apart. The films were to be pulled by clamp at a rate of 5mm/min. It is the maximum stress applied to a point at which the strip specimen breaks. It is performed to check the strength and elasticity of the film by using tensile tester. It is calculated by the applied load at rupture divided by the cross-sectional area of the strip as given in the equation below.

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

**Surface pH**

The films were allowed to swell in closed petridish at temperature for half-hour in 1 ml of water. Solution was placed under digital pH meter to work out the surface pH. Film is placed on a Petri dish and moistened with 0.5 ml of water. Kept for 30 seconds. The pH is noted after bringing the electrode of the pH meter in touch with the surface of film. Outcome is decided by taking the mean of three readings.

**Drug Contain Uniformity Test:-**

The test for the content uniformity is administered taking a sample film of size 2×2 sq cm which is placed during a beaker containing 10 ml of an appropriate medium. The contents are stirred during a cyclo-mixer to dissolve the film which is then transferred to a volumetric flask (10ml). The absorbance of the answer is measured against the corresponding blank solution at particular wavelength employing a standard assay method described for the actual API mentioned in any of the quality pharmacopoeia. Content uniformity is decided by estimating the API content in individual film. Limit of content uniformity is 85-115 %. The assay method described in pharmacopeia is followed. it's determined by measuring the drug content within the individual film.

**Disintegration Time:-**

Disintegration time provides a sign about the disintegration characteristics and dissolution characteristics of the film. The require size of film (2×2 $cm^2$) was placed during a chrome steel wire mesh containing 25 ml of pH 6.8 simulated salivary fluid. Time taken by film to interrupt and dissolve was measured as in-vitro disintegration time and in-vitro dissolution time. Disintegration of orally fast dissolving films requires USP disintegration apparatus. The disintegration deadline of 30 seconds or less for orally disintegrating tablets described in CDER guidance are often applied to fast dissolving oral strips. Disintegration time vary counting on the formulation but typically the disintegration range from 5 to 30 seconds. Although, no official guidance is out there for oral fast disintegrating films strips.

**Dissolution Test:-**

Dissolution studies of films is performed by using USP type II apparatus in 6.8 phosphate buffer (900ml) and 0.1N HCl (900ml). The temperature (37±0.5°C) and therefore the rotation speed is 50 rpm. 5ml samples is withdrawn at various time intervals and analyzed spectrophotometrically.

**Folding Endurance:-**

It was measured by folding the film at an equivalent place repeatedly until a clear crack is observed. This provides a sign of brittleness of the film. Folding endurance is decided by repeated folding of the strip at an equivalent place till the strip breaks. The amount of times the film is folded without breaking is that the folding endurance value. This provides a sign of the brittleness of the film. The film again and again folded at same point until get breaks. F.endurance value is taken into account as number of times it's folded without breaking the film again and again folded at same point until get breaks. F. endurance value is taken into account as number of times it's folded without breaking.

**Percentage Elongation:-**

It is percentage ratio of the increase long to the first length. it had been calculated by measuring the rise long of the film after tensile measurement by using the subsequent formulae.

| | | |
|---|---|---|
| Percent Elongation = | [L-L0] X 100 | Where,<br>L was the Final length<br>L0 was initial length. |
| | L0 | |

**Elongation Test:-**

Kinston Universal Testing Instrument is employed. Films are pulled by 2 clamps at a rate of 100 mm/min. Force and elongation is measured when film breaks.

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**In-vitro / Dissolution Studies / Release:-**

An in-vitro dissolution study for all the batches was performed for five minutes and every film was placed with the assistance of forceps during a 50 ml glass beaker containing 30 ml of simulated salivary fluid pH 6.8 Dissolution medium was kept at 37º C ± 0.5 º C and magnetic stirrer was rotated at 50 rpm. It's administered by USP XXIII Type II apparatus in phosphate buffer pH 6.8 in 500 ml media and 0.1N HCl 500 ml media at the temperature is 37±0.5°C, and therefore the rotation speed should be 50 rpm. The samples are withdrawn at various time intervals and will analyze spectrophotometrically.

**Young's Modulus (YM):-**

Young's modulus or coefficient of elasticity is that the measure of stiffness of strip. it's represented because the ratio of applied stress over strain within the region of elastic deformation as follows:

| | |
|---|---|
| Young's modulus= | Slope *100 |
| | Strip thickness * Cross head speed |
| Young's modulus = | (Force at corresponding strain/cross section area) ×1 |
| | (corresponding strain) |

**Stability Study:-**

It is to be conducted as per the International Conference on Harmonization pointers.

