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A REVIEW ON FAST DISSOLVING ORAL FILMS: AN INNOVATIVE DRUG DELIVERY SYSTEM

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ABSTARCT

The oral route is most popular route for the administration of therapeutic agents because of the low cost of therapy and ease of administration lead to high levels of patient compliance The most popular oral solid dosage forms are tablets and capsules. Many patients find it difficult to swallow tablets and hard gelatin capsules particularly pediatric and geriatric patients and do not take their medicines as prescribed. Difficulty in swallowing or dysphasia is seen to afflict nearly 35% of the general population. In some cases such as motion sickness, sudden episode of allergic attack or coughing, fear of choking and an unavailability of water, the swallowing of tablet or capsules may become difficult. To overcome these difficulties, several fast-dissolving drug delivery systems have been developed. Oral fast dissolving film is relatively a new dosage form in which thin film is prepared using hydrophilic polymers, which rapidly dissolves on tongue or buccal cavity. The film overcomes the danger/fear of choking. An ideal film should have the properties like pleasant taste, high stability, ease of handling and administration, no water necessary for application.

Key Words: Fast dissolving films, Oral strips, Film forming polymer, solvent casting, Tensile strength.

1. INTRODUCTION

Oral route is a most preferred route of drug administration for systemic effect due to its ease of administration, non-invasiveness, adaptability, patient compliance and acceptability. Tablet is the most preferred dosage form due to ease of manufacturing, transportation and more patient compliance. Generally geriatric, pediatric, nauseous, bed ridden and noncompliance patients experience difficulties in swallowing the conventional oral dosage form and do not take their medicines as prescribed. It is estimated that 50 % of the population was affected by this problem, which finally results in a higher chance of noncompliance & ineffective therapy. The elderly constitute a major portion of today's population mainly because of increased life expectancy of individuals.Dysphagia or difficulty in swallowing is common problem, this disorder is coupled with several medical conditions including stroke, AIDS, thyroidectomy, Parkinson's disease, head and neck radiation therapy and other neurological disorders as well as encephalopathy. The most common complaint with tablet is size, fear of chocking. The problem of swallowing tablets is more evident in geriatric and pediatric patients, as well as travelling patients who may not have ready access to water.To overcome this Oral fast disintegrating drug delivery systems were developed, these systems were initially developed within the late Seventies as an alternative to tablets, capsules and syrups for pediatric & geriatric patients who experience difficulties in swallowing traditional oral solid dosage forms. These dosage forms either dissolve or disintegrate generally within a 3 minute in mouth, without need of water. Oral fast Disintegrating dosage form have started gaining popularity & acceptance as new drug delivery system due to better patient compliance.

2. FAST DISSOLVING DURG DELIVERY SYSTEM

Fast dissolving drug delivery system is a new generation delivery system also known as fast dissolving/disintegrating film for the oral delivery of the drugs which came into existence in the late 1970's as an alternative to tablets, capsules, syrups and other formulations for pediatric and geriatric patients who experience difficulties in swallowing traditional solid dosage forms which combines both the advantages of conventional tablet and of liquid formulation. FDDS is easy to administer and provides better patient compliance in the elderly, pediatric, mentally retarded, nauseated and uncooperative patients. The delivery system consists of a very thin oral strip which is simply placed on the patient's tongue or any other oral mucosal tissue and instantly gets wetted by saliva. The film rapidly hydrates onto the site of application. It then rapidly dissolves and disintegrates to release the medication for oro-mucosal absorption. Fast dissolving oral thin films are widely accepted by patients and also to the caregiver for their ease-of-delivery, portability and accurate dosing . The robustness of the film depends upon the type and amount of polymer used and general dissolution time for orally dissolving film is 5–20 min. as per pharmacopoeia. They also provide quick onset of action within few seconds as the oro-mucosal absorption of the drug occurs directly from the site of administration to the systemic circulation avoiding the first-pass metabolism to produce the desired effect.

