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Screening Optimization and Characterization of Polymers for Orally Dissolving Films: A Review

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ABSTRACT
Orally fast dissolving films (OFDFs) have been introduced in the market recently as they provide convenience and ease of use over other dosage forms such as orally disintegrating tablets. This technology 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, so OFDFs are gaining the interest of large number of pharmaceutical industries. Orally fast dissolving film is the type of drug delivery system which when placed in the oral cavity, disintegrate or dissolve within few seconds without the intake of water. OFDFs are very similar to postage stamp in their shape, size and thickness. These films have a potential to deliver the drug systemically through intragastric, sublingual or buccal route of administration and also has been used for local action. This type of technology offer a convenient way of dosing medication, not to special population groups like pediatric, geriatric, bedridden patients, mentally ill patients, but also to the general population. The present review provides an account of various formulation considerations, method of preparation and quality control of the OFDFs.

Keywords: Fast dissolving films, Fast disintegration, Oral strips, Tensile strength.

I. INTRODUCTION

Screening Optimization and Characterization of Polymers for Orally Dissolving Films (ODFs) is an important process in the development of novel drug delivery systems. ODFs are thin films that can dissolve in the mouth, allowing for rapid drug absorption through the oral mucosa. This makes them a promising alternative to traditional oral dosage forms such as tablets and capsules, particularly for patients who have difficulty swallowing or have gastrointestinal problems.[1,2]

The development of ODFs requires the identification and selection of suitable polymers that can provide the necessary physical and chemical properties for the films to perform effectively. This process involves screening a wide range of polymers to identify those that have the required solubility, film-forming ability, and mechanical properties, among other characteristics.

Optimization of the selected polymers is then carried out to determine the ideal ratios and concentrations required to achieve the desired properties of the ODFs. This can involve the use of various techniques such as response surface methodology, which allows for the efficient determination of the optimal combination of variables that will result in the desired properties of the ODFs.[2,3]

Characterization of the optimized ODFs is then carried out to determine their physical and chemical properties, including film thickness, surface morphology, mechanical strength, and drug release characteristics. This is done using a range of analytical techniques such as scanning electron microscopy, differential scanning calorimetry, and Fourier-transform infrared spectroscopy.

The screening, optimization, and characterization of polymers for ODFs are important processes that can impact the effectiveness and safety of the final drug delivery system. Proper screening can ensure that only suitable polymers are used, reducing the risk of adverse effects on patients. Optimization can ensure that the ODFs have the desired properties, resulting in better drug delivery and patient outcomes. Characterization can provide valuable insights into the behavior and performance of the ODFs, helping to refine the development process and improve the final product.

Overall, the development of ODFs requires a comprehensive and iterative approach, involving the careful screening, optimization, and

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characterization of polymers to ensure the final product meets the necessary standards for safety and effectiveness.[3]

Absorption pathway through oral mucosa

The absorption pathway through the oral mucosa is a route of drug administration that involves delivering drugs directly into the bloodstream through the mucous membrane lining the mouth. This pathway is also known as sublingual or buccal absorption, depending on the exact location in the mouth where the drug is placed.

When a drug is placed under the tongue or inside the cheek, it comes into contact with the mucous membrane lining the oral cavity. This mucosa is highly vascularized, meaning it has a rich blood supply that allows for efficient absorption of drugs into the bloodstream. In addition, the oral mucosa has a thin epithelial layer that allows drugs to pass through quickly.[4]

The drugs that are most commonly administered through the oral mucosa are those that are highly lipid-soluble, meaning they dissolve readily in lipids (fats). Examples include nitroglycerin, which is used to treat angina (chest pain), and certain types of hormones and steroids.

Once the drug is absorbed through the oral mucosa, it enters the bloodstream and is transported throughout the body, where it can exert its therapeutic effects. Because the absorption pathway through the oral mucosa bypasses the digestive system, drugs administered in this way can avoid first-pass metabolism, which can reduce the amount of drug that reaches the systemic circulation.[5]

Overall, the absorption pathway through the oral mucosa provides a rapid and efficient means of delivering certain types of drugs into the bloodstream, allowing for faster onset of action and potentially reducing the risk of gastrointestinal side effects.

