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A Review on: Fast Dissolving Oral Film

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ABSTRACT

Recently, fast dissolving oral films have started gaining fame and acceptance as new drug delivery systems, which aim to enhance safety and efficacy of a drug molecule to achieve better patient compliance. It is a robust form a drug delivery system where the film is placed on the top or the floor of the tongue. When put on the tongue, this film dissolves instantaneously, releasing the drug which dissolves in the saliva. Buccal drug delivery has lately become an important route of drug administration. But many of the patients (paediatrics and geriatrics) are unwilling to take solid preparations due to fear of choking. This has made the pharmaceutical industry look for alternatives routes of drug delivery like film drug delivery. Fast dissolving oral drug delivery system have started gaining popularity and acceptance as new drug delivery system, because they are easy to administer, better patient compliance, rapid drug absorption, and sudden onset of drug action with instant bioavailability is possible. This review reflects information regarding formulation ingredient, technologies and evaluation test employed in the preparation of fast dissolving oral films.

KEYWORDS: *Fast dissolving oral films, buccal drug delivery, paediatric patients, geriatrics patients*

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INTRODUCTION

Among the different routes, the most agreeable routes, for the patient is oral route. Most of the pharmaceutical companies have directed their research activity in developing viable dosage alternatives from oral route for paediatrics, geriatrics, noncompliant or nauseous patients. Almost 90% of the drugs are administered to the body via oral route for the treatment of various disorders and diseases as it is regarded as the safest, most economical method of drug delivery and have the highest patient compliance. The drug is either dissolved or swallowed, which then enters into the systemic circulation to produce the desired effect. Fast dissolving oral film, a novel drug delivery system for the oral delivery of the drug is an ultrathin film prepared using hydrophilic polymers that rapidly dissolves on the top or floor of the tongue or buccal cavity. It is an ultrathin strip (50-150 microns thick) of postage stamp size with an active agent and other excipient developed on the basis on transdermal patch technology. These fast-dissolving oral films have persistent to extend in sales and launched and patient compliance and convenient products effectively addressing issues for pharmaceuticals as well as nutraceuticals that have been traditionally administered as oral solid dosages.

Today, fast oral films are a well proven and world-wide accepted technology for the systemic delivery of active pharmaceutical ingredients (APIs)[1,2]. To overcome this oral fast disintegrating drug delivery system were developed, these systems were initially developed within the late seventies as an alternative to tablets, capsules and syrups for paediatric and 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 and acceptance as new drug delivery system due to better patient compliance[3]Technology Catalysts forecasts the market for drug products in oral thin film formulations to be valued at $500 million in 2007 and could reach $2 billion in near future [4,5,6]. However only a few products consisting bitter molecules have been able to be commercialized because of the complexity associated with the ODT. A large number of drugs can be formulated as mouth dissolving films.

Innovative products may increase the therapeutic possibilities in the following indications[7,8].

- Pediatrics (Antitussives, Expectorants, Antiasthamatics)
- Geriatrics (Antiepileptic, Expectorants)
- Gastrointestinal diseases
- Nausea (due to Cytostatic therapy)
- CNS (Antiparkinsonism therapy)

Fast dissolving drug delivery system (FDDS)

Fast dissolving drug delivery system is a new generation delivery system also known as fast dissolving/disintegrating film for the oral delivery of the drug which came into existence in the late 1970s as an alternative to tablets, capsules, syrups and other formulation for paediatric and geriatric patients who experience difficulties in swallowing traditional solid dosage forms which combines both the advantages of conventional tablet and of liquid formulation.[4] FDDS is easy to administer and provides better patient compliance in the elderly, paediatric, mentally retarded, nauseated and uncooperative patients.[9] This delivery system consists of the solid dosage form that dissolve quickly i.e. within a matter of seconds in the oral cavity without the administration of water. The delivery system consists of a very thin oral strip which is simply placed on the patients tongue or any other oral mucosal tissue and instantly gets wetted by saliva.[10] The film rapidly hydrates onto the site of application. It then rapidly dissolves and disintegrates to release the medication fororo-mucosal absorption. 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. [11,12] 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.[13]

Special features of oral thin films [14,15]

- Thin elegant
- Available in various sizes and shapes
- Un-obstructive
- Excellent mucoadhesion.
- Fast disintegration and rapid release.

Ideal properties of fast dissolving films[16,17,18]

- It should be compatible with the other ingredients.
- The therapeutic dose of the drug should not be greater than 40mg.
- It should be less friable and have good mechanical strength to withstand the post manufacturing handling.
- It should quickly dissolve to release drug instantaneously in mouth.
- It should have an acceptable taste with pleasing mouth feel.

