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A Review on Fast Dissolving Oral Film

SONWANE ANJALI NAVNATH[1], ANJALI R. GAVHANE[2], DR. GANESH TOLSARWAD[3], DIGVIJAY KENDRE[4]
[1, 2, 3, 4] *Swami Vivekanand College of Pharmacy, Udgir*

Abstract- ***Fast dissolving oral films (FDOFs) are an innovative drug-delivery system designed to improve patient compliance, particularly among pediatric, geriatric, and dysphagic patients who face difficulty swallowing conventional solid dosage forms. These thin polymeric films rapidly disintegrate in the oral cavity without the need for water, providing quick onset of action and enhanced bioavailability by partially bypassing first-pass metabolism. The present study focuses on understanding the formulation aspects of FDOFs, including the role of polymers, plasticizers, and other excipients in determining the mechanical strength, disintegration time, and drug-release profile of the films. Various technologies and applications of oral films were reviewed to highlight their advantages, limitations, and future potential in drug delivery.***

Index Terms- ***Fast Dissolving Oral Films, Oral Drug Delivery, Polymer Formulation, Plasticizers, Rapid Disintegration, Bioavailability, Mohaddessin, Thin Film Technology, Taste Masking, Patient Compliance***

I. INTRODUCTION

Oral drug delivery system

Oral route is the most preferred route for the delivery of the drugs till date as it bears various advantages over the other route of drug administration, but oral drug delivery systems still need some advancements to be made because of their some drawbacks related to particular class of patients which includes geriatric, pediatric and dysphasic patients associated with many medical conditions as they have difficulty in swallowing or chewing solid dosage forms. Even with fast dissolving tablets there is a fear of choking due to its tablet type appearance. Amongst other factors, palatability of formulations of pediatric oral medications is one of the most significant factors influencing compliance to therapeutic regimens. [1, 2]

Although solid dosage forms are widely accepted by elders and adolescents, younger children tend to prefer liquid formulations that are easier to swallow, several novel technologies for oral delivery have recently become available to address the physicochemical and pharmacokinetic characteristics of drugs, while improving patient compliance. Electrostatic drug deposition and coating and computer-assisted three-dimensional printing (3DP) tablet manufacture have also recently become available. So, Fast-dissolving drug-delivery systems came into existence in the late 1970's as an alternative to tablets, capsules and syrups for pediatric and geriatric patients who experience difficulties in swallowing traditional oral solid-dosage forms.

Research and development in the oral drug delivery segment has led to transition of dosage forms from simple conventional tablets or capsules to modified release tablets or capsules to oral disintegrating tablet (ODT) to wafer to the recent development of oral fast dissolving films (OFDFs). Amongst the plethora of avenues explored for the rapid drug releasing products, oral strip technology is gaining much attention) (ODFT) was already popular amongst the people in the early 2000 year with the introduction and widespread use of Listerine pocket strips, a new launch in the mouthwash range. 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.

Oral fast dissolving film (OFDF) is one such novel approach to increase consumer acceptance by virtue of rapid dissolution, self-administration without water or chewing. The film is an ideal intraoral fast-dissolving drug delivery system, which satisfies the unmet needs of the market, is easy to handle and administer, maintains a simple and convenient packaging. Alleviates unpleasant taste, and is straightforward to manufacture. The film is placed on the top or the floor of the tongue. It is retained at the site of application and rapidly releases the active agent for local and/or systemic absorption. The

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development of a fast-dissolving film also provides an opportunity for a line extension in the market place, a wide range of drugs (e.g. neuroleptics, cardiovascular drugs, analgesics, antihistamines, antiasthma tic and drugs for erectile dysfunction) can be considered candidates for this dosage form,, [7,12,13]
A large number of drugs can be formulated as mouth dissolving films. Innovative products may increase the therapeutic possibilities in the following indications.

1. Pediatrics (Antitussives, Expectorants. Antiesthetic)
2. Geriatrics (Antiepileptic. Expectorants)
3. Gastrointestinal diseases
4. Nausea (due to Cytostatic therapy)
5. Pain (Migraine)
6. CNS (Ant Parkinsonism therapy)

Mouth dissolving films offers an elegant route for systemic drug delivery. The improved systemic bioavailability results from bypassing first pass effect and better permeability due to a well-supplied vascular and lymphatic drainage. Also, large surface areas of absorption, easy ingestion and swallowing, pain avoidance make the oral mucosa a very attractive and selective site for systemic drug delivery. Recent developments in the technology have presented viable dosage alternatives from oral route for wide variety of group of patients. Buccal drug delivery has lately become an important fast dissolve, rapid dissolve, rapid melt or quick disintegration. However, the function and concept of all these dosage forms are similar. By definition, a solid dosage form that dissolves or disintegrates quickly in the oral cavity, resulting in solution or suspension without the need for the administration of water, is known as an oral fast-dispersing or fast-dissolving dosage form. [1.4]

