Pharmaceutical Oral Films: Advances in Formulation Strategies, Manufacturing Technologies, Evaluation, Therapeutic Applications, and Future Perspectives

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***Abstract*—Pharmaceutical oral films (POFs) have emerged as an advanced patient-centric drug delivery platform with multiple advantages over traditional solid oral dosage forms such as rapid disintegration, ease of administration, increased patient compliance, and the potential to enhance bioavailability through transmucosal absorption. Their applicability for juvenile, geriatric and dysphagic patients has drawn great attention in pharmacological research as well as in clinical practice. The present study highlights a detailed discussion on categorization, formulation components, production procedures, physicochemical and mechanical assessment criteria and therapeutic uses of pharmaceutical oral films. The emphasis is on the most widely used film-forming polymers, plasticizers, taste-masking techniques, and innovative production techniques such as solvent casting, hot-melt extrusion, electrospinning, and three-dimensional (3D) printing. It also features recent advances in nanotechnology, customized medicine and intelligent manufacturing technologies. Moreover, present limitations such as low drug loading capacity, moisture sensitivity, difficulty in scale-up and regulatory issues are critically explored, along with the future research prospects. The continuous improvement in materials science, pharmaceutical engineering and precision medicine is projected to considerably enlarge the therapeutic use of pharmaceutical oral films and make them a versatile and promising platform for future generation drug delivery systems.**

I. INTRODUCTION

Oral route is still the most popular route for medication delivery because to its simplicity, cost effectiveness, high patient compliance and ease of large scale production. For decades, stability and correct dosing have made conventional oral dosage forms such as tablets and capsules the mainstay of pharmacotherapy. However, these dosage forms have a number of drawbacks such as dysphagia, delayed start of action, inconsistent gastrointestinal absorption, and substantial first pass hepatic metabolism.[1,2] Such problems are particularly important in juvenile, elderly and neurologically challenged patients, where poor drug adherence might jeopardize treatment success. Hence, there is an increasing interest in the development of patient-friendly drug delivery methods that enhance compliance without sacrificing the therapeutic efficacy. Among them, pharmaceutical oral films (POFs) are potential alternative due to simplicity of administration, quick drug release and enhanced patient acceptance.[1-3] Pharmaceutical oral films, or oral thin films (OTFs) or orodispersible films depending on the intended application, are thin polymeric dosage forms intended to be swiftly hydrated, dissolved or adhered to the oral mucosa. They can deliver medications locally in the oral cavity or systemically via buccal and sublingual absorption, therefore decreasing degradation in the gastrointestinal tract and partially avoiding first-pass metabolism for appropriate drug molecules. Their ease of administration without water, developments in taste-masking technology and fast-dissolving polymers have made them particularly useful in pediatric, geriatric, dysphagic and emergency care situations.[1,2,6,7]

In the field of POFs, there have been substantial breakthroughs in formulation design and production

technology, spurred by increasing interest in customized healthcare. Conventional solvent casting is the most common fabrication technique due to its ease and low cost, but new techniques such as hot-melt extrusion, electrospinning, inkjet printing, and 3D printing allow solvent-free processing, precise dose customization, and continuous manufacturing. These developments have enhanced the mechanical characteristics, stability and controlled drug release, hence increasing the potential of oral films as a tailored drug delivery device.[1,2,3,5]

The therapeutic window of POFs has been significantly widened in recent years to include delivery of analgesics, antiemetics, antihistamines, antimigraine medicines, medications for the central nervous system, antimicrobials, and nutraceuticals. Moreover, the use of nanotechnology based carriers like as nanoparticles, nanoemulsions, nanocrystals and lipid based systems have improved the delivery of poorly water soluble pharmaceuticals and other difficult to deliver therapeutic agents by increasing solubility, permeability and bioavailability. The inclusion of Quality by Design (QbD), process analytical technology (PAT) and artificial intelligence (AI) aided formulation methodologies further aids the creation of resilient and efficient manufacturing processes. However, there are still several hurdles for large-scale commercialization of POFs such as low drug loading capacity, susceptibility to moisture, complicated flavor masking, mechanical fragility and requirement for unique packaging. Moreover, effective clinical translation will need consistent medication distribution, long-term stability, scalable production and unified regulatory standards. Further work on new materials, manufacturing processes and multimodal drug delivery systems is planned to solve these constraints and extend the therapeutic potential of oral films.[15-17] Considering the fast development in the field of formulation science, manufacturing techniques and customized medicine, a current and complete evaluation of pharmaceutical oral films is necessary. Therefore, this review covers the classification, formulation components, manufacturing techniques, evaluation techniques, therapeutic applications, recent advancements and future perspectives of POFs. This review provides a critical overview of the present developments and emerging opportunities in drug delivery through the oral film platform.[2,4,21,29]