Anatomy of oral cavity

The structure and anatomy of oral cavity is studied for understanding the environment provided for delivering drugs [Fig. 1]. 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.[19] 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.[20] 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 dosageforms.[21]

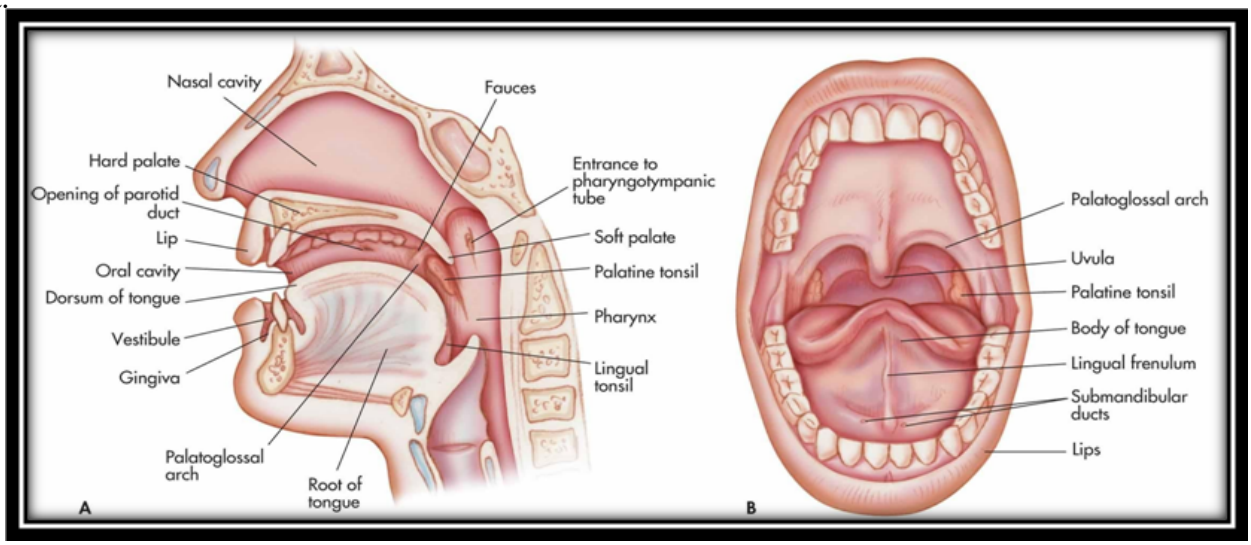

Figure 1: Anatomy of the oral cavity

Advantages of fast dissolving films[22]

- Taste masking
- Enhanced stability
- Improve bioavailability for certain therapeutic ingredient.
- Rapid onset of action.
- No risk of chocking.
- Convenient dosing or accurate dosing.
- No need of water to swallow or chewed.
- Pleasant mouth feel, leave negligible or no residue in the mouth after administration.
- 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.
- Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed.
- Flexible and portable in nature so they provide ease in handling, transportation and storage.

Disadvantages of fast dissolving films [23]

- Drugs which are unstable at buccal pH cannot be administered**.**
- Drugs which irritate the mucosa cannot be administered by this route.
- A drug with small dose requirement can only be administered.
- Taste masking- Most drugs have the bitter taste, and need taste masking.
- It also shows the fragile, granule property.
- It is hygroscopic in nature so it must be kept in dry places.

Table 1: Comparison between Fast Dissolving Oral films and Dissolving Tablets [24,25]

The comparison between Fast Dissolving Oral Films and Fast Dissolving Tablets was given table 1.

Sr. no	Fast Dissolving Oral Film	Fast Dissolving Tablet
1.	Large surface area gives greater dissolution.	Less surface area gives lesser dissolution than FDOF
2.	Patient compliance is more.	Patient compliance is less than FDOF.
3.	Fast dissolving films are of thickness 0.015-.05 inches.	Fast dissolving tablets is of the same size of a conventional tablet.
4.	Only low dose can be incorporated in the formulation.	High dose can also be incorporated in the formulation.

Formulation Components of FDOFs

Active pharmaceutical ingredient [26]

A film composition contains 1-30% w/w of the active pharmaceutical ingredient. Always use low dose active pharmaceutical ingredients because high dose of drug is difficult to incorporate in fast dissolving film. A number of drugs can be used as fast dissolving film including anti-histamine, anti-diarrheal, anti-depressants, vasodilators, anti-asthmatic, anti-emetic, etc.[23]Dimenhydrinate can also be incorporated into ODFs for taste masking. Common examples of drugs incorporated into ODFs are salbutamol sulfate, rizatriptan benzoate, verapamil, ondansetron, dexamethasone, rofecoxib, cetirizine, pilocarpine, tianeptine sodium, indomethacin, etc. are mentionedinedin.[27]

Film forming polymer [28,29]

Polymer are the most important ingredient of the fast-dissolving oral film. Generally, 45% w/w of polymer is used which is based on total weight of dry film. The selection of polymer is one of the most important and critical parameters for the successful development of oral films because of their tensile strength which depends upon the type and amount of polymer used. Mainly hydrophilic polymers are used in the oral strips as they rapidly disintegrate in the oral cavity as they come in contact with saliva. Currently, both natural and synthetic polymers are used for the preparation of fast dissolving film.