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FIGURE NO: 1. Fast Dissolving Oral Film

ANATOMY OF ORAL CAVITY

The structure and anatomy of oral cavity is studied for understanding the environment provided for delivering drugs . The oral mucosa allows direct access of drug to the systemic circulation and avoids first pass metabolism. The epithelium of the oral cavity is quite similar to that of the skin, with slight differences with regard to keratinization, protective and lubricant mucous which is spread across its surface. The permeability of oral mucosa is 4–1000 times greater than that of the skin. The oral cavity is divided into two regions: outer being the oral vestibule bounded by the lips and cheeks; the hard and soft palates, the floor of the mouth and tonsils .Oral drug delivery has been known for decades as the most widely utilized route of administration among all the routes that have been explored for the systemic delivery of drugs via various pharmaceutical products of different dosage forms.

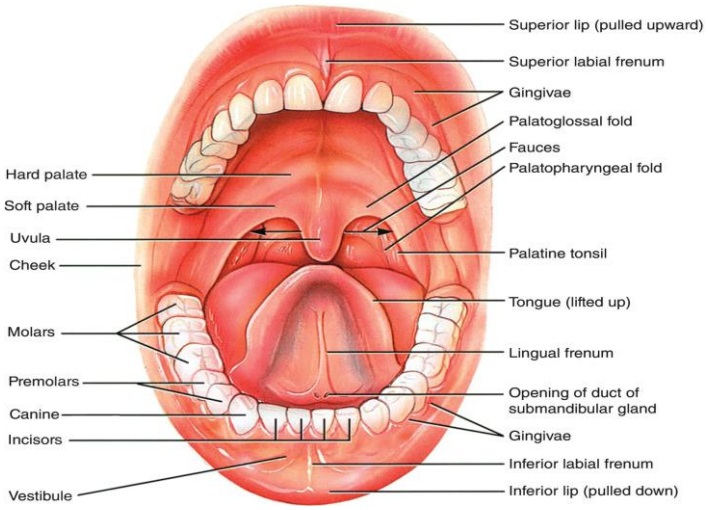

FIGURE NO; 2 ANATOMY OF ORAL CAVITY

SPECIAL FEAUTERS OF MOUTH DISSOLVING FILMS

- Thin elegant film
- Available in various size and shapes
- Unobstructive
- Excellent mucoadhesion
- Fast disintegration
- Rapid release

IDEAL PROPERTIES OF FAST DISSOLVING FILMS

- It should have an acceptable taste.
- It should give a pleasing mouth feel.
- It should be less friable and have good mechanical strength to withstand the post manufacturing handling.
- It should be stable in environmental conditions.
- Subsequent to oral administration, it should leave least or no residue in mouth.
- It should quickly dissolve to release drug instantaneously in mouth.
- It should be compatible with the other ingredients.

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CLASSIFICATION OF FAST DISSOLVING ORAL FILMS

Oral films come in three distinct subcategories:

a. Flash delivery

b. Mucoadhesive sustained release wafers

c. Mucoadhesive melt-away wafers

a. Flash Delivery

Flash delivery oral films are designed to rapidly dissolve or disintegrate in the mouth, allowing for fast and efficient drug delivery through the oral mucosa. These films are typically used for drugs with a short half life, low bioavailability, or that require rapid onset of action. Flash delivery films can also improve patient compliance by providing a convenient and discreet drug delivery method

b. Mucoadhesive Sustained Release Wafers

Mucoadhesive sustained release wafers are designed to adhere to the buccal or sublingual mucosa and release the drug over an extended period of time. These films are typically used for drugs that have a short half-life, require sustained drug delivery, or are not well absorbed through the gastrointestinal tract. Mucoadhesive sustained release wafers can also avoid the hepatic first-pass effect and improve drug bioavailability.

c. Mucoadhesive Melt-Away Wafers

Mucoadhesive melt-away wafers are designed to adhere to the buccal or sublingual mucosa and rapidly dissolve or melt in the mouth, allowing for fast and efficient drug delivery through the oral mucosa. These films are typically used for drugs that have a short half-life, low bioavailability, or require rapid onset of action. Mucoadhesive melt-away wafers can also improve patient compliance by providing a convenient and discreet drug delivery method.