Thin-film and strip intraoral dosage forms have been developed by several companies including LTS (Lohmann Therapie-System) AG, Zengen Inc., and Lavipharm Laboratories (Quick-Dis™ and Slow-Dis™ technology), Pfizer's Warner-Lambert consumer healthcare division (Listerine® PocketPaks™). Chloraseptic® Relief Strips™ were the first oral thin-film product to incorporate a drug and were introduced in the United States in September 2003 by Prestige Brands International for relief of sore throat, [1]

II. AIM AND OBJECTIVE

Aim
To study of fast dissolving oral films.
Objective of selecting particular topic of practice school

The primary objectives of the work were:
- To study of oral fast dissolving films.
- To study the effect of various polymers and plasticizers in different concentrations on the release of oral film.

III. SALIENT FEATURES OF FAST DISSOLVING ORAL FILM

a. Requires no water; have quick disintegration and dissolution of the dosage form.
b. Leaves minimal or no residue in the mouth after administration.
c. No risk of choking.
d. Provide advantages of liquid medication in the form of solid preparation.
e. Amenable and adaptable to existing processing and packaging machinery.
f. Thin elegant film
g. Available in various size and shapes
h. Unobstructive
i. Excellent cohesion
j. Fast disintegration and rapid release [16]

IV. IDEAL CHARACTERISTICS OF A SUITABLE DRUG CANDIDATE

a. The drug to be incorporated should have low dose up to 40 mg
b. The drugs with smaller and moderate molecular weight are preferable
c. The drug should have good stability and solubility in water as well as saliva
d. It should be partially ionized at the off of oral cavity
e. It should have the ability to permeate oral mucosal tissue.

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V. ADVANTAGES OF FAST DISSOLVING ORAL FILM

Fast dissolving oral film combines all the advantages of tablets (accurate dose, self-administration) with those of liquid dosage forms (easy swallowing, quick bioavailability). The administration of drugs by the oral route last several advantages-10.2034
Over other route of administration such as:

5.1.1Clinical Advantages:

- Improved oral absorption
- Improved bioavailability due to less amount of degradation of drug.

5.1.2 Medical Advantages:

- Overcomes unacceptable taste of drugs by masking bitter taste of drugs with taste masking agents.
- Improved patient compliance, especially patients suffering from dysphasia and pediatric and geriatric population.

5.1.3 Technical Advantages:

- Contain sugars and other GRAS excipients.
- Improved stability due to better packaging.
- No special set up required for the industry .[16,10,17,18]

5.2 Disadvantages of Fast Dissolving Oral Films

a. Drugs which irritate the mucosa cannot be administered by this route.
b. Drug with small dose requirement can only be administered.
c. Taste masking- Most drugs have bitter taste, and need taste masking.
d. Special packaging- OFDFs are fragile and must be protected from water so it needs special packaging.
e. Dose uniformity is a technical challenge
f. Expensive packaging of oral film.[7,10,17]

VI. BENEFITS OF FAST DISSOLVING ORAL FILM OVER FAST DISINTEGRATING TABLETS

a. No friability loss.
b. Require less expensive processing and packaging materials.
c. No fear of choking.
d. Requires less excipients
e. Less time-consuming process.
f. More elegant
g. More economical. [17.19]

VII. OVERVIEW OF THE ORAL CAVITY

The oral mucosa is composed of an outermost layer of stratified squamous epithelium. Below this lies a basement membrane, a lamina propria followed by the submucosa as the innermost layer. The oral mucosa in general is intermediate between that of the epidermis and intestinal mucosa in terms of permeability. It is estimated that the permeability of the buccal mucosa is 4-4000 times greater than that of the skin. There are considerable differences in permeability between different regions of the oral cavity because of the diverse structures and functions of the different oral mucosa.

