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A Review on Oral Dispersible Films incorporating solid dispersion techniques for selective cox 2 inhibitor

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ABSTRACT

Oral dispersible films (ODFs) are flexible drug delivery systems made on both large and small scales. Despite formulation challenges, global research focuses on expanding their use for diverse APIs. Patient-centric strategies emphasize personalization, taste masking, easy administration, and better compliance. Future progress depends on novel excipients that can improve the delivery of complex molecules like proteins and oligonucleotides. Rheumatoid Arthiritis doesn't change the solvent casting process itself, but it shapes the formulation goals. ODFs are preferred for RA patients because they're easier to administer when swallowing or hand mobility is difficult. Solvent casting allows precise dosing, taste masking, and improved solubility of COX-2 inhibitors, making therapy more patient-friendly. Stability and ease of handling are also prioritized to suit long-term RA treatment needs. Selective COX-2 inhibitors (coxibs) are a class of NSAIDs designed to reduce inflammation and pain by selectively blocking the COX-2 enzyme, while sparing COX-1, which protects the stomach lining. They are effective for arthritis and pain management but carry cardiovascular risks.

KEYWORDS: Oral dispersible films, drug delivery, pharmaceutical manufacturing, polymers.

1. INTRODUCTION

Oral dispersible films (ODFs) are a rapidly developing drug delivery system that has attracted considerable interest recently because of their adaptability, patient-centered design, and potential to enhance therapeutic outcomes. These thin, flexible films provide a practical alternative to conventional tablets and capsules, as they dissolve rapidly in the oral cavity without water. Their versatility makes them appropriate for a variety of pharmaceutical applications since it enables both large-scale industrial production and small-scale laboratory development. Global research efforts continue to broaden the scope of ODFs to include a variety of active pharmaceutical ingredients (APIs), from small molecules to complex biomolecules, despite formulation challenges like achieving uniform drug distribution, guaranteeing mechanical strength, and maintaining stability. (1)

The increasing interest in ODFs is directly related to patient-centered approaches in contemporary medication delivery. Personalized therapy, taste masking to increase palatability, convenience of administration, and improved compliance, especially for populations with special needs, are the main focus of these tactics. ODFs are particularly beneficial for people with long-term illnesses like RA. RA frequently reduces hand movement and can make swallowing challenging, which makes traditional

oral dosage forms less practical. ODFs, on the other hand, offer an easy-to-use, noninvasive method of administration that requires little work, increasing long-term treatment regimen adherence. (2)

The most popular method for producing ODFs is still solvent casting. This method improves the solubility of medications that are poorly soluble in water, permits exact control over drug dosage, and makes flavor masking easier. RA has a big impact on the formulation objectives even though it doesn't change the solvent casting process itself. Stability, ease of use, and suitability for long-term usage are given top priority for RA patients in order to guarantee that treatments continue to be easy and effective over long treatment durations. (3)

Selective cyclooxygenase-2 (COX-2) inhibitors, often known as coxibs, have become a significant class of medications in the treatment of RA. Coxibs are a subclass of nonsteroidal anti-inflammatory medications (NSAIDs) that selectively inhibit the COX-2 enzyme, which is mainly responsible for pain and inflammation, while leaving COX-1, which protects the integrity of the stomach mucosa, intact. By

lowering gastrointestinal side effects and increasing tolerance in long-term therapy, this selectivity offers a major benefit over conventional NSAIDs. Coxibs are useful in the treatment of RA because they have proven effective in reducing inflammation and discomfort associated with arthritis. However, worries about cardiovascular risks limit their clinical use, requiring cautious patient selection and monitoring. (4)

Future advancements in ODF technology will rely on the creation of new excipients and sophisticated formulation techniques that can handle complicated medicinal molecules, including proteins, peptides, and oligonucleotides. ODFs have the potential to be a revolutionary medication delivery technology by fusing advances in excipient science with patient-focused design concepts. Their increasing significance in pharmaceutical research and clinical practice is highlighted by their ability to improve compliance, increase therapeutic efficacy, and address the particular difficulties of chronic inflammatory illnesses like RA. (5)

Hot-melt extrusion, electrospinning, 3D printing, nanoparticle-loaded films, and supercritical fluid and spray-drying hybrid approaches are examples of modern ODF manufacturing techniques that go beyond solvent casting. Each of these techniques improves drug loading, personalization, or rapid dissolution while presenting unique scale-up and stability trade-offs.(6)

New and emerging ODF manufacturing techniques

Electrospinning / Nanofiber films

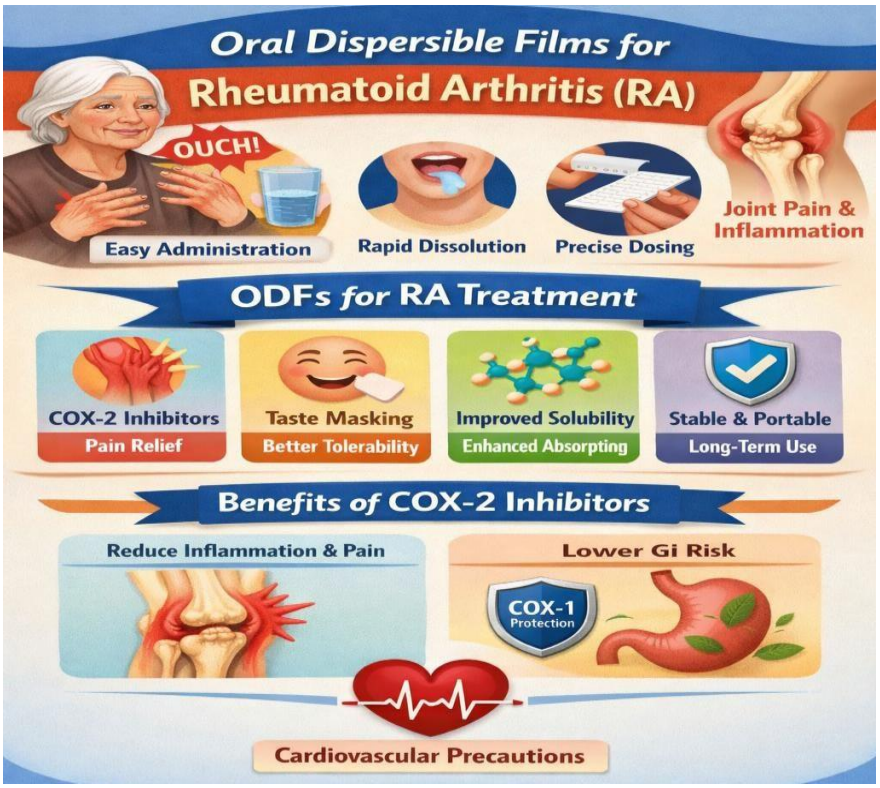
Creates ultrafine fibrous mats with a large surface area for improved bioavailability and extremely quick breakdown. Ideal for: low-dose APIs and formulations with quick onset. (7)

3D printing (inkjet, fused deposition, semi-solid extrusion)

Allows for complex geometries for controlled release, multilayer films (which separate incompatible actives), and customized dosing. Ideal for: customized medicine and hospital pharmacy**.** (8)

Spray drying and supercritical fluid assisted methods

Create amorphous dispersions or nanoparticles, which can be cast or laminated into films using more environmentally friendly solvent profiles. Ideal for: producing nanoparticles and solvent-sensitive procedures. (9)



The three most popular emerging ODF manufacturing techniques electrospinning, 3D printing, and spray-drying/supercritical-fluid methods offer complementary strengths: amorphous/nanoparticle generation with greener solvent options (spray-drying/SCF), precise personalization and multilayer architectures (3D printing), and ultra-rapid dissolution and high surface area (electrospinning). Although scale-up and uniformity control remain major challenges, electrospinning produces ultrafine nanofibrous mats with very high surface area that enable ultra-rapid dissolution and improved bioavailability, making it particularly appealing for low-dose, fast-onset APIs. Recent work investigates hybridizing electro spun fibres with additive manufacturing to boost mechanical strength and functional layering (10)

Hospital pharmacies and personalized medicine can benefit greatly from 3D printing (inkjet, fused deposition, semi-solid extrusion), which allows for customized dosing, multilayer films that separate incompatible actives, and complex geometries for controlled or staged release. However, current bottlenecks include throughput, rheological formulation control, and regulatory validation; process parameters like drying time and layer thickness directly affect moisture content, disintegration time, and mechanical properties of printed ODFs. (11)

