

Advancements in Fast Dissolving Oral Films

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Abstract The term "fast dissolving oral drug delivery system" refers to a system that dissolves or disintegrates in a matter of seconds or minutes when held in the mouth without water and swallowed. Oral fast dissolving films have emerged as a viable drug delivery technique in recent years, owing to a number of advantages for pediatrics and geriatric patients who have difficulty in swallowing. These little, thin oral film strips are meant to make medicine administration easier when the film is placed on or under the tongue. These films allow the medicine to be delivered directly into the bloodstream via buccal or sublingual routes. Oral films have been shown to improve the onset of action, reduce dosage, and increase bioavailability. This review article discusses the history, benefits, and limitations of oral rapid dissolving films, as well as formulation considerations, manufacturing processes, evaluation parameters, packaging, and marketed products. Due to its unique properties, novel attributes, competitive standing, and cost adequacy, it can be inferred that it is one of the fastest-growing dosage forms with a lot of potential, particularly for commercial applications.

Keywords Fast Dispersible Films, Oral Route, Deglutition, Patient Compliance

1. Introduction

The oral route is one of the most convenient, cost-effective, and favoured routes of drug administration. Nonetheless certain patients especially, pediatrics and geriatrics, have difficulty in swallowing some oral solid dosage forms like tablets, and hard gelatin capsules [1].

Deglutition is a complex and exceedingly synchronized three-step process i.e., pharyngeal and oesophageal physical process of consuming a solid/liquid. In conditions like presbyphagia and dysphagia, patients frequently face significant problems of swallowing the medication. The patients who have vomiting tendency, bipolar discords, oral cancer, and Parkinson's disease have trouble in consuming solid oral dosages like tablets and capsules.

To overcome the problems related to swallowing in these patients and to satisfy the need of patients, a relatively novel, innovational, and useful orodispersible films (ODFs) are developed [2]. This inventive drug delivery system was initially developed in the late 1970s [3]. The principal idea of orodispersible films came from the confectionery industry. Oral films are also called oral strips, mouth dissolving films, fast dissolving oral films, and oral dispersive films [4].

ODFs when placed on the tongue come in contact with saliva and get hydrated. After hydration, they rapidly disintegrate/disperse and release the medicament [5, 6]. Salivary glands which are present in the oral cavity secrete the saliva. Mainly three types of salivary glands are present in the oral cavity i.e. submandibular, parotid, and sublingual glands. The main component of saliva is water which contains 1 % inorganic and organic materials. Saliva is a less viscous, weak buffer that has a pH range from 5.5 - 7. The salivary glands secrete about 0.5-2 L of saliva which is enough to hydrate oral mucosal dosage form [7].

Benefits of ODFs: Following are the various benefits of orodispersible films [6-8]:

1. Provide a good mouth feel.
2. Oral cavity has a large surface area which gives fast disintegration and dissolution of the oral dosage form.

3. Orodispersible films avoid first-pass metabolism as it directly absorbs through buccal mucosa and enters into the systemic circulation.
4. Improve bioavailability of the drug.
5. Improve patient compliance.
6. Quick administration.
7. Pain avoidance.
8. Water nil therapy.

Limitations of ODFs: Following are the various limitations of orodispersible films [4-9]:

1. High Doses of drugs cannot be incorporated.
2. Extremely bitter drugs cannot be incorporated.
3. Drugs that irritate oral mucosa cannot be formulated as ODFs.
4. ODFs need special packaging for product protection and stability.

2. Origination and Advancement

2.1. ODF as a Product

Dr. L. L. Frederick Deadman initially came up with an oral thin dosage form in the early 60s and undertook slow development till the end of the 70s. Afterward, ODFs remained as a concept until 2001. The development of ODFs started with non-medicinal products when Pfizer Consumer Healthcare, NJ launched the ODF called Listerine® pocketpacks®, which is mouth freshening film. Following Pfizer's success, many industries have entered the ODFs area and established a variety of over-the-counter (OTC) and prescription drugs that are already approved and marketed.