Table 2: List of polymers used in oral thin films [30]

Group	Class	Example
Natural	Carbohydrate Proteins Resin	Pullulan, pectin, sodium alginate, maltodextrin, sodium starch glycolate. Gelatine Polymerized rosin. (novel film former)
Synthetic	Cellulose Derivatives Vinyl polymer Acrylic polymer	Hydroxypropyl methylcellulose (E3, E5, E15, K3, K15, K50), Methylcellulose. (A3, A6, A15), Carboxy methylcellulose secekol-30, Sodium carboxymethyl cellulose. Microcrystalline cellulose. Poly vinyl pyrrolidone (K-90, K-30), Poly vinyl alcohol, Poly ethylene oxide. Eudragit (RD-100, 9,10, 11, 12 and RL- 100)

Ideal Properties of The Film Forming Polymers.[31,32]

1. The polymer employed should be non-toxic, non-irritant and devoid of anyleachable impurities.
2. It would be ideal to have a polymer that would have local enzyme inhibition action.
3. It should have good wetting and spread ability property.
4. The polymer should exhibit sufficient peel, shear and tensile strengths.
5. The polymer should be cheap and readily available.
6. It should not cause any secondary infections in the oral mucosa/ dental region.
7. It should have a good mouth feel property.
8. It should be tasteless.
9. It should have long shelf life.

Plasticizers (0-20%)

Plasticizer helps to improve the flexibility and reduces the brittleness of the strip by reducing the glass transition temperature of the polymer. The selection of plasticizer depends on its compatibility with the polymer and the type of solvent used in the formulation[33,34]. Commonly used plasticizers are glycerol, propylene glycol, low molecular weight polyethylene glycols (PEGs), phthalate derivatives like dimethyl, diethyl, and dibutyl phthalate, citrate derivatives such as tributyl, triethyl, acetyl citrate, triacetin and castor oil. The plasticizers concentration of 0–20 % w/w of dry polymer weight is used by avoiding the film cracking, splitting and peeling of the strip [35,36]. The use of certain plasticizers mayalso affect the absorption rate of the drug [37]. The properties of plasticizer are important to decrease the glass transition temperature of the polymer in the range of 40-60ºC for a nonaqueous solvent system and below 75 ºC for aqueous systems [38]. Cellulosic hydrophilic polymers were easily plasticized with hydroxyl-containing plasticizers like PEG, propylene glycol, glycerol, and polyols. In contrast, less hydrophilic cellulosic polymers were plasticized with esters of citric acid and phthalic acid [39]. Glycerol acts as a better plasticizer for polyvinyl alcohol while diethylene glycol can be used for both Hypromellose as well as polyvinyl alcohol films.

Surfactants[40,41]

Surfactants are use as wetting or solubilising or dispersing agent so that the film is getting dissolved within seconds and release active agent immediately. Commonly employed are poloxamer 407, benzalkonium chloride, etc. Out of these most predominantly used surfactant is poloxamer 407.

Sweetening agents [42,43,44]

Sucrose is the most commonly used sweeteners in FDOFs. Sucrose is very soluble I water and being colourless dose not impart any undesirable colour to the final formulation. Some of the commonly employed sweeteners are dextrose, sucrose, fructose, glucose, isomaltose, etc. Artificial sweeteners like saccharine, cyclamate, aspartame (first generation), sucralose, alitame and neotame (second generation) can also be used. The sweetness of fructose is perceived rapidly in the mouth as compared to sucrose and dextrose. Fructose is sweeter than sorbitol and mannitol and thus used widely as a sweetener. Low molecular weight carbohydrates and specially sucrose are most commonly used sweeteners. Sucrose is very soluble in water and being colourless does not impart any undesirable colour to the final formulation. It is stable over the pH range 4-8. It masks the taste of both salty and bitter drugs. Polyhydric alcohols such as sorbitol, mannitol, and is malt can be used in combination as they additionally provide good mouth-feel and cooling sensation. Polyhydric alcohols are less carcinogenic and do not have bitter after taste which is a vital aspect in formulating oral preparations. The artificial sweeteners have gained more popularity in pharmaceutical preparations. Saccharin, cyclamate

and aspartame are the first generation of the artificial sweeteners followed by acesulfame-K, sucralose, alitame and neotame which fall under the second-generation artificial sweeteners. Acesulfame-K and sucralose have more than 200- and 600-time sweetness. Neotame and alitame have more than 2000- and 8000-time sweetening power as compared to sucrose. Rebiana which is an herbal sweetener, derived from plant Stevia rebaudiana (South American plant) has more than 200 -300-time sweetness.

Saliva stimulating agents [45]

Saliva stimulating agents are used to increase the rate of production of saliva that would help in the faster disintegration of the rapid dissolving strip formulations. Examples of salivary stimulants are citric acid, malic acid, lactic acid, ascorbic acid and tartaric acid. Among these the most preferred one is citric acid.These agents are used alone or in combination between 2 to 6% w/w of weight of the film.

