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# A REVIEW ON TO DESIGN AN ORAL THIN FILM FOR FAST DRUG ACTION

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## ABSTRACT

Thin films are being explored by the pharmaceutical sector as a potential new drug delivery method. It has been said that thin films offer an alternative to traditional dose forms. They offer quick, local, or systemic effects and are a very flexible platform. Furthermore, these systems are simple to use independently, particularly for patients with dysphagia, elderly, pediatric, or bedridden patients, as well as those who have trouble getting water. There are several ways to provide these drug delivery systems, including transdermal, buccal, sublingual, ophthalmic, and oral. A patient-friendly antitussive fast-dissolving oral film based on dextromethorphan hydrobromide (Dex) is developed in this work using optimization research. Oral medication strips are made from a variety of materials, including plasticizers, active pharmaceutical compounds, sweeteners, saliva enhancers, flavourings, colouring agents, stabilizing agents, and thickening agents.

**KEYWORDS:** Thin film, pediatric, buccal, ophthalmic, plasticizers, saliva enhancers, stabilizing agents.

## INTRODUCTION

The oral route remains the favoured method for prescription therapeutic drugs despite significant advancements in drug delivery because of its affordability, ease of administration, and high patient acceptance. Among the many oral transmucosal formulations, fast-dissolving films (FDFs) appear to be the most promising. This is because of their enormous surface area, which enables quick dissolution and disintegration in the oral cavity without the need for water.

One of the most popular medications is "dextromethorphan hydrobromide" (Dex), a non-opioid antitussive that provides short-term relief from coughs caused by bronchitis, hay fever, upper respiratory tract infections, sinus inflammation, sore throats, and common colds. Dex causes a cough reflex by interfering with brain signals. They are made of extremely thin polymeric strips that contain an active pharmacological ingredient and are designed to dissolve in the mouth within seconds. Because the medication can function quickly through the oral mucosa, this dosage form is beneficial. Oral thin films are produced as large sheets that are divided into separate dose units for packaging. Oral thin films are used as local anaesthetics for conditions such as teething, cold sores, oral ulcers, and toothaches. This dosage form can be used for a variety of medications, including cough cures, antiasthmatics, antihistaminics, erectile dysfunction medications, sore throat medications, gastrointestinal disorders, nausea, pain, and CNS medications. OTFs are instantly moistened with saliva when placed on the tongue. To enable systemic and/or local absorption, medications are distributed and/or dissolved. ODTs are brittle and may shatter during transportation.

Studies have demonstrated that thin films can improve the initial and lasting effects of drugs, reduce the frequency of dosing, and boost drug efficacy.

According to the European Medicines Agency, an orodispers film is a thin film that readily dissolves in the oral mucosa. OTFs are currently available and continue to grow in many prescription and over-the-counter product categories, particularly for cough, cold, sore throat, erectile dysfunction, allergic reactions, asthma, gastrointestinal disorders, pain, snoring complaints, sleep issues, and multivitamin combinations.[1,2]

**ADVANTAGE**

1. one benefit of OTF is that it can be administered easily to people who are mentally ill and noncompliant.
2. Helpful in situations where prompt action is required, like motion sickness, allergic reactions, coughing, or asthma.
3. Has a variety of applications in pharmaceuticals, over-the-counter medications, prescription treatments, and dietary supplements for the treatment of erectile dysfunction, gastro-oesophageal reflux disease, pain, cough/cold, sleep issues, etc.
4. The administration doesn't require water, making it appropriate for travel.
5. A number of drugs are absorbed from the mouth, throat, and oesophagus as saliva passes down into the stomach, boosting their bioavailability.
6. It may improve the bioavailability of drugs that are poorly soluble in water by offering a large surface area and dissolving rapidly.
7. There is very little to no aftertaste. OTF has the advantage of being simple to administer to mentally ill and noncompliant individuals.
8. Is able to provide the same advantages as a solid formulation for liquid medications.
9. Compatible with current packaging and processing equipment.
10. Economical.
11. Compared to liquids, it offers accurate dose.
12. There is outstanding chemical stability.
13. Not requiring measurement, which is a significant drawback with liquids.
14. Provides market expansion and product differentiation.
15. The product development life cycle can be extended by being produced and released in 12 to 16 months.[3,4]