Sublingual gland

Salivary glands are present in the floor of the mouth underneath the tongue. Sublingual glands are also known as the salivary glands that are located beneath the tongue secrete saliva which gets mixed with the food, so that the food gets lubricated, formed into a soft bolus and can be easily swallowed. Absorption of drugs is directly from the site into systemic circulation owing to its relatively lesser thickness, high permeability and rich blood supply they are also known as sublingual glands. They produce mucin in turn produces saliva. The oral cavity is lined with mucous membrane which comprises of squamous cells and mucous glands. Salivary gland contains the group of cells which secrete saliva into the mouth through salivary ducts. Salivary gland includes comprises of Parotid, Submandibular and Sub-maxillary glands. The fluid which is produced by the glands gets mix with the food, so the food gets easily chewed. The absorption is transfer of the drug from its site of administration into systemic circulation, so

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it can be said that absorption is directly proportional layer thickness. The absorption of the drug follows in this way Sublingual >Buccal> Gingival >Palatal. Due to high permeability and rich blood supply, the sublingual route can produce rapid onset of action so the drug with short delivery period can be delivered and dose regimen is frequent.

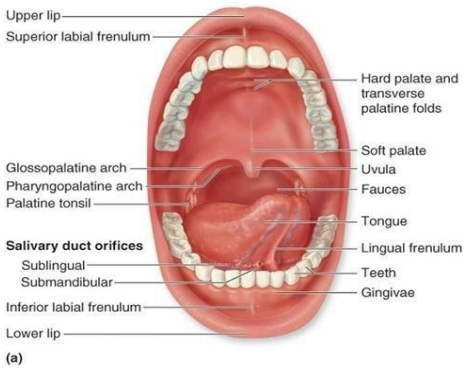

Fig. no. 01: overview of oral mucosa

Mechanism of absorption

Sublingual administration drug solutes are rapidly absorbed into the reticulated vein, which lies underneath the oral mucosa and transported through the facial veins, internal jugular vein, and braciocephalic vein and are then drained into the systemic circulation. Upon sublingual administration drug reaches directly in to the blood stream through the ventral surface of the tongue and floor of the mouth. The main mechanism for the absorption of the drug in to oral mucosa is via passive diffusion into the lipoidal membrane the absorption of the drug through the sublingual route is 3 to 10 times greater than oral route and is only surpassed by hypodermic injection.

VIII. FACTORS AFFECTING ABSORPTION

a. Binding to the oral mucosa: Systemic availability of drugs that bind to oral mucosa is poor.
b. PH and pKa of the saliva: As the mean pH of the saliva is 6.0, this pH favors the absorption of drugs which remain unionized. Also, the absorption of the drugs through the oral mucosa occurs if the pka is greater than 2 for an acid and less than 10 for a base.
c. Lipophilicity of the drug
d. For a drug to be absorbed completely through sublingual route, the drug must have slightly higher lipid solubility than that required for Gl absorption is necessary for passive permeation.
e. Thickness of the oral epithelium: As the thickness of sublingual epithelium is 100-200 µm which is less as compared to buccal thickness. So the absorption of drugs is faster due to thinner epithelium and also the immersion of drug in smaller volume of saliva.

IX. COMPARISON BETWEEN ORALLY FAST DISSOLVING FILMS AND ORAL DISINTEGRATING TABLET

Table no.1

Orally Fast Dissolving Films	Orally Disintegrating Tablets
Larger surface area gives greater dissolution.	Less surface area gives less dissolution than OFDF.
These are flexible and durable.	These are brittle and less durable than OFDF
Only low dose can be incorporated.	High dose can be incorporated.
OFDF thickness are 50 to 500 µm.	ODT thickness as like convention tablet.
Patient compliance is more.	Patient compliance is less than ODF

X. PROFILING

A solid dosage form that dissolves or disintegrates quickly in the oral cavity, resulting in solution or suspension without the need for the administration of water, is known as an oral fast-dispersing or fast-dissolving dosage form.[14]

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XI. FORMULATION INGREDIENTS

Following general composition of drug and excipients in percentage

- Drug 1-25%
- Water soluble polymer 40-50%
- Plasticizers 0-20%
- Fillers, colours, flavours etc. 0-4

Drug (1-25%)

The drugs selected oral films should possess good stability in saliva and water with low dose. It is always useful to have micronized API which will improve the texture of the film and also for better dissolution and uniformity in the oral fast dissolving films. Several class of drugs can be formulated as mouth dissolving films including antiasthamatics (Salbutamol sulphate, Montelukast), antihistamine (Levicitrizine), antinational (Verapmil), antiulcer (Omeprazole), antiemetic (Domperidone), expectorants, antitussives, NSAID'S (Valdecoxib, Meloxicam, paracetamol).