Spray-drying and supercritical fluid (SCF) assisted techniques transform drug-polymer solutions into amorphous dispersions or nanoparticles that can be cast or laminated into films, providing improved solubility for poorly soluble APIs and the potential for greener solvent profiles (e.g., supercritical CO_2). These techniques are well suited to solvent-sensitive processes and nanoparticle generation, but they necessitate the purchase of specialized equipment and strict process control. (12)

When combined, these technologies suggest hybrid manufacturing strategies to address complex formulation goals like delivering peptides, proteins, or oligonucleotides in ODFs while balancing scalability, regulatory readiness, and patient-centric attributes (taste masking, handling, stability). For instance, combining electrospun nanofibers for rapid disintegration with 3D-printed multilayer architectures for dose personalization and spray-dried nanoparticles for solubility enhancement.(13) Strong in-process controls, non-destructive quality testing (like NIR), and excipient compatibility studies should be given top priority by Indian inventors and hospital formulators in order to expedite the transition from lab-scale demonstrations to clinically beneficial, patient-friendly ODF products.(14)

Anatomy of oral cavity

The mouth cavity's anatomy and structure are examined to comprehend the setting in which medications are administered. The oral mucosa prevents first pass metabolism and permits direct medication entry to the systemic circulation. With a few minor variations in keratinization and the lubricating and protecting mucus that covers its surface, the oral cavity's epithelium is fairly comparable to that of the skin 3. The oral mucosa is 4–1000 times more permeable than the skin. The oral cavity is separated into two areas: the floor of the mouth, the tonsils, the hard and soft palates, and the outer oral vestibule, which is surrounded by the lips and cheeks. For many years, oral medication delivery has been the most popular method of administration for systemic drug delivery through a variety of Fast dissolving drug delivery (FDDS) The fast dissolving drug delivery system, also called fast dissolving or fast disintegrating films for oral drug delivery, was developed in the late 1970s as an alternative to tablets, capsules, syrups, and other formulations for pediatric and elderly patients who have trouble swallowing traditional solid dosage forms. It combines the benefits of both conventional tablet and liquid formulation.(16) FDDS is simple to use and improves patient compliance in old, young, mentally retarded, sick, and recalcitrant patients. The solid dosage forms used in this distribution method dissolve in the oral cavity in a matter of seconds without the need for water. The solid dosage forms used in this distribution method dissolve in the oral cavity in a matter of seconds without the need for comprises of a very thin oral strip that is applied to the patient's tongue or any other oral mucosal tissue and is immediately moistened by saliva. The film quickly hydrates at the application spot.(17) water. The delivery method

pharmaceutical products in various dose forms.(15)

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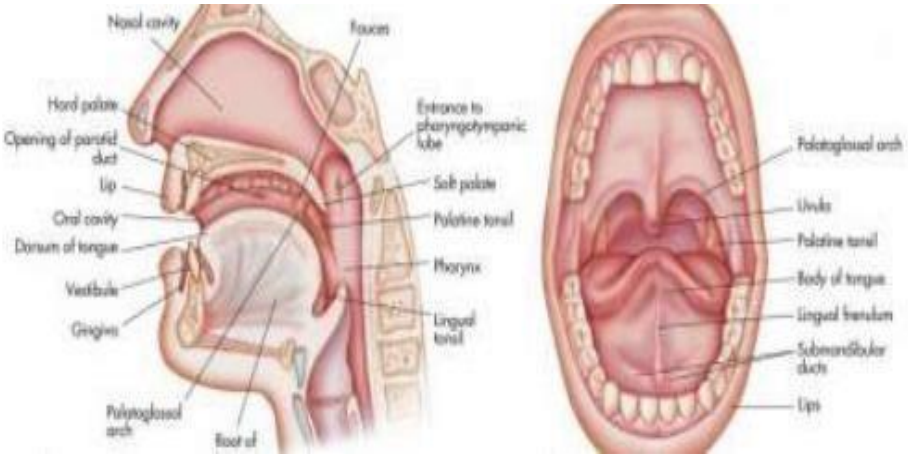

Fig 1: Anatomy of oral cavity

Oral dispersible films

Oral Dispersible Films (ODFs) are thin, flexible, polymer-based dosage forms that are applied to the tongue or buccal mucosa. There, they quickly dissolve in saliva without the need for water, releasing the medication for absorption through the gastrointestinal tract or oral cavity.(18)

Thin dosage type that resembles a strip quickly breaks down in saliva Water is not needed for administration increases patient compliance, particularly for dysphagic, elderly, and paediatric patients.(19)

Fig 2: ORAL DISPERSIBLE FILMS

Advantages of oral dispersible films

The film administered sublingually and buccally deliver the drug with strong potential to improve the onset of action, lower the dose, and enhance the efficacy and safety profile of the medicament. Compared to liquid formulations, oral film allows for better dosage precision because each strip is made to contain the exact amount of medication. Oral film ensures more exact delivery of medications. Oral film can promote compliance due to the intuitive nature of dose form and its inherent ease of administration. These qualities are particularly helpful for patients with neurological diseases, children, and the elderly, where accurate and thorough dosing might be challenging. Oral films capacity to dissolve swiftly without the need for water provides an alternative to individuals with dysphasia and to patients suffering from nausea, such as those patients receiving chemotherapy(20)

Disadvantages of oral dispersible films

The amount of medication that can be included in each unit dose of oral disintegrating films is limited. For lyophilized dosage forms, the drug dose must generally be less than 400 mg for insoluble medications and less than 60 mg for soluble drugs. Also, due to the nature of quick dissolving oral films, special packaging is needed for products that are fragile, which may add to the cost. Dose consistency is an issue. It draws moisture from atmosphere. For the stability and safety of the product, appropriate packaging is needed. (20)

Limitations of oral dispersible films

Low drug -loading capacity: Only a modest amount of medication (typically ≤ 30 mg) can be included into oral dispersible films. Therefore, they are not suitable for high-dose medications.(21) Taste masking challenges: Patient compliance may be hampered by the film's failure to fully cover up an unpleasant taste or bitterness of drugs because it dissolves directly in the oral cavity.(22) Moisture sensitivity: Due to their great sensitivity to moisture and humidity, ODFs may lose their mechanical strength, get sticky, and become less stable while being stored. (23) Limited applicability to medicines with poor solubility: Drugs with poor water solubility may show uneven distribution in the film and erratic dissolving behaviour.(24)

Formulation Techniques

One among the pharmaceutical technique known as "solid dispersion" involves dispersing a medicine that is poorly soluble in water in a solid carrier to increase its solubility and bioavailability. Particle size reduction, increased wettability, and the drug's transformation into an amorphous state which dissolves more quickly than crystalline forms are the primary mechanisms of action. (25)

Mechanisms of solubility enhancement

Solid dispersion increases solubility through a number of interrelated mechanisms that influence the drug's physical state and interaction with the carrier. First, particle size is reduced because the medicine is disseminated at the molecular or colloidal level within the carrier, thereby increasing the surface area accessible for disintegration. (26) Second, the carrier's hydrophilic character increases wettability, allowing water molecules to more easily penetrate and dissolve the drug particles. Third, many solid dispersions transform the substance from crystalline to amorphous state. Because amorphous pharmaceuticals have greater free energy and lack a solid lattice structure, they disintegrate faster than their crystalline counterparts. (27) Furthermore, the production of solid solutions in which drug molecules are molecularly scattered within the polymer matrix results in a homogeneous system that promotes uniform and rapid dissolution. In some circumstances, eutectic mixes develop when the medication and carrier crystallize together, resulting in fine dispersions that dissolve more efficiently. These mechanisms particle size reduction, enhanced wettability, amorphization, solid solution formation, and eutectic mixture development synergistically improve the solubility and bioavailability of weakly water-soluble medicines. (28)

Solid dispersion preparation techniques

The fusion (melting) method

It is a popular approach for creating solid dispersions, notably for increasing the solubility and dissolution rate of weakly water-soluble medicines. The medication is closely combined with a hydrophilic polymer, such as PEG, PVP, or poloxamers. The combination is heated until both components melt, resulting in a uniform melted mass. When cooled, this mass solidifies as an amorphous dispersion with the drug molecules scattered throughout the polymer matrix. The drug's amorphous state is thermodynamically less stable than its crystalline form, but it provides a considerable advantage: improved solubility and bioavailability due to increased molecular mobility and lower lattice energy barriers. (29)

This approach is especially useful for thermally stable pharmaceuticals, which can resist the heating process without degradation. Common carriers employed in this approach include PEG 4000 and Poloxamer 188, which not only aid in solubilization but also act as stabilizers to prevent the medication from recrystallizing during storage. Overall, the fusion method is a simple, cost-effective, and efficient approach to increase optimization and assure uniform dispersion.(30)