Figure 1 illustrates the origination and advancement of ODFs as a product from non-medicinal products to OTC and prescription products. Some reputed brands introduced the first medicated ODF for throat pain, consisting of benzocaine and menthol, and named Chloraseptic® Sore Throat Relief strips. In 2004, Novartis came up with Theraflu® and Triaminic® for cough and cold, which are OTC products. Thereafter, Pfizer introduced ODF for nasal decongestion using the OTC drug phenylephrine (Sudafed PE®), in 2005. In 2006 and 2009, Novartis introduced another two OTC products like simethicone for abdominal pain or bloating and ketoprofen for pain management, respectively. In 2008, C. B. Fleet Company, USA has launched the sennoside herb ODF to treat constipation. In 2010, the first time the market has seen ODFs containing

prescription drugs. Reckitt Benckiser, USA used MonoSol® Pharmfilm® technology to prepare a film of buprenorphine and naloxone combination for pain management after receiving FDA approval. Labtech GmbH prepared ondansetron film (Setofilm®) using rapid film drug delivery system which was specifically designed for chemotherapy patients as they normally experience intense nausea leading to difficulty in swallowing traditional solid dosage forms. MonoSol Rx LLC has also released an ODF from ondansetron called Zuplenz®. In 2013, Labtec GmbH introduced ODF of zolmitriptan for the treatment of migraine. The first film of risperidone was introduced by Hexal, Germany for schizophrenia. Velox Biologics (P) Ltd. launched Smart strips® consisting of nutritional supplements and on other hand, GlaxoSmithKline, UK launched nicotine strips for cigarette cravings in the 50s. Likewise, Forrester Pharma, South Africa introduced ODFs of herbal extract hederahelix (Ivyfilm®) for cough and cold. Sandoz, Switzerland launched ODFs of sildenafil citrate in 2014, for erectile dysfunction. Approved by the FDA in 2018, oral clobazam film is bioequivalent to tablets of clobazam.

As ODFs as a product were developing from non-medicated products to prescription products, on the other hand, ODFs patented technology was also evolving. Figure 2 illustrated the list of patented ODFs technology described by Borges and colleagues.

In the early 1960s, films made of gelatin and rice were employed for the formation of oral films. The method involved spraying, coating, or dipping films of gelatin or rice paper in a solution containing a drug followed by drying. The Pharma Film™ technology was developed in 2001 in which apparatus was used for casting oral films, sublingual films, or buccal films. In 2005, Melting Film™ technology was introduced by employing cellulose-based polymers for casting various drugs. In 2006, Rapid Film™ technology was developed in which polyvinyl alcohol-starch mixture and polyethylene glycol were used for casting films. Single or multi-layered films were fabricated. Thinsol™ technology was developed in 2007, in which casting solution contains enzymatically digested carboxymethylcellulose, emulsifier, plasticizer, and a suitable solvent. Versa Film™ technology was developed in 2009 and employed crystallization inhibitors in the casting solution. In 2012, Smart Film™ technology was developed, in which casting solution comprising taste-masking agents and natural bio-polymer from black fungus was used [2].