Perks of ofdfs:

Here are some of the perks of OFDFs:

1. Convenience: OFDFs are easy to take and do not require water to swallow, which makes them ideal for people who have difficulty swallowing pills or for those who are always on the go.[6]
2. Fast-acting: OFDFs dissolve quickly in the mouth and are absorbed directly into the bloodstream, allowing for faster onset of action compared to traditional tablets or capsules.
3. Accurate dosing: OFDFs are pre-dosed and offer accurate and consistent dosing, ensuring that patients receive the correct amount of medication.[7]
4. Improved compliance: OFDFs are convenient and easy to take, which can improve patient compliance and adherence to medication regimens.[8]
5. Enhanced shelf-life stability: OFDFs have a longer shelf-life compared to other forms of medication because they are less susceptible to degradation from moisture or oxygen, ensuring that the medication remains effective for longer periods of time.[3]

Limitation of ofds.

Here are some of the limitations of OFDFs:

1. Sensitivity to moisture: OFDFs are sensitive to moisture, which can cause them to degrade or lose their effectiveness. As a result, they need to be stored in a cool, dry place.
2. Limited drug loading: OFDFs have limited space to incorporate active pharmaceutical ingredients, which can limit the dose that can be delivered per film.
3. Higher production costs: OFDFs require specialized manufacturing equipment and processes, which can be more expensive than traditional tablets or capsules.
4. Stability issues: Some active pharmaceutical ingredients may not be stable in the presence of the film-forming agents or other excipients used in OFDFs, which can limit their use.
5. Choking hazard: OFDFs can pose a choking hazard if they are not properly dissolved in the mouth before swallowing.
6. Limited availability: OFDFs are not yet widely available for all medications and are limited to certain drug formulations and doses.[9,10]

Formulation and Development of Phytochemical Loaded of OFDFs:

Formulation and development of phytochemical loaded oral fast-dissolving films (OFDFs) involves several steps, including the selection of appropriate phytochemicals with desirable pharmacological activity, solubility, and stability. Film-forming agents, such as HPMC, PVA, and pullulan, are selected based on their ability to dissolve quickly in the mouth and form a film that adheres to the oral mucosa. Plasticizers, such as glycerol, propylene glycol, and sorbitol, are added to improve the flexibility and elasticity of the OFDFs. Flavoring agents, such as mint, lemon, and strawberry, are included to improve the taste and mask the bitter taste of some phytochemicals.[11]

International Journal of Pharmaceutical Research and Applications
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The active ingredients are then incorporated into the OFDFs at the desired dose. The formulation is optimized to ensure the OFDFs have the desired properties, including quick disintegration and dissolution, adequate mechanical strength, and good mouthfeel. The OFDFs are then evaluated for their physicochemical properties, such as thickness, weight, and drug content uniformity, as well as their in vitro and in vivo performance.[3]

Formulation Aspect:

The formulation aspect of oral fast-dissolving films (OFDFs) involves careful selection and optimization of the ingredients to achieve the desired properties. The choice of film-forming agents, such as HPMC, PVA, and pullulan, is critical to achieve rapid dissolution in the mouth. The mechanical strength of the film and stability of the active ingredient also determine the choice of film-forming agents. Plasticizers, such as glycerol, propylene glycol, and sorbitol, are added to improve the flexibility and elasticity of the OFDFs.[12] The concentration of plasticizers is optimized to achieve the desired film properties. The active ingredients are incorporated into the OFDFs at the desired dose, with careful consideration given to the therapeutic indication and pharmacological effects.[6] The concentration of the active ingredient is optimized to ensure adequate drug loading and uniform distribution. Flavoring agents may also be included to mask the bitter taste of some active ingredients and improve patient acceptability. The formulation is optimized to achieve quick disintegration and dissolution, adequate mechanical strength, and good mouthfeel. Finally, the OFDFs are evaluated for their physicochemical properties, such as thickness, weight, and drug content uniformity, as well as their in vitro and in vivo performance.[13]

Method Used For Formulation Of OFDFs

The method used for the formulation of oral fast-dissolving films (OFDFs) depends on the specific formulation requirements and the equipment available. Some of the commonly used methods for the formulation of OFDFs include:[14]

1. **Solvent casting method:** This method involves dissolving the film-forming polymer and plasticizer in a suitable solvent to form a uniform solution. The active ingredient and other excipients are added to the solution, which is then cast on a flat surface, dried, and cut into film strips of the desired size.[3,6,15]
2. **Hot-melt extrusion method**: In this method, the film-forming polymer and plasticizer are melted together at high temperatures to form a homogenous melt. The active ingredient and other excipients are then added to the melt, which is then extruded through a die and cooled to form a solid film.[16]
3. **Spray-coating method**: This method involves coating a substrate with a thin layer of film-forming polymer solution or suspension containing the active ingredient and other excipients. The coated substrate is then dried to form a thin film.
4. **Electrospinning method:** In this method, a high voltage is applied to a polymer solution or suspension containing the active ingredient and other excipients. The resulting electric field causes the solution to form fibers that are collected on a substrate, dried, and cut into film strips of the desired size.
5. **Freeze-drying method**: This method involves freezing a solution or suspension containing the film-forming polymer, plasticizer, active ingredient, and other excipients. The frozen mixture is then dried under vacuum to remove the solvent and form a solid film.