Solvent Evaporation Method

Another typical process for creating solid dispersions is solvent evaporation, which is particularly beneficial when working with heat-sensitive medicines. In this process, the medication and an appropriate polymer are first dissolved in a volatile solvent to generate a homogeneous solution. Once dissolved, the solvent is carefully evaporated, leaving behind a solid matrix with the medication spread throughout the polymer. (31) This solid dispersion increases the dissolving rate of poorly

soluble medicines by lowering crystallinity and boosting wettability. One of the main advantages of this technology is that it does not require high temperatures, making it excellent for heat-sensitive pharmaceuticals that may degrade during melting operations. (30)

However, one significant drawback is the likelihood of residual solvent remaining in the end product, which can cause safety and regulatory issues if not carefully eliminated. Thus, while solvent evaporation is a diverse and effective method of improving medication solubility, careful solvent removal is required to assure product quality and patient safety. (32)

Formulation Aspects for Oral Dissolving Films

Active Pharmaceutical Ingredient

Active Pharmaceutical Ingredient: ODFs can contain a variety of pharmacological classes, including antihistamines, antidiarrheals, antidepressants, vasodilators, anti-asthmatics, and anti-emetics. Dimenhydrinate can also be used in ODFs to disguise the taste. ODFs frequently contain salbutamol sulfate, rizatriptan benzoate, verapamil, ondansetron, dexamethasone, rofecoxib, cetirizine, pilocarpine, tianeptine sodium, indomethacin, and other medications. (33)

Film Forming Polymer

Water-soluble polymers are employed as film formers because they provide fast disintegration, a pleasant mouthfeel, and mechanical strength to the films. The strength of the strip is determined by the type of polymer and the amount used in the formulations. A variety of polymers are available for film creation, the most common of which are pullulan, gelatin, and hypromellose.(34) Water-soluble polymers include pullulan, gelatin, guar gum, xanthan gum, hydroxyl propyl methyl cellulose (HPMC), modified starches, PVPK30, PVA, and HPMC E3/E5/E6/E15.

Ideal properties of the polymers used in the oral film: Polymers should be nontoxic, non- irritant and non-bitter. Polymers should be tasteless. It should be devoid of leachable impurities. It should be inexpensive and readily available. It should not be an obstacle in the disintegration time. It should have good wetting and spreadibility property . It should exhibit sufficient peel, shear and tensile strength(35)

Hydrophilic polymers

The successful development of an ODF is a function of justified selection and concentration of polymers as the mechanical strength of films is strongly associated with these factors. They can be used either alone or in combination with other polymers to modify film properties. The concentration of used polymers is also important factor while developing an ODF. The integrity of fast dissolving oral films is dependent upon careful selection of polymer nature and concentration. Generally, polymer concentration used in preparing ODFs is aroun4d 5% w/w of total weight of dry thin strip, however, it can be increased up to 60– 65% w/w in order to attain the film of desired attributes and characteristics. Polymer used as a film forming agent in formulation of thin strips should possess certain properties. In recent era, both natural and artificial polymers are used for developing ODF formulation. Polymer used as a film forming agent in formulation of thin strips should possess certain properties. In recent era, both natural and artificial polymers are used for developing ODF formulation.(36) Different polymers are used to alter the various properties of films. Pullulan has improved solubility in addition to its flexibility-enhancing properties, and films containing pullulan have great tensile strength and stability over a wide temperature range. The molecular weights of gelatins affect the qualities of manufactured films, and employing polymers with a higher average molecular weight results in a more pleasing film. Chitosan combined with high methoxy pectin (HMP) or low methoxy pectin (LMP) produces high-quality strips. Because of their hydrophilic character, films made from cellulose-derived polymers such as hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), methyl cellulose (MC), and carboxymethyl cellulose (CMC) have a lower water vapor barrier Polyethylene glycol (PEG) also has a good film forming properties either alone or in combination with other polymer.(37).

Plasticizers

In general, adding plasticizer to formulations improves mechanical qualities including tensile

strength and % elongation. Plasticizer concentrations commonly vary between 0% and 20% w/w. Examples of plasticizers include PEG, glycerol, diethyl phthalate, triethyl citrate, tributyl citrate, and etc. (42)

Sweetening Agent

Sweeteners have become an important part of the food products as well as pharmaceutical products intended to be disintegrated or dissolved in the oral cavity. Natural sweeteners as well as artificial sweeteners are used to improve the palatability of the mouth dissolving formulations. Some suitable sweeteners include: Water soluble natural sweetener: xylose, ribose, glucose, sucrose, maltose, stevioside etc. Water soluble artificial sweetener: sodium or calcium saccharin salts, acesulfame-K etc. Dipeptide based sweetener: aspartame(43)

Drug/Film	Polymer(s)	Key Findings
Triclosan	HPMC (Methocel E3, E5, E15 Premium LV)	Methocel E15 Premium LV produced films with appropriate properties.
Famotidine	HPMC + PEG	Desired physico-chemical properties achieved.
Piroxicam	Maltodextrins (MDX) + low dose dextrose	Enabled incorporation of water-insoluble drug into fast dissolving films.
Nebivolol HCl	HPMC, Pullulan, PVP	Polymer concentration strongly influenced mechanical properties and drug release.
Chlorhexidine	Alginate, HPMC, Chitosan	Mono- and double-layered buccoadhesive films showed improved controlled drug release.
Granisetron HCl	Pullulan + HPMC	Pullulan (40–45%) gave poor film properties; HPMC up to 40% made films hard to peel; >50% HPMC increased stickiness and drug release. (41)

Table No:2 Formulation of model ODF details

Saliva Stimulating Agent

Salivary stimulants are often acidic in nature, boosting the production of saliva in the buccal cavity and so accelerating the disintegration of ODFs. Some regularly used saliva stimulating substances are citric acid, malic acid, tartaric acid, ascorbic acid, and lactic acid. (44)

Surfactant

Surfactants are utilized as solubilizing, wetting, or dispersing agents, which dissolves the film in seconds and releases the active substance immediately. Surfactants also enhance the solubility of poorly soluble medicines in rapidly dissolving buccal films. Examples include Polaxamer 407, sodium lauryl sulfate, benzalkonium chloride, benzthonium chloride, and tweens and spans etc(45)

Flavour

Flavours are required to disguise the bitter or unpleasant taste of the inserted medicine. The amount of flavor varies on its type and strength. Any US-FDA authorized flavor can be utilized, such as sweet, sour, or mint flavor. One study found that mint, licorice, and sucralose combination flavors effectively disguise the bitter taste of diclofenac sodium. Electronic tongues are used to distinguish between the effects of various taste masking agents (TMAs)(46)

Colouring Agent

Pigments such as titanium dioxide or FD&C approved coloring additives are incorporated (not exceeding concentration levels of 1%w/w) in oral strips when part of the formulation ingredients or medications are present in insoluble or suspension form. (47)

Methods of preparation

Solvent Casting Method

It is a very old filmmaking approach. In this approach, the medicine is dissolved or suspended in a solution including polymers, plasticizers, and other excipients that have been dissolved in a volatile solvent such as ethanol or water. It is referred to as film dope; it is then cast in a petri plate and processed through drying equipment such as an oven to eliminate all volatile solvents. The dry film is then die-cut into strips and placed in sealed, atmospherically resistant pouches. This method is suitable for films containing heat-sensitive drugs/API since the temperature required to remove the volatile solvents is considerably low than the hot melt extrusion method. (48)

Solvent casting is the most common method for preparing ODFs using water-soluble excipients, polymers, and drugs dissolved in de-ionized water; as a result, a homogeneous mixture is formed by applying high shear forces generated by a shear processor. The prepared solution is then put onto a petri plate and allowed to dry at a high temperature to produce high-quality films. An orodispersible film of tianeptine sodium was successfully made utilizing the solvent casting approach with various grades of Lycoat and HPMC.(49) Using the solvent casting approach, the film-forming polymer is typically immersed in a suitable solvent overnight. Before finalizing a formulation, the drug's compatibility with the solvent and other excipients is considered. Air bubbles trapped during formulation can interfere with the homogeneity of produced films. Thus, the mixture is deaerated using a vacuum pump. Mosapride's orodispersible film formulation was also successfully created utilizing the solvent casting approach. Viscosity of the solution to be poured is an important consideration in the casting procedure. Pullulan concentrations ranging from 2% to 8% produce low viscosity solutions that allow for facile film casting. Fast dissolving films of anastrozole were also successfully made using the solvent casting approach with HPMC (E5) and polyvinyl alcohol (PVA).(50)

