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Design, Formulation, and Evaluation of Fast Dissolving Oral Film Containing Lisinopril

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Abstract:

Orally disintegrating drug-delivery system server major benefit over the conventional dosage forms because the drug disintegrates rapidly and dissolve in saliva without the use of water. Lisinopril dihydrate is long-acting angiotensin-converting enzyme (ACE) inhibitor, used in treat hypertension, heart failure and myocardial infarction. the drug to be absorbed slowly and incompletely from GI tract, bioavailability 25% and onset of action is 1 hr. in order to increase the bioavailability and improve onset of action. Lisinopril was formulated as orally disintegrating tablets. Six formulations were prepared using (talc, saccharin sodium, PVP K30, sodium starch glycolate, crospovidone, croscarmellose sodium, aspartame, aerosol, sodium lauryl sulfate, avicel pH101, mannitol, Mg stearate and Roseberry flavor).

Keywords: Talc, saccharin sodium, PVP K30, sodium starch glycolate, crospovidone, croscarmellose sodium, aspartame, aerosol, sodium lauryl sulfate, avicel pH101, mannitol, Mg stearate and Roseberry flavour.

1. Introduction

A fine thin film containing an active ingredient that dissolves or disintegrates in the saliva at aremarkably fast rate, within few seconds without the aid of water or chewing, is the definition ofa fast-dissolving oral film (FDOF).

The most up-to-date oral solid dosage form is fast-dissolving oral films (FDOFs), which provide more comfort and flexibility. It improves the absorption of active pharmaceutical ingredients (APIs) by dissolving them in saliva and allowing them to be swallowed without chewing or water. The oral mucosa is four to a thousand times more permeable than the epidermis, allowing for rapid drug absorption and rapid bioavailability. Formulated drug- opening foams (FDOFs) are made from hydrophilic polymers that dissolve rapidly in the mouth and release the medication into the bloodstream via the buccal mucosa. [1] A fast-dissolving drug delivery method is developed to enhance bioavailability of drugs with modest dosages and significant first-pass metabolism.

Comparison between oral fast-dissolving films and oral disintegrating tablets

Table 1: Comparison between oral fast-dissolving films and oral disintegrating tablets.

Oral dissolving films	Oral disintegrating tablets
It is a film	It is a tablet
Greater dissolution due to large surface area	Lesser dissolution due to less surface area

Better durable than oral disintegrating tablets	Less durable as compared with oral films
More Patient compliance	Less patient compliance than films
A low dose can only be incorporated	High doses can be incorporated
No risk of chocking	It has a fear of chocking

2. Oral Dissolving Film Theory

In this setup, a thin film is present. Sublingual administration improves bioavailability because the drug dissolves faster and bypasses first-pass metabolism.

Because SA is more easily absorbed, it breaks down and dissolves rapidly in the mouth. The following are the three main types of oral films:

1. Films have a rapid dissolving or releasing time (when held to the mouth).
2. Mucoadhesive films that dissolve (for use in the buccal or gingival area). The third option is buccal mucosa-adhering sustained-release films. [3]

1.1 Mechanism of oral mouth dissolving film theory:

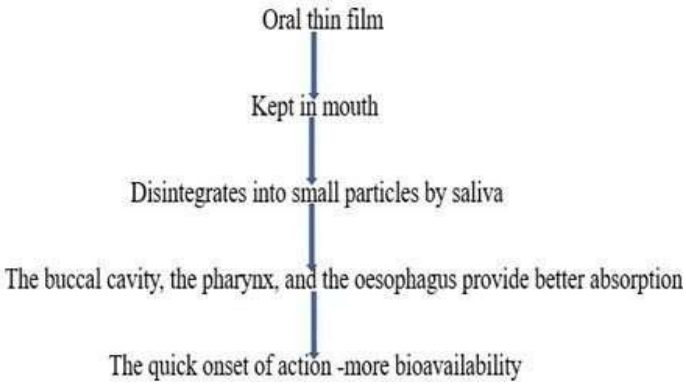


Figure 1: Mechanism of oral mouth dissolving film theory

Need for fast-dissolving drug delivery systems:

Patients with dysphasia may find it easier to take their medication as prescribed when it dissolves quickly. If a medicine is subject to patent protection, the marketing department will find that FDDS is a useful tool for managing the medical life cycle.