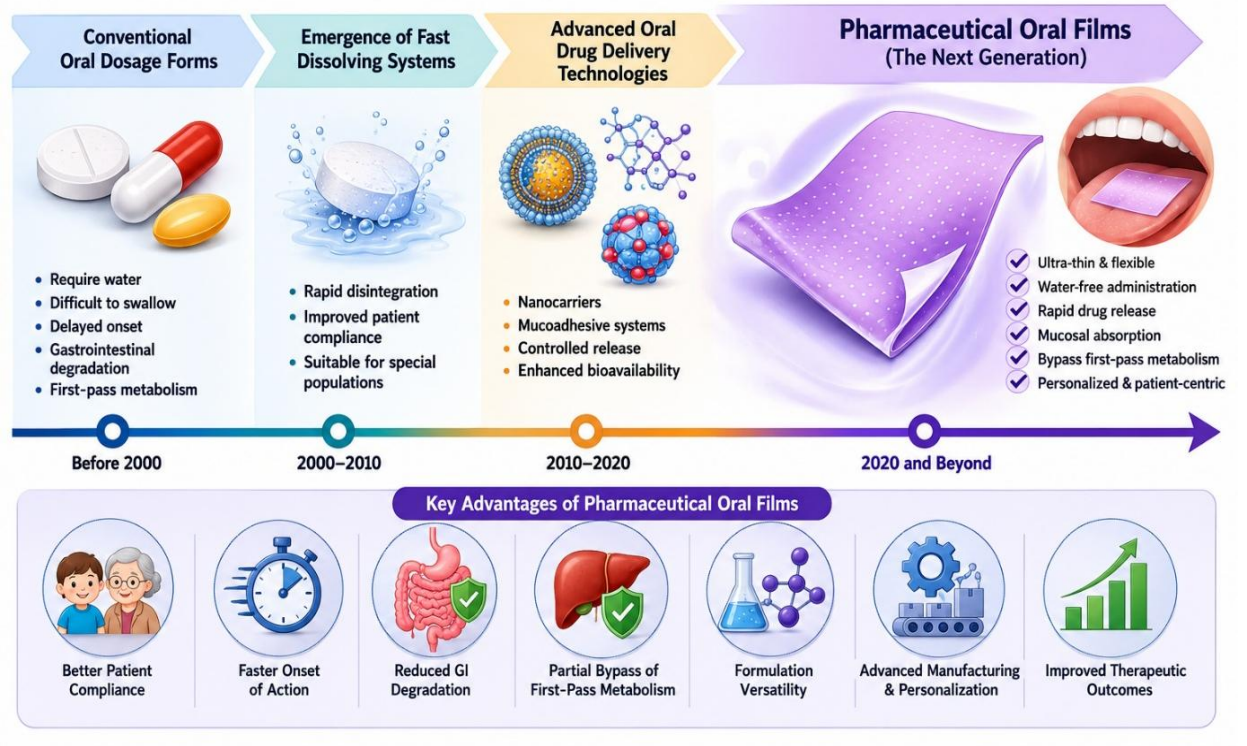

Fig 1: Evolution of Oral Drug Delivery Systems and Emergence of Pharmaceutical Oral Films.

II. DEFINITION AND CLASSIFICATION OF PHARMACEUTICAL ORAL FILMS

Definition of Pharmaceutical Oral Films

Pharmaceutical Oral Films Definition

Pharmaceutical oral films (POFs) are thin, flexible polymeric dosage forms that are meant to deliver active pharmaceutical ingredients (APIs) into the mouth cavity for local or systemic therapeutic effects. They are usually composed of one or more hydrophilic film forming polymers incorporating the drug and functional excipients such as plasticizers, sweeteners, flavouring agents, saliva stimulants and stabilizers for imparting required mechanical strength, flexibility, rapid disintegration and acceptability to the patient. Depending on the formulation design and place of administration, POFs may be designed to dissolve quickly, disintegrate or stick to the oral mucosa for local drug delivery inside the oral cavity or systemic distribution via buccal and sublingual absorption. POFs are particularly useful for those with swallowing issues since they do not require much or any water for administration unlike typical oral solid dose forms. Their large surface area, thin structure, and close contact with the oral mucosa promote rapid hydration and drug release, and buccal and sublingual delivery may partially bypass gastrointestinal degradation and hepatic first-pass metabolism, thereby enhancing systemic drug availability for appropriate drug candidates.[3,4,31,33]

The composition and performance of POFs can be customized according to the physicochemical parameters of the integrated medication and intended therapeutic use. They can be developed, depending on the desired release profile, as immediate-release, mucoadhesive or controlled-release systems. Recent advances in formulation technologies, including nanocarrier-based delivery systems, amorphous solid dispersions, taste-masking strategies, and 3D printing, have further expanded the versatility of POFs, making them a promising platform for patient-centric and personalized drug delivery.[6,8]

Classification of Pharmaceutical Films for Oral Use

Pharmaceutical oral films (POFs) can be categorized based on their location of administration, drug release characteristics, structural design, and functional features. This categorization gives the systematic approach to pick optimal formulation methods, manufacturing procedures and assessment parameters according to the desired therapeutic use (Table 1).

