World Journal of Biology Pharmacy and Health Sciences
eISSN: 2582-5542
Cross Ref DOI: 10.30574/wjbphs
Journal homepage: https://wjbphs.com/

(REVIEW ARTICLE)

Orodispersible films as platform for drug delivery systems: Review and patent update

Kamlesh Patel *, Amit Porwal, Prakash Tiwari and Janhvi Jaiswal

Department of Pharmaceutics, Faculty of Pharmacy, UPUMS, Saifai, Etawah, Uttar Pradesh, India.

World Journal of Biology Pharmacy and Health Sciences, 2026, 26(02), 078-092

Publication history: Received on 29 March 2026; revised on 06 May 2026; accepted on 09 May 2026

Article DOI: https://doi.org/10.30574/wjbphs.2026.26.2.0249

Abstract

The Pharmaceutical sector is researching innovative medication delivery using orodispersible films system. They have used as a multipurpose system which offers rapid, systemic or local effects and are referred to instead of using traditional dose forms. Furthermore, these frameworks are simple to use on their own, particularly for dysphagic patients, the elderly, young, or patients confined to bed, additionally as people who have trouble getting water. These routes of administration can be administered in a number of ways, among them oral, buccal, sublingual, ocular, and transdermal. The ingredients used to make oral films include Saliva-stimulating substances, polymers, and plasticizers, colors, Sweeteners and feels. A range of film-making techniques, including rolling, thermal melt extrusion, casting solvent, and solid dispersion, are documented in the current literary works. Providing a prompt start to activity and covering up this harsh taste about drugs are the goals.

Keywords: Orodispersible Film (ODF); Polymers; Drug Delivery Systems; Solvent Casting

1. Introduction

In order to provide an alternative to traditional dose forms and rapidly dissolving medication systems for delivery were first created at the end of 1970. For example, quickly dissolving pills and capsules were created for senior citizens and young individuals who have difficulty consuming conventional dosage formats. Typically, an ODF's about comparable to a postal stamp in size [1]. It avoids hepatic first pass by offering immediate entrance into the systemic circulation. Efficacy and simplicity of administration [2]. Oral Thin Film (OTF) are described by the USFDA as "a thin, flexible, non-flammable polymeric film strip that contains one or more dispersed active pharmaceutical components which are intended to be placed on the tongue for rapid disintegration or dissolution in the saliva prior to ingestion for delivery into the gastrointestinal tract" [3]. ODFs are a specific type of formulations that can dissolve quickly when combined with saliva since they are often created with hydrophilic polymers. The two most popular types of oral disintegrating drug delivery methods are oral crumbling films and dissolving pills [4]. Initially, oral films were sold as personal air fresheners and hygiene items like soap and oral care strips. For medicinal purposes, several oral dosage forms were introduced to the pharmaceutical marketplaces in Europe and the United States. Listerine pocket packs, first oral strip, were created by Pfizer and used as mouth fresheners [5].