Flavouring agents [46]

Flavours used in the formulation must be non-toxic, soluble, stable and compatible with the excipients. The quantity of flavouring agent required to mask the taste depends on the flavour type and its strength. Commonly employed arefruity flavours (vanilla, cocoa, chocolate, citrus), flavour oils (peppermint oil, cinnamon oil, oil of nutmeg). Flavours can also be chosen from oleo resins, synthetic flavour oils and extract derived from various parts of the plants like fruits, flowers etc.The amount of flavour needed to mask the taste depends on the flavour type and its strength.

Colouring agents

Generally incorporated colouring agents are FD&C colours, natural colours, pigments such as titanium dioxide, etc. The colouring agents should not exceed concentration levels of 1% w/w.[47,48]Some saliva stimulating agents may also be added to enhance the disintegration and toget rapid release. Some of these agents are citric acid, tartaric acid, malic acid, ascorbic acid and succinic acid.

Manufacturing methods

To manufacture fast dissolving oral films, following methods are generally employed:

A. Semisolid casting

B. Rolling

C. Solvent casting

D. Hot melt extrusion

E. Solid dispersion extrusion

A. Semisolid casting[49]

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 mas is casted in to the films or ribbons.

B. Rolling method [50]

In this method the film is prepared by preparation of a pre-mix, addition of an active and subsequent formation of a film. Prepare pre-mix with film forming polymer, polar solvent and other additives except a drug Add pre mix to master batch feed tank. Fed it via a 1st metering pump and control valve to either or both of the 1st and 2nd mixer. Add required amount of drug to the desired mixer. Blend the drug with master batch pre mix to give a uniform matrix. Then a specific amount of uniform matrix is then fed to the pan through 2nd metering pumps. The film is finally formed on the substrate and carried away via the support roller. The wet film is then dried using controlled bottom drying.

C. Solvent casting [51,52,53]

In this method water soluble polymers are dissolved in water and the drug along with other ingredients is dissolved in suitable solvent. Then both the solutions are mixed, stirred, finally casted into the petri plate and dried.

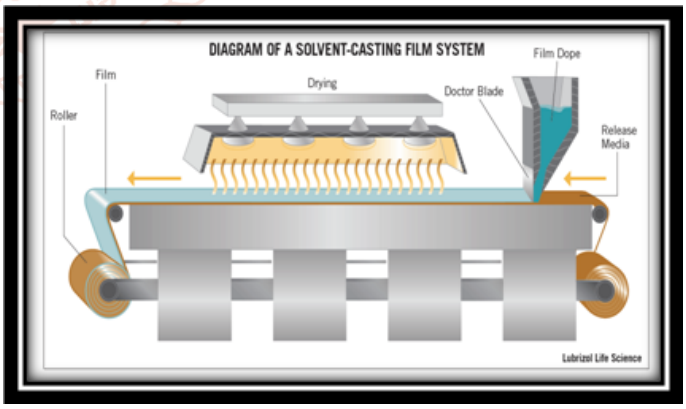

Figure 2: Solvent Casting.

Advantages:

- Better uniformity of thickness and better clarity than extrusion.
- Film has fine gloss and freedom from defects such as die lines.
- Film has more flexibility and better physical properties.
- Finished film thickness is 12-100um

Disadvantages:

- The polymer must be soluble in a volatile solvent or water.
- A stable solution with a reasonable minimum solid content and viscosity should be formed.
- Formation of homogeneous film and release from the casting support must be possible.

D. Hot melt extrusion [54]

The processing temperature should be 80°C in 1st zone, 115°C in 2nd zone, 100°C in 3rd zone and 65°C in 4th zone. The screw speed should set at 15 rpm to set the granule inside the extruder for approximately 3-4 min. Drug and polymer are blended in sigma blade mixer 10 min. Plasticizer is added slowly. Granulation of mixture in the presence of anti-sticking agent. Granules are store overnight and sieved through 250um sieve. Dried granules are fed into the extruder. Processing is done for 3-4 min. At temperature as mentioned above. Extrudate is pressed at temperature at 65°C to obtain a film of thickness 200um.

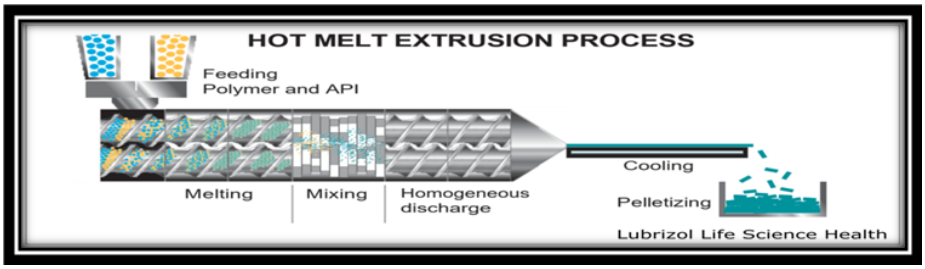

Figure 3: Holt melt extrusion

Advantages:

- Without the use of any solvent or water.
- Fewer processing steps.
- Compressibility properties of the API may not be of importance.
- A better alternative for poorly soluble drugs.
- Have stability at varying pH and moisture levels.
- Better content uniformity.
- Improved bioavailability of poorly soluble compounds.