According to Site of Administration

POFs are classified as orodispersible, buccal and sublingual films according on the place of delivery. Orodispersible films dissolve fast in saliva and release the medicine for ingestion or partial absorption through the oral mucosa and hence are especially useful for juvenile, geriatric and dysphagic patients. Buccal films are put in the inner cheek and are intended to provide sustained local or systemic drug administration via transmucosal absorption, whereas sublingual films are placed under the tongue for quick systemic absorption through the highly vascularized sublingual mucosa.[9,11]

According to Drug Release Characteristics

Based on the drug release behavior, POFs are divided as immediate-release, delayed-release, and controlled-release films. Immediate release films offer immediate medication release and beginning of action. Controlled release formulations use mucoadhesive polymers or multilayer systems to extend drug release over a longer period of time. Delayed-release films, although less frequent, are formulated to provide site-specific or time-dependent drug release.

According to Structural Design

Depending on the structural architecture, POFs can be designed as monolayer, bilayer or multilayer films. Single-layer films consist of a homogenous drug-polymer matrix and are usually utilized for quick drug release. On the other hand, bilayer and multilayer films enable the sequential release of drugs, better flavor masking, increased mechanical strength or the combination of numerous active medicinal ingredients in a single dosage form.[13]

Functional Properties Based

Functionally, POFs may be classified as fast-dissolving, mucoadhesive, taste-masked and modified-release films. Each kind is prepared to fulfill the individual therapeutic needs such as quick drug administration, better palatability, increased mucosal residence time, and controlled drug release.[14,15]

POF's flexibility means they can be used in a wide range of medicinal applications. The choice of an acceptable film type is mainly based on the

physicochemical qualities of the medication, the required release profile, the targeted patient group and the proposed therapeutic application.

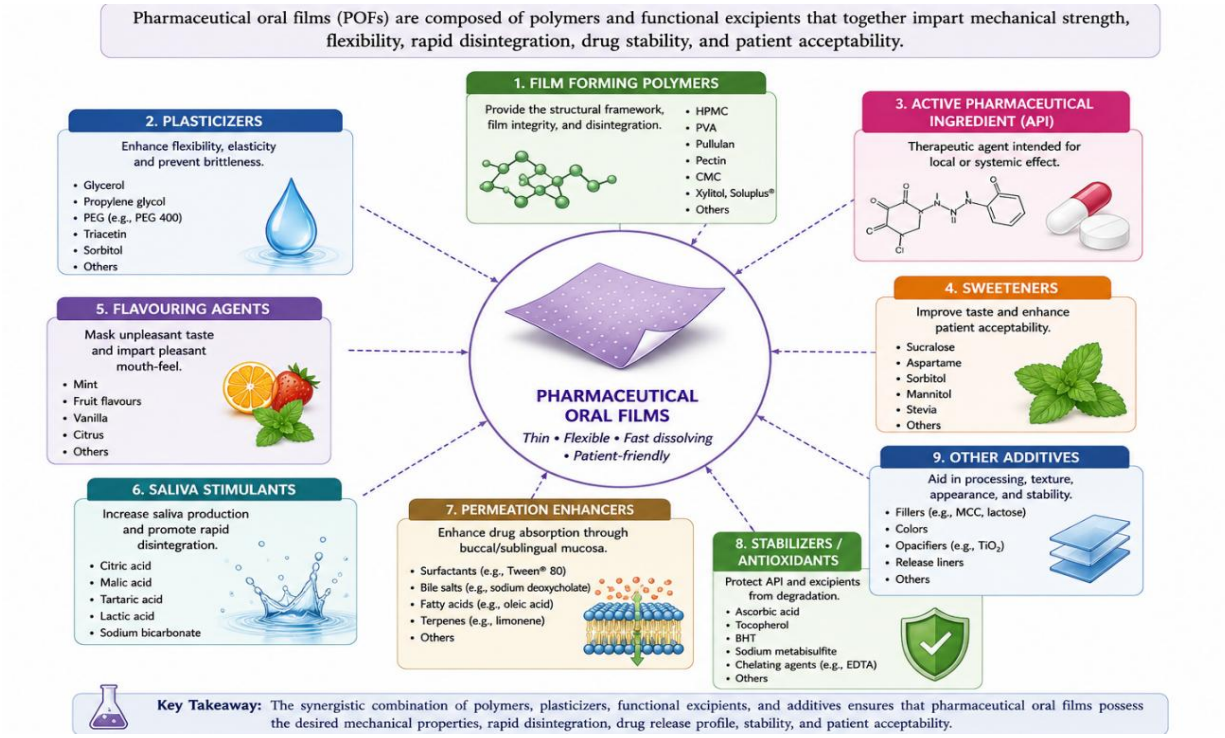

Figure 2. Classification of Pharmaceutical Oral Films Based on Site of Administration, Drug Release Characteristics, Structural Design, and Functional Properties.