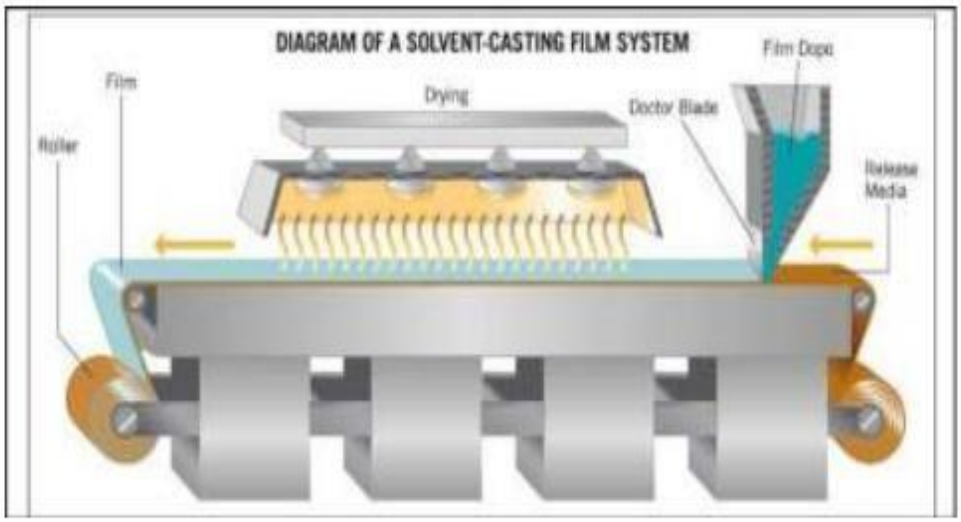

Fig no 3: Description of Solvent casting method Advantages

Thickness homogeneity and clarity are superior to extrusion The film has a nice gloss and is devoid of flaws such as die lines. Film has more flexibility and improved physical qualities. The optimum finished film thickness is typically 12-100 µm, but different thicknesses can be used to fulfill API loading and dissolving requirements..(51)

Disadvantages

The polymer should be soluble in a volatile solvent or water. A stable solution with a tolerable minimum solid content and viscosity must be formed. It must be feasible to form a homogeneous film and then release from the casting support. (52)

Solvent casting method

Component	Function	Typical Quantity Range	Example (Etoricoxib ODF)
Selective COX-2 inhibitor (Celecoxib or Etoricoxib)	Active pharmaceutical ingredient (API)	10–40 mg per film (dose depends on potency)	20 mg
Film-forming polymer (HPMC E5, PVP K30, or Xanthan gum)	Provides structure and flexibility	2–4 % w/v	3 g HPMC E5
Plasticizer (PEG 400 or Glycerol)	Improves flexibility and prevents brittleness	0.5–1.5 % w/v	1 mL PEG 400
Super disintegrant (Plantago ovata, Crospovidone, or Sodium starch glycolate)	Accelerates disintegration	0.5–1 % w/v	0.8 g Plantago ovata
Surfactant (Tween 80 or Poloxamer 188)	Enhances wetting and dispersion	0.1–0.3 % w/v	0.2 mL Tween 80
Sweetener (Sucralose or Mannitol)	Taste masking	1–2 % w/v	1.5 g Sucralose
Flavoring agent (Peppermint or Strawberry flavor)	Improves palatability	0.1–0.2 % w/v	0.15 mL Peppermint
Solvent system (Water + Ethanol or Methanol)	Dissolves all components	q.s. to 100 mL	100 mL total

Table No:3 Solvent casting method formulation details (55)

Semisolid Casting Method

When using acid-insoluble polymers, the semisolid casting process is typically employed. This method involves making a solution of a water-soluble film-forming polymer and pouring it into an acid-insoluble polymer solution generated in sodium or ammonium hydroxide. Plasticizer is then added to create the gel mass. The amount of plasticizer supplied has an impact on the gel mass's characteristics. After that, heat-controlled rollers or drums are used to cast the gel mixture into film or ribbons. The film-forming polymer to acid-insoluble polymer ratio should be 1:Four. This technique produces films with a thickness of roughly 0.0150.05 inches. (56)

Hot Melt Extrusion

This technique uses a heating procedure to shape polymer into a film. The extruder first fills the hopper with the drug polymer combination, which it then moves, mixes, and melts. The melt is given the necessary shape by a die. With this approach, the drug polymer mixture has a shorter residence time (less than two minutes) and a lower temperature. This process can run continuously with minimal product waste and does not require organic solvents. Operating parameters can be controlled efficiently using this way. (57)

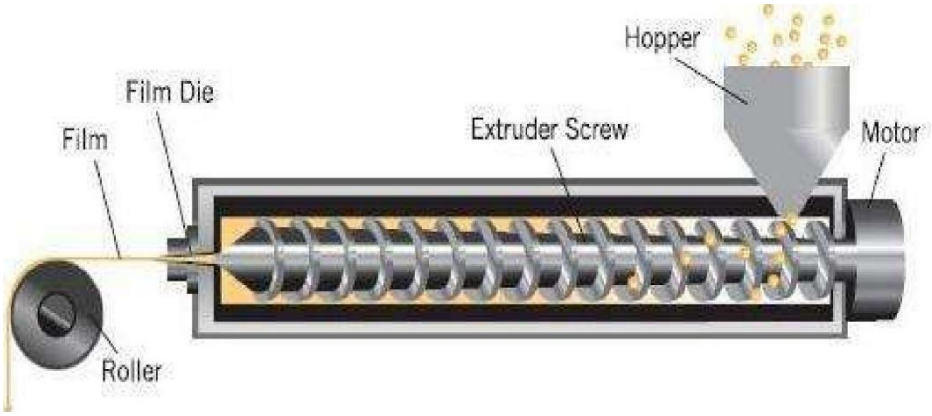

Fig 5: HOT MELT EXTRUDER.

Solid Dispersion Extrusion: The term "solid dispersion" describes the solid-state dispersion of active substances in an inert carrier when amorphous hydrophilic polymers are present. The medicine is first dissolved in an appropriate liquid solvent. This solution is then added to a polyethylene glycol melt at a temperature lower than 700C without the liquid solvent being removed. Finally, the solid dispersions are shaped by passing them through dies. Take precautions when making solid dispersions. The polymeric form of drug precipitated in the solid dispersions may be impacted by the liquid solvent utilized, and the chosen solvent or dissolved drug may not be miscible with the melt of polyethylene glycol. (58)

Rolling method:

In the rolling procedure, a pre-mix is made before the active medication is added and the film is ready. Film-forming polymer, polar solvent, plasticizer, and other excipients are included in the pre-mix batch; the medicine is added to the master batch. To ensure uniformity, the master batch and premix of the necessary quantity are pumped into different containers, and the medicine is then blended with the master pre-mix for a predetermined amount of time. After that, the mixture is delivered to the roller; the metering roller applies the mixture to the roller while controlling its thickness. The support roller forms the film and carries it away. The second metering pump feeds a predetermined amount of matrix into the pan. The film thickness was determined by the metering roller. Finally, the support roller forms the film on the substrate and carries it away. Avoiding the presence of outside air during the drying process is preferable since the created film is moist and is subsequently dried utilizing controlled bottom drying. Following drying, the film is cut into various forms and sizes as needed.(59)

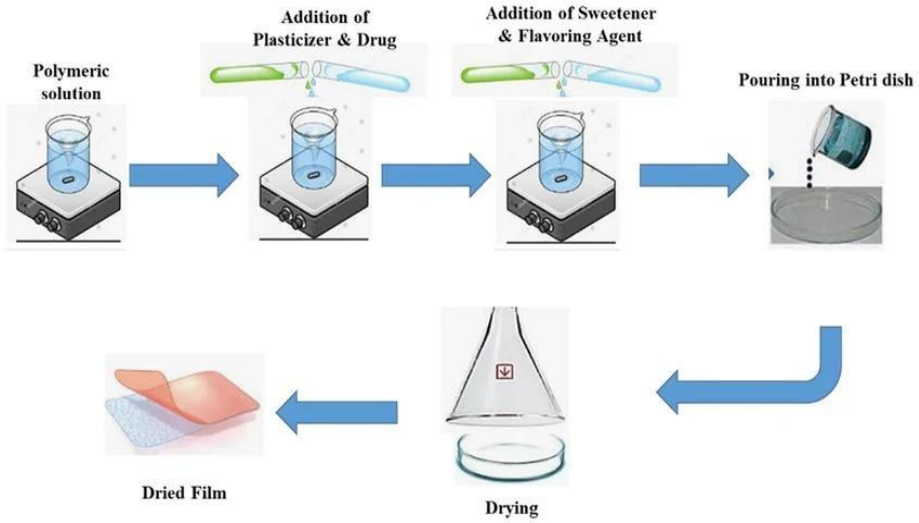

Fig 4: Solvent Casting Method.