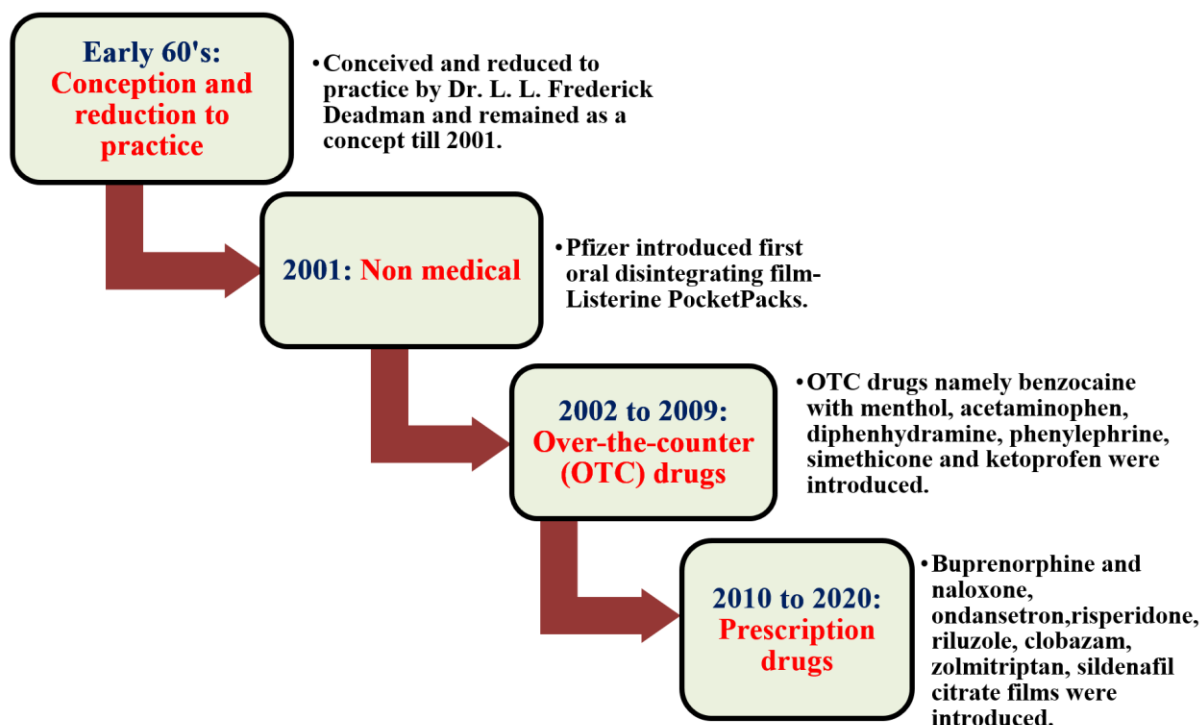


Figure 1. Evolution of ODFs as a product

2.2 ODFs Technology

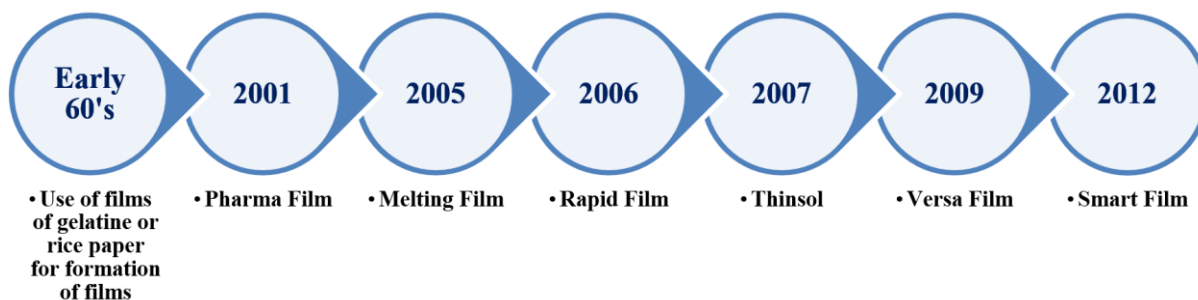


Figure 2. Evolution of patented ODF technologies

3. Formulation of ODFs

A common composition of orodispersible film formulation should consist of the following ingredients:

3.1. Active Pharmaceutical Ingredients

All types of medicaments can be formulated as an orodispersible film but the drugs which have low doses and require faster or immediate onset of action are more suitable candidates [10]. For good dissolution and uniformity of the ODF, it is preferable that active pharmaceutical ingredient (API) must be pulverized. Most of the APIs for ODF technology have bitter taste drug candidates that should be masked by using different taste-masking methods. The simplest taste-masking method involves homogenizing and co-processing

bitter-tasting API with pleasant-tasting excipients. This method is called the obscuration technique [11].

Different classes of drugs can be formulated as ODFs e.g., anti-histamine, anti-diarrheal, anti-convulsant, anti-migraine, anti-emetic, anti-asthmatic, anti-depressants, vasodilators, antiulcer, anti-tussive and non steroidal anti-inflammatory drugs (NSAIDs) [12].

3.2. Ideal Properties of API for ODF

1. The drug must have low doses of 40 mg.
2. The API should have low molecular weight.
3. Taste of the drug should be pleasant.
4. The drug must have good solubility and stability in water and saliva.

5. API should be partially unionized at the pH of the buccal cavity.
6. It must be permeable to oral mucosal tissue.
7. BCS class II and class III drugs are formulated as ODFs [2,6,13,14].

Various classes of drugs that can be incorporated into film formulation are mentioned in Table 1.