Table 1. Classification of Pharmaceutical Oral Films with Characteristics, Representative Drug Examples, Commercial Products, and Therapeutic Applications [3,4,5,13,21,22]

Classification	Subtype	Characteristics	Representative Drug Examples	Commercial Product(s)	Therapeutic Applications
Based on Site of Administration	Orodispersible Films (ODFs)	Thin films that rapidly disintegrate in saliva without the need for water, enabling quick drug release and improved patient compliance.	Ondansetron, Rizatriptan, Donepezil	Zuplenz® (Ondansetron), Exservan® (Riluzole)	Nausea and vomiting, migraine, Alzheimer's disease, amyotrophic lateral sclerosis (ALS), pediatric and geriatric therapy
	Buccal Films	Mucoadhesive films applied to the inner cheek for local or	Fentanyl, Miconazole, Propranolol	Onsolis® (Fentanyl), Belbuca® (Buprenorphine)	Breakthrough cancer pain, chronic pain management, oral fungal

		systemic drug delivery with prolonged residence time.			infections, cardiovascular disorders
	Sublingual Films	Administered beneath the tongue for rapid transmucosal absorption while minimizing first-pass metabolism.	Buprenorphine, Naloxone, Asenapine, Apomorphine	Suboxone® (Buprenorphine/Naloxone), Kynmobi® (Apomorphine)	Opioid dependence, Parkinson's disease ("OFF" episodes), schizophrenia, angina
Based on Drug Release Characteristics	Immediate-Release Films	Rapid hydration and dissolution for fast therapeutic action.	Ondansetron, Cetirizine, Sumatriptan	Zuplenz®, Listerine® PocketPaks (breath strips; non-drug example)	Motion sickness, allergic disorders, migraine, emergency therapy
	Controlled-Release Films	Formulated using mucoadhesive or multilayer polymer systems to sustain drug release.	Lidocaine, Clotrimazole, Propranolol	Mostly investigational formulations	Oral candidiasis, chronic pain, cardiovascular disorders
	Delayed-Release Films	Designed to release the drug after a predetermined lag period or in response to physiological stimuli.	Experimental APIs	Currently under research	Chronotherapy and targeted drug delivery
Based on Structural Design	Single-layer Films	Drug and excipients are uniformly dispersed within a single polymeric matrix; simple and economical	Ondansetron, Sildenafil	Zuplenz®	Immediate-release therapy

		manufacturing.			
	Bilayer Films	Two distinct layers allow separation of incompatible drugs or combination of immediate and sustained drug release.	Combination drug formulations	Investigational products	Combination therapy and sequential drug delivery
	Multilayer Films	Multiple functional layers improve taste masking, drug stability, and controlled release.	Experimental formulations	Under development	Advanced and personalized drug delivery
Based on Functional Characteristics	Fast-Dissolving Films	Rapid disintegration (typically within 30–60 s), ensuring quick onset of action.	Ondansetron, Cetirizine	Zuplenz®	Emergency conditions, pediatric and geriatric use
	Mucoadhesive Films	Adhere firmly to oral mucosa for prolonged drug residence and enhanced absorption.	Lidocaine, Triamcinolone acetonide, Miconazole	Loramyc® (Miconazole Buccal Tablet*)	Oral ulcers, periodontal diseases, oral candidiasis, local anesthesia
	Taste-Masked Films	Incorporate sweeteners, flavours, cyclodextrins, or coated drug particles to improve palatability.	Levocetirizine, Paracetamol	Various pediatric investigational formulations	Pediatric drug delivery and bitter-tasting drugs
	Modified-Release Films	Engineered using advanced polymers for sustained, pulsatile, or site-specific drug release.	Experimental formulations	Under development	Chronic disease management and personalized medicine

III. ADVANTAGES & DISADVANTAGES OF PHARMACEUTICAL ORAL FILMS

Pharmaceutical oral films (POFs) have emerged as a feasible patient-centric medicine administration technology since they may overcome various limitations of conventional oral dosage forms. Their simple administration, rapid degradation, formulation flexibility and bioavailability improvement abilities have widened their usage in a lot of therapeutic areas. These advantages are nonetheless still limited by the formulation, manufacturing and regulatory barriers to their large-scale adoption.