* Corresponding author: Kamlesh Patel

1.1. Flow Chart for Dosage Form: Oral Solid Development [6]

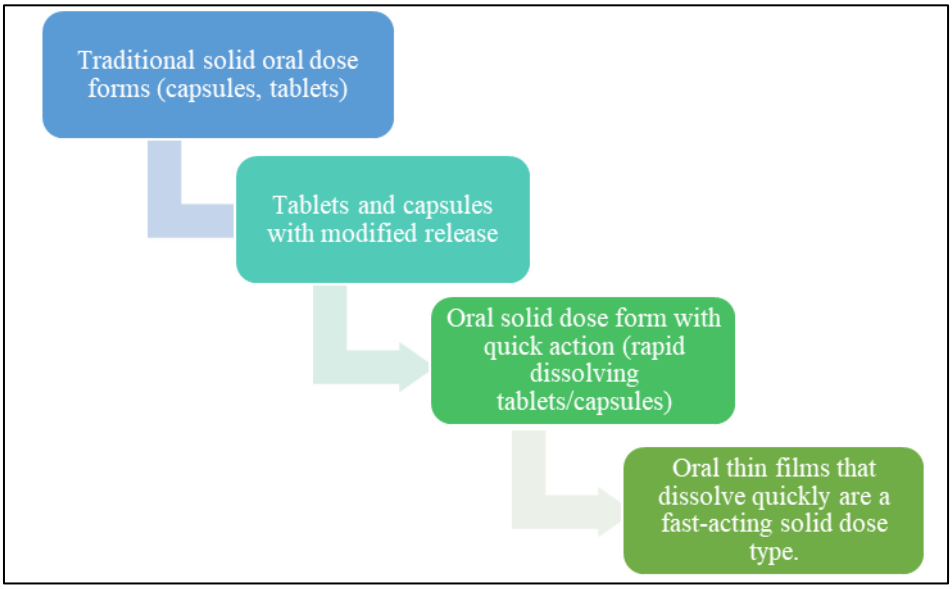

Figure 1 Flow Chart for Dosage Form

1.2. Advantages of ODF [1,5]:

- Mouthfeel that is pleasant and fresh.
- There is no chance of choking.
- Simple application-no problems with chewing or swallowing.
- Avoiding first-pass metabolism.
- It is feasible to administer a precise dosage.
- There are small sizes offered for better patient compliance.
- Rapid commencement of action.
- It hides the bitter taste as well.
- Reduce gastrointestinal discomfort.

1.3. Disadvantages of ODF [1,5]:

- Sometimes they reflect a sensitive and rough quality.
- Naturally hygroscopic, thus needs to be kept in a dry location.
- Need specific packing to guarantee the product's stability and security.
- An oral film cannot include the high dose.
- Restrictions may apply to eating and drinking.
- Unstable drugs cannot be administered at mucosal pH.
- A medicine with nauseating odour cannot be delivered.
- It is generally hygroscopic. It makes long-term protection challenging as a result.

1.4. Ideal Properties of an Effective Potential Drug [8]

- The taste of the medicine should be appealing.
- The dosage of the medication that is to be taken should be modest, not exceeding 40 mg.
- The drug's molecular weight should be modest and smaller.
- The medication must be stable and soluble in saliva and water.
- At the pH level of the oral cavity, it should be significantly unionized.
- It should have the ability to penetrate the oral mucosa.

2. Formulation

Thin films called ODFs are disintegrate swiftly and have a place between 5 and 20 cm^2. The medication is inserted as a matrix using hydrophilic polymers. The active medication up to 15 mg ingredient could be included to extra excipients, like colorants, plasticizers, sweeteners, flavor maskers, etc. By making films more flexible, workable, and spreadable, plasticizer reduces the glass changing temperature of polymers [7].

Table 1 Formulation of ODF [5,7,8]

Constituents	Quantity	Reference
Drug	5%-30% w/w	11
Polymer	45% w/w	12
Plasticizers	1%-20% w/w	
Saliva stimulating agent	2%-6% w/w	13
Surfactants	q. s.	
Colouring agent	q. s.	
Sweetening agent	3%-6% w/w	
Flavoring agent	q. s.	

2.1. Drug

Table 2 Different Category of Drugs [12,13]

Category of drugs	Examples
Anti-emetics	Prochlorperazine, trimethobenzamide, dimenhydrinate, granisetron, palonosetron, dronabinol, aprepitant, ramosetron, metopimazine, nabilone, tropisetron, metoclopramide, prochlorperazine, and dolasetron.
Selective serotonin reuptake inhibitors	Fluoxetine, sertraline, paroxetine, fluvoxamine, citalopram and alaproclate.
Anti-migraines	Almotriptan, dihydroergotamine mesylate, eletriptan, frovatriptan, naratriptan, rizatriptan, and zolmitriptan.
Statins	Atorvastatin, cerivastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin and simvastatin.
Dopamine D1 and D2 antagonists	Amisulpride, bromperidol, cabergoline, domperidone, fenoldopam, haloperidol, metoclopramide, pergolide mesylate, prochlorperazine, quetiapine, ropinirole hydrochloride, sulpiride, metopimazine, tiapride and zotepine.
Nootropics	Almitrine dimesylate and raubasine, cevimeline hydrochloride, codergocrine mesylate, donepezil, ginkgo biloba extract (EGb 761), memantine, nicergoline, piracetam, rivastigmine, galantamine, sulbutiamine, tacrine and vinpocetine.
Anti-histaminic	Levocetrizine, Loratadine.
NSAIDs	Ketorolac, Indomethacin, Valdecoxib, Piroxicam.