3. Market view

The need for non-invasive delivery systems in pharmaceuticals remains high due to several factors. Current administration regimens often face limited patient compliance, there is a small market for pharmaceutical companies, and managing diseases can be expensive. As a result, pharmaceutical marketing has driven the development of easily accessible fast dissolving/disintegrating products. One key reason pharmaceutical companies pursue these new dosage forms is to extend the market exclusivity of their drugs. As a drug's patent life nears its end, companies frequently innovate by developing new and improved dosage forms of the same therapeutic entity. These new forms can offer

patients more convenient dosing schedules or easier administration methods, thus enhancing patient compliance and satisfaction.

Fast dissolving/disintegrating dosage forms have several benefits. They improve patient compliance by simplifying the administration process, especially for populations that have difficulty swallowing pills, such as children and the elderly. These formulations can also provide quicker onset of action, which is beneficial in situations where rapid relief is necessary. Prolonged-release formulations share similarities with fast dissolving/disintegrating formulations in that they both aim to enhance the therapeutic experience and provide better control over drug release and absorption. However, fast dissolving/disintegrating formulations are particularly valuable for their ease of use and ability to rapidly deliver medication without the need for water. In conclusion, the development of non-invasive, fast dissolving/disintegrating dosage forms is a strategic response to both clinical and market demands. These formulations not only improve patient compliance and satisfaction but also offer pharmaceutical companies a means to extend market exclusivity and increase revenue by targeting specific patient needs.

Table 2: Classification of mouth-dissolving film

Properties	Flash release	Mucoadhesive meltaway wafer	Mucoadhesive sustained release wafer
Area	2-8	2-7	2-4
Thickness	20-70	50-500	50-250
Structure	Single layer system	Single or multilayer	Multilayer
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	Max 8-10 hrs.
Application	Tongue	Gingival and buccal region	Gingival (another region in the oral cavity)

Medication comes in several forms, including tablets, granules, powders, and liquids. It is common practice to construct pills so that they are chewed or swallowed whole in order to give patients a precise dosage of medicine. Light pressure may cause the tablet and capsule components of the pills to retain their shapes. Solid dose forms might be challenging for certain patients to chew and swallow, especially younger children and the elderly. A lot of elderly and young patients are scared to take these pricey pills because they are afraid they may choke. Multiple rapid-dissolving medication delivery systems have been developed to aid these people. Several methods exist for the production of drug delivery systems that dissolve quickly, including as wet granulation, direct compression, and freeze- drying.[4]

Lamination by hot-melt extrusion or solvent casting is a common method for creating fast- dissolving films made of plasticized hydrocolloids or mixtures of them. Depending on the properties of the film-forming chemical, many major concerns may arise during the production of dosage forms. Issues like film formation are common issues including slitting flaking, cutting cracking, and foaming caused by boiling or solvent evaporation of the material. It is expected that the films would maintain their resistance to moisture over time. In order to make them easier to handle, they should be pliable, exhibit the right amount of tensile tension, and not cling to either the packaging or the fingers.[5]

ORAL MUCOSA DESCRIPTION: [6]

The oral mucosa consists of several distinct layers, with the uppermost layer being the stratified squamous epithelium. Below this layer lies the submucosa, which serves as the next inner membrane. This stratified squamous epithelium is similar to the epithelium that covers the rest of the body, displaying a typical progression of cell maturation and differentiation. As the epithelial cells move from the basal layer, where they originate, to the superficial layer, they increase in size and become progressively flatter. This process of epithelial cell turnover occurs relatively quickly, with complete renewal happening within approximately 5 to 6 days. The presence of conditions such as cavities can lead to a thicker oral mucosa compared to its normal state.