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 mouthfeel 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, carboxy methyl cellulose cekol 30, hydroxy propyl methyl cellulose E-3 and K-3, methyl cellulose A- 3, A-6 and A-15, pectin, sodium alginate, hydroxyl propyl cellulose, maltodextrins and eudragit RD10,11

Plasticizers (0-20%)

Plasticizer is used for improve Flexibility with reduce Brittleness of films. 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.

Surfactants

Surfactants are used as wetting or solublising or dispersing agent so that the film is getting dissolved within seconds and release active agent immediately. Commonly employed are polaxamer 407, bezathonium chloride, sodium lauryl sulfate, tweens, benzalkonium chloride, etc. Out of these most predominantly used surfactant is polaxamer 407.

Sweetening agents

Sweeteners have become the important part of pharmaceutical products intended to be disintegrated or dissolved in the oral cavity. Some of the commonly employed sweeteners are dextrose, sucrose, fructose, glucose, isomaltose, polyhydric alcohols (sorbitol, mannitol), etc. Artificial sweeteners like saccharin, cyclamate, aspartame (first generation) and acesulfame K, sucralose, alitame, neotame (second generation) can also be used.

Saliva stimulating agents

Saliva stimulating agents are used to increase the rate of production of saliva that would help in the faster disintegration of the rapid dissoving 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.

Flavouring agents

The quantity of flavouring agent required to mask the taste depends on the flavour type and its strength. Commonly employed are fruity flavours (vanilla, cocoa, coffee, chocolate, citrus), flavor 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.

Colouring agents
Generally incorporated colouring agents are FDandC colours, natural colours, pigments such as titanium dioxide etc.

XII. DIFFERENT TECHNOLOGIES USED IN FILM FORMULATION (PATENTED TECHNOLOGIES)

X Gel:
X Gel™ film provides unique product benefits for healthcare and pharmaceutical products: It is non-animal derived, approved on religious grounds, and is suitable for vegetarians; the film is genetically modified organism (GMO) free and continuous production processing provides an economic and competitive manufacturing platform. XGel™ film can be taste masked, coloured, layered, and capable of being enteric properties whilst also having the ability to incorporate active pharmaceutical ingredients.

Soluleaves:
This technology is applied to flavor-release products such as mouth fresheners and vitamin products, For pharmaceutical uses, this method of administration is especially useful for pediatric or elderly patients who may have difficulty swallowing traditional tablets or capsules. Soluleaves™ films can also be designed to adhere to mucous membranes and to release the active ingredient slowly over 15 min.

Wafer tab:
Wafer tab™ is a drug delivery system that incorporates pharmaceutical actives into an ingestible film strip. The system provides rapid dissolution and release of actives when the strip comes into contact with saliva in the mouth. The Wafertab™ filmstrip can be flavored for additionally improved taste masking. The active ingredient is precisely dosed and integrated into the body of a pre manufactured XGel™ film, thus preventing exposure to unnecessary heat and moisture and potentially enhancing product stability. The Wafertab™ system lends itself to many possibilities for innovative product design, enabling multiple films with different actives to be bonded together. Wafertab™ can be prepared in a variety of shapes and sizes and is an ideal method for delivery of medicines, which require fast release.

Foam burst:
It is a special variant of the Sol leaves™ technology where an inert gas is passed into the film during production. This results in a film with a honeycombed structure, which dissolves rapidly giving a novel mouth sensation. Foamburst™™ has attracted interest from food and confectionary manufacturers as a means of carrying and releasing flavors.

Micap:
Micapple signed an option agreement in 2004 to combine its expertise in microencapsulation technology with the Bio Progress water soluble films. The developments will be aimed at providing new delivery mechanisms for the $1.4 billion global market for smoking cessation products (SCPs). [20]

XIII. CLASSIFICATION OF FAST DISSOLVING TECHNOLOGY

For ease of description, fast-dissolve technologies can be divided into three broad groups:

- Lyophilized systems
- Compressed tablet-based systems.
- Thin film strips

1] Lyophilized systems:
The technology around these systems involves taking a suspension or solution of drug with other structural excipients, through the use of a mould or blister pack, forming tablet shaped units. The units or tablets are then frozen and lyophilized in the pack or mould. The resulting units have a very high porosity, which allows rapid water or saliva penetration and very rapid disintegration.

2] Compressed tablet-based systems:
This system is produced using standard tablet technology by direct compression of excipients. Depending on the method of manufacture, the tables technologies have different levels of hardness and

friability. The speed of disimegration for fast dissolve tablets compared with a standard tablet is achieved by formulating using water soluble excipients, superdisintegrant or effervescent components, to allow rapid penetration of water into the core of the tablet.