An important feature of POFs is that they do not require water for administration and are therefore especially suitable for juvenile, geriatric, dysphagic and immobile patients. Their thin structure and large surface area allow quick hydration and drug release leading to a faster onset of action than certain conventional oral dose forms. In addition, buccal and sublingual methods may bypass some of the gastrointestinal degradation and first pass metabolism in the liver, hence improving systemic availability of the medicine for eligible patients. Taste-masking agents, permeability boosters and advanced polymers have been added to increase formulation flexibility and patient compliance. In addition, innovative manufacturing techniques such as hot-melt extrusion, inkjet printing, and three-dimensional (3D) printing have facilitated the development of tailored oral films with better dose precision and therapeutic effectiveness.Despite these benefits, there are still a number of hurdles. The drug loading capacity of POFs is constrained, which limits the application in potent drugs requiring low doses. The film thickness, mechanical properties and disintegration behavior may be adversely influenced by higher drug loading. Hydrophilic polymers are sensitive to moisture and should be packaged in a way that maintains product stability throughout storage. Other formulation challenges include proper taste masking, homogenous drug distribution, and maintaining consistent mechanical properties throughout large-scale manufacture. Moreover, regulatory guidances are being developed on oral film formulations that emphasize the need for common quality evaluation methods and robust manufacturing procedures. Ongoing advances in polymer science, solvent-free manufacturing techniques and digital pharmaceutical engineering are projected to minimize these limitations and encourage the wider clinical use of pharmaceutical oral films.

Table 2. Advantages and Limitations of Pharmaceutical Oral Films [2,3,5,13,31]

Advantages	Scientific Significance	Limitations	Possible Strategies to Overcome
Easy administration without water	Improves patient compliance, especially in pediatric, geriatric, and dysphagic patients	Limited drug loading capacity	Nanocarriers, multilayer films, amorphous solid dispersions
Rapid disintegration and drug release	Faster onset of therapeutic action	Moisture sensitivity	Moisture-resistant packaging, optimized polymers
Partial avoidance of first-pass metabolism	Improved bioavailability for suitable drugs	Poor mechanical strength	Polymer blending and optimized plasticizer concentration
Accurate dose uniformity	Improved dosing precision	Taste masking challenges	Cyclodextrins, ion-exchange resins, microencapsulation
Improved patient acceptability	Better adherence to long-term therapy	Uniform drug distribution	Process optimization and Quality by Design (QbD)
Flexible formulation design	Immediate, sustained, and mucoadhesive drug delivery	Manufacturing complexity	Continuous manufacturing and hot-melt extrusion
Suitable for personalized medicine	Dose customization using 3D printing	Limited regulatory guidelines	Harmonized regulatory standards and validation protocols

Portable and convenient	Easy handling and transportation	Higher production cost	Scale-up optimization and automated manufacturing

IV. FORMULATION INGREDIENTS OF PHARMACEUTICAL ORAL FILMS

The performance of pharmaceutical oral films (POFs) is mainly controlled by the careful selection and adjustment of formulation components. Each excipient has a role not only in the physicochemical and mechanical characteristics of the film but also in its disintegration behavior, drug release profile, stability and patient acceptance. An ideal oral film should have sufficient mechanical strength to resist handling and packing but still be flexible enough to be easily handled, hydrated rapidly, distribute the medicine uniformly, and have desirable organoleptic properties. Hence, the selection of formulation excipients is dictated by the physicochemical characteristics of the active pharmaceutical ingredient (API), the planned route of administration, the desired drug release profile, and the manufacturing process applied.[2,3,21]
The main components of formulation of pharmaceutical oral films include film forming polymers, active pharmaceutical compounds, plasticizers, sweeteners, flavouring agents, saliva stimulating agents, surfactants, permeability enhancers, colourants and other functional excipients. The synergism between these substances offers a stable, versatile and patient-friendly dose form with optimum therapeutic effectiveness. Recent advances in formulation science have further simplified the use of nanocarriers, amorphous solid dispersions, cyclodextrin complexes and lipid-based delivery systems to improve drug solubility, bioavailability and taste masking, thus expanding the applicability of oral film technology to a wider range of drug molecules.[2,3,21]