Table 1. Most preferred drug classes for oral thin films

Class of drug	Examples
Anti-tussive	Dextromethorphan hydrobromide, levopropoxyphene napsylate, etc.
Anti-epileptic	Carbamazepine, phenytoin etc.
Anti-asthmatic	Salbutamol, theophylline, etc.
Anti-emetic	Ondansetron, dexamethasone etc.
NSAIDs	Ibuprofen, diclofenac etc.
Anti-migraine	Rizatriptan, zolmitriptan etc.

3.3. Film Forming Polymer

The mechanical strength of film formulation is dependent on the concentration of polymer used in the film. To achieve the desired properties of films combination of polymers is preferred instead of using a single polymer. Hydrophilic polymers are most commonly used in the formulation of oral films, as they cause rapid breakdown of film in the oral cavity. The polymer used for the preparation of oral film should be non-toxic and non-irritant to the oral mucosa, and have good

spreadability and shelf-life [4,15,16]. Both natural and synthetic polymers can be used as film-forming polymers (Table 2).

3.4. Plasticizer

Plasticizer improves the flexibility and mechanical properties of the film such as tensile strength and elongation of the oral films. Plasticizer reduces the glass transition temperature of the polymer and improves the film properties. e.g., Propylene glycol, glycerol, polyethylene glycol, dimethyl dibutyl phthalate, diethyl phthalate, triethyl citrate, acetyl citrate, castor oil, and triacetin [4,16].

3.5. Saliva Stimulating Agents

The main motive of using a saliva stimulating agent in the film preparation is to increase the production of saliva in the mouth. These agents stimulate the secretion of saliva, which helps in the rapid breakdown and dissolution of the film. e.g., Citric acid, maleic acid, ascorbic acid, tartaric acid, etc. [6,17].

3.6. Sweetening Agents

Sweetening agents are incorporated in the film formulation to increase product palatability. Both artificial and natural sweeteners are used [18,19] (Table 3).

Table 2. List of film-forming polymers

Natural polymer	Synthetic polymer	Semisynthetic polymer
Maltodextrin	Polyethylene glycol 400	Hydroxypropyl cellulose
Chitosan	Kollicoat	HPMC E3
Gelatin	Polyvinyl pyrrolidone	HPMC E5
Sodium alginate		HPMC E15
Rosin		
Pectin		
Starch		
Gum carrageenan		
Pullulan		

Table 3. List of sweetening agents

Natural Sweeteners	Artificial Sweeteners		Novel Sweeteners
	Nutritive	Non-nutritive	
Fructose	Maltose	Sucralose	Trehalose
Glucose	Fructose	Saccharine	Tagatose
Honey	Glucose	Neotame	
Mannitol		Aspartame	
Sorbitol			

Liquorice
Glycerol
Sucrose

3.7. Flavouring Agents

The flavoring agents are used to hide the bitter or unpleasant taste of the drug. The United States – Food and Drug Administration (US-FDA) approved flavours in film preparation. e.g., Mint, orange, strawberry, raspberry, oleoresins, plant extract, vanillin, chocolate, coffee, and peppermint [20].

3.8. Coloring Agents

The coloring agents which are approved by Food, Drug and Cosmetics (FD and C) are incorporated in oral films. e.g., Titanium dioxide, pigments, and natural and pantonetone-matched colors [4].

3.9. Solvent System

A solvent system is important in film preparation concerning surface texture and disintegration time. Aqueous and organic solvents can be used. Sometimes for better film properties combination of solvents is used [19].

4. Formulation Methods

Following methods are used for preparation of ODFs:

4.1. Solvent Casting Method

Hydrophilic film-forming polymers are made soluble in water. The active pharmaceutical ingredient (API) and other excipients dissolve in an appropriate solvent. Both solutions are then mixed on a magnetic stirrer. The air entrapped in the solution is removed using a vacuum. The resultant solution is then cast onto a base of the petri plate and dried at 40 -50 °C. After drying the films are eventually cut into suitable sizes [21] (Figure 3).

4.2. Semisolid Casting Method

A solution of hydrophilic film-forming polymer is prepared in water, then this solution is added to an acid-insoluble polymer solution. The plasticizer is added to the above solution to form a gel-like mass. The casting of gel-like mass into films/ribbons is done by using heat

controlled drums [22]. The thickness of films should be in the range of 0.015 - 0.05 inches (Figure 4). The ratio of acid-insoluble to water-soluble polymer is 1:4.