A therapeutic candidate should ideally have a small molecular mass, small dosage, high permeability and solubility (BCS-Class I medication). In order to increase subject or patient compliance, researchers are currently investigating oral BCS-Class II thin films medications likewise as organoleptic characteristics such as "taste" which are crucial for producing a medicine as Rapid dissolving films (RDFs) [9]. According to BCS, USFDA classifies highly permeable and poorly soluble chemicals as Class II; substances classified as Class IV whose permeability and solubility are poor. The active component of class II or IV medications must be prepared as a solid or solution that is distributed throughout a polymer in order to achieve an availability that is appropriate with the therapeutic effect. However, it is challenging to stabilize such

dispersions or solutions, which eventually results in decrease of bioavailability and recrystallization gradually. A single solution in this issue when managing weakly soluble active ingredients is to reduce the dimensions of the compound (via milling or other recognized methods) in order for increase the rate of solubility and optimize its in-vivo absorption. The Noyes-Whitney formula is a traditional formula that was created in relation to the velocity at which a material dissolves in a liquid. For example, including polymers that form films right prior to their incorporation into the RDF description can create a nanosuspension of the active ingredient [10]. The medication makes up 5 to 30% w/w of a common mixture. For oral mouth dissolving, small dosage molecules work best. films that exhibit a dissolution period less than sixty seconds that contained 10% w/w of dried film weight in multivitamins [11].

2.2. Making the undesirable Taste of the Drug

Since the Oro-dispersible film composition is intended to be applied on the tongue, medications with an unpleasant or bitter taste may make the patient feel sick to their stomach. Therefore, a variety of taste-masking techniques for the medication, such as polymer coating, Ion-exchange resins, cyclodextrin inclusion interaction, and microencapsulation, liposomes, and prodrugs [13].

Sodium hydroxide and sodium bicarbonate were used to successfully conceal the bitterness of the medication sildenafil citrate. As a ratio in the medication is 3:6.4 to 12.8% (w/w) of sodium hydroxide to sodium bicarbonate [14].

In the same way, ketoprofen burns and has an awful bitter taste. It even aggravates the mucosal membrane of the throat after swallowing. For the formulator, hiding the bitter taste of such a medication is undoubtedly a difficult task. The researchers first tried using alkaline chemicals to hide flavor. Nevertheless, those efforts were unable to totally cover up the flavor [15].

Table 3 Taste masking technologies for bitter Drugs

Drugs	**Taste masking technology**	**Material used**
Famotidine [16] Terfenadrine [17]	Coating with polymers	methyl cellulose, Hydroxyl propyl cellulose Sodium alginate, Carageenan
Ibuprofen [18]	Inclusion complexation with β-cyclodextrins	Hydroxylpropyl-β cyclodextrin
Sulphathiazale [19]	Solid dispersion systems	Povidone
Beclamide [10]	Microencapsulation	Gelatin
Pseudoephedrine [14]	Gelatin Ion-exchange resins	Amberlite CG 50
Chloroquine phosphate [15]	Liposomes	Egg phosphatidyl choline
Chloramphenicol, Clindamycin Triamcinolone [19]	Prodrugs	Palmitate ester Diacetate ester

2.3. Film shaping polymer

Film shaping polymers should be water soluble since the film composition degrades and disintegrates quickly in the oral cavity. Polymeric substances can be utilised alone or in connection with other materials to create the necessary coating, which ought to be adequately durable to avoid harm when handling, shipping, and at simultaneously demonstrating quick disintegration in the mouth. The type along with amount of polymers employed to the composition ascertain the film's resilience. Raising the polymer's molecular weight film bases lengthens the polymers' disintegration period [20]. Since polymers and drugs make up the majority of the film formulation, their ratio to one another is controlled by two factors:

- The minimum percentage of w/w polymer concentration needed to create a matrix containing medications and additional excipients with the required viscoelastic and mechanical properties.
- The required viscosity determines the percentage w/v amount of a polymer mixture that will be made into a film. The ideal viscosity is one that creates a smooth, spreadable layer and keeps suspended materials from sinking [21].