The thickness of the oral mucosa varies depending on the specific location within the mouth, generally ranging from 500 to 800 microns. The composition of the epithelium also differs across various regions. For instance, the keratinized epithelium contains triglycerides that act as a protective barrier, providing mechanical resilience and resistance to abrasion. Conversely, the non-keratinized epithelium, despite lacking triglycerides, maintains a comparable level of impermeability. This impermeability is achieved through the presence of other lipid components, although in smaller quantities. Traces of cholesterol, ceramides, and other polar lipids contribute to the barrier properties of the oral mucosa, ensuring it remains an effective barrier against environmental insults and microbial invasion.

Permeability:

The oral mucosa consists of a stratified squamous epithelium and submucosa, exhibiting significant permeability compared to the skin—being approximately 44,000 times more permeable. This high permeability is attributed to the porous nature and minor leakage characteristics of the oral mucosal epithelium. The permeability of the oral mucosa varies across different regions due to structural differences. The sublingual mucosa is notably more permeable than the mucosa on the palate or the cheek. The permeability barriers within the oral mucosa are primarily formed by intercellular materials that are coated with membrane-coating granules (MCGs).MCGs are critical in the formation of permeability barriers. These granules adhere to the cell surface at the apical end of the cell during cellular differentiation. Once formed, the contents of the protoplast sheath and MCGs leak into the intercellular space of the third epithelial layer, creating a barrier that is readily discernible in the top layer. Substances like horseradish peroxidase and lanthanum nitrate are used in penetration tests to study these barriers. Flat cell layers on the submucosal surface act as barriers to cell permeation, while cells with larger diameters have a higher capacity for permeation. Contrary to expectations, keratinization is not particularly effective at preventing permeability. In non-keratinized epithelial cells, MCGs contain a non-lamellar stack of lipids, including ceramides, sphingomyelin, and unchambered ceramide. In keratinized epithelium, these lipids form a barrier, but it is not as effective at preventing substance permeation. The outer epithelial layer and the basement membrane also contribute significantly to preventing mucosal penetration.