Disadvantages:

- Thermal degradation due to use of high temperature.
- Flow properties of the polymer are essential to processing.
- A limited number of available polymers.
- All excipients must be devoid of water or any other volatile solvent.
- Required high power input

E. Solid dispersion extrusion

The term solid dispersion refers to the dispersion of one or more active ingredients in an inert carrier in a solid state in the presence of amorphous hydrophilic polymers. Drug is dissolved in suitable liquid solvent. Then solution is incorporated into the melt of polyethylene glycol, obtainable below 70°C finally the solid dispersion is shaped into the films by means of dies.

CHARACTERIZATION OF DISSOLVING FILMS [55,56,57]

Morphology study

The morphology of the film is studied using Scanning Electron Microscopy (SEM), at a definite magnification.

Thickness

It can be measured by micrometre screw gauge at different locations. It is crucial to determine uniformity in the thickness of the film as this is directly related to the accuracy of dose in the strip.

Organoleptic evaluation

For this purpose, in vitro methods of utilizing taste sensors and specially designed apparatus are being used. These invitro taste assessment apparatus for high throughput taste screening of oral pharmaceutical formulations.

Mechanical properties

Three mechanical properties namely tear resistance, elastic modulus and tensile strength percentage elongation are ca

Tear resistance

Principally very low rate of loading 51mm is employed and is designed to measure the force to initiate tearing. The maximum stress or force (that is generally found near the onset of tearing) necessary to tear the specimen is noted as the tear resistance value in newtons (or pounds-force).

Elastic modulus

It is calculated by formula

Elastic modulus =force at corresponding strain × 1 / cross sectional area of corresponding strain

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 × 100/film thickness× film width

Folding endurance
Folding endurance is determined by repeated folding of the strip at the same place till the strip breaks. The number of times the film is folded without breaking is computed as the folding endurance value.

Percentage elongation
It is calculated by formula

% Elongation = Increase in length of strip x100 / initial length of strip

Swelling property
Each film sample is weighed and placed in a preweighed stainless steel wire mesh. Then the mesh containing sample is submerged into 15ml medium (simulated saliva solution) in a plastic container. Increase in the weight of the film was determined at preset time interval until a constant weight was observed.

$$\text{Degree of swelling} = \frac{Wt - Wo}{Wo}$$

Where, Wt is weight of film at time t, and Wo is weight of film at time zero.

Weight variation
Weight variation is studied by individually weighing 10 randomly selected films and by calculating the average weight.

Disintegration time
Disintegration of orally fast dissolving films requires US disintegration apparatus. The disintegration time limit of 30 seconds or less for orally disintegrating tablet described in Centre for Drug Evaluation and Research (CDER) guidance can be applied to fast dissolving oral strips. Disintegration time will vary depending on the formulation but typically the disintegration ranges from 5 to 30 secs. Although, no official guidance for oral fast disintegrating films strip.

Dissolution test
Dissolution testing can be performed using the standard basket or paddle apparatus described in any of the pharmacopoeia. The dissolution medium will essentially be selected as per the sink condition and highest dose of the API. Many times, the dissolution test can be difficult due to tendency of the strip to float onto the dissolution medium when the paddle apparatus is employed.

Stability studies
Stability studies have to be carried out at accelerated condition (65% relative humidity and 35℃ temperature) in the humidity chamber.

Packaging of Fast Dissolving Film.[58]
In the pharmaceutical industry it is vital that the package selected adequately preserve the integrity of the product. Expensive packaging, specific processing, and special care are required during manufacturing and storage to protect the dosage of other fast dissolving dosage forms. A variety of packaging options are available for fast dissolving films. Single packaging is mandatory for films, which are pharmaceutical products; an aluminium pouch is the most commonly used packaging format. APR-Labtech has developed the Rapid card, a proprietary and patented packaging system, which is specially designed for the Rapid films. The rapid card has same size as a credit card and holds three raid films on each side. Every dose can be taken out individually.

The material selected must have the following characteristics

- They must protect the preparation from environmental conditions.
- They must be FDA approved.
- They must meet applicable tamper-resistant requirement
- They must be non-toxic.
- They must not be reactive with the product.
- They must not impart to the product tastes or odours.

Foil, paper or plastic pouches:
The flexible pouch is a packaging concept capable of providing not only a package that is temper-resistance, but also by the proper selection of material, a package with a high degree of environmental protection. A flexible pouch is usually formed during the product filling operation by either vertical or horizontal forming, filling, or sealing equipment. The pouches can be single pouches or aluminium pouches.

Single pouch and Aluminium pouch:
Soluble film drug delivery pouch is a peelable pouch for "quick dissolve" soluble films with high barrier properties. The pouch is transparent for product display. Using a 2-structure combination allows for one side to be clear and the other to use a cost-effective foil lamination. The foil lamination has essentially zero transmission of both gas and moisture. The package provides a flexible thin film alternative for nutraceutical and pharmaceutical applications. The single dose pouch provides both product and dosage protection. Aluminium pouch is the most commonly used pouch.