2.4. Ideal characteristics of polymer [22]

- Safe and not reactive
- Not contaminated by leachable substances
- Film disintegration period shouldn't be delayed.
- Affordable and unpleasant
- It must be able to distribute and moisten well
- Must possess adequate tensile, shear, and peel strength
- The active pharmaceutical ingredient or other formulation excipients shouldn't have their characteristics changed
- It shouldn't contribute to oral mucosal secondary infections
- Tensile and peel strength should be at their highest levels

Table 4 Polymers employed in the preparation of orodispersible films [20]

Polymer	Examples
Natural polymer	Gum polysaccharides, Pullulan, starch, gelatin, pectin, sodium alginate, maltodextrins, Acacia
Synthetic polymer	Hydroxypropyl methylcellulose, sodium carboxymethylcellulose, polyethylene oxide, hydroxypropyl cellulose, polyvinylpyrrolidone, polyvinyl alcohol, ethyl cellulose

2.5. Plasticizers

An essential component of the oral film is a plasticizer. The way that a plasticizer interacts with the polymer determines the type of a solvent that was used to cast the film. It makes the film flexible and more stretchy. It improves the film's characteristics by reducing the polymer's glass transition temperature. It reduces the polymer's glass transition temperature to less than 75 degrees Celsius in aqueous solvent systems while ranging from 40 and 60 degrees Celsius in non-aqueous solvent systems. They ought to be erratic. The amount of plasticizer employed ranges from 1% to 20% of dry polymer. [23]. By making the polymer stronger, Oral disintegrating films become less brittle when plasticizer is added. These substances are selected according to how effectively they mimic other excipients, drugs, and polymers. Plasticizer enhances the flow properties and durability of the polymer. Glycerol, castor oil, polyethylene glycol (PEG), polypropylene glycol, low molecular PEG, and diethyl phthalate are a few plasticizers that are used to make mouth dissolving films (MDFs). For films made with PVA, glycerol is a better plasticizer. Both PVA and HPC films are made of polyethylene glycol (PEG) [24]. Since phthalates have been shown to be carcinogenic, they are no longer utilized in the formulation. When plasticizer is used incorrectly, films may bloom, crack, peel, and split [25].

2.6. Salivary stimulating agent

Saliva stimulants are employed to raise salivary flow, that facilitates the oral film formulations' quicker disintegration. Acids used as salivary stimulants may be present in the formulations. Lactic, citric, tartaric, malic, and ascorbic acids [11]. Citric acid is the most preferred among them. Sweeteners are occasionally utilized as salivary stimulants as well. Saliva stimulants are used at levels ranging from 2% to 6% w/w. They may be utilized alone or in combination.[26].

2.7. Surfactants

Surfactants are utilized as dispersing, wetting, or solvent-forming agents to breakdown the film fast and release the active ingredient right away. Commonly used surfactants include Tweens, benzalkonium chloride, sodium lauryl sulfate, and benzethonium chloride. Polaxamer 407, a solubilizing, wetting, and dispersion chemical, is one of the most significant surfactants [27].

2.8. Colouring agent

In order to enhance the oral film's flavor and fresh mouthfeel, Cooling agents such as WS-23, WS-3, and Ultracoll II are incorporated, often in combination with flavors [28].

2.9. Sweetening agent

The unpleasant flavor of the medications is covered up by sweeteners. Naturally occurring sweetener and synthetic sweetener are the two types of sweeteners used to improve the mouth-dissolving formulation's flavor. Artificial sweeteners are increasingly being used in pharmaceutical formulations. Natural sweeteners include ribose, glucose,

mannose, fructose, galactose, sucrose, and corn syrup. Artificial sweeteners include aspartame, sucralose, and saccharin. [24]. Aspartame and saccharin are the first artificial sweeteners. These are prohibited in several nations due to their proven carcinogenic properties. Research is being done to determine the level of cancerous potential. The next new generation of sugar substitutes includes sucralose, alitame, neotame, and acesulfame-K. Acesulfame-K and sucralose are at least 600 and 200-fold sweeter, respectively. The plant Stevia rebaudiana is the source of rebiana, a natural sweetener. It is at than 200–300 times sweeter [30].

Table 5 Sweeteners, their manufacturer, brand, and concentration

Sweeteners	Brand name	Manufacturer	Acceptable daily intake (mg/ kg body weight)
Aspartame [31]	NutraSweet Ajinomoto Holland Sweetener Company	NutraSweet AminoSweet Sanecta	40- 50
Acesulfame-K [32]	Sunette	Celanese	9
Sucralose [33]	Splenda	Johnson & Johnson subsidiary McNeil Nutritionals LLC	5
Rebiana [34]	Stevia	Stevia Corp.	4
Monoammonium glycyrrhizinate [35]	Magnasweet®	Mafco	0.015- 0.2

2.10. Flavoring agent

The kind of medication to be added determines the flavor choice. A person's consent to an oral dissolution or disintegrating formulation is decided by the formulation's first taste, that is detected in the initial moments following type of dosing consumption, also its aftertaste, which last for at least ten minutes [36]. Menthol, cinnamon, clove, orange, mint, lemon, vanillin, peppermint, apple, and pineapple are among the flavors used in pharmaceutical preparation. They have anesthetic affect taste sensory receptors and function by transferring their own scents and tastes.[37].