**DISADVANTAGE**

1. The drying time needed for OTFs is a major manufacturing challenge that manufacturers face. It takes a day for the films to dry at room temperature, which lowers the production pace because thermolabile medications forbid the use of hot air furnaces and high temperatures.
2. Because the films lose stability in high relative humidity conditions due to their high hygroscopicity.
3. It is challenging to obtain dose consistency in oral thin films.
4. It is not possible to synthesize medications into thin films if they irritate the oral mucosa or are unstable at the buccal pH.
5. Because the dissolving time is impacted, co-administration of several medications is still difficult.
6. Only drugs with low dosage requirements can be given. vii. Bitter-tasting medications require taste masking.
7. OTFs need special packaging to keep water out.[5,6]

**IDEAL CHARACTERISTICS OF A DRUG TO BE SELECTED FOR ORAL THIN FILM**

- The medication should taste good.
- Drugs with doses up to 40 mg are chosen.
- Drugs with intermediate or smaller molecular weights are favored.
- The medications that are more stable and soluble in saliva and water are chosen.
- It shouldn't fully ionize at the oral cavity's pH. The medications should pass through the oral mucosal membrane.
- They should dissolve or disintegrate in the mouth in a matter of seconds, without the need for water to swallow.
- Drugs that feel good in the mouth are chosen.
- The medication should work well with flavour masking. Drugs should be less sensitive to environmental factors like humidity and temperature.
- The medication should leave little to no residue in the mouth after oral administration.[7,8]

**METHODS OF PREPARATION**

**1. Hot-melt extrusion technique**

To improve the solubility and bioavailability of medications, hot-melt extrusion uniformly combines medicines with carriers in a molten state to form filaments or powders. Because it does not include organic solvents, it is environmentally friendly and is commonly used for oral films. To improve drug solubility and bioavailability, hot-melt extrusion evenly blends medications with carriers in a molten state to create filaments or powders. Because it does not contain organic solvents, it is environmentally safe and is frequently used for oral films.[9,10]

**2. Electrospinning technique**

This technique forms non-woven mats for drug delivery using an electric field to produce nanofibers from polymer solutions. Polymer solutions were charged and ejected onto a grounded drum to create chitosan/pullulan FDOFs. The viscosity, conductivity, and surface tension of the solutions were measured, and the ratio of chitosan to pullulan was varied. The morphology of the resultant nanofibers was examined using scanning electron microscopy. To regulate the release of the medication, successive electrospinning was used to create multilayer films, such as ethyl cellulose/gelatin nanofibrous films. Additional uses include dual-layer mucoadhesive buccal patches that combine PVP/Eudragit RS 100 with a polycaprolactone backing for unidirectional drug administration.[11,12]

**3. Printing Technology**

Printing technology uses computer-aided design (CAD) to deposit materials layer-by-layer to construct three-dimensional structures. Oral films for medication distribution are among the many products that can be manufactured using this technique. Using this technique, a liquid formulation containing the API was precisely deposited into substrate. Drop-on-demand printing, an alternative technique for depositing molten formulations onto a substrate to produce ODFs, is also described. Another method for producing mucoadhesive buccal films for unidirectional drug release is fused deposition modelling (FDM) 3D printing. Hot-melt extrusion was used to create drug-loaded filaments using PVA, xylitol, and diclofenac sodium, with or without chitosan. These filaments were printed into four-layered films using a MakerBot Replicator 2X FDM printer. For films with backing layers, commercial wafer edible sheets are manually added to the printing platform, or ethyl cellulose is 3D printed on top. To include heat-sensitive medications, such as lidocaine, in HPMC-based buccal films with ethyl cellulose unidirectional drug release, fatouros. developed a combined FDM and inkjet approach.[13,14]

**4. Solvent Casting**

A popular method for making films is solvent casting, particularly in the pharmaceutical sector, to make orodispersible films (ODFs). Using an appropriate solvent, the polymer and active pharmaceutical ingredient (API) are dissolved. Subsequently, a substrate, such as polyethylene terephthalate (PET) foil, was covered with the resultant solution, known as the film casting mass. To allow the solvent to evaporate, the film is dried in a controlled setting, usually an oven. As the solvent evaporates, the polymer and API molecules draw closer to one another, eventually solidifying into a thin, homogeneous coating. The composition of the casting solution and the drying conditions affect the mechanical strength, porosity, and disintegration time of the final film. This method is particularly advantageous for heat-sensitive pharmaceuticals and excipients because it avoids the high temperatures associated with other film processes, such as hot-melt extrusion. However, the solvent casting approach has drawbacks, including difficulties in scaling up, residual issues related to solvents, environmental effects, and challenges in generating high drug loads owing to problems with solubility and crystallization.[15,16]

**POLYMERS AND OTHER COMPONENTS USED IN FILM**

The film formulation rapidly dissolves in the oral cavity, hence the film-forming polymers used must be water soluble. The polymers can be used alone or in combination with others to produce the right film, which must be robust enough to withstand handling or transportation damage and show rapid disintegration in the mouth. The type and amount of polymer used in the composition influence the film's resistance. The time it takes for the polymers to break down is extended by raising the molecular weight of the polymer film bases.