4.1 Active Ingredient (API)

The therapeutic component is the active pharmaceutical ingredient inserted in the matrix of the polymeric film. Selection of suitable API is one of the most crucial factors in oral film formulation, as its physicochemical qualities directly affect drug loading, film integrity, disintegration behavior, dissolving rate and overall therapeutic efficacy . Drugs for distribution as oral films should ideally be low dosage, have sufficient water solubility, be adequately stable and possess appropriate permeability through the oral mucosa. Oral film-based administration methods are especially useful for molecules that are subject to substantial hepatic first-pass metabolism or need to have quick commencement of action.[2,4]
The amount of medicine that may be included in an oral film is often restricted by film thickness and mechanical qualities. For most commercially available formulations the drug loading is usually less than 30–50 mg per film however advances in formulation technologies like incorporation of nanocrystals, amorphous solid dispersions and multilayer film design have allowed for higher drug loading without compromising film quality. As part of formulation development, the physicochemical properties of the API, such as particle size, crystallinity, hygroscopicity, and compatibility with formulation excipients should be thoroughly assessed to guarantee content consistency and long-term stability.[2,4]

4.2 Polymers Forming Films

Film-forming polymers are the structural backbone of pharmaceutical oral films and primarily determine film formation, mechanical strength, flexibility, swelling behavior, disintegration time and drug release properties. An ideal polymer should have good film forming ability, non-toxicity, biocompatibility, fast hydration, appropriate mechanical characteristics and compatibility with included medication and other excipients of the formulation. Regulatory approval and simplicity of large scale manufacture are other crucial aspects in the selection of appropriate polymers.[13]
Hydrophilic polymers are the most commonly used as film-forming materials owing to their quick hydration and great patient acceptance. Synthetic polymers such as hydroxypropyl methylcellulose (HPMC), polyvinyl alcohol (PVA), polyvinylpyrrolidone (PVP), polyethylene oxide (PEO) and hydroxypropyl cellulose (HPC) are widely utilized due to their excellent mechanical strength, transparency and repeatability . Also natural polymers including pullulan, sodium alginate, gelatin, chitosan, pectin, starch, xanthan gum and maltodextrin have been developed increasingly due to their biodegradability, biocompatibility and sustainability . Blending polymers is a widely used method to combine the good

features of diverse materials, which improves the flexibility, tensile strength, drug release capabilities, and moisture resistance of the films.The concentration and molecular weight of the polymer are important parameters in the determination of film thickness, folding endurance, tensile strength, surface shape and dissolution behaviour. The disintegration time may be longer and the patient acceptance may be lower for the high polymer concentration, whereas the low polymer content may affect the film integrity and mechanical stability. The adjustment of polymer type and concentration is therefore one of the most critical parts of oral film formulation.[23]

Table 3. Common Film-Forming Polymers Used in Pharmaceutical Oral Films [13,23,24]

Polymer	Category	Major Characteristics	Advantages	Limitations	Typical Applications
Hydroxypropyl methylcellulose (HPMC)	Synthetic	Excellent film-forming ability, rapid hydration	Transparent films, good mechanical strength	Moisture sensitive	Immediate-release oral films
Polyvinyl alcohol (PVA)	Synthetic	High tensile strength and flexibility	Excellent mechanical properties	Relatively slow disintegration	Buccal and mucoadhesive films
Polyvinylpyrrolidone (PVP)	Synthetic	Highly water soluble	Rapid dissolution	Hygroscopic	Fast-dissolving oral films
Hydroxypropyl cellulose (HPC)	Synthetic	Flexible and compatible with many APIs	Good film elasticity	Moderate moisture uptake	Oral and buccal films
Polyethylene oxide (PEO)	Synthetic	Excellent flexibility	Suitable for hot-melt extrusion	Thermal sensitivity	Controlled-release films
Pullulan	Natural	Transparent, edible, oxygen barrier	Rapid dissolution and pleasant mouthfeel	High production cost	Orodispersible films
Sodium alginate	Natural	Bioadhesive and biodegradable	Controlled drug release	Poor mechanical strength alone	Mucoadhesive films
Chitosan	Natural	Mucoadhesive and permeation-enhancing	Improves mucosal absorption	Limited solubility at neutral pH	Buccal drug delivery
Gelatin	Natural	Excellent film-forming ability	Biocompatible and flexible	Moisture sensitive	Fast-dissolving films
Pectin	Natural	Biodegradable polysaccharide	Good mucoadhesion	Requires polymer blending	Buccal formulations
Maltodextrin	Natural	Water soluble and palatable	Rapid disintegration	Low mechanical strength	Pediatric oral films
Starch	Natural	Renewable and inexpensive	Biodegradable	Brittle without plasticizer	Orodispersible films

4.3. Plasticizers

Plasticizers are important excipients in pharmaceutical oral films since they increase flexibility, elasticity and mechanical integrity of the film and reduce brittleness during handling, packing and storage. They act to decrease the intermolecular interactions between neighboring polymer chains, which increases the polymer mobility and reduces the glass transition

temperature (Tg). Thus, plasticizers allow the manufacture of smooth, flexible films with improved tensile strength, folding endurance, and resistance to cracking. The choice of suitable plasticizer is determined by its compatibility with the film-forming polymer, physicochemical stability, safety profile and effect on drug release characteristics. Plasticizers are usually added in the range of 5–30% (w/w) of the polymer weight depending on the kind of polymer and the desired film qualities. Too much plasticizer makes the film too soft or too tacky, with poor tensile strength and extensive drying times. Too little plasticizer frequently makes the film brittle and breaks when handled. Thus, plasticizer concentration optimization is a vital stage in formulation development.