2. Buccal Slow-Release Film

This type of oral film releases the drug slowly and continuously over an extended period of time, typically hours to days, and delivers the drug through the buccal mucosa. It is particularly useful for drugs that have a short half-life or require sustained drug delivery. The buccal slow-release film can also avoid the hepatic first-pass effect, which can increase drug bioavailability

3. Transdermal Film:

This type of oral film delivers the drug through the skin and is typically used for drugs that require systemic delivery or have a high first-pass effect. Transdermal films can also provide a non-invasive and convenient drug delivery method, particularly for patients who have difficulty swallowing or require long-term drug therapy.

3. ADVANTAGES

1) No need of water for administration.
2) Convenient for paediatric, geriatric and dysphasic patients having difficulty in swallowing. 3. Rapid disintegrating and dissolution in the oral cavity due to larger surface area of films.
3) Rapid onset of action with increased bioavailability due to bypassing hepatic first pass effect.
4) Reduce dose, enhances the efficacy and safety profile of the drug with reduced side effects.
5) Flexible and portable in nature so they provide ease in handling, transportation and storage.
6) Ease of administration to mentally ill, disabled, uncooperative patients and the patients who are on reduced liquid intake plans or are nauseated.
7) Beneficial in cases such as motion sickness, acute pain, sudden allergic attack, asthmatic attack and coughing, where an ultra-rapid onset of action is required.
8) Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed.
9) Accuracy in dose as compared to liquid formulations.
10) Pleasant mouth feel, leave negligible or no residue in the mouth after administration.

4. DISADVANTAGES

1) Drugs which are unstable at buccal pH cannot be administered.
2) Drugs which irritate the mucosa cannot be administered by this route.
3) Drug with small dose requirement can only be administered.
4) Taste masking- Most drugs have bitter taste, and need taste masking ..Special packaging- OFDFs are fragile and must be protected from water so it needs special packaging.

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PROPERTIES OF ORAL FILMS

Property	Flash release	Mucoadhesive melt release	Muchoadhesive sustained release
Area{cm^2}	2-8	2-7	2-4
Thickness{um}	20-70	50-500	50-250
Excipients	Soluble, highly hydrophilic polymer	Soluble, hydrophilic polymer	Low/non soluble polymer
structure	Film single layer	Single /multiple layer	Multiplelayer system
Site of action	Systemic or local	Systemic or local	Systemic or local
Drug phase	Solid solution	Solid solution / suspended drug particle	Suspension/solid solution
Application	Tongue[upper plate]	Gingival/ buccal region	Gingival /other region of oral cavity
Dissolution	Maximum 60 sec	Disintegartion in few-mins, forming gel	Maximum 8 – 10 hrs

FORMULATION INGREDIENTS

Formulation considerations

From the regulatory prospective all the excipients used in the formulation and development of oral films and they are regarded as safe (GRAS listed) and should be approved for use in oral pharmaceutical dosage forms. The area of oral thin films is 1-20cm2 (depend on dose and drug loading containing drug).

1. Drug [1-25%]

several class of drugs can be formulated as mouth dissolving films including anti asthamatics (Salbutamol sulphate), antiulcer (Omeprazole), expectorants, antitussives, NSAID'S(Valdecoxib, Meloxicam).

2. Water Soluble Polymers[40-50%]

Water Soluble Polymers (40-50%) To obtain the desired film properties, polymers can be used alone or in combination. Generally water-soluble polymers are used as film formers as they achieve rapid disintegration, good mouth feel and mechanical properties to the films. The strength of the film depends on the type of polymer and the amount in the formulation. By increasing the molecular weight of polymer film bases, disintegration rate of the polymer decreases. Polymers frequently used as film formers are water soluble grades of cellulose ethers, polyvinyl alcohol, polysaccharides, polyvinylpyrrolidone K 90, polyethylene glycols, pullulan, gelatin, carboxmethylcellulose cekol 30, hydroxy propyl methyl cellulose E-3 and K-3, methyl cellulose A-3, A-6 and A-15, pectin, sodium alginate hydroxypropylcellulose, maltodextrins and eudragit RD10.