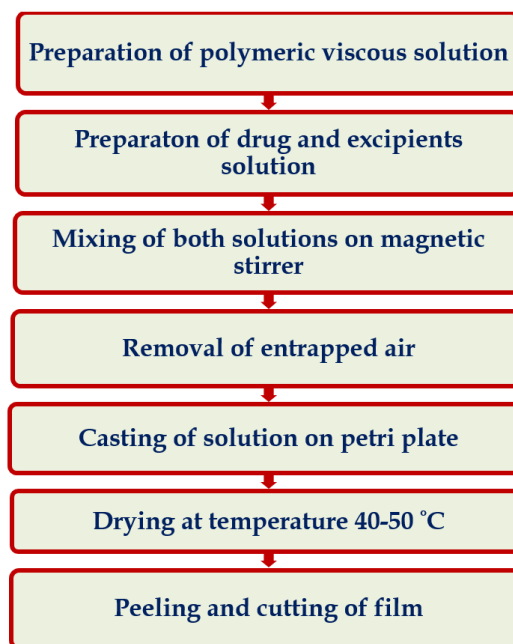


Figure 3. Schematic representation of solvent casting method

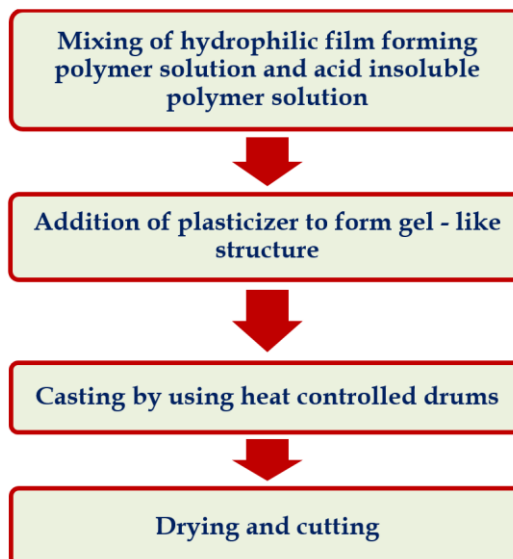


Figure 4. Schematic representation of semisolid casting method

4.3. Hot Melt Extrusion

This method is normally used for the preparation of granules sustained-release tablets, and transdermal and transmucosal drug delivery systems. The drug and other excipients are mixed in dry form, then exposed to a heating process at a controlled temperature and speed, which causes the melting of the mixture. The molten mass is used for casting (Figure 5). The thermolabile substances cannot be used in this method [19,23].

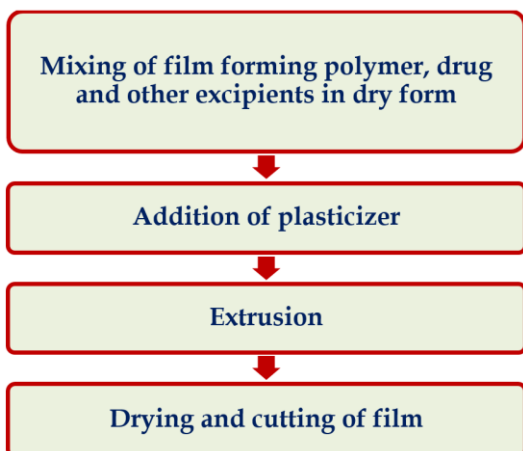


Figure 5. Schematic representation of hot melt extrusion method

4.4. Solid Dispersion Extrusion

In this method, immiscible components are mixed with the drug and then solid dispersions are prepared. In the end, dies are used to form the solid dispersions into a film [24] (Figure 6).

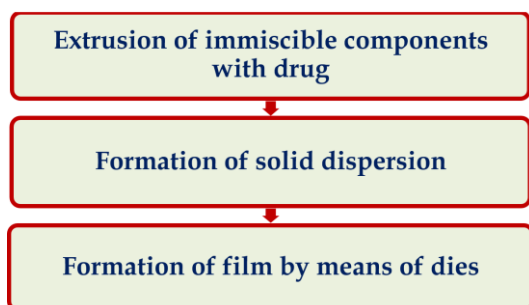


Figure 6. Schematic representation of solid dispersion extrusion method

4.5. Rolling Method

In this method, a solution or suspension of a drug with film-forming polymer is formed and subjected to a roller to form a smooth and uniform film. The film is dried on the rollers and cut into specific shapes and sizes (Figure 7).