Glycerol, propylene glycol, polyethylene glycol (PEG 400 and PEG 600), sorbitol and triethyl citrate are the most often used hydrophilic plasticizers for oral films. Of them, glycerol and PEG 400 are especially preferred because they are more compatible with cellulose derivatives and can boost flexibility without impairing drug release. Sorbitol is often included in pediatric formulations for its moderate sweetness and film texture improvement. More recently, citrate esters have been considered due to their decreased hygroscopicity and greater long-term stability over traditional polyols.[23,24]

Besides enhancing flexibility, plasticizers also affect several important quality properties such as moisture absorption, film transparency, disintegration time and dissolution behavior. Therefore, attention should be paid to the choice and concentration of the plasticizer to obtain the ideal balance between the required mechanical properties and fast drug release.

Table 4. Common Plasticizers Used in Pharmaceutical Oral Films [23,24]

Plasticizer	Chemical Class	Primary Function	Advantages	Limitations
Glycerol	Polyol	Improves flexibility and elasticity	Excellent compatibility, economical	Hygroscopic at high concentrations
Polyethylene glycol (PEG 400)	Polyether	Enhances flexibility and reduces brittleness	Good polymer compatibility	May prolong drying time
Polyethylene glycol (PEG 600)	Polyether	Improves mechanical strength	Suitable for stronger films	Higher viscosity
Propylene glycol	Glycol	Reduces film brittleness	Good plasticizing efficiency	Hygroscopic
Sorbitol	Sugar alcohol	Plasticizer and sweetener	Improves palatability	May crystallize during storage
Triethyl citrate	Citrate ester	Enhances flexibility with lower moisture uptake	Good stability	Higher cost
Dibutyl sebacate	Ester	Increases elasticity	Suitable for specialized formulations	Limited use in oral films

4.4 Sweeteners, flavourings and saliva-stimulating agents

Patient acceptance is one of the main factors for the therapeutic success of pharmacological oral films. The dose form is in direct contact with the oral cavity during administration, therefore, unpleasant taste or mouthfeel might significantly affect patient adherence, particularly in juvenile and geriatric populations. Sweetening compounds, flavoring agents and saliva stimulants are therefore commonly added into oral film formulations to increase organoleptic features and to allow quick breakdown.

Sweetening compounds are used mainly to hide the bitter taste of many active medicinal substances. Natural sweeteners include sucrose, glucose, fructose, xylitol, and mannitol and artificial sweeteners such as aspartame, sucralose, saccharin sodium, and acesulfame potassium are often used. Artificial sweeteners are often used because they give strong sweetness at lower levels and decrease the calorie content of the formulation. Sweetener is selected based

on stability, compatibility with other excipients, taste profile and regulatory approval.

Flavouring agents work along with sweets to conceal any lingering bitter taste and to provide a pleasant sensory experience. Commonly added are flavoring agents such as mint, peppermint, orange, lemon, strawberry, vanilla and cherry . The choice of taste is often based on the medicinal indication, the intended patient demographic and regional preferences of consumers.

Saliva-stimulating agents act by boosting the production of saliva soon after delivery, which promotes film hydration and breakdown. For this purpose organic acids such as citric, malic, tartaric, fumaric and ascorbic acids are typically included. In addition to boosting saliva production, these chemicals provide a pleasant feeling in the mouth and enhance the dissolving of hydrophilic polymers. Excessive concentrations may lead to oral discomfort or negatively impact film stability and so need to be optimised accordingly.[3,24]

Table 5. Sweetening Agents, Flavouring Agents and Saliva-Stimulating Agents Used in Pharmaceutical Oral Films [3,24]

Excipient Category	Common Examples	Primary Function	Selection Considerations
Natural sweeteners	Sucrose, Fructose, Glucose, Xylitol, Mannitol	Taste masking and improved palatability	Caloric value, stability, sweetness intensity
Artificial sweeteners	Aspartame, Sucralose, Saccharin sodium, Acesulfame potassium	High-intensity sweetness	Stability, aftertaste, regulatory approval
Flavouring agents	Peppermint, Menthol, Orange, Lemon, Strawberry, Vanilla, Cherry	Improve mouthfeel and patient acceptance	Drug compatibility and patient preference
Saliva stimulants	Citric acid, Malic acid, Tartaric acid, Fumaric acid, Ascorbic acid	Promote rapid hydration and disintegration	Acid strength, concentration, irritation potential

4.5 Surfactants, Permeation Enhancers Colouring Agents and Other Functional Ingredients

Besides the main components of the formulation, pharmaceutical oral films are commonly supplemented with many auxiliary excipients to increase drug solubilization, mucosal penetration, appearance, stability and manufacturability . These excipients are often used in very small quantities, but they contribute significantly to the quality and therapeutic performance of the finished dosage form.