3. Plasticizer [0-20%]

Plasticizer enhances mechanical properties such as tensile strength and elongation to the film by reducing the glass transition temperature of the polymer. It also reduces brittleness of the strip as a result improves its flexibility. Choice of plasticizer depends upon type of solvent used and its compatibility with the polymer. Some of the commonly employed plasticizers are phthalate derivatives like dimethyl, diethyl and dibutyl phthalate, low molecular weight polyethylene glycols, castor oil, citrate derivatives like tributyl, triethyl, acetyl citrate, triacetin and glycerol. Improper use of plasticizer may lead to blooming, film cracking, splitting and peeling of the strip

4. Surfactants

They are used as solubilizing and wetting agents making the film to dissolve rapidly within seconds. Sodium lauryl sulphate, tween 80, benzalkonium chloride are some of the widely used surfactants. In recent times Polaxamer 407 has been majorly used as wetting and solubilizing agent

5 Saliva Stimulating agents

The purpose of using saliva stimulating agents is to increase the rate of production of saliva that would aid in the faster disintegration of the rapid dissolving strip formulations. These agents are used alone or in combination between 2 6% w/w of the strip. Citric acid, malic acid, lactic acid, ascorbic acid and tartaric acid are the few examples of salivary stimulants.

6 Flavoring Agents

Flavouring Agents can be selected from the synthetic flavor oil, oleo resins, extracts derived from various parts of the plant like leaves, fruits, and flowers. Any flavor can be added such as essential oil or water soluble extracts of menthol,

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intense mints such as peppermint, sweet mint, spearmint, wintergreen, cinnamon, clove, sour fruit flavor such as lemon, orange or sweet confectionary. Flavours such as vanillin, chocolate or fruit essence like apple, raspberry, cherry, pineapple.

7 Coloring agents

FDC approved natural coloring agents and natural juice concentrates are most commonly used. The concentration should not exceed 1%w/w. Pigments like titanium dioxide, silicon dioxide are also used as prominent coloring agents for oral films .

5. MANUFACTURING METHODS

To manufacture the Fast dissolving oral films, following methods are generally employed

1. Solvent casting method
2. Hot melt extrusion method
3. Semisolid casting method
4. Rolling method
5. Solid dispersion extrusion

1. SOLVENT CASTING METHOD

Solvent casting is a simple and cost-effective technique for producing oral films. In this technique, the film forming polymers and excipients are dissolved in a suitable solvent, such as water or ethanol, to form a homogeneous solution. The drug is then added to the solution, and the mixture is cast onto a flat surface, such as a glass plate or a Teflon-coated surface. The solvent is evaporated, leaving behind a thin film that contains the drug.

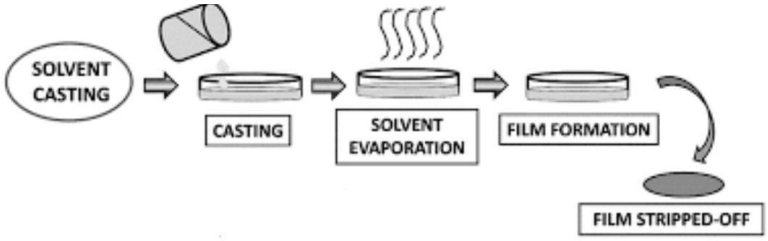

FIG NO:3 SOLVENT CASTING METHOD

2. HOT MELT EXTRUSION PROCESS

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

• Fewer operation units

• Better content uniformity

• An anhydrous process

Hot-melt extrusion is a more advanced technique for producing oral films. In this technique, the film forming polymers and excipients are mixed with the drug in a twin-screw extruder at high temperatures. The mixture is then extruded through a die to form a continuous film that is cooled and cut into the desired shape.