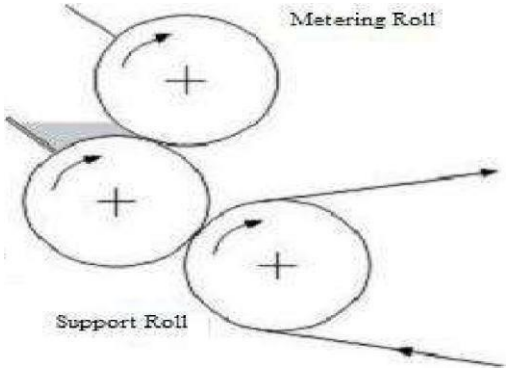

Fig 6: Rolling Method.

RECENT MANUFACTURING TECHNOLOGIES

XGel

Vegetarians tend to choose this kind of film because it doesn't use animal sources. They have intestinal qualities and are employed to cover up the taste, color, and layer.API is also included. They can be used to create any type of oral dose form because they are soluble in water. It can be made in a variety of sizes and shapes. It's a great way to administer the medications. (60)

Soluleaves

Soluleaves are added to flavor-releasing products including vitamins, confections, and fresheners. This technology is utilized in a variety of ODF products to effectively and pleasantly transport the pharmaceutical active ingredient to the oral cavity. When the film comes into contact with saliva, the soluleaves are designed to dissolve rapidly, releasing the API. Soluleaves are hence ideal for oral administration and wide-ranging release. This technique is frequently appropriate for elderly and pediatric patients who have trouble swallowing tablets and capsules.

Wafertab

One method for loading a medication into films for topical or oral administration is the wafer tab. API additives are added to the film after casting. This technology allows the medicine to dissolve and release quickly when it comes into contact with saliva in this system where the drug is in the form of an ingestible filmstrip. Additionally, wafertab is used to create and enhance flavor. The medication can be weighed and added to the pre-made film to aid increase the product's stability and avoid moisture and heat. Wafertab contributes to increased opportunities for drug discovery. Wafertabs come in a variety of sizes and forms and it helps in quick release of drugs and also the patients who can’t swallow easily (61)

Foamburst

Their new potency was accepted in 2004 on the month of September. wherein foamed film capsules are made. An alternative to Soluleaves is foam burst. During the production process, gases are blown into the film, filling in its empty space and creating a honeycombed structure. Because to the honeycombed structure, which is constructed softly, the capsule dissolves fast and causes a melt-in-your-mouth sensation.(62)

Micap

In order to combine its microencapsulation facility with Bio Progress water soluble film, Micap struck a bond in 2004. They are a bioscience company that uses a single cell organism to create a natural micro capsule for the food, pharmaceutical, and agrochemical industries utilizing a patented micro-encapsulation technology. (63)

Packaging of orally disintegrating films

Packaging Option	Description	Special Considerations
Foil paper/plastic pouches	Basic protective covering	Suitable for general use
Single pouches	Individual unit packaging	Convenient for single-dose administration
Aluminium pouches	Strong protective material	Provides enhanced barrier against external factors
Blister packaging	Contains several units	Easy dispensing and unit protection
Barrier films	High moisture resistance	Most frequently used for moisture-sensitive medications
Primary closing bag	Provides space for logos, codes, directions, and information	Developed using Labtec GmbH's rapid film technology
Laminating method	Production technique for films	Ensures stability and uniformity
Cost comparison	Packaging cost	Similar to that of tablets. (64)

Table No:4 Packaging of orally disintegrating films

Evaluation of oral dispersible films

Physical characterization

Physical characterization can be carried out by visual inspection for characteristics such as colour, brittleness, peeling ability, transparency, surface smoothness, tack property and film forming capacity(65)

Film thickness

The film thickness can be measured by micrometre screw gauge (Mitutoyo, Japan) at 5 different locations and the average value was calculated. This is essential to determine uniformity in the film thickness which is subsequently related to the accuracy of dose in the film(66)

Weight variation

For weight variation three films (3 x 3 cm) of every formulation were weighed individually using Analytical balance ((Mettler, AJ150, Greifensee, Switzerland), then average weight was calculated(67)

Tensile strength

Tensile strength is the maximum stress applied to a point at which the film specimen breaks [35].

Tensile strength of the films (3x3 cm) was measured using texture analyser (Shimadzu EZ-SX, Japan). Tensile strength is calculated by the applied load at rupture divided by the cross-sectional area of the film as given by the equation below.

Tensile strength = Load failure Film thickness x film width(68)

Surface pH

One film (3x3 cm) of each formulation was transferred into a petri dish and moistened with 1 ml of distilled water and kept for 1 h. The surface pH was measured by bringing the electrode of the pH meter (Mettler Toledo, Greifensee, Switzerland) in contact with the surface of the film and allowing it to equilibrate for 1 min (69)

Drug content uniformity

Three films (3×3cm) were transferred into separate graduated flasks containing 100 ml of phosphate buffer pH 6.5 and stirred for 2 hours. The contents were filtered, suitably diluted and analysed spectrophotometrically at 362 nm(70)

Disintegration

Disintegration was determined by placing an ODF onto a petri dish and 0.2 ml water was placed on the film. Time taken to break the film was measured as the disintegration time. Test was carried out in triplicate for optimised formulation (71)

Folding endurance

The folding endurance is expressed as the number of folds required to break the specimen or to develop visible cracks. This gives the indication of brittleness of the film. A strip of 3x 3 cm was subjected to this test by folding the film repeatedly at the same plane for several times

until a visible crack was observed, and the values were reported(72)

Stability studies

Optimised batch of Meloxicam-ODF was packed in aluminium pouch and sealed. The package was then stored at (40 °C ± 2 °C/ 75% RH ± 5% RH) condition for a period of 3 months. Films were evaluated for tensile strength, % elongation and drug content(73)

Moisture content: Determined by expose to the environment with a relative humidity 75% at room temperature for 72h. Percentage moisture uptake is calculated as % weight gain of the films.

New Aspects Technologies

Aspect	Details
Manufacturing advances	3D printing and hot-melt extrusion enable precision dosing, multilayer designs, and combination therapies.
Nanotechnology integration	Improves solubility and bioavailability, allowing delivery of complex biologics, peptides, and nucleic acids.
Personalized medicine	Patient-specific formulations at point of care enhance compliance and therapeutic outcomes.
Patient-centric benefits	Especially useful for pediatric and elderly populations; taste masking, flavor customization, and flexible packaging improve acceptance.
Clinical applications	Local treatments for oral disorders and systemic medicines like fast-acting analgesics and anti-inflammatory drugs.
Regulatory progress	Standardized evaluation criteria are being established, accelerating commercialization and adoption.
Challenges	Drug load restrictions, stability issues, and high cost of advanced technologies.
Future outlook	Expected to evolve from niche dosage forms into mainstream pharmaceutical platforms, driving patient-friendly innovation. .(73)(74)(75)(76)

Table No:5 New Aspects Technologies in ODT Films

Case studies of reviewed oral dispersible films

The Pharma Excipients Review emphasizes the potential of nanoparticle-loaded oral dispersible films (ODFs) to improve drug absorption. It includes case studies on multilayer 3D-printed films designed to separate incompatible drugs, as well as clinical trials and marketed ODF products such as ondansetron films for nausea. Similarly, the International Journal of Research and Review discusses case studies of ODFs delivering anti-ulcer, anti-asthmatic, antihistamine, and analgesic drugs, including detailed insights into manufacturing methods such as solvent casting, hot melt extrusion, and roll casting, emphasizing scalability, patient compliance, and rapid onset of action.(77) To supplement these findings, the PMC Pharmaceutics Review investigates taste-masked ODFs tailored for pediatric and geriatric patients, examining functional excipients that enable permeation of proteins, peptides, and oligonucleotides, and noting the growing importance of personalized ODFs tailored to individual patient needs.(78)

Future prospects of oral dispersible films

Oral dispersible films will progress from simple solvent-cast strips to multifunctional, patient-centric platforms that offer quick onset, individualized dosage, and increased payloads.