Blister card with multiple units:
The blister container consists of two components: the blister, which is the formed cavity that holds the product, and the lid stock, which is the material that

seals to the blister. The blister package is formed by heat –softening a sheet of thermoplastic resin and vacuum-drawing the softened sheet of plastic into a contoured mold. After cooling the sheet is released from the mold and proceeds to the filling station of the packaging machine. The semi –rigid blister previously formed is filled with the product and lidded with the heat sealable backing material. The film selection should be based upon the degree of protection required. Generally, the lid stock is made of aluminium foil. The material used to form the cavity is typically a plastic, which can be designed to protect the dosage form from moisture.

Figure 4: Blister Card

Barrier Films:

Many drug preparations are extremely sensitive to moisture and therefore require high barrier films. Several materials may be used to provide moisture protection such as Polychloro trifluoro ethylene (PCTFE) film, Polypropylene. Polypropylene does not stress crack under any conditions. It is an excellent gas and vapour barrier. Lack of clarity is still a drawback.

Application of Fast Dissolving Films [59,60]

Oral mucosal delivery via buccal, sublingual, and mucosal route by use of FDFs could become a preferential delivery method for therapies in which rapid absorption is desired, including those used to manage pain, allergies, sleep difficulties, and central nervous system disorders. Dissolvable FDFs evolved over the past few years from the confection and oral care markets in the form of breath strips and became a novel and widely accepted form by consumers for delivering vitamins and personal care products.

Topical applications

The use of dissolvable films may be feasible in the delivery of active agents such as analgesics or antimicrobial ingredients for wound care and other applications.

Gastro retentive dosage systems

Dissolvable films are being considered in dosage forms for which water soluble and poorly soluble molecules of various molecular weights are contained in a film format. Dissolution of the films could be triggered by the pH or enzyme secretions of the gastrointestinal tract, and could potentially be used to treat gastrointestinal disorders.

Diagnostic devices

Dissolvable films may be loaded with sensitive reagents to allow controlled release when exposed to a biological fluid or to create isolation barriers for separating multiple reagents to enable a timed reaction within a diagnostic device.

CONCLUSION

Recently FDF has gained popularity as dosage form and is most acceptable and accurate oral dosage form which bypass the hepatic system and show moretherapeutic response. The pharmaceutical companies prefer this dosage form due to both patient compliance (especially paediatric and geriatric) as well as industrial acceptability of a liquid. 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 patient life of existing products. FDOFs 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 explain the extentensive research actively going on this technology. 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.

REFERENCES

[1] Puja chaurasiya, Rajesh Kharel, R Manasa, Deepa V, Rajashekhar, K.A Shriddhar. A review on oral fast dissolving films A Novel Drug Delivery System. Asian Journal of Research Chemistry and Pharmaceutical science 4(6), 1601-175.

[2] Mahalingam k Mohad Nazish. Fast dissolving sublingual film- A review. Indian Journal of Novel Drug Delivery 8(2), Apr-June, 2016, 54-61.

[3] Mary Elizabeth RN, Martelli BS. Sublingual and buccal medication administration. Encyclopedia of Nursing and Allied Health, 20050229

[4] Lea L. Sublingual Administration. Colon Health 1996; 13.

[5] Harris, D. and J.R. Robinson, 1992. Drug delivery via the mucous membranes of the oral cavity. J. Pharmaceutical Sci., 81: 1-10.

[6] Chauhan NS, TomarA, Sharma K, Mittal A, Bajaj U. Formulation and evaluation of fast dissolving oral film of dicyclomine as potential route of buccal delivery. Int. J. Drug Dev. Res., 2012; 4(2):408-417.

[7] Frey P.Films strips and pharmaceuticals, pharm mf. & package. Sourcer, winter; 2006. P. 92-93.

[8] Shojaei, A.H., 1998. Buccal Mucosa as A Route for Systemic Drug Delivery: A Review. J. Pharmacy and Pharmaceutical Sci., 1(1): 15-30.

[9] Oral, quickly disintegrating film, which cannot spit out, for an antiemetic or an anti migraine agent. Petra O, Thomas K, Kai-Thomas K, Karin K. US2008/0213343 A1, 2008.

[10] Choudhary DR, Patel V, Patel H, Kundawala. Exploration of film forming properties of film film formers used in the formulation of rapid dissolving films. Int J Chem tech Res, 2011; 3(2):531-3.

[11] Priya YD, Chowdary YA, Murthy, Murthy TEGK, Seshagiri B. Approaches for taste masking of bitter drugs. J Adv Drug Res, 2011; 1(2)58-67.

[12] Kunte S, Tandale P. Fast dissolving strip: a novel approach for delivery of Verapamil. J Pharm Bioall Sci., 2010; 2(4):325-8.