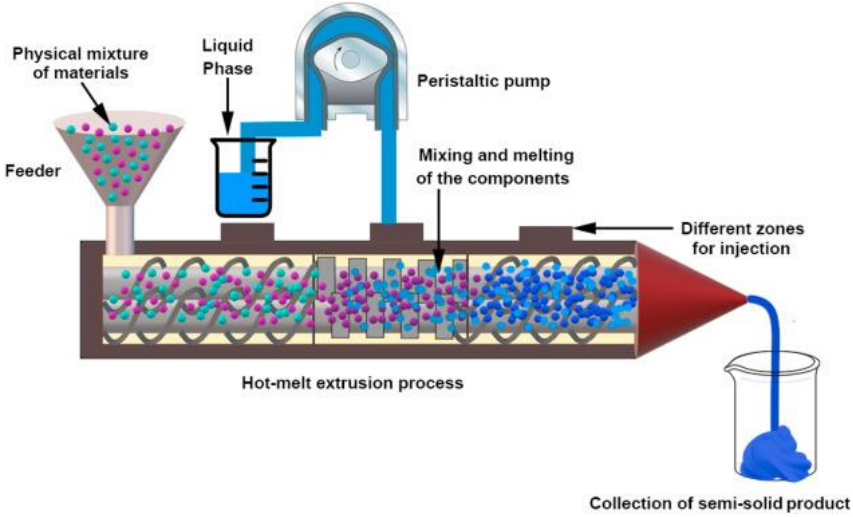

FIG NO 4: HOT MELT EXTRUSION PROCESS

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3. SEMI SOLID CASTING METHOD

In this method at first a solution of water soluble film forming polymer is prepared. Then the resulting solution is added to a solution of acid insoluble polymer (e.g. cellulose acetate phthalate) which was prepared in ammonium or sodium hydroxide. The ratio of the acid insoluble polymer to film forming polymer should be 1:4. A gel mass is obtained on addition of suitable amount of plasticizer. By the means of heat controlled drums, finally the gel mass is casted in to the films or ribbons

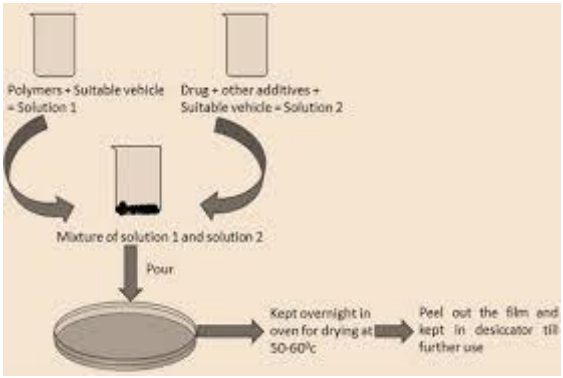

FIG NO 5: SEMI SOLID CASTING METHOD

4. Rolling Method

In rolling method a solution or suspension of drug with film forming polymer is prepared and subjected to the roller. The solution or suspension should have specific rheological consideration. The solvent is mainly water and mixture of water and alcohol. The film is dried on the rollers and cutted in to desired shapes and size and flat surface to form a film. The film is dried and carefully removed a film. Carefully.

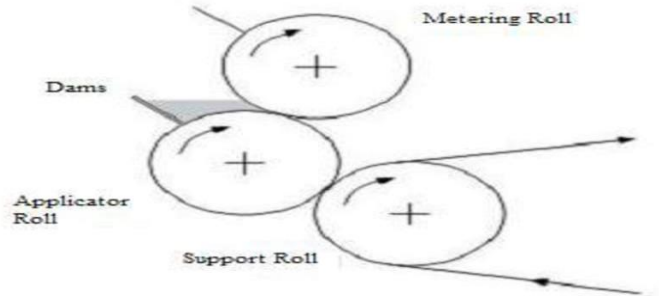

FIG NO 6: ROLLING METHOD

5. Solid dispersion extrusion Solid dispersion extrusion Solid dispersion refers to the dispersion of two or more active ingredients in a carrier in the presence of amorphous hydrophilic polymers in solid state. The API is dissolved in suitable solvent and incorporated into PEG. The drug and solvents are immiscible in nature. Solid dispersions are then shaped into films by means of dies.