Two factors affect the relative amounts of polymers and APIs, which together make up the majority of the film formulation: a) A minimum percent weight-weight concentration of polymer must be present in a matrix containing APIs and other excipients with suitable mechanical and viscoelastic properties. b) The percentage w/v concentration of polymer in solution to be cast as film is controlled by the necessary viscosity. The viscosity should be ideal to prevent suspended elements from settling and to produce a smooth, spreadable coating.[17,18]

**Plasticizers:** By decreasing the glass transition temperature of the polymer, plasticizers improve the flexibility and reduce the brittleness of the film. Additionally, plasticizers improve tensile strength and reduce brittleness. The polymer and solvent should work well with the plasticizer. Plasticizers also increase the polymers' tensile strength. Glycerol, propylene glycol, low-molecular-weight polyethylene glycols, citrate derivatives such as tributyl and triethyl citrate, triacetin, and castor oil are some of the most popular plasticizers.

Excessive or improper usage of plasticizer can cause film to peel, split, and fracture. Certain plasticizers may affect the rate of absorption of the medication. The film should have a lifetime of flexibility, owing to the plasticizer. Plasticization is caused by two processes: the addition of a physically active plasticizer for both internal and external plasticization. Molecular groups within the polymer chemically interact during internal plasticization. External plasticization is the best plasticization technique because it prevents chemical interactions within the product. Cellulosic hydrophilic polymers were easily converted into plastics using hydroxyl-containing plasticizers such as polyethylene glycol, propylene glycol, glycerol, and polyols.[19]

**Surfactant:** Surfactants quickly break down the film and release the API by acting as wetting or dispersion agents. The two most used surfactants are sodium lauryl sulphate and polysorbates. One of the most important surfactants, poloxamer 407, is a dispersion, solubilizing, and wetting agent. Aditya D. et al. designed and tested fast-dissolving films to deliver Triclosan to the oral cavity. It used film-forming materials like HPMC, xylitol, and xanthan gum. The potential for Poloxamer 407 and hydroxypropyl-cyclodextrin (HP-CD) to improve Triclosan's solubility was investigated.

The films' dissolving properties and in vitro antibacterial activity were evaluated. Poloxamer 407-containing films demonstrated a greater in vitro dissolving profile and in vitro antibacterial activity than HP-CD-containing films. Additionally, the effects of adding eugenol on the in vivo performance of Poloxamer 407-containing films were evaluated using human volunteers. Without changing the in vivo dissolving time, eugenol-containing films improved viewer approval in terms of tongue refreshing and flavour masking.[20]

**Sweeting Agent**: Both natural and artificial sweeteners are added to the rapidly dissolving oral thin films to make them more appealing. Sweeteners include fructose, glucose, maltose, sucrose, and dextrose. The sweetness of fructose is perceived by the tongue faster than that of sucrose and dextrose. Fructose is often used because it tastes sweeter than sorbitol and mannitol. Because polyhydric alcohols like sorbitol, mannitol, isomalt, and maltitol also have a cooling effect and a pleasing mouthfeel, you can mix them.

Polyhydric alcohols also have a milder aftertaste and are less carcinogenic. Most polyols have a sweetness-imparting property that is less than half that of sucrose, with the exception of xylitol and maltitol, which both have sweetness comparable to sucrose. The use of natural sugars in these products must be restricted for those with diabetes. As a result, artificial sweeteners are becoming more and more common in food and pharmaceutical preparations. Saccharin and aspartame make up the first generation of artificial sweeteners.[21]

**Salivary stimulants**: Saliva stimulants help the formulations break down more quickly and increase salivary flow. In general, food-grade acids can be used to create saliva-stimulating compounds. Tartaric acid, ascorbic acid, lactic acid, malic acid, and citric acid are a few of the compounds that cause salivation. The most widely utilized and well-liked of these is citric acid. These can be used separately or in combination. Salivation stimulation can be ascertained by comparing the amounts of resting flow with stimulated flow at the same time and under the same conditions.[22]

**Super disintegrants:** Super disintegrants promote quick disintegration when added to a formulation because of the combined actions of water absorption and swelling. Super disintegrants absorb water and expand, increasing the dispersibility of the system and accelerating breakdown and disintegration. Strong contact with water is necessary for disintegration. The mechanism of disintegration could be swelling, wicking, distortion, or a combination of these.[23]