Specific rheological considerations should be considered during the preparation of solution or suspension. The most common solvent used is water and a combination of alcohol and water [25-27].

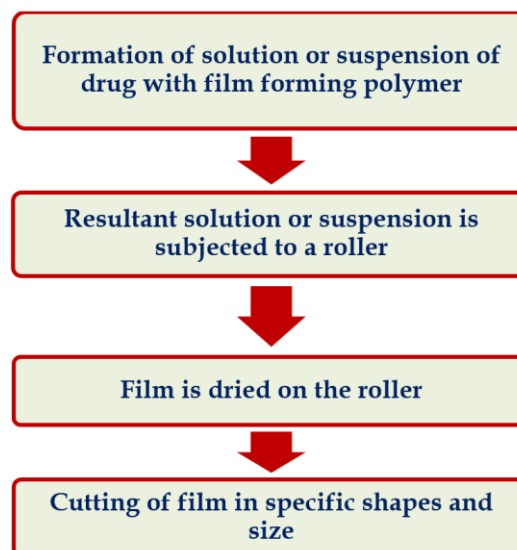


Figure 7. Schematic representation of rolling method

5. Evaluation of ODFs

Following parameters are used for evaluation of ODFs:

5.1. Thickness

Thickness is measured by using a micrometer screw gauge. The thickness of the film is measured in triplicate at different points on the film. Average thickness is determined as it is directly related to dose accuracy [19,28].

5.2. Weight Variation

Weight variation of oral films is determined by cutting the film and determining the weight of the film. This process is done in triplicate and the average weight is calculated [29].

5.3. Folding Endurance

Folding endurance of the film is determined by repeated folding of film at some point till the film breaks. The number of times the film is folded without breaking, is the value of folding endurance. Folding endurance is directly promotional to the mechanical strength of the film [30-32].

5.4. Tensile Strength

Tensile strength is the maximum pressure at which film specimen breaks [19]. It is calculated by using the following formula:

$$\text{Tensile strength} = \frac{\text{Force at break}}{\text{Film thickness} \times \text{Film width}}$$

5.5. Surface pH

When the film is placed in the oral cavity, to avoid irritation in oral mucosa, the film's pH should be near to that of saliva, i.e., 6.8. The pH of the film should be measured in triplicate. The pH of the film is determined by placing the film in a petri dish and moistening it with distilled water. The pH is measured by touching the film surface with an electrode of pH meter [33,34].

5.6. Moisture Uptake

To determine the moisture uptake film is cut with the size of 2x2 cm². Subsequently, the film is revealed to relative humidity of 75% at room temperature (RT) for 7 days [35]. Moisture uptake is calculated as:

$$\% \text{ Moisture uptake} = \frac{\text{Final weight} - \text{Initial weight}}{\text{Initial weight}}$$

5.7. Moisture Loss

The film is cut with a size of 2x2 cm² and placed in a desiccator containing calcium carbonate for 3 days. The moisture loss determines the hygroscopicity of a film [36]. It is calculated by using the following formula:

$$\% \text{ Moisture loss} = \frac{\text{Final weight} - \text{Initial weight}}{\text{Initial weight}} \times 100$$

5.8. Drug Content

This is determined by any standard assay method mentioned in some of the standard pharmacopeias for the specific drug. The usual limit for drug content uniformity is 85-115 % [1].

5.9. *In vitro* Disintegration Time

A disintegration apparatus is required to determine the disintegration time of the oral film. The disintegration criteria for oro-dispersible tablets that are 30 sec or less, as indicated by Center for Drug Evaluation and Research (CDER), are too utilized for oral thin films. There is no official guideline accessible for fast disintegrating oral films [5,19].

5.10. *In vitro* Drug Release

In vitro drug release was determined with a USP basket-type apparatus using simulated saliva (pH 6.8) as a dissolution medium at 50 rpm. *In vitro* drug release was accomplished in USP basket-type apparatus by utilizing the simulated salivary fluid (pH 6.8) as a dissolution medium at 50 revolutions per minute. Aliquots of 5 ml were pulled back at a particular time interval and the same volume of dissolution medium was added. The aliquots were measured for drug content at the greatest wavelength of API utilizing a UV spectrophotometer. The total percentage of drug release was calculated [1,37].