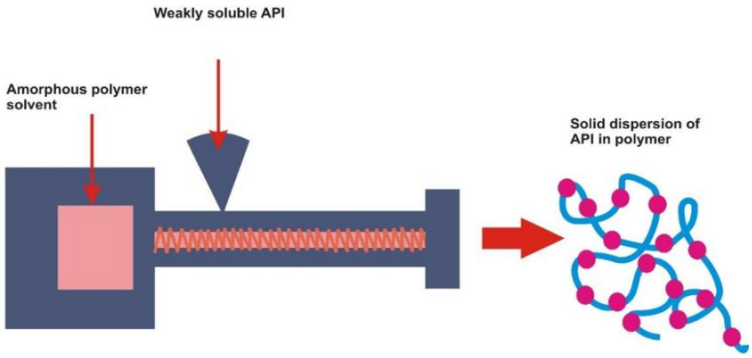

Figure no 7: solid dispersion extrusion

EVALUATION TESTS

A. Mechanical properties

1. Thickness test

A micro meter screw gauge is used to measure the strip thickness. In order to obtain uniformity of film, thickness is measured at 5 different locations. The thickness of the film should be less than 5%

2. Tack test

Tack is the tenacity with which the film adheres to the accessory that has been pressed into contact with strip. This test also determines the dryness.

3. Tensile strength Tensile strength is the maximum stress applied to a point at which the strip specimen breaks. It is calculated by formula

Tensile strength =load at failure x 100

Strip thickness x strip width

4. Percentage elongation

It is calculated by formula

%Elongation =Increases in length of strip x 100

Initial length of strip

5. Young's modulus:

Young's modulus or elastic modulus is the measure of stiffness of strip. It is represented as the ratio of applied stress over strain in the region of elastic deformation as follows: Hard and brittle strips demonstrate a high tensile strength and Young's modulus with small elongation. Typical Young's modulus value for film is 0.30 ± 0.07MPa.

Young's modulus = slope x 100

Strip thickness x cross head speed

6. Tear resistance:

Tear resistance of plastic film or sheeting is a complex function of its ultimate resistance to rupture. The maximum stress or force (that is generally found near the Onset of tearing) required to tear the specimen is recorded as the tear resistance value in Newton (or pounds-force).

7. Folding endurance

: To determine folding endurance, a strip of film is cut and repeatedly folded at the same place till it broke. The number of times the film could be folded at the same place without breaking gives the value of folding endurance. Typical folding endurance for film is between 100-150.

B. Organoleptic evaluation

For this purpose Invitro methods of utilizing taste sensors and specially designed apparatus are being used. These Invitro taste assessment apparatus are opted for high-throughput taste screening of oral pharmaceutical formulations.

1. Swelling index:

The studies of swelling index of the film are conducted in simulated salivary fluid. The film sample is weighed and placed in a pre-weighed stainless steel wire sieve. The mesh containing the film is submerged into 50ml of simulated salivary medium contained in a mortar. Increase in weight of the film is determined at each interval until a constant weight is observed. The degree of swelling is calculated using the formula: SI = wt - wo / wo Where, SI = swelling index, Wt. = weight of the film at time "t", and wo = weight of the film at t = 0

2. Surface of PH

Surface pH of the film was determined by placing the film on the surface of 1.5% w/v agar gel followed by placing pH paper (pH range 1-11) on film. The change in the colour of pH paper was observed and report.