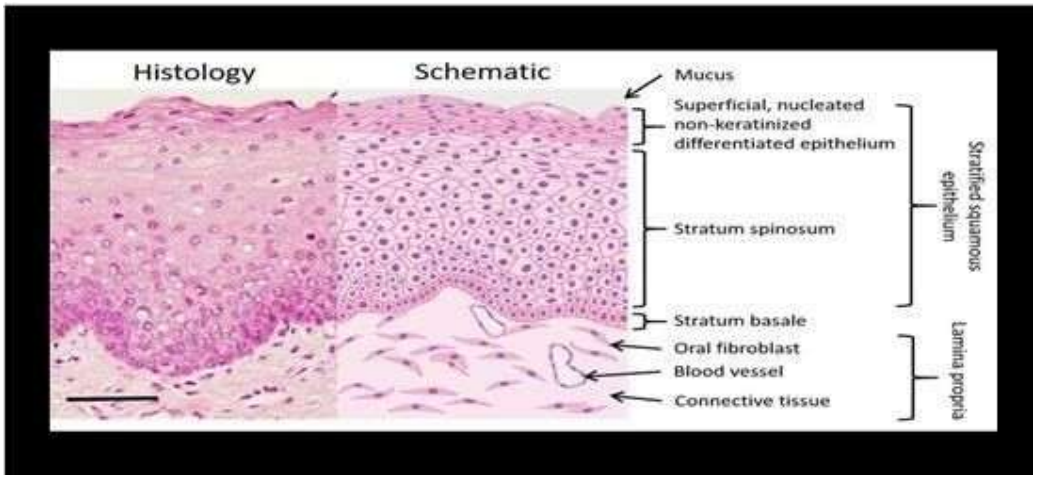
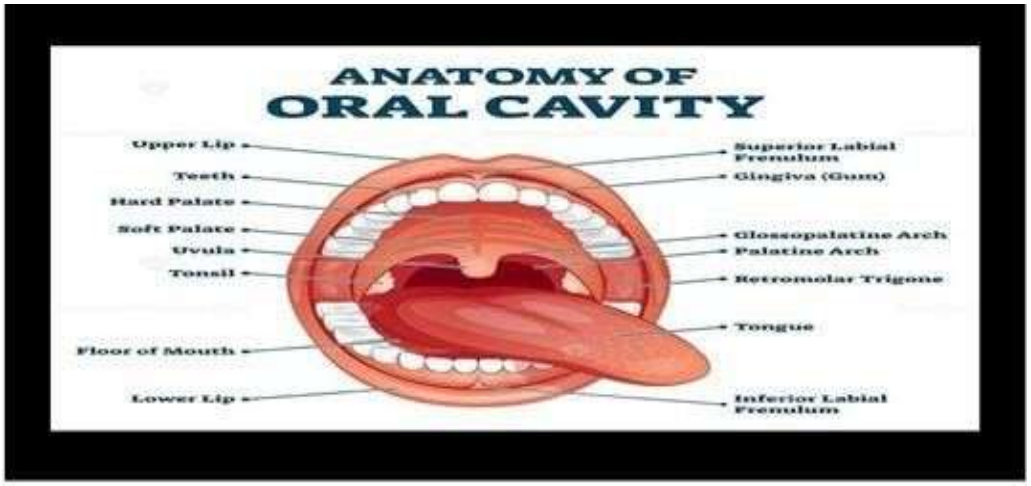


Figure 3: Structure of human oral mucosa

Figure 4: Anatomy of the oral cavity



4. Advantages:

Fast dissolving oral films offer several advantages that contribute to their growing popularity in drug delivery systems:

i. Increased Patient Adherence: These films improve patient compliance due to their ease of use. Patients are more likely to adhere to their medication regimen when the administration method is simple and convenient.

ii. Flexibility and Convenience: Unlike orally disintegrating tablets, which can be fragile and brittle, rapidly dissolving thin oral films are flexible, making them easy to travel with, store, and handle without the risk of breaking.

iii. Dose Accuracy: Each film provides an accurate dose, unlike drop or syrup formulations wheredose accuracy can be challenging.

iv. No Need for Water: Oral films do not require water for administration, making them ideal for patients with swallowing difficulties (dysphagia), regular emesis, or those who experience motion sickness and cannot swallow large amounts of water.

v. Rapid Drug Dissolution and Absorption: The films dissolve quickly in the oral cavity due to their increased surface area and the high vascularization of the oral mucosa. This allows the drug to bypass the first-pass hepatic metabolism and directly enter the bloodstream, leading torapid onset of action.
vi. Enhanced Oral Bioavailability: By bypassing the gastrointestinal tract and hepatic first-passmetabolism, these films can increase the oral bioavailability of the drug molecules.
vii. Cost-Effective Production: The manufacturing process for these films can be relatively simple, utilizing low-tech techniques and affordable equipment, making them accessible and cost-effective to produce.

5. **Disadvantages**:
While fast dissolving oral films (OFDFs) offer several advantages, there are also notable disadvantages that must be considered:

i. Instability at Buccal pH: Medications that are unstable at the pH levels found in the oral cavity cannot be delivered using this route. The buccal environment's pH can compromise the integrity and efficacy of certain drugs.
ii. Mucosal Irritation: Drugs that irritate the mucosal lining cannot be administered through oral films. The irritation can lead to discomfort and potential damage to the mucosal tissue.
iii. Limited Dose Capacity: Only medications requiring small doses can be effectively delivered via oral films. This limitation is due to the physical size and thickness constraints of the films,which restrict the amount of active ingredient they can contain.
iv. Flavor Masking: Many medications have a naturally bitter or unpleasant taste, necessitating effective taste-masking techniques. This can complicate the formulation process, adding an extra layer of development and testing to ensure patient compliance.
v. Special Packaging Requirements: OFDFs are delicate and highly sensitive to moisture. They require special packaging to protect them from environmental factors such as humidity, whichcan affect their stability and efficacy. This need for specialized packaging can increase production costs and complexity.