[13] Sloboda M, Bharnatt S. Formulation flexibility broadens the scope for oral thin film technology. Adhesive Res, 2011; 22-4.

[14] Reema P, Richard GZ. Dissolvable film. US 2007/0042023 A12007:1-8.

[15] Bhyan B, Jangra S, Kaur M, Singh H. Orally fast dissolving film: Innovation in formulation and technology. Int. J. Pharm. Sci. Rev. Res., 2011; 9(2):50-57.

[16] Bala R, Pravin Pawar, Sushil Khanna, Sandeep Arora. Orally dissolving strip: A new approach to oral drug delivery system. Int. J.Pharm. Invest, 2013; 3(2); 67-76.

[17] Kulkarni AS, Deokule HA. Exploration of different polymers for use in the formulation of oral fast dissolving strips. J. Current Pharm. Res., 2010; 2(1):33-35.

[18] Heer D, Aggarwal G, Kumar SLH. Recent trends of fast dissolving drug delivery system-An overview of formulation technology. Pharmacophore, 2013; 4(1): 1-9.

[19] Mahajan A, Chhabra N, Aggarwal G. Formulation and Characterization of Fast Dissolving Buccal Films: A Review. Der Pharm Lett., 2011; 3(1): 152165. 29.

[20] Controlled Drug Delivery Concepts and Advances. Vyas SP, Khar RK. New Delhi: Vallabh Prakashan; 2002; 1: 157–160

[21] Gandhi SD, Pandya PR, Umbarkar R, Tambawala T, Shah MA. Mucoadhesive drug delivery systems an unusual maneuver for site-specific drug delivery system.. Pharm Sci Monit an Int J Pharm Sci., 2011; 2(3): 132–52.

[22] Theory and Practice of Contemporary Pharmaceutics. Ghosh TK, Jasti BR, editors. CRC Press, 2005; 282–367: 150–155.

[23] Choudhary DR, Patel VA, Chhalotiya UK, Patel HV, Kundawala AJ. Development and characterization of pharmacokinetic parameters of fast-dissolving films containing levocetirizine. Sci. Pharm, 2012; 80: 779–787.

[24] Heer D, Aggarwal G, Kumar SLH. Recent trends of fast dissolving drug delivery system-An overview of formulation technology. Pharmacophore, 2013; 4(1): 1-9. 28

[25] Mitchell and M.D. Read, 2005. Pharmaceutical Technology, pp: 1-6.

[26] Arya A, Chandra A, Sharma V, Pathak K. Fast dissolving oral films: An innovative drug delivery system and dosage form. Int. J. Chem Tech. Res., 2010; 2(1): 576-583

[27] Muhammad Irfan, SumeiraRabel, QuratulainBukhtar, Muhammad Imran Qadir, Farhat Jabeen, Ahmed Khan. Orally disintegrating films: A modern expansion in drug delivery system. Saudi Pharmaceutical Journal, 2016; 24: 537–546.

[28] Chauhan I, Yasir M, Nagar P. Insights into polymers: film formers in mouth dissolving films. Drug Invent. Today, 2012; 3: 56–73.

[29] Pein M, Breitkreutz, J. Development of a tastemaskedorodispersible film containing dimenhydrinate. Preis. Pharmaceutics, 2012; 4: 551– 562.

[30] Corniello C. Quick Dissolving Strip; from concept to commercialization. Drug Development Technology, 2006; 6: 68-71.

[31] Kalyan S, Bansal M. Recent trends in the development of oral dissolving film. Int. J. Pharm tech Res., 2012; 4: 725-733. 43.

[32] lruzo F and Cupone EI: Diclofenac fast dissolving film: suppression of bitterness by a taste-sensing system. Drug Dev. Ind. Pharmacy, 2010; 1-8.

[33] Gavaskar Basani, Kumar Subhash Vijaya, guru Sharan: Overview on fast dissolving films ,Int Jr of Pharmacy and Pharmaceutical Sciences 2009; 2: 29-33.

[34] Interactions in cellulose derivative films for oral drug delivery. Sakellariou, P.; Rowe, R.C.Prog. Polym. Sci., 1995, 20, 889-942.

[35] 41. Fast Dissolving Oral Films: A Review Naga SowjanyaJuluru International Journal Of Advances In Pharmacy, Biology And Chemistry Vol. 2(1), Jan- Mar 2013.

[36] Handbook of Pharmaceutical Excipients. Wale. A and Weller. P J., 2nd edition, 1994, 24, 27, 352,448.

[37] Film coating theory and practice. Banker, G.S. J. Pharm. Sci., 1966, 55, 81-89.

[38] The effect of polymer molecular weight on the incidence of film cracking and splitting on film-coated tablets. Rowe, F.C.; Forse, S.F. J. Pharm. Pharmacol., 1980, 32(8), 583-584.

[39] The effect of plasticizer type and concentration on the incidence of bridging of intagliations on film-coated tablets. Rowe, R.C.; Forse, S.F. J. Pharm. Pharmacol., 1981, 33(3), 174-175.