3. Contact Angle:

Contact angle are measured by Goniometer at room temperature. Take a dry film and place a drop of distilled water on the surface of the dry film. Images of water droplet were recorded with in 10 sec of deposition by means of digital camera. The contact angle was measured on both side of drop and average is taken

4. Transparency

The transparency of the films can be determined using a simple UV spectrophotometer. Cut the film samples into rectangles and placed on the internal side of the spectrophotometer cell. The determine transmittance of films at 600 nm. The transparency of the films was calculated as follows: Transparency = (logT600)/b = - €c Where, T600 is the transmittance at 600 nm b is the film thickness (mm) c is concentration

5. Uniformity of drug content:

This parameter can be determined by dissolving known weight of film by homogenization in 100 ml of simulated saliva of pH 6.8 for 30 min with continuous shaking. Content uniformity is determined by estimating the API content in individual film. Limit of content uniformity is 85-115%.

6. Moisture content

Initially the prepared film was weighed and placed in the desiccators containing cadmium chloride. After 3 days the film was reweighed to obtain the percentage of moisture loss

%moisture content =initial weight –final weight x x100

Initial weight

7. Disintegration test:

Disintegrating time is defined as the time (seconds) at which a film breaks when brought in contact with water or saliva. The disintegration time limit of 30 s or less for orally disintegrating tablets described in CDER guidance can be applied to fast dissolving oral film. Pharmacopoeia disintegrating test apparatus may be used for this study. Typical disintegration time for film is 5-30 s.

8. In-vitro Dissolution test

By this method cumulative drug release and cumulative percentage of drug retained were calculated. In-vitro drug dissolution was performed using USP paddle type apparatus. The studies were carried out at 37°C with stirring speed of 75 rpm in 900 ml phosphate buffer (pH 6.8). 5 ml of samples were withdrawn at predetermined time intervals of 2, 4, 6, 8, 10 min and replaced with the same volume of buffer. The samples were collected and the concentration was determined at appropriate wavelength using UV-visible spectrophotometer.

LIST OF MARKTED FAST DISSOLVING ORAL FILMS

ORAL FILM	ACTIVE INGREDIENT	MANUFACTURE /MARKETED	CATEGORY
1.Triaminic	Diphenhydramine HCL	Novartis	Anti allergic
2. Liaterine	Cool mint	Pfizer	Mouth fresheners
3.Theraflu	Dextromethorphan	Novartis	Anti allergic
4.Dextromethorphan	Dextromethorphan	Hughes medical corporation	Anti-tussive agent
5.Caffeine films	Caffeine	Dowchemical company	Post-operative nausea and vomiting
7.Donepezil	Donepezil	Labtec Gmbh	Anticholinesterases
8.Suppress r	Menthol	Innogen r, Inc	Mouth freshner
9.Setofilm	Ondansetron	Bio alliance Pharma	Preventing nausea And vomiting
10.Sudafed PE	phenyleprine	Wolters Kluwer health Inc.	Relieving congestion
11.Klonopin wafer	Clonazepam	Solvay pharmaceuticals	Treatment of anxiety
12.Zuplenz	ondansetron	Monosol RX	Preventing nausea and vomiting

6. CONCLUSION

Oral fast dissolving films are not well defined in the literature but, no doubt a revolutionary and an innovative drug delivery system for all the population groups, specifically geriatric, pediatric patients and patients with swallowing difficulties. Oral fast dissolving films are also having great potential of delivering the medicinal agent systemically as well locally and have several advantages over many dosage forms even over the fast disintegrating tablets. This explains the extensive research actively going on this technology. Recently FDF has gained popularity as dosage form and is most acceptable and accurate oral dosage form which bypass the hepatic system and show more therapeutic response. Oral films can replace the over-the counter drug, generic and brand name from market due to lower cost and consumer preference. This technology is a good tool for product life cycle management for increasing the patent life of existing products. So this technology is growing in fast pace challenging most of the pharmaceutical companies to develop oral films for a wide range of active pharmaceutical ingredients.

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