Table 6 Taste-masking flavors for various tastes [38]

Basic taste	Taste-masking flavors
Bitter	Wild cherry, mint, anise, walnut, chocolate
Sweet	Vanilla, fruit, berry
Salty	Butterscotch, peach, vanilla, wintergreen mint, maple, apricot
Sour	Raspberry, citrus, licorice root

3. Conventional STEPS FOR ORODISPERSIBLE FILM MANUFACTURING

Some advancements and creative methods have surfaced in the last few years. Certain variations of these casting and extrusion production techniques, like semisolid casting and solid-dispersed extrusion, have also been reported and employed separately or in combinations [39]. Creative manufacturing techniques like printing or rolling. Additionally, approaches have been described [40].

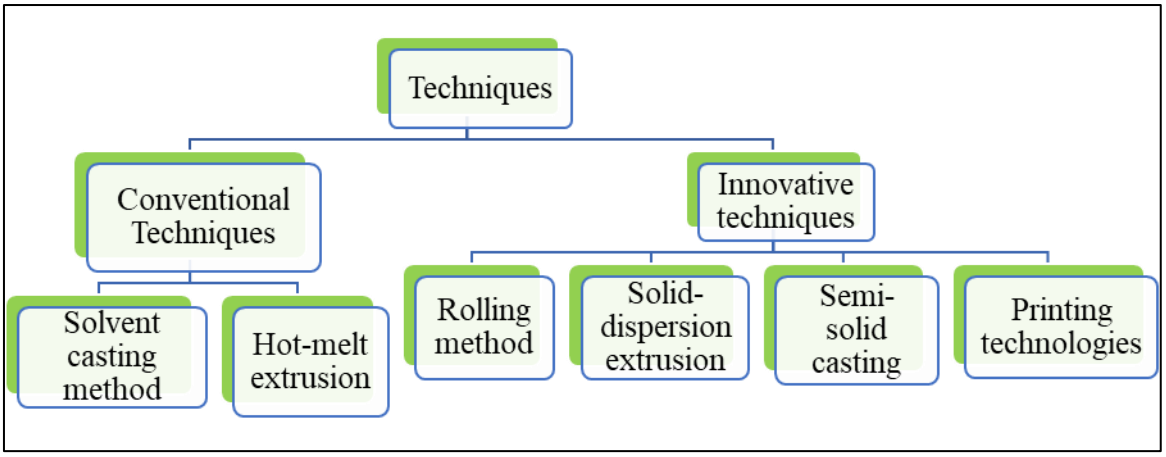

Figure 2 Process Overview [39]

3.1. Solvent casting method

The most popular method for making ODFs is solvent casting, which uses water-soluble excipients and polymers, and drugs dissolved in ionized water. Strong shear pressures generated by a shear processor are then applied to make a homogenous mixture. After that, a triplate is filled with the generated solution, and to create superior films, High temperatures are used to allow the solvent to dry [7].