6 **Solid dispersion extrusion:**The purpose is to diffuse the active ingredient into a melted polymer solution so that it may be loaded more easily. There can be one or more active ingredients that are dissolved in a suitable liquid solvent that functions as an inert carrier. This occurs in the presence of an amorphous hydrophilic polymer at 70°C without the requirement to remove the liquid solventin order to get the solid dispersion required. Finally, the dyes are used to form the solid dispersions into films[4]

7 Rolling method: The rolling method is a technique used for preparing oral fast-dissolving films (OFDFs). The steps involved include preparing a solution or suspension of the active ingredient and excipients, pouring the solution or suspension onto a flat surface, spreading it evenly with a spreading tool, and then rolling the film using a roller or a similar device. This method is commonly used in the manufacture of OFDFs due to its simplicity and scalability.[17]

Current Research On Phytochemical Loaded OFDFs:

Phytochemicals are bioactive compounds derived from plants that have various pharmacological activities. Research on

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phytochemical-loaded oral fast-dissolving films (OFDFs) is currently ongoing, with several studies exploring the potential benefits of these films in delivering phytochemicals to the body.

One recent study published in the Journal of Drug Delivery Science and Technology investigated the use of OFDFs loaded with curcumin, a natural compound found in turmeric with anti-inflammatory and antioxidant properties. The study found that the OFDFs were able to deliver a sufficient amount of curcumin to the body, with good bioavailability and improved therapeutic efficacy compared to traditional dosage forms.

Another study published in the journal Pharmaceutical Development and Technology investigated the use of OFDFs loaded with quercetin, a flavonoid with antioxidant and anti-inflammatory properties. The study found that the OFDFs had improved dissolution and permeation properties, which could potentially enhance the bioavailability and efficacy of quercetin.

Overall, these studies suggest that phytochemical-loaded OFDFs have potential as an effective and efficient delivery system for phytochemicals with various pharmacological activities. Further research is needed to explore the use of OFDFs in delivering other phytochemicals and to optimize the formulation and manufacturing process.

Various Technologies Used In Oral Film Formulation:

X-Gel:

X Gel film Technology developed by Bio Progress is causing a revolution in the product offerings and manufacturing methods now available to the pharmaceutical industry.[18,19]

Soluleaves:

This is applied to flavor-release products such as mouth fresheners, confectionery and vitamin products. Solute leaves technology can be used to deliver active ingredients to oral cavity efficiently and in a pleasant and easily portable form.[20]

Wafertab:

Wafertab is a patented delivery system that uses a unique process to prepare drug-loaded thin films which can be used in topical or oral application. Active ingredients are incorporated into the film after casting.[21,22]

Foamburst:

Foam burst is a new patent granted in September 2004 which is for capsules made of foamed film. Gas is blown into the film during production, resulting in a film with a honeycombed structure.The voids in the film may be gas-filled, empty or filled with other materials to produce specific taste-burst characteristics or to deliver active drugs. The light honeycombed structure results in capsules that dissolve rapidly, causing a melt-in-the mouth sensation.[23]

Micap:

Micap Signed an option agreement in 2004 to combine its expertise inmicro encapsulation technology with the Bio Progresswater-soluble films.

Patented Technologies:

The patented technologies for manufacturing of fast dissolving drug delivery system are Zydus, Orasolv, Durasolv, Flashdose, Wowtab and Nanocrystal Technology.[24,25]

List of Marketed Fast Dissolving Oral Films

Product	Manufacturer	API	Use
Listerine	Pfizer	Cool mint	Mouth fresheners
Triaminic	Novartis	Dextromethorphan HBr	Cough suppressants
Suppress®	InnoZen®, Inc	Menthol	Mouth fresheners
Chloraseptic	Prestige	Benzocaine Menthol	Local anesthetic
Gas-X	Novartis	Simethicone	Anti Flatuating
Theraflu	Novartis	Dextromethorphan HBr	Anti allergic
Setofilm	BioalliancePharma	Ondansetron	Prevention of Nausea and Vomiting
Zuplenz(R)	MonoSol Rx	Ondansetron	Prevention of Nausea and Vomiting
Donepezil Rapid film	Labtec	Donepezil	Alzheimer's disease
Sudafed PE	Wolters Kluwer Health Inc.	Phenyleprine	Relieving Congestion
Klonopin Wafer	Solvay Pharmaceuticals	Clonazepam	Treatment of anxiety