3D printing allows for on-demand, personalized films and multilayer architectures that isolate incompatible actives and modify release patterns, making hospital-based tailoring possible. Hot-melt extrusion (HME) combined with continuous lamination provides a solvent-free, industrially scalable method for producing homogeneous films and incorporating solid dispersions of poorly soluble APIs. (79)

Electrospun nanofiber films and nanoparticle-loaded films will provide ultra-fast disintegration and increased bioavailability for low-dose and

Study (year)	Drug & objective	Manufacturing method	Key outcome (one line)
Celecoxib (2019)	Improve oral bioavailability of poorly soluble celecoxib	Nanocrystalline solid dispersion (wet media milling + lyophilization)	3.1× AUC increase; stable nanocrystals ~150 nm.
Sildenafil (electro spun)	Fast-dissolving paediatric ODF	Electrospinning (pullulan, water solvent)	Nanofiber ODFs disintegrated in seconds; high surface area → rapid dissolution.
Sildenafil (clinical, 2018)	Compare ODF vs tablet PK/tolerability	Oro-dispersible film (commercial ODF)	Faster early absorption and higher AUC_{60}; improved tolerability.
Ondansetron (multiple)	Rapid antiemetic onset	Solvent casting with HPMC + super disintegrants	Disintegration <30 s; comparable or faster release vs marketed product.
Levocetirizine (2017)	Taste-masked paediatric ODF	Solvent casting (pullulan/HPMC variants)	Disintegration ~20–30 s; >95% release in 10 min; stable at 40°C/75% RH (short term).

Table No:6 Case studies of oral dispersible films

poorly soluble medications; both technologies also safeguard labile compounds.

Advances in supercritical fluid and spray-drying hybrid technologies will give more environmentally friendly ways to produce amorphous dispersions and nanoparticles that can be incorporated into films.

To extend ODFs to peptides, oligonucleotides, and high-molecular-weight polar medicines, it is critical to develop functional excipients such as permeation enhancers, stabilizing polymers, and taste masking agents.(80)

The pharmaceutical industry has achieved significant advances in oral medication delivery technology. The market has evolved significantly from traditional tablets/capsules to new quick disintegrating and rapidly acting tablets/films.

Various drawbacks, such as decreased bioavailability of oral solid medications, the hassle of delivering injections, and imprecise dosing by liquid formulations, have shifted pharmaceutical companies' focus to developing novel oral dosage forms that address these limitations (81).

Fast dissolving oral thin films are intended to address the majority of these issues. The concept is not novel, and numerous over-the-counter oral thin films are widely accessible.

Prescription medications have been developed into oral thin films due to their high consumer acceptance and increasing demand for over-the-counter oral film products.

This growing area is attracting interest from both major and start-up pharmaceutical companies. There are no clinical trials related with the generic approval procedure. (84)

Risks, limitations, and mitigation

Stability: Amorphous and nanoforms can recrystallize; mitigate with polymeric stabilizers and ICH accelerated testing

Scale-up: lab techniques (electrospinning, 3D printing) need process intensification; consider hybrid HME workflows.

Regulatory: novel excipients and nanoparticle claims: require toxicology and clinical data engage regulators early and compile excipient safety dossiers.

CONCLUSION

The incorporation of solid dispersion techniques into oral dispersible films (ODFs) for selective COX2 inhibitors marks a significant step forward in current pharmaceutics, bridging the gap between formulation science and patient-centered drug administration. Selective COX-2 inhibitors, such as celecoxib and etoricoxib, are clinically useful for their anti-inflammatory and analgesic characteristics, but their low water solubility and irregular bioavailability have long hampered successful treatment. Solid dispersion technology, which disperses the medicine in hydrophilic carriers, increases dissolution rates and keeps the drug supersaturated, enhancing absorption and therapeutic efficacy. When included into ODFs, this strategy not only ensures quick disintegration and dissolution in the oral cavity, but also provides a practical, non-invasive dosage form that caters to populations with swallowing issues, including paediatric , geriatric, and dysphagic patients.(88)

To summarize, ODFs incorporating solid dispersion techniques provide a strong and adaptable platform for the administration of selective COX-2 inhibitors. They combine the pharmacokinetic benefits of increased solubility with the practical benefits of easy administration, opening the door for better therapeutic outcomes. With further research and technological improvement, this technique has enormous promise not only for COX-2 inhibitors but also for a larger spectrum of poorly soluble medications, representing a critical step toward the future of tailored and accessible drug delivery.(89)

REFERENCE

1.Jacob S, Boddu SHS, Bhandare R, Ahmad SS, Nair AB. Orodispersible Films: Current Innovations and Emerging Trends. Pharmaceutics [Internet]. 2023 Dec 1 [cited 2026 Jan 28];15(12).

2.Ozon EA, Sarbu I, Popovici V, Mitu MA, Musuc AM, Karampelas O, et al. ThreeDimensional Printing Technologies in Oral Films Manufacturing—A Minireview. Process 2023, Vol 11, Page 2628.

3.Chaudhari AP, Patil BA, Tadavi SA, Pawar. DSP. Mouth Dissolving Film: An Innovative and Effective Drug Delivery System. Int J Res Pharm Allied Sci [Internet]. 2023 May 12 [cited 2026 May 8];2(2):78–89.

4.Lipfert P, Seitz R, Arndt JO. Studies of local anesthetic action on natural spike activity in the aortic nerve of cats. Anesthesiology [Internet]. 1987 [cited 2026 May 8];66(2):210–3.

5.He M, Zhu L, Yang N, Li H, Yang Q. Recent advances of oral film as platform for drug delivery. Int J Pharm. 2021 Jul 15;604.

6.Gupta MS, Kumar TP, Davidson R, Kuppu GR, Pathak K, Gowda DV. Printing Methods in the Production of Orodispersible Films. AAPS PharmSciTech 2021 223 [Internet]. 2021 Apr 9 [cited 2026 May 8];22(3):129-.

7.Juarez-Navarro KJ, Guarino V, Alvarez-Perez MA. Converging Electrospinning and 3DPrinting Technologies: From Innovative Design for Tissue Engineering to Global Patent Trends and Technology Transfer. Fibers 2025, Vol 13, Page 83 [Internet]. 2025 Jun 19 [cited May 8];13(6):83.

8.Preis M, Woertz C, Schneider K, Kukawka J, Broscheit J, Roewer N, et al. Design and evaluation of bilayered buccal film preparations for local administration of lidocaine hydrochloride. Eur J Pharm Biopharm. 2014;86(3):552–61.

9.Malamatari M, Charisi A, Malamataris S, Kachrimanis K, Nikolakakis I. Spray Drying for the Preparation of Nanoparticle-Based Drug Formulations as Dry Powders for Inhalation. Process 2020, Vol 8, Page 788 [Internet]. 2020 Jul 6 [cited 2026 May 8];8(7):788.

10.Juarez-Navarro KJ, Guarino V, Alvarez-Perez MA. Converging Electrospinning and 3DPrinting Technologies: From Innovative Design for Tissue Engineering to Global Patent Trends and Technology Transfer. Fibers 2025, Vol 13, Page 83 [Internet]. 2025 Jun 19 [cited May 11];13(6):83.

11.Elton Gatt, Nicolette Sammut Bartolo, Lilian M Azzopardi,A systematic review of 3D printing of pharmaceutical drug products: Barriers and enablers, European Journal of Pharmaceutics and Biopharmaceutics,Volume 227,2026,115211,ISSN 0939-6411,https://doi.org/10.1016/j.ejpb.2026.115211.

12.Gandini A. Freelance Creatives: Good Jobs, or Bad Jobs? 8th Int Conf Crit Manag Stud 10 Jul 2013-12 Jul 2013; Univ Manchester Manchester, United Kingdom Univ Manchester Libr 2013. 2013;

13.Zhang Z, Zhang W, Peng X, Zhang X, Wang Y, Yu B, et al. Integration of Electrospinning and 3D Printing Technology. Electrospun Nanofibers Princ Technol Nov Appl [Internet]. 2022 Jan 1 [cited 2026 May 12];657–91.

14.Quinlan F, Ycas G, Osterman S, Diddams SA. A 12.5 GHz-spaced optical frequency comb spanning >400 nm for near-infrared astronomical spectrograph calibration. Rev Sci Instrum. 2010 Jun 1;81(6):063105.

15.Iqbal Mir H, Asija R, Goyal A. International Journal of All Research Writings 87. Formulate And Evaluate Film Coated Tablets Of Amlodipine Besylate And Metoprolol Succinate. 2020 [cited 2026 May 12];2(1).

16.Dr.T.E.Gopala Krishna Murthy - Google Scholar [Internet]. [cited 2026 May 12].

17.Gupta A, Sharma V, Singh L. Process variable studies for preparation of optimized system for bupropion hydrochloride using CCD. J Drug Deliv Ther. 2019;9(2-s):281–90.