3] Thin film strips:

Oral films also called oral wafers, 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. Today, FDFs are a proven and accepted technology for the systemic delivery of APIs for over-the counter (OTC) medications and are in the early to mid-development stages for prescription drugs. This has been attributed to the success of the breath freshener products by consumers such as Listerine Pocket Paks in the US consumer market. Such systems use a variety of hydrophilic polymers to produce a 50-200 mm film. The film is manufactured as a large sheet and then cut into individual dosage units for packaging in a range of pharmaceutically acceptable formats, [22]

XIV. APPLICATIONS OF FAST DISSOLVING ORAL FILMS

Oral films are preferred for local action and abo to manage pain, allergies, sleeping difficulty and CNS disorders.

1. 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.

2. 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 used to treat gastrointestinal disorders.

3. 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.

4. Vaccines:

Fast dissolving films can be delivered in the form of vaccine which is stable at room temperature so it is quickly dissolved in mouth and in saliva. Rotavirus vaccine prepared in United States is room temperature stable fast-dissolving buccal film delivery system for vaccines.

a. Oral films are applicable to enhance the bioavailability of poorly bioavailable drugs.
b. Taste masking of bitter drugs.
c. Dissolvable films are 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 with a diagnostic device, [23]

XV. PACKAGING OF ORAL FILM

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 aluminum pouch is the most commonly used packaging format. APR-Labtec 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:

a. They must protect the preparation from environmental conditions.
b. They must be FDA approved.
c. They must meet applicable tamper-resistant requirement
d. They must be non-toxic.
e. They must not be reactive with the product.
f. They must not impart to the product tastes or Odors

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Single pouch and Aluminum 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. Aluminum pouch is the most commonly used pouch.

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 scaling equipment. The pouches can be single pouches or aluminum pouches.

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 film selection should be based upon the Degree of protection required. Generally the lid stock is made of aluminum foil. The material used to form the cavity is typically a plastic. Which can be designed to protect the dosage form from moisture.

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 Polychlorotrifluoroethylene film, Polypropylene.

Continuous roll dispenser:
An automatic drug tape Dispensing and metering device and a disposable Cassette containing a roll of drug tape housed in a Small reusable portable dispenser unit. The dispenser contains a measurement device for carefully measuring the length of tape as it is dispensed. A Counter monitors the remaining doses of drug tape remaining within the dispenser. A timer device may be provided to alert the patient that it is time for the Medicament to be dispensed. As the lid of the dispenser unit is opened, the measured length of drug Tape is severed from the roll by a cutter blade incorporated into the lid. The dosage and Administration of the medicament to be given a Patient may be set by adjusting the tape length released for each single dose and selecting the time Intervals between dosages. The invention comprises also ingestible tapes of medicament [24]

XVI.DISCUSSION AND RESULT

Fast Dissolving Oral Films (FDOFs) represent a modern drug-delivery system designed to improve patient compliance, especially among pediatric, geriatric, and dysphagic individuals who struggle with swallowing conventional tablets. The present study focused on the key formulation aspects of FDOFs, including the use of polymers, plasticizers, surfactants, and taste-masking agents. Findings from literature indicate that water-soluble polymers such as HPMC, PVA, and pullulan play a major role in determining film strength, flexibility, and rapid disintegration. Plasticizers like glycerol and PEG enhance elasticity and prevent brittleness, while surfactants improve wetting and contribute to faster drug release. Taste-masking agents and flavours significantly improve palatability, making the films more acceptable to patients.

The oral cavity’s high permeability enables rapid drug absorption and helps bypass first-pass metabolism, leading to improved bioavailability compared to traditional oral dosage forms. Results also show that properly optimized films dissolve within seconds and provide a faster onset of action than orally disintegrating tablets. Mechanical evaluation of reported formulations confirmed good tensile strength and uniformity.

Overall, the combined findings demonstrate that FDOFs are a promising, patient-friendly, and efficient dosage form with strong potential for delivering a wide range of therapeutic agents.

CONCLUSION

OFDFs are not well defined in the literature but, no doubt revolutionary and an innovative drug delivery system for all the population groups, specifically geriatric, paediatric patients and patients with swallowing difficulties. OFDFs are also having great potential of delivering the medicinal agent systemically as well locally and have several advantages over many dosages form seven over the fast-disintegrating tablets. This explains the extensive research actively going on this technology.

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[24] Dipta yan Paul, Priyanka Ray Gurunanak Institute of Pharmaceutical science & technology, 157/f Nilgunj Road, Sodepur, Panihati, Kolkata -114, West Bengal, India