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Application of Oral Fast Dissolving Films

Oral fast-dissolving films (OFDFs) have several applications in the pharmaceutical industry. Some of the common applications of OFDFs include:

1. Rapid onset of action: OFDFs dissolve quickly in the mouth and allow for rapid absorption of the active ingredients, resulting in a faster onset of action compared to traditional dosage forms.[31]
2. Improved patient compliance: OFDFs are easy to administer and do not require water or other liquids for ingestion, making them more convenient for patients, especially those with difficulty swallowing tablets or capsules.
3. Pediatric and geriatric populations: OFDFs are particularly useful in populations such as children and the elderly, who may have difficulty swallowing conventional tablets or capsules.[32]
4. Taste masking: OFDFs can be formulated with taste-masking agents to improve the palatability of bitter or unpleasant-tasting drugs, making them more acceptable to patients.
5. Local delivery: OFDFs can be used for the local delivery of drugs to the oral cavity, such as local anesthetics or antimicrobial agents.[33]
6. Systemic delivery: OFDFs can also be used for systemic drug delivery, particularly for drugs with high first-pass metabolism, as the rapid absorption in the mouth can bypass the liver and increase bioavailability.

Overall, OFDFs have several advantages over traditional dosage forms and offer a promising alternative for drug delivery in various patient populations and for different types of drugs.

Evaluation parameter:[26,27,28,29,30]

1.**Thickness:** The thickness of the all different films was measured using a baker precision measuring instrument, china. It was measured by placing each film between the anvil and the presser foot of the dial guage is different location and the average thickness was calculated.

2. **Tensile strength:** Tensile strength is maximum stress applied to at which film specimen breakes. It is calculated by the load at rupture divided by the cross section area of the film.

Tensile strength = F max/A film

3. **Youngs modulus:** - It is use to estimate stiffness. It is found as balance applied stress to the strain in the region. it is determind by,

Youngs modulus = force of corresponding strain/cross sectional area.

4. **Tail flick test:** The ventral surface of the tail of the animal was placed on the heating coil of digital anal gesiometer and the basal reaction times were noted. About 3-5 basal coxib was fixed of 10 mg/kg body weight.

5. **Thermodynamic stability test**: Optimize formulations then subjected to different thermodynamic stability study test namely centrifugation and freeze thaw cycles by thermodynamic stability test.

6. **Viscosity**: Evaluate the viscosity of the optimized formulation by Brookfield viscometer.

7. **Drug content**: Determine the percentage of drug content of formulation from the calibration curve by using uv spectrometer.

8. **Weight of films**: Oral fast dissolving films can be weighed on analytical balance and average weight can bedetermined for each film. It is desirable that films should have nearly constant weight. It is useful to ensure that a film contains the proper amount of excipients and APIs.

9. **pH value:** PH is measured by the dissolving one oral film in 10ml distilled water and measuring the pH of the obtained solution should have nearly uniform pH value.

10. **Elongation:** When stress is applied, a film sample stretches and this is referred to as strain. Strain is basically the deformation of film divided by original dimension of the sample. Generally elongation of film increases as the plasticizer content increases.

Percent elongation= L*100/Lo

L = Increase in length of film Lo = Initial length of film.

11. **Folding endurance** : Folding endurance gives the brittleness of a film. The method followed to determine endurance value is that the film specimen (2 × 2 cm2) are repeatedly folded at the same place until it breaks or a visible crack is observed. The number of times the film is folded without breaking or without any visible crack is the calculated folding endurance value.

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 2 Mar-Apr 2023, pp: 909-917 www.ijprajournal.com ISSN: 2249-7781

12.**In vitro disintegration test** :Disintegration time is the time when an oral film starts breaking when brought in contact with water or saliva. For a fast dissolving film, the time of disintegration should be in range of 5-30 s. United State Pharmacopoeia (USP) disintegration apparatus can be used to study disintegration time. In another method, the disintegration time can be visually determined by dipping the film in 25 ml water in a beaker. The beaker should be shaken gently and the time was noted when the film starts to breaks or disintegrates.

13.**In vitro dissolution studies:** Dissolution is defined as the amount of drug substance that goes into the solution per unit time under standardized conditions of liquid/solid interface, temperature, and solvent concentration. The standard basket or paddle apparatus described in any of the pharmacopoeia can be used for dissolution testing. The selection of dissolution medium will essentially depend as per the sink conditions and highest dose of API. The temperature of dissolution medium should be maintained at 37 ± 0.5°C and rpm at 50. When the paddle apparatus is employed, it has a disadvantage that oral films have a tendency to float over the dissolution medium. Mashru et al. used stainless steel wire mesh with sieve opening of approximately 700 µm used to dip salbutamol fast dissolving film inside the dissolution medium.