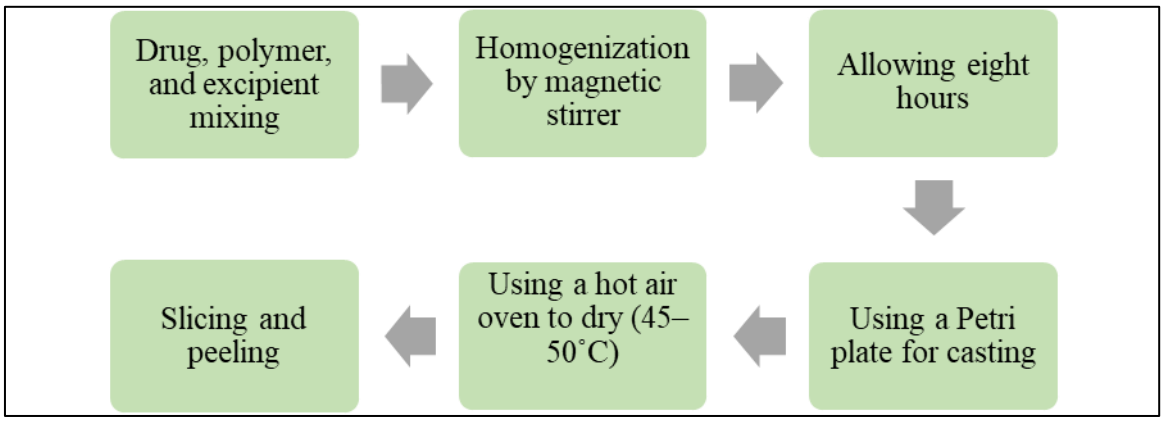

Figure 3 Solvent casting technique flow chart

3.2. Melt-heated extrusion

Melt-heated extrusion, the medication and polymer mixture is melted under regulated pressure and temperature. To create thin films, the molten mass is subsequently extruded through a die. This solvent-free method is perfect for heat-stable medications and is also eco-friendly. Additionally, it makes it possible to incorporate medications that are poorly soluble in water, increasing their bioavailability [7].

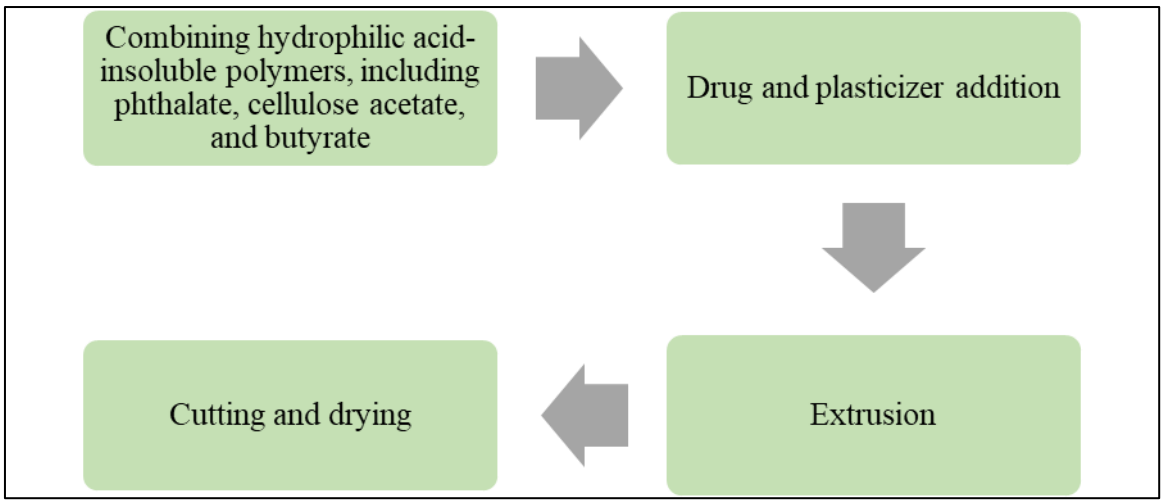

Figure 4 Hot-melt extrusion technique flow chart

3.3. Rolling Technique

The rolling technique requires the solution must possess specific rheological characteristics in order to roll onto the drum. The drug and polymer are suspended in water or alcohol using rollers. The solvent then evaporates [7,41].

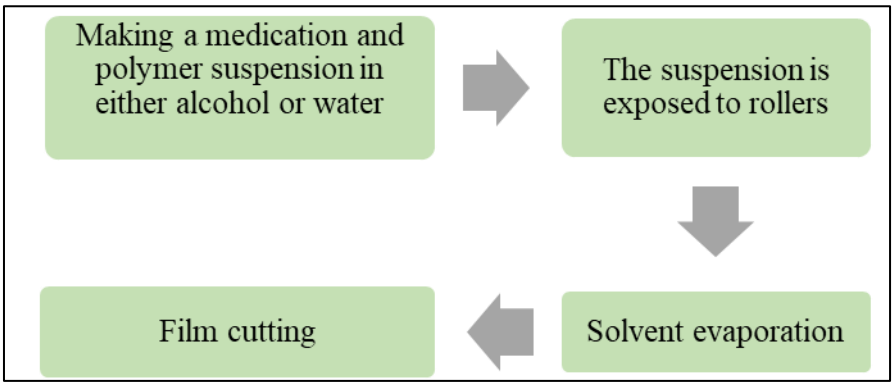

Figure 5 Rolling technique flow chart

3.4. Solid-dispersion extrusion

The medication and immiscible ingredients combine to produce dispersions that are solid. Lastly, dies are used to shape the solid dispersions into films [6].