5.11. Stability Study

Stability considerations were performed for optimized films and were put in aluminium foil and uncovered to 40 ± 0.5 °C and 75 ± 5 % RH (ICH guidelines) for four weeks. After 4 weeks, the oral films were assessed for their physical appearance, drug content, and *in vitro* drug release [29].

6. Packaging

Packing contemplation is considered for basic parameters like storage, protection, and steadiness of dosage form. The pliable or paper pouches are thought to supply not as if were temper resistance but moreover a high degree of natural security. Single pouch and aluminium pouch are used for packaging. It is a two-structure combination having one side transparent and other low-priced foil lamination can be utilized. The cover ought to have transmission of air and dampness. Blister card comprises two parts that are cavity for holding the item and a cover stock fixing it. Barrier films are utilized for those substances which are amazingly moisture delicate. It is adaptable and does not stretch or break in any circumstance. APR (Applied Pharmaceutical Research) and Labtech GmbH have patented packaging frame, and the Rapid Card[®] is specially designed for oral dissolving film, with dimensions proportional to the credit card and tilted to hold three strips on each side. It is made of a sealing pocket that manages sufficient space for logos, codes, enlightening or other data. Another packaging framework Core-Peel[®] is created by Amcor flexibles and is picking up ubiquity within the field of packaging of ODF [19, 38]. The oral thin film formulations available in market are shown in Table 4 [39-42].

Table 4. Marketed oral film formulation

Trade name	Drug	Year	Manufacturer	Use
IGALMI™	Dexmedetomidine	2022	Bioxel Therapeutics	Acute agitation
Suboxone®	Buprenorphine and Naloxone	2019	Indivior	Opioid dependence
Sildenafil Sandoz®	Sildenafil	2014	Sandoz	Erectile dysfunction
Klonopin® Wafer	Clonazepam	2013	Solvay Pharmaceuticals	Panic disorder and seizure
Zuplenz®	Ondansetron	2012	Vestig Pharmaceuticals	Cancer chemotherapy and radiotherapy-induced nausea and vomiting
Suboxone®	Buprenorphine and Naloxone	2010	Reckitt Benckiser Pharmaceuticals Inc.	Opioid independence
Benadryl®	Diphenhydramine HCl	2006	Pfizer	Motion sickness, coughing
Gas-X®	Simethicone	2006	Novartis	Treatment of flatulence
Sudafed®	Phenylephrine	2005	Wolters Kluwer Health Inc.	Allergies, colds
Supress®	Menthol	2005	InnoZenR Inc.	Mouth freshening
Chloraseptic®	Benzocaine/Menthol	2004	Prestige	Sore throat
Theraflu®	Dextromethorphan HBr	2004	Novartis	Relieve cough, colds
Listerine Pocket Packs®	Menthol	2001	Pfizer	Mouth freshening

7. Conclusions

The demand for quick dissolving film technology is continuously increasing to build a new tomorrow as a novel and innovative dosage form for all age groups, particularly pediatric, geriatric, and swallowing-difficult patients. This unique oral film dosage form can contain a variety of active components, including over-the-counter (OTC) medications, and prescription drugs. Due to its numerous advantages and low production cost, it may be a viable alternative to traditional dosage forms. In conclusion, ODFs are a relatively new, versatile, and patient-centered pharmaceutical dosage form in the realm of personalized medications, with unique properties. Because they are portable and do not require water to be swallowed/consumed, they have a lot of potential for attaining patient compliance in unique populations. ODFs are applied to the top of the tongue and quickly release the active pharmaceutical ingredient, which is either ingested with saliva or absorbed through the buccal mucosa in the presence of permeation enhancers, resulting in increased bioavailability. For the creation of ODFs, a variety of fabrication processes are available, the most popular and industrially acceptable of which is solvent casting. The hot-melt extrusion method is also used; however, it must be used with caution when working with heat-sensitive medications. It describes the extensive research on this technology that is actively pursued. Therefore, this technology is growing rapidly and poses a challenge for a pharmaceutical company, which is developing oral dissolution films using a variety of pharmaceuticals.

Conflict of Interest Statement

Authors declare that they have no conflict of interest.

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