Advantages:[34,35,36,37,38,39]

1. Rapid onset of action: OFDFs dissolve rapidly in the mouth, allowing the active ingredient to be quickly absorbed into the bloodstream. This leads to a more rapid onset of action compared to traditional dosage forms, which need to be swallowed and then dissolve in the gastrointestinal tract.
2. Improved patient compliance: OFDFs are easy to administer and do not require water for swallowing. This makes them more convenient for patients who have difficulty swallowing tablets or capsules. Moreover, OFDFs are discreet and can be taken anywhere, without the need for water or special handling.
3. Accurate dosing: OFDFs offer accurate dosing of the active ingredient because they are prepared using precise manufacturing techniques. This ensures that each film contains the same amount of active ingredient, leading to consistent dosing and improved efficacy.
4. Taste masking: OFDFs can be formulated to mask the bitter taste of certain drugs, making them more palatable and easier to swallow. This is particularly important for pediatric and geriatric patients, who may refuse to take bitter-tasting drugs.
5. Localized or systemic drug delivery: OFDFs can be formulated to deliver drugs locally or systemically. For example, drugs can be formulated in OFDFs for buccal, sublingual, or transmucosal delivery, allowing for rapid absorption and localized action. Alternatively, drugs can be formulated in OFDFs for systemic delivery, allowing for controlled release and extended action.
6. Reduced gastrointestinal irritation: OFDFs avoid the need for swallowing, which can reduce gastrointestinal irritation and side effects. This is particularly important for drugs that can cause gastrointestinal irritation, such as non-steroidal anti-inflammatory drugs (NSAIDs).
7. Stable and easy to store: OFDFs are stable and do not require refrigeration, making them easy to store and transport. This reduces the cost and complexity of storage and distribution, compared to other dosage forms that may require special storage conditions.
8. Enhanced bioavailability: OFDFs can enhance the bioavailability of certain drugs by avoiding first-pass metabolism in the liver. This leads to higher plasma concentrations of the active ingredient and improved efficacy.

Disadvantages:[40,41,42,43,44]

1. Limited drug loading capacity: OFDFs have a limited drug loading capacity, which can make it challenging to formulate drugs with higher doses. This can limit the use of OFDFs for certain drugs or therapeutic applications.
2. Formulation complexity: OFDFs require precise formulation to achieve the desired properties, such as rapid dissolution, mechanical strength, and taste masking. This can make the formulation process complex and time-consuming.
3. Sensitivity to environmental factors: OFDFs can be sensitive to environmental factors, such as temperature and humidity, which can affect their stability and performance. This can pose a challenge during storage and transportation.
4. Risk of swallowing: Although OFDFs are designed to dissolve rapidly in the mouth, there

International Journal of Pharmaceutical Research and Applications
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is still a risk of swallowing them before they have completely dissolved. This can lead to inconsistent dosing and reduced efficacy.

5. Cost: OFDFs can be more expensive to manufacture than traditional dosage forms, due to the specialized equipment and techniques required for production. This can increase the cost of the final product and limit its availability.
6. Limited shelf life: OFDFs have a limited shelf life compared to other dosage forms, which can affect their long-term stability and effectiveness. This can pose a challenge for drugs that need to be stored for an extended period.
7. Limited taste masking options: While OFDFs can be formulated to mask the taste of certain drugs, there are limitations to the available taste masking options. Some drugs may be difficult to mask, which can affect patient compliance and acceptance.

II. CONCLUSION:

Oral fast dissolving films (OFDFs) have emerged as a promising drug delivery system due to their convenience, ease of administration, and rapid dissolution in the oral cavity. OFDFs offer a viable alternative to traditional dosage forms such as tablets, capsules, and injections, particularly for patients who have difficulty swallowing or have a sensitive gag reflex.

The use of OFDFs has been demonstrated in the delivery of various types of drugs, including antihistamines, analgesics, antipsychotics, and antimicrobials. OFDFs also provide enhanced bioavailability, increased patient compliance, and reduced side effects compared to conventional oral dosage forms.

However, there are still some challenges associated with the formulation and manufacturing of OFDFs, including their stability, taste masking, and mechanical properties. Further research is needed to address these challenges and optimize the performance of OFDFs.In conclusion, OFDFs are a promising drug delivery system with several advantages over traditional dosage forms. With continued research and development, OFDFs have the potential to revolutionize the way medications are delivered to patients.

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