6. Mechanism of Action of Lisinopril [11]
Lisinopril is an angiotensin-converting enzyme (ACE) inhibitor primarily used to treat hypertension and heart failure, and to improve survival after myocardial infarction.

1. Inhibition of ACE:
- Lisinopril inhibits the angiotensin-converting enzyme (ACE), which is responsible for converting angiotensin I to angiotensin II.
- Angiotensin II is a potent vasoconstrictor that increases blood pressure by causing blood vessels to narrow. It also stimulates the release of aldosterone from the adrenal cortex, leadingto sodium and water retention.

2. Reduction of Angiotensin II Levels:
- By inhibiting ACE, lisinopril decreases the production of angiotensin II.
- This reduction leads to vasodilation (widening of blood vessels), which decreases blood pressure.
- Lower levels of angiotensin II also result in decreased aldosterone secretion, reducing sodiumand water retention and lowering blood volume.

3. Effects on Bradykinin:
- ACE also degrades bradykinin, a peptide that promotes vasodilation.
- By inhibiting ACE, lisinopril increases bradykinin levels, which further contributes to vasodilation and blood pressure reduction.

- However, increased bradykinin levels are also associated with some of the side effects of lisinopril, such as a persistent dry cough and angioedema.

4. Improvement in Heart Function:

- In heart failure, Lisinopril reduces the workload on the heart by lowering systemic vascular resistance (afterload) and blood volume (preload).
- This improves cardiac output and reduces symptoms of heart failure, such as edema and shortness of breath.

5. Renal Protection:

- Lisinopril is beneficial in protecting the kidneys, particularly in patients with diabetic nephropathy.
- By reducing intraglomerular pressure through vasodilation of efferent arterioles, lisinoprilslows the progression of kidney disease.

Table 3: Composition of mouth-dissolving film

SR.NO	COMPONENT	CONCENTRATION
1	Active pharmaceutical ingredient	5%-30% w/w
2	Film-forming polymer [water soluble polymer]	45%w/w
3	Plasticizer	0-20%w/w
4	Super disintegrants	4%-5%w/w
5	Saliva stimulating agent	2%-6%w/w
6	Surfactant	QS
7	Flavoring agent	QS
8	Sweetening agent	QS
9	Stabilizing agent	0.05%-0.1%w/w
10	Fillers	QS

i. Active Pharmaceutical Ingredient[12]

One to three percent weight by weight of the active medicinal substance is included in the film's composition. Because it is difficult to mix large doses of medicine into quick dissolving films, always utilize modest doses of active pharmaceutical substances. A wide variety of medications, such as those used to treat histamine, diarrhea, depression, asthma, and nausea, may be administered orally in the form of a fast-dissolving film. For the purpose of disguising flavor, dimenhydrinate may also be added to ODFs. Salbutamol sulfate, verapamil, ondansetron, dexamethasone, rofecoxib, cetirizine, pilocarpine, tianeptine sodium, indomethacin, etc. are common examples of medications that are often included in ODFs.

ii. Film-Forming Polymers:

Polymers are critical components in the formulation of fast dissolving oral films (FDOFs). Their selection, type, and quantity significantly influence the film's robustness, disintegration rate, and

overall performance. Here is a detailed description of the role of polymers in FDOFs: Importance of Polymers

1. Film Robustness:

- The structural integrity and mechanical strength of the oral film are primarily determined bythe polymer content.
- Typically, 45% w/w of the polymer is used based on the total weight of the dry film, ensuringadequate tensile strength and flexibility.