18.Cupone IE, Sansone A, Marra F, Giori AM, Jannini EA. Orodispersible Film (ODF) Platform Based on

Maltodextrin for Therapeutical Applications. Pharm 2022, Vol 14, Page 2011 [Internet]. 2022 Sep 22 [cited 2026 Jan 28];14(10):2011.
19.Patel S. |Review. Int J Pharm Sci [Internet]. 2026 [cited 2026 May 12];4:994–1000. Available from: https://www.ijpsjournal.com.
20.Malik A, Chauhan SB, Jain C. Pharmaceutically engineered olfactory-masking agents: Innovating oral drug delivery through multisensory excipient design. DARU J Pharm Sci 2026 341 [Internet]. 2026 May 11 [cited 2026 May 12];34(1):28.
21.Centkowska K, Szadkowska M, Basztura M, Sznitowska M. Homogeneity and mechanical properties of orodispersible films loaded with pellets. 2024 [cited 2026 May 12]; Available from: https://doi.org/10.1016/j.ejpb.2024.114537.
22.Ferlak J, Guzenda W, Osmałek T. Orodispersible Films—Current State of the Art, Limitations, Advances and Future Perspectives. Pharm 2023, Vol 15, Page 361.
23.Sharma D, Kumar D, Sehrawat S, Kumar D, Kumar S. Various Aspects of Solid Dispersion Technology: A Review. Res J Pharm Technol [Internet]. 2025 Apr 12 [cited 2026 May 8];18(4):1872–8.
24.Prakash Maurya C, Bansal S, Singh R, kumar Srivastava A, scholar R, professor A, et al. Issue 6 www.jetir.org (ISSN-2349-5162). JETIR2506842 J Emerg Technol Innov Res [Internet]. 2025 [cited 2026 May 12];12.
25.Mishra R, Devi A, Scholar R. Solid dispersion: an overview of different methodology and techniques. Int J Res Anal Rev [Internet]. 2024 [cited 2026 May 8];392. Available from: www.ijrar.org.
26.Kumar R, Thakur AK, Chaudhari P, Banerjee N. Particle Size Reduction Techniques of Pharmaceutical Compounds for the Enhancement of Their Dissolution Rate and Bioavailability. J Pharm Innov 2021 172./s122.47-02009530-5.
27.Nair AR, Lakshman YD, Anand VSK, Sree KSN, Bhat K, Dengale SJ. Overview of Extensively Employed Polymeric Carriers in Solid Dispersion Technology. AAPS PharmSciTech [Internet]. 2020 Nov 1 [cited 2026 May 8];21(8):309.
28.Yugatama A, Muti'ah A, Azizah S, Choiri S, Huang YL. Sciences of Pharmacy · The Effect of Poloxamer 188 on the Solubility and Dissolution Behaviors of Piroxicam-PEG 4000 Solid Dispersions.
29.Sharma K. Solvent evaporation method for the preparation of solid dispersions. 1:2018.
30.International Council For Harmonisation of Technical Requirements For Pharmaceuticals For Human Use Impurities: Guideline for Residual Solvents Q3C(R7). 2018.
31.Chaudhary H, Gauri S, Rathee P, Kumar V. Development and optimization of fast dissolving oro-dispersible films of granisetron HCl using Box–Behnken statistical design. Bull Fac Pharmacy, Cairo Univ [Internet]. 2013 Dec 1 [cited 2026 May 12];51(2):193–201.
32.Yasir M, Nagar P, Chauhan I. Drug Invention Today Insights into Polymers: Film Formers in Mouth Dissolving Films. Drug Invent Today [Internet]. 2011 [cited 2026 May 12];3(12):280–9.
33.Rahul Rohidas Maske, Vijay Rajaram Mahajan, Sakshi Bhagwan Bhalerao. Polymers used in mouth dissolving film: A review. World J Adv Res Rev. 2022 Dec 30;16(3):378–89.
34.Lau ETL, Steadman KJ, Cichero JAY, Nissen LM. Dosage form modification and oral drug delivery in older people. Adv Drug Deliv Rev. 2018 Oct 1;135:75–84.
35.Ghadge AB, Dighe SS, Kanade R, Santosh Pendbhaje S. Polymer used in sublingual film formulation: A comprehensive review". Introduction. © 2025 IJNRD | [Internet]. 2025 [cited 2026 May 12];10:653.
36.Kumar, R., Lal, N., Rahat, R. et al. Therapeutic potential and formulation considerations of orally disintegrating films in acute disorders. Discov. Pharm. Sci. 1, 30 (2025). https://doi.org/10.1007/s44395-025-00033-1.
37.Cilurzo F, Cupone IE, Minghetti P, Selmin F, Montanari L. Fast dissolving films made of maltodextrins. Eur J Pharm Biopharm [Internet]. 2008 Nov [cited 2026 May 13];70(3):895–900.
38.Parejiya PB, Patel RC, Mehta DM, Shelat PK, Barot BS. Quick dissolving films of nebivolol hydrochloride: formulation and optimization by a simplex lattice design. J Pharm Investig 2013 434 [Internet]. 2013 Jun 20 [cited 2026 May 13];43(4):343–51. Available from: https://link.springer.com/article/10.1007/s40005-013-0080-5.
39.Chaudhary H, Gauri S, Rathee P, Kumar V. Development and optimization of fast dissolving oro-dispersible films of granisetron HCl using Box–Behnken statistical design. Bull Fac Pharmacy, Cairo Univ [Internet]. 2013 Dec 1 [cited 2026 May 13];51(2):193–201.
40.Anjana IS, Sujith Varma K, George A, Anupriya AB. Orodispersible Film, A new concept in Drug Delivery Technology. Res J Pharm Technol [Internet]. 2024 May 15 [cited 2026 May 12];17(5):2391–7. Available from: https://rjptonline.org/AbstractView.aspx?PID=2024-17-570
41.Šahinović M, Vranić E, Rahić O, Behrem S, Tucak-Smajić A, Hadžiabdić J, et al. Sweeteners in Orodispersible Films: How Much is too Much? Drug Res (Stuttg) [Internet]. 2024 Jan 8 [cited 2026 May 12];74(4):180–6. Available from: https://pubmed.ncbi.nlm.nih.gov/38508227.
42.Sakellariou P, Rowe RC. Interactions in cellulose derivative films for oral drug delivery. Prog Polym Sci. 1995;20(5):889–942.
43.Jacob S, Boddu SHS, Bhandare R, Ahmad SS, Nair AB. Orodispersible Films: Current Innovations and Emerging Trends. Pharmaceutics. 2023 Dec 11;15(12):2753. doi: 10.3390/pharmaceutics15122753. PMID: 38140094; PMCID: PMC10747242.
44.Alotaibi HF, Elsamaligy S, Mahrous GM, Bayomi MA, Mahmoud HA. Design of taste masked enteric orodispersible tablets of diclofenac sodium by applying fluid bed coating technology. Saudi Pharm J SPJ [Internet]. 2018 Mar 1 [cited 2026 May 12];27(3):354. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC6438907.
45.eCFR :: 21 CFR 73.2575 -- Titanium dioxide. [Internet]. [cited 2026 May 12]. Available from: https://www.ecfr.gov/current/title-21/chapter-/subchapter-