[40] Effect of inert tablet ingredients on drug absorption I. Effect of polyethylene glycol 4000 on the intestinal absorption of four barbiturates. Singh, P.; Guillory, J.K.; Sokoloski, T.D; Benet, L.Z.; Bhatia, V.N. J. Pharm. Sci., 1966, 55(1), 6-68

[41] Formation of films from polymer dispersions. Browhn, G.L. J. Polym. Sci., 1956, 22 (102), 423-434. 40. Orally dissolving film strips (ODFS): the final evolution of Orally dissolving dosage forms. Hariharan, M.; Bogue, A. Drug Del. Technol., 2009, 9(2), 24.29.

[42] Muhammad Irfan, Ahmad Khan Orally Disintegrating Films: A modern expansion in drug delivery system. Saudi Ph Jr volume 24, Issue 5, Sept 2016: 537-546.

[43] Shimoda H and Taniguchi K: Preparation of fast dissolving oral thin film containing dexamethasone: A possible application to antiemesis during cancer chemotherapy. European Journal of Pharmaceutics and Biopharmaceutics, 2009; 73: 361-365.

[44] Development of ebiana, a natural, non-caloric sweetener, Prakash.G.E, DuBois.J.F, Clos.K.L, Wilkens and Fosdick. L.E., Food Chem. Toxicol. 2008, 46, S75-S82. 45

[45] Nishimura M, Matsuura K, Sukioka T, Yamashita H, Inagaki N, Sugiyama T and Itoh Y: In-vitro and in-vivo characteristics of prochlorperazine oral disintegrating film. International Journal of Pharmaceutical Sciences, 2009; 98–102.

[46] Gohel MC and Sharma R: Development of taste masked film of valdecoxib for oral use. Indian Journal of Pharmaceutical Sciences, 2010; 320-323.

[47] Madgulkar A, Khar RK, Harindran J, Mujumdar DK, Nagarsenker MS. Dosage form design Pharmaceutical and Formulation Consideration In: Allen LV, Popovich NG, Ansel HC, editors. Ansel's Pharmaceutical Dosage forms and Drug Delivery Systems: South Asian Edition 9th Ed Wolters Kluwer (India) Pvt Ltd, New Delhi, 2011; 134-136.

[48] Siddiqui N, Garg G, Sharma P. A Short Review on "A Novel Approach in Oral Fast Dissolving Drug Delivery System and Their Patents. Advances in Biological Research, 2011; 5(6): 291-303.

[49] Dixit RP, Puthli SP, Oral strip technology: Overview and future potential. Journal of Controlled Release, 2009; 139: 94–107.

[50] Cilruzo F and Cupone EI: Fast dissolving films made of maltodextrins. European Journal of Pharmaceutics and Biopharmaceutics, 2008; 70: 895-900

[51] Vishwakarma DK, Tripathi AK, Yogesh P and Maddheshiya B: Review article on mouth dissolving film. Journal of Global Pharma Technology, 2011; 3(1): 1-8.

[52] Rathi V, Senthil V, Kammili L and Hans R: A brief review on oral film technology. International Journal of Research in Ayurveda and Pharmacy, 2011; 2(4): 1138-1147.

[53] Deepak Sharma, Diljit Kaur, Shivani Verma, Davindar Singh, Mandeep Singh, Gurmeet Singh, Rajeev Garg Fast Dissolving Oral Films Technology: A Recent Tend For An Innovative Oral Drug Delivery System, Int Jr of Drug Delivery 7 (2015) 60-75.

[54] Siddiqui N, Garg G, Sharma P. A Short Review on "A Novel Approach in Oral Fast Dissolving Drug Delivery System and Their Patents. Advances in Biological Research, 2011; 5(6): 291-303.

[55] Bharthi P, Gopalrao M, Akila R. Characterization and Applications of Pullulan and Chitosan produced by fermentation. J Microbio Biotech Res. Pvt. Ltd., 5(2): 21-27.

[56] Subhash Vijaya Kumar, Basanti Gavaskar, Guru Sharan, Madhusudhan Rao Y, Overview on Fast Dissolving Films. International Journal of Pharmacy and Pharmaceutical Sciences, 2010; 2(3): 29-33.

[57] Patel Nibha K, Pancholi SS, An Overview on Sublingual Route for Systemic Drug Delivery. International Journal of Research in Pharmaceutical and Biomedical Sciences, 2012; 3(2): 913-23.

[58] Aggarwal Jyoti. Singh Gurpreet. Saini Seema. Rana AC, Fast Dissolving Films: A Novel Approach to Oral Drug Delivery. International Research Journal of Pharmacy, 2011; 2(12): 69-74.

[59] Vishwkarma DK, Tripathi AK, Yogesh P and Maddheshiya B, Review Article on Mouth Dissolving Film. Journal of Global Pharma Technology, 2011; 3(1): 1-8.

[60] Patel AR, Prajapati DS and Raval JA: Fast dissolving films (FDFS) as a newer venture in fast dissolving dosage forms. International Journal of Drug Development and Research, 2010.