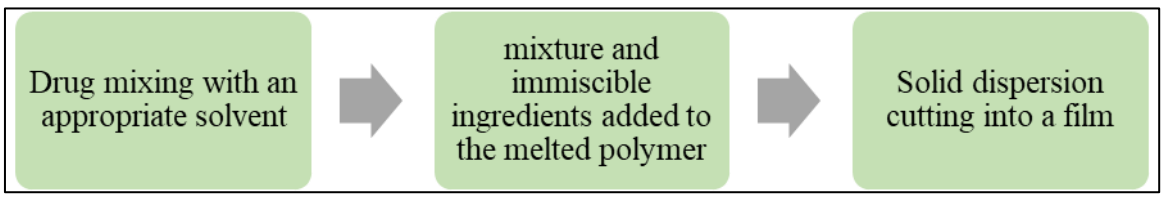

Figure 6 Solid-dispersion extrusion technique flow chart

3.5. Semi-solid casting

Cellulose acetate phthalate as well as cellulose acetate butyrate are examples of acid insoluble polymers that are used to make films; the proportion of acid insoluble polymer to film-making polymer should be 1:4. This technique is best suited when using acid insoluble polymers [41].

3.6. Printing technologies

Thin sheets of polymers could develop using innovative methods, like the 3D printer. In theory, it might be a step toward developing the dosage type that works best for each patient. This could potentially alleviate the problem of pharmacies and the pharmaceutical industry meeting the demand for tailored medicine in the future [42]. Inkjet printers that can be used to produce precisely dosed units of pharmaceutical ingredients by depositing drug-loaded inks onto a polymeric film. Additionally, A thin layer of polymer was applied to the drug-loaded substrate using flexographic printing, and API was printed on a variety of substrates using inkjet printing. A combination of these two technologies has also been used to prepare films [45].

4. Characterization and evaluation

4.1. Visual appearance

Visual inspection is used to verify the film's physical appearance, while touch or feel is used to assess the surface roughness [44,45].

4.2. Weight variation

Five films of each recipe are separately determined the weight variation by weighing on an electronic balance. We compute both the mean weight and the deviation from the mean weight[46].

4.3. pH measurement

The pH of a solution made from one mouth film dissolved in ten milliliters of pure water can be determined. After touching the surface of the formulation with the electrode of the pH meter and allowing it to settle for a minute, the pH is recorded. Three measurements are averaged for each formulation [47,48].

4.4. Dimensions

A micrometer screw gauge can be used to measure the film's thickness at five or more crucial points. This is necessary to guarantee that the film's thickness is constant since it directly influences the dosing accuracy of the film [49,50].

4.5. Folding endurance

The films' folding durability determines their flexibility. It is calculated by repeatedly folding a short strip till it breaks in the same location. It is measured by the number of folds a film withstands at one location before breaking. [51,52].

4.6. Tensile strength

It is defined as the maximum load a specimen can bear before failure. It is obtained by dividing the rupture load by the cross-sectional area of the film, as presented below [53].

The formula for tensile strength is as follows:

$$Load\ at\ break\ \times\ film\ thickness\ \times\ film\ width$$

4.7. Swelling index

Before being inserted into a previously weighed stainless steel wire mesh, each film sample is evaluated. The film-containing mesh of the sample is then immersed in a 15 ml saliva simulated medium. solution in a container made of plastic. At specified intervals, the mass of the film is increased until a steady They were measured. A calculation is made to determine the swelling level. Applying the formula [54,55].

$$\text{Degree of swelling} = W_t - W_0 \,/\, W_0$$

Where,

- Wt is the film's weight at time t
- Wo is the film's weight at time zero

4.8. *In vitro* film disintegration time

The disintegration test has carried out due to placing the film on the surface of 5 milliliters of pH 6.8 phosphate buffer inside the petri dish. The disintegration period is the amount of time needed for the film to break down. In this experiment, the average of the three values is computed using three films in the same batch [56,57].

4.9. Drug content uniformity

The film with the required dimensions dissolves phosphate buffer pH 6.8. Wattmann filter paper is used to filter it after it has been sonicated for fifteen minutes. The drug's concentrations is determined after the absorbance is measured using a UV spectrophotometer [53].

4.10. Studies of *in vitro* dissolution

The drug's rates of release are computed using USP. Testing equipment for USP Type II paddle apparatus. After the film has been cut to the proper size, it is put in dissolving media. Three hundred milliliters of newly made phosphate buffer (pH 6.8), kept at 37 ± 0.5 ºC, and agitated at 50 rpm make up the dissolving medium. At different intervals of 2, 4, 6, 8, 10, 12, 14, 16, 18, and 20 minutes, 5 ml samples are removed and replaced with new media. The samples undergo UV analysis, and the drug release percentage is computed [57,58].