**Coloured materials:** FD&C-approved colouring agents, EU colour, natural colouring agents, or pigments may be used up to 1% weight per weight. The nicotine oral disintegrating film was made with FD&C Yellow as a colouring additive. Titanium dioxide was used as a colouring ingredient in the production of the Ondansetron Rapid Film.[24,25]

**Flavored materials:** The choice of flavour depends on the type of medication to be used. A person's acceptance of an oral disintegrating or dissolving formulation is determined by the first flavour, which is detected in the first few seconds after the dosage form is taken, and the after taste of the formulation, which last for at least around ten minutes.[26,27]

**EVALUTION[28,29,30,31,32]**

- **Physical Appearance**: Examining colour, consistency, and surface flaws visually. guarantees the absence of air bubbles, cracks, and visual quality.
- **Thickness**: A micrometre screw gauge was used to measure the thickness. This attests to the film thickness's consistency.
- **Weight Variation**: Using a digital balance to weigh individual film units. It verifies that the dosage and film mass are consistent.
- **Drug Content Uniformity**: After crushing the film, it was put in a solvent and shook for twenty-four hours. After filtering the solution, a UV spectrophotometer was used to determine the drug content of the samples. This guarantees consistent and precise medication distribution.
- **Folding endurance**: Folding endurance is measured manually by folding repeatedly until a break occurs. It evaluates the flexibility and mechanical strength.
- **Surface Morphology**: The structural integrity, porosity, and smoothness of the film were evaluated using Scanning Electron Microscopy (SEM).
- **Stability Studies**: A range of temperatures and humidity levels were used for ICH-guided testing. establishes the shelf life and storage needs.
- **Thickness**: Since the thickness measurement is closely correlated with the amount of medication in the OTF, it is necessary. In addition, a suitable thickness is required for the films to be applied comfortably. For instance, buccal thin films should be between 50 and 1000 µm thick.
- **Flexibility**: A thin film's flexibility is assessed by repeatedly folding it at the same location at a 180° angle until it breaks. It is stated how many folds were accomplished before breaking. A film is deemed to have exceptional flexibility if it can fold 300 times or more.
- **Determining the pH value**: OTFs is crucial for the medications' quick release, taste characteristics, and solubility/dispersion in the oral cavity. To do this, 1.5%–2% (w/v) agar is dissolved in the isotonic solution. After that, the mixture is put into a petri dish and left to gel at room temperature. It is covered with thin-film samples. The pH of pH sheets ranging from 1 to 11 is then measured by touching them to OTFs and seeing how the paper's colour changes.

- **Determination of swelling degrees**: The polymeric film's swelling is crucial for assessing OTFs' water absorption capacities and learning about their water resistance. Within the allotted time, randomly chosen OTFs are weighed separately and maintained in a petri dish containing simulated physiological fluid. Each film is then weighed and measured at various intervals until the weight rise stabilizes. The following formula is used to determine the degree of edema.
- **Content uniformity**: Each film is filtered after being dissolved in an appropriate solvent, and the drug content in each film is determined using the proper quantification technique. A relative standard deviation percentage of no more than 6% is anticipated.
- **Disintegration test**: The amount of time (in seconds) that a film disperses when it comes into contact with water or saliva is known as the disintegration time. The start of the thin film's disintegration or dispersion is known as the disintegration time. The physical characteristics of water-soluble films are mostly determined by the film's weight and thickness. The disintegration periods of OTFs can also be ascertained using the disintegration test equipment listed in pharmacopoeias. The film composition's disintegration period typically ranges from 5 to 30 seconds; this phenomenon varies depending on the formulation content. There is no authoritative manual for determining how long films that degrade quickly will take to disintegrate.
- **Dissolve rate test**: While certain improvements were made to the equipment to be used for dissolve rate testing, several studies in the literature used Franz diffusion cells to assess drug release from polymeric films. The placing of film specimens is the biggest challenge in the dissolution rate assay. Additionally, a number of techniques have been used in the literature where a double-sided adhesive band is used to attach the film's dissolution rate to the bottom of the glass container or the mixing device.
- **Determination of release kinetics:** The computer program is used to identify the proper kinetic model based on the dissolution findings of all film formulations including API in either pure water or pH 6.8 artificial saliva. The formulations' compatibility with 0. degree, 1. degree, Korsmeyer-Peppas, or Higuchi models is determined by mathematical programs and formulas.
- **Surface and structural morphology**: A SEM is used to analyze surface and structural morphology. This allows for the determination of the distribution of particles and the existence of smoothness, surface roughness, or pores.

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