2. Tensile Strength:

- The tensile strength of the film is a critical parameter that depends on the type and amount of polymer used.
- A well-chosen polymer provides the necessary strength to withstand handling, packaging, and administration without breaking or tearing.

3. Disintegration and Dissolution:

- Hydrophilic polymers are preferred in FDOFs as they rapidly disintegrate and dissolve upon contact with saliva.
- This rapid dissolution is essential for the quick release and absorption of the active pharmaceutical ingredient (API) in the oral cavity.
- Types of Polymers

4. Natural Polymers:

- Examples include pullulan, xanthan gum, guar gum, and starch derivatives.
- Natural polymers are often chosen for their biocompatibility, safety, and ability to form filmswith desirable mechanical properties.

5. Synthetic Polymers:

- Common synthetic polymers used in FDOFs include polyvinyl alcohol (PVA), polyethylene glycol (PEG), hydroxypropyl methylcellulose (HPMC), and polyvinylpyrrolidone (PVP).
- Synthetic polymers offer consistent quality, predictable performance, and the ability to tailor the film properties to specific needs.

Evaluation Parameters of FDOFs:

a. Thickness

As the thickness of a film is directly concern with drug content uniformity so it is necessary to ascertain uniformity in the thickness of the film. It can be measured by micrometer screw gauge or calibrated digital Vernier Calipers at different strategic locations. The thickness of the film should be in the range 5-200 μm.

b. Dryness test/tack tests

About eight stages of the film drying process have been identified and they are set□to□touch, dust□free, tack□free (surface dry), Dry□to touch, dry□hard, dry□through (dry□to□handle), dry□to□ recoat and dry print□free. Although these tests are primarily used for paint films most of the studies can be adapted intricately to evaluate pharmaceutical OFDF. The details of evaluationof these parameters can be checked elsewhere and are beyond the scope of this review. Tack is the

tenacity with which the strip adheres to an accessory (a piece of paper) that has been pressed into contact with the strip. Instruments are also available for this study.

c. Tensile strength

Tensile strength is the maximum stress applied to a point at which the strip specimen breaks. It is calculated by the applied load at rupture divided by the cross□sectional area of the strip asgiven in the equation below:

$$Tensile\ strength = \frac{load\ of\ breakage}{Strip\ thicknes \times Strip\ width}$$

d. Percent elongation

When stress is applied, a strip sample stretches and this is referred to as strain. A strain is basically the deformation of strip divided by the original dimension of the sample. Generally, elongation of strip increases as the plasticizer content increases.

$$\%\ elongation = \frac{increase\ in\ length \times 100}{orginal\ length}$$

e. Swelling property

Film swelling studies are conducted using simulated saliva solution. Each film sample is weighed and placed in a pre-weighed stainless steel wire mesh. The mesh containing film sample is submerged into a 15ml medium in a plastic container. Increase in the weight of the film was determined at pre-set time interval until a constant weight was observed. The degree of swelling was calculated using parameters wt is a weight of film at time t and wo is a weight of film at time zero.

$$\alpha = \frac{wt - w0}{\ldots\ldots\ldots}$$

f. 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: Where T600 is the transmittance at 600 nm and b is the film thickness (mm) and cis concentration.

g. Assay/ Content uniformity

This is determined by any standard assay method described for the particular API in any of the standard pharmacopeias. Content uniformity is determined by estimating the API content in an individual strip. Limit of content uniformity is 85–115 percent.

h. Disintegration time

A disintegration of orally fast dissolving films requires USP disintegration apparatus. The disintegration time limit of 30 seconds or less for orally disintegrating tablets described in CDER guidance can be applied to fast dissolving oral strips. Disintegration time will vary depending on the formulation but typically the disintegration range from 5 to 30 seconds. Although, no official guidance is available for oral fast disintegrating films strips. 4.14 Dissolution test Dissolution testing can be performed using the standard basket or paddle apparatus described in any of the pharmacopeias. The dissolution medium will essentially be selected as per the sink conditions and highest dose of the API.