4.11. Stability studies

Under various environmental circumstances, the Oro-dispersible films' stability is examined. According to ICH forms, the formulations enclosed in aluminum foil undergo three months of rapid stability testing at 75 ± 5% % relative humidity and 40 ± 2°C. Over the course of three months, samples are collected at frequent intervals of one month, and the previously described process is used to analyze the samples for changes in physical appearance as well as other factors [59,60].

5. Patent Update

Table 7 Patent Update

SI. No.	Code Country	Patent Number	Title	Applicant	Brand Name	Ref.
1	US	US20090047350	Perforated water-soluble polymer based edible films	Bangalore Ramesh	-	[61]
2	US	US7425292	Thin film with non-self-aggregating uniform heterogeneity and drug delivery systems made from there from	Aquestive Therapeutics Inc	PharmaFilm	[62]
3	US	US20210022990	Thermally gelling drug formulations	UNM Rainforest Innovations	-	[63]
4	US	US20110136815	Solid oral film dosage forms and methods for making same	IntelGenx	Versa Film	[64]
5	US	US9301948B2	Instantly wettable oral film dosage form without surfactant or polyalcohol	IntelGenx	Versa Film	[65]
6	US	2008/0213343	Oral, Quickly Disintegrating Film, which Cannot be Spit Out, for an Antiemetic or Antimigraine Agent	Hexal Pharmaceuticals	Melting Film	[66]
7	US	2008/0200452	Oral, Rapidly Disintegrating Film, Which Cannot be Spat Out, for a Neuroleptic Oral films comprising	Hexal Pharmaceuticals	Melting Film	[67]
8	EP	EP2632443B1	Preparation of orodispersible films	Hexal Pharmaceuticals	Melting Film	[68]
9	WO	WO2014/076117	Orodispersible film compositions Pharmaceutical orodispersible film	Hexal Pharmaceuticals	Melting Film	[69]
10	WO	WO2008040534	Non-mucoadhesive film dosage forms	LabtecGmbh	Rapidfilm	[70]
11	WO	WO2009043588	pH regulating antibacterial films for the oral or vaginal cavity	LabtecGmbh	Rapidfilm	[71]
12	WO	WO2011124570	Oral film formulations	LabtecGmbh	Rapidfilm	[72]
13	WO	WO2009055923	Ingestible film composition	BioEnvelop	Thinsol	[73]
14	WO	WO2020014431	Rapidly disintegrating oral film matrix	Cure Pharmaceutical	Cure Film	[74]
15	US	US10092651	High-content fast dissolving film with masking of bitter taste comprising sildenafil as active ingredient	Seoul Pharma Co Ltd.	Smart Film	[75]
16	US	US20200360461A1	Orodispersible film composition comprising enalapril for the treatment of hypertension in a pediatric population	Pharmathen SA	-	[76]
17	IN	2199/MUM/2015	Stabilized orodispersible film and its preparation	Dnyaneshwar R Pawar	-	[77]
18	KR	KR20200069611	Orodispersible films using fermented extract of *SparassisCrispa*	Agricultural Company Corp Smart F&B Co. Ltd.	-	[78]
19	US	US20200108011A1	Structured orodispersible films [SOFTs]	LTS Lohmann Therapy Systems	-	[79]
20	WO	WO2019198105A1	Composition of active ingredient loaded edible ink and methods of making suitable substrates for active ingredient printing on orodispersible films	Zim laboratories Ltd.	Thinoral	[80]

Note: **IN** stands for India, **KR** for Korea, **CN** for China, **US** for the United States, **EP** for Europe, and **WO** for an international patent application under the Patent Co-operation Treaty (PCT).

6. Conclusion

The current analysis concludes that highest accurate moreover palatable oral system necessary circumvents the liver system and reveals a higher sensitivity to treatment in Orodispersible film. Both patient compliance (particularly in pediatric and geriatric patients) and industry acceptability are the reasons why pharmaceutical corporations favor this dosage type. OTC medications, generic medications, and name-brand medications can be replaced with oral films because they are less expensive and more favored by consumers. For product life cycle management, this kind of Innovation has a helpful device for prolonging the patient life of products that currently exist.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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