**Packaging:-**

A sort of packaging choices is obtainable for quick dissolving films. Single packaging is obligatory for films, that ar pharmaceutical products; associate degree atomic number 13 pouch is that the foremost unremarkably used packaging format. APR-Labtec has developed the speedy card, a proprietary and proprietary packaging system, that is specially designed for the speedy films. The speedy card has same size as a mastercard and holds 3 raid films on all sides. each dose ar usually taken out severally.

**COMPARISON BETWEEN FAST DISSOLVING TABLETS AND FILMS: [9]**

| Fast Dissolving Tablets | Fast Dissolving Films |
|---|---|
| Lesser dissolution due to less surface area | Greater dissolution due to large surface area |
| Less durable as compared with oral films | Better durable than oral disintegrating tablets |
| Less patients compliance than films | More patient compliance |
| High dose can be incorporated | Low dose can only be incorporated |
| It has fear of chocking | No risk of chocking |
| It is in the form of tablet. | The form is film |
| Lesser dissolution due to less surface area. | Greater dissolution due to larger surface area |
| Less durable as compared with orodispersible film. | Better durable than orodispersible tablets |
| Less patient compliance than film | More patients compliance |
| High dose can be incorporated. | Low dose can be incorporated. |

**Table no. 5**

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**COMMERCIALLY AVAILABLE ORAL MUCOADHESIVE DRUG DELIVERY SYSTEMS [15]**

| Drug | Dosage form | Type of release | Product name | Manufacturer |
|---|---|---|---|---|
| **Chlorhexidine digluconate** | Oromucosal gel | Controlled | Corsodyl gel | GalaxoSmithKline |
| **Hydrocortisone sodium succinate** | Oromucosal pallets | Controlled | Corlan pellets | Celltech |
| **Buprenorphine HCl and Naloxone** | Tablet | Quick | Sulbutex | Reckitt Benckiser |
| **Proclorperazine** | Tablet | Controlled | Buccastem | Reckitt Benckiser |
| **Testosterone** | Tablet | Controlled | Straint SR | Columbia Pharmaceuticals |
| **Zolpidem** | Spray | Quick | Zolpimist | NovaDel |

**Table no. 9**

## II. SUMMARY:-

The oral route is that the common route for transfer the drug. The tablets and capsules square measure the wide used medicaments in oral indefinite quantity kind. however currently for several of the pediatric, geriatric and upset patients UN agency realize issue in swallowing, the Oral Dissolving Films (ODF) square measure usually given to beat such issues. Mouth dissoluble films (MDFs) evolved over the past few years from the confection and oral care markets inside the kind of breath strips and became a totally distinctive and wide accepted kind by shoppers. MDF that disintegrate or dissolve inside 1min once placed inside the mouth while not food or mastication. Also, used for the style masking of wide bitter tasted medication that square measure most important for the pediatric patients. quick dissolving films became a totally distinctive approach to oral drug delivery system as a result of it provides convenience and easy use over different indefinite quantity forms like orally disintegrating tablets, buccal tablets and articulator tablets, therefore mouth dissolving films square measure gaining the interest of giant range of pharmaceutical industries.

## III. CONCLUSION:-

The temporary review on oral film concludes with the note that they are thought of as a most promising and vital drug delivery system thanks to their fast disintegration embody dissolution properties particularly with pediatric medicine and medicine patients. Albeit most of the formulations nowadays square measure developed as ODTs, oral films have gained additional quality thanks to their simple movability, improved patient compliance and easy administration. They'll be applied by each oral and buccal route. Except for obtaining used as medication films (local anaesthetic, vitamins supplements and cold hypersensitivity reaction remedies). Oral tissue layer delivery offers a convenient approach of dosing medication, not solely to special populations with swallowing difficulties, however additionally to the population. Mucoadhesive indefinite quantity forms offer prolonged Contact time at the situation of attachment, having high patient compliance and square measure economic as compare to different indefinite quantity forms. They'll even be used for refreshing the breath. This technology is growing in quick pace difficult most of the pharmaceutical corporations to develop oral films for an honest vary of active pharmaceutical ingredients.

## IV. FUTURE PROSPECTIVE:-

Fast dissolving oral films have higher patient compliance and may improve biopharmaceutical properties, improve effectualness and higher safety, compared with typical oral indefinite quantity forms. When the quick Dissolving Tablets, the new product as quick Dissolving Oral quick square measure meant for the appliance inside the mouth which they're innovative and promising indefinite quantity kind particularly to be utilized in elder patients. The event of quick dissolving drug product additionally provides an opportunity for a line extension throughout a marketplace, for an honest vary of medication. In future, this system is most

acceptable. Thanks to increasing patient demand, the popularity of these indefinite quantity forms can expand the study in future.

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