Many times the dissolution test can be difficult due to a tendency of the strip to float onto the dissolution medium when the paddle apparatus is employed.

i. Young's modulus

Young's modulus or elastic modulus is the measure of the 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.

$$Youns\ moduls = \frac{increase\ in\ length \times 100}{orginal\ length}$$

a. Tear resistance

Tear resistance of plastic film or sheeting is a complex function of its ultimate resistance to rupture. Basically very low rate of loading 51 mm (2 in)/min 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) required to tear the specimen is recorded as the tear resistance value in Newton's (or pounds□force).

b. 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.

c. Organoleptic evaluation

For evaluation of psychophysical evaluation of the product, special controlled human taste panels are used. In-vitro methods of utilizing taste sensors, specially designed apparatus and drug release by modified pharmacopoeial methods are being used for this purpose. These in itro taste assessment apparatus and methodologies are well suited for high□throughput taste screening of oral pharmaceutical formulations.

d. Surface pH of the film

Surface pH of the films 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 films. The change in the colour of pH paper should be observed.

7. NEED OF THE STUDY OR FUTURE PROSPECTS:

Future Prospects:

In the pharmaceutical industry, great advancements have been made in oral drug delivery technologies. The market has come a long way from the conventional tablets/capsules to modern-day fast disintegrating and rapidly acting tablets/films. Various limitations such as lower bioavailability of oral solid drugs, the inconvenience of administering injections, inaccurate dosing by liquid formulations are keystone which has turned the focus of pharmaceutical companies to develop novel oral dosage forms that eliminate these limitations. Fast dissolving oral thin films are designed to meet most of these challenges. The concept isn't new and several over the counter oral thin films are readily available. Good acceptance from the users and an increasing demand of over the counter oral film products has led to the development of prescription drugs into oral thin films. This emerging area is gaining attention from both established and start-up pharmaceutical firms. Companies are utilizing their oral thin film technologies to develop different types of oral thin films (e.g. oral dispersible, sublingual, buccal). In addition to the drugs, several hormones and vaccines are also being formulated into oral thin films with the aim of providing improved patient compliance. Some of the key players in this area include MonoSol Rx, Applied Pharma Research/Labtec GmbH, BioDelivery Sciences and NAL Pharma. Many companies are collaborating with these technology providers and utilizing oral thin films as a

lifecycle management tool for their branded drugs that have lost patent in other dosage forms. There are not many prescriptions for oral thin films currently available in the market; however, the pipeline holds a wider promise. Despite the uncertainties related to the development, approval and penetration rate, the market is likely to witness stable growth in the coming decade. According to the clinical and regulatory aspects in the US Food and Drug Administration (US FDA), if the product is bioequivalent to that of the existing oral product the drug, an Abbreviated New Drug Application (ANDA) route is followed. There are no clinical studies associated with this generic approval processes (section 505 (j) of the Food, Drug, and Cosmetic Act). The example of such case would be a comparative bioequivalence between an orally disintegrating tablet (ODT) formulation and orally dissolving film (ODF) product. However, developed oral film product may exhibit different pharmacokinetic profile compared to the existing marketed product. The ODF is categorized as "new dosage form" and the section 505 (b) (2) approval processes needs to be followed. In this case, a new clinical study would be required. The advantage of new clinical study is that it would award 3 years of marketing exclusivity to the product. Preclinical toxicity studies are not required if the molecule is the same as that of the approved product. Safety, tolerability, and efficacy features are to be demonstrated in such trials. Oral mucosa-irritation testing is carried out in both animal models and humans. The future looks very promising for the film technology in the time to come as new technologies are rapidly introduced to prepare thin films.

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