A/part-73/subpartC/section-73.2575?utm_source=copilot.com.
46.Mosquera-Giraldo LI, Donoso M, Stefanski K, Foster K, Gesenberg C, Abraham P, et al. Solvent-Casted Films to Assist Polymer Selection for Amorphous Solid Dispersions During Preclinical Studies: In-vitro and In-vivo Exploration. Pharm Res 2021 385 [Internet]. 2021 Apr 20 [cited 2026 May 8];38(5):901–14. Available from: https://link.springer.com/article/10.1007/s11095-021-03040-w.
47.Brahmaiah Bonthagarala - Google Scholar [Internet]. [cited 2026 May 12]. Available from: https://scholar.google.com/citations?user=2H30CNoAAAAJ&hl=en&oi=sra
48.Dinge A, Nagarsenker M. Formulation and Evaluation of Fast Dissolving Films for Delivery of Triclosan to the Oral Cavity. AAPS PharmSciTech 2008 92 [Internet]. 2008 Feb 15 [cited 2026 May 12];9(2):349–56. Available from: https://link.springer.com/article/10.1208/s12249-008-9047-7.
49.Shin JH, Han JA. Influence of Casting Variables on Release Kinetics of Orally Disintegrating Film. Foods [Internet]. 2024 May 1 [cited 2026 May 12];13(9):1418. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC11083982.
50.Solvent Casting Method for Oral Thin Film Preparation - Oral Thin Film - CD Formulation [Internet]. [cited 2026 May 12]. Available from: https://www.formulationbio.com/oral-thinfilm/solvent-casting-method-for-oral-thin-film-preparation.html.
51.Dissolving Films: Film Manufacture, Solvent-Cast Films, Extruded Films | Agno Pharmaceuticals [Internet]. [cited 2026 May 8]. Available from: https://agnopharma.com/technical-briefs/dissolving-films/?utm_source=copilot.com. Application Notes and Protocols for Polymer Film Fabrication via Solvent Casting. 2026; Flow diagram describing the solvent casting method for the preparation... | Download Scientific Diagram [Internet]. [cited 2026 May 12]. Available from: https://www.researchgate.net/figure/Flow-diagram-describing-the-solvent-casting-methodfor-the-preparation-of-FDOSs_fig1_346649116
52.Kridli GT, Friedman PA, Boileau JM. Manufacturing processes for light alloys. Mater Des Manuf Light Veh. 2010;235–74.
53. Hot Melt Extrusion - Pharmaceutical HME | AbbVie CMO [Internet]. [cited 2026 May 8]. Available from: https://www.abbviecontractmfg.com/services/hot-meltextrusion.html.
54.Totre A, Chaurasia G. A Review on Solid Dispersion Techniques: A Exclusive Approach for Enhancing Drug Solubility and Bioavailability. 2503 [cited 2026 May 8];7(3). Available from: www.ijfmr.com Rolling Method for Oral Thin Film Preparation - Oral Thin Film - CD Formulation [Internet]. [cited 2026 May 9]. Available from: https://www.formulationbio.com/oral-thinfilm/rolling-method-for-oral-thin-film-preparation.html.
55.Zayed GM, Rasoul SA El, Ibrahim MA, Saddik MS, Alshora DH. In vitro and in vivo characterization of domperidone-loaded fast dissolving buccal films. Saudi Pharm J [Internet]. 2020 Mar 1 [cited 2026 May 13];28(3):266–73.
56.Cai B, Söderkvist K, Engqvist H, Bredenberg S. A new drug release method in early development of transdermal drug delivery systems. Pain Res Treat. 2012;2012.
57.El-Setouhy DA, El-Malak NSA. Formulation of a Novel Tianeptine Sodium Orodispersible Film. AAPS PharmSciTech 2010 113 [Internet]. 2010 Jun 8 [cited 2026 May 13];11(3):1018–25. Available from: https://link.springer.com/article/10.1208/s12249-0109464-2 Form 6-K [Internet].
58. Malkawi R, Malkawi WI, Al-Mahmoud Y, Tawalbeh J. Current Trends on Solid Dispersions: Past, Present, and Future. Adv Pharmacol Pharm Sci. 2022 Oct 22;2022:5916013. doi: 10.1155/2022/5916013. PMID: 36317015; PMCID: PMC9617737.
59.Islam N, Khan NU, Razzaq A, Menaa F, Khan ZU, Hussain A, et al. Loratadine oral bioavailability enhancement via solid dispersion loaded oro-dispersible films: Formulation, characterization and pharmacokinetics. Colloids Surfaces B Biointerfaces [Internet]. 2023 Oct 1 [cited 2026 Jan 30];230:113526.
60.Shinde AJ, Garala KC, More HN. Development and characterization of transdermal therapeutics system of tramadol hydrochloride. Asian J Pharm [Internet]. 2008 [cited 2026 Jan 30];2(4).
61.Kunte S, Tandale P. Fast dissolving strips: A novel approach for the delivery of verapamil. J Pharm Bioallied Sci [Internet]. 2010 [cited 2026 Jan 30];2(4):325.
62.EZ Test - Specs : SHIMADZU (Shimadzu Corporation) [Internet]. [cited 2026 May 12]. Available from: https://www.shimadzu.com/an/products/materials-testing/uni-ttm/eztest/spec.html.
63.Formulation, Development & Evaluation of Oral Fast Dissolving Anti-Allergic Film of Levocetrizine Dihydrochloride - ProQuest [Internet]. [cited 2026 Feb 3].
64.Wasilewska K, Winnicka K. How to assess orodispersible film quality? A review of applied methods and their modifications. Acta Pharm [Internet]. 2019 Jun 30 [cited 2026 Feb 4];69(2):155–76. Available from: https://doi.org/10.2478/acph-2019-0018.
65.Low AQJ, Parmentier J, Khong YM, Chai CCE, Tun TY, Berania JE, et al. Effect of type and ratio of solubilising polymer on characteristics of hot-melt extruded orodispersible films. Int J Pharm [Internet]. 2013 Oct 15 [cited 2026 Feb 4];455(1–2):138–47. Available from: ttps://www.sciencedirect.com/science/article/abs/pii/S0378517313006728.
66.https://database.ich.org/sites/default/files/Q1A%28R2%29%20Guideline.pdf.
67.Jain A, Ahirwar HC, Tayal S, Mohanty PK. Fast dissolving oral films: a tabular update. J Drug Deliv Ther [Internet]. 2018 [cited 2026 Feb 4];8(4):10–9.
68.Elbl J, Gajdziok J, Kolarczyk J. 3D printing of multilayered orodispersible films with inprocess drying. Int J Pharm [Internet]. 2020 Feb 15 [cited 2026 May 9];575:118883.
69.Todkari PP, Hatwar PR, Bakal RL, Meshram SI. Corresponding author: Prathmesh P. Todkari Oro dispersible Films (ODFs): A patient-centric approach in drug delivery. GSC Biol Pharm Sci [Internet]. 2025 [cited 2026 May 12];2025(03):125–31.

70.Kardile DP, Awate PB, Bhagat VC, Bhusari AC, Narote NA, Shete R V, et al. Review on Nanoparticle Loaded Oral Film an Innovative Approach for Poorly Water-Soluble Drug Delivery. Biol Forum-An Int J. 2023;15(3):138.
71.Muralidhar S, Narayana T V, Sumaltha G, Rani N, Jayasree Prasanna R, Sri Nandini S. Oral Dissolving Films: A Review. Int J Res Rev. 2023;10(9).
72.Badgujar BP, Mundada AS. The technologies used for developing orally disintegrating tablets: A review. Acta Pharm. 2011 Jun 1;61(2):117–39.
73.Kumar M, Singh MK, Arora G, Palaniappan SK, Ayyappan V, Muthukutti GP, et al. A comprehensive review on next-gen electrospun nanofibers for multidirectional applications from energy storage to precise medicine. Macromol Res 2025 3312 [Internet]. 2025 Sep 26 [cited 2026 May 9];33(12):1613–48.
74.Kaur G, Arora M, Ravi Kumar MNV. Oral Drug Delivery Technologies—A Decade of Developments. J Pharmacol Exp Ther [Internet]. 2019 [cited 2026 May 13];370(3):529.
75.Ramani CC, Puranik PK, Dorle AK. Study of diabietic acid as matrix forming material. Int J Pharm [Internet]. 1996 Jun 21 [cited 2026 May 13];137(1):11–9.
76.Kathpalia H, Gupte A. An introduction to fast dissolving oral thin film drug delivery systems: a review. Curr Drug Deliv. 2013 Dec;10(6):667-84. doi: 10.2174/15672018100613112515024 9. PMID: 24274635.
77.Bhaskar R, Ola M, Khade S, Pawar A, Tikhe R, Madwe V, et al. Oral Thin Films: A Modern Frontier in Drug Delivery Systems. J Drug Deliv Ther [Internet]. 2025 Apr 15 [cited 2026 May 13];15(4):150–64. Available from: https://www.jddtonline.info/index.php/jddt/article/view/7067/6701.
78.Shi Q, Chen H, Wang Y, Wang R, Xu J, Zhang C. Amorphous Solid Dispersions: Role of the Polymer and Its Importance in Physical Stability and In Vitro Performance. Pharm 2022, Vol 14, Page 1747 [Internet]. 2022 Aug 22 [cited 2026 May 9];14(8):1747.
79.Ghosh A, Orasugh JT, Ray SS, Chattopadhyay D. Integration of 3D Printing–Coelectrospinning: Concept Shifting in Biomedical Applications. ACS Omega [Internet]. 2023 Aug 8 [cited 2026 May 9];8(31):28002.
80.O'Brien Laramy M, Foley DA, Pak RH, Lewis JA, McKinney E, Egan PM, et al. Chemistry, manufacturing and controls strategies for using novel excipients in lipid nanoparticles. Nat Nanotechnol 2025 203.
81.Rasool F, Naseem A, Javaid H, Afzal Z. Enhancing the solubility of celecoxib via lyophilized solid dispersions using computational and experimental approaches. Sci Reports 2025 151.
82.Baghel S, Cathcart H, O'Reilly NJ. Polymeric Amorphous Solid Dispersions: A Review of Amorphization, Crystallization, Stabilization, Solid-State Characterization, and Aqueous Solubilization of Biopharmaceutical Classification System Class II Drugs. J Pharm Sci [Internet]. 2016 Sep 1 [cited 2026 May 9];105(9):2527–44.