Surfactants lower the surface tension, resulting in better wetting of the polymer matrix and promote the dissolving of weakly water-soluble medicines. Depending on the compatibility with the medicine and the formulation needs, non-ionic surfactants such as Polysorbate 80 (Tween 80), Poloxamer 188, Poloxamer 407 and Sodium Lauryl Sulfate (SLS) are commonly used. Appropriate surfactant selection enhances content homogeneity and speeds drug release without compromising film integrity.

Buccal and sublingual films include permeation enhancers in order to promote the transfer of drugs across the oral mucosa. Common permeation enhancers are oleic acid, sodium deoxycholate, bile salts, menthol, ethanol, dimethyl sulfoxide (DMSO) and Transcutol. These chemicals induce transient alteration in membrane permeability boosting the systemic absorption of the drugs without permanent harm to the tissues.

Colouring agents are introduced mainly to improve the look of the product and to help in the identification of the product. Water-soluble colourants allowed for pharmaceutical usage, such as FD&C colors, iron oxides and titanium dioxide (where permitted) are often included at minimum amounts to ensure consistency without influencing drug release.

Other functional excipients may also include antioxidants, preservatives, buffering agents, anti-sticking agents, and stabilizers to increase the stability and manufacturability of the formulation. Sensitive APIs and preservatives (e.g., methylparaben and propylparaben) may be included in solvent-cast formulations to prevent microbial growth during storage, and antioxidants (e.g., ascorbic acid, butylated hydroxytoluene and tocopherol) reduce the oxidative degradation of sensitive APIs. Buffering compounds

help to maintain optimum microenvironmental pH, hence increasing medication stability and dissolving properties. The choice of these excipients should always take into account the regulatory requirements, safety and compatibility with the other formulation components.[3,4,24]

Table 6. Functional Excipients Used in Pharmaceutical Oral Films [3,4,24]

Excipient Category	Representative Examples	Primary Function	Typical Applications
Surfactants	Tween 80, Poloxamer 188, Poloxamer 407, Sodium Lauryl Sulfate	Improve wetting, drug solubilization, and dissolution	Poorly water-soluble drugs
Permeation enhancers	Oleic acid, Menthol, Sodium deoxycholate, Transcutol®, Ethanol	Enhance transmucosal drug absorption	Buccal and sublingual films
Colouring agents	FD&C dyes, Iron oxides	Product identification and aesthetic appearance	Commercial formulations
Antioxidants	Ascorbic acid, Tocopherol, BHT	Prevent oxidative degradation	Oxidation-sensitive drugs
Preservatives	Methylparaben, Propylparaben	Prevent microbial growth	Solvent-cast formulations
Buffering agents	Sodium citrate, Phosphate buffer	Maintain optimal microenvironmental pH	pH-sensitive formulations
Anti-sticking agents	Talc, Colloidal silicon dioxide	Improve processing and packaging	Industrial manufacturing

V. PRODUCTION TECHNIQUES OF MEDICATED ORAL FILMS

Manufacturing process is one of the important factors affecting quality, mechanical qualities, consistency of drug content, disintegration behavior and performance of pharmaceutical oral films. The choice of the fabrication process depends on the physicochemical qualities of the medicine and excipients, the intended drug release profile, the size of manufacturing, and regulatory constraints. The optimal manufacturing method should yield a homogeneous drug distribution, consistent film thickness, scalability, low residual solvent content and cost-effective production. Traditional methods, such as solvent casting, are still widely used due to their simplicity and flexibility, while new methods, such as hot-melt extrusion, electrospinning and three-dimensional (3D) printing, have received more attention to improve manufacturing efficiency and achieve personalized drug delivery.Solvent casting is recognized as the best proven process available to prepare pharmaceutical oral films since it creates films with great homogeneity and clarity. However, issues with solvent removal, drying time and residual solvent content have led to the development of solvent-free alternatives such as hot-melt extrusion. Emerging methods such as electrospinning, inkjet printing and 3D printing provide further advantages such as exact customisation of doses, continuous manufacture and inclusion of poorly soluble medicines or thermolabile biomolecules. However, these procedures require sophisticated equipment and process improvement for large industrial application.[2,4,24]

Table 7. Manufacturing Techniques Used for Pharmaceutical Oral Films

Technique	Principle	Advantages	Limitations	Typical Applications
Solvent Casting [13,24]	Drug and excipients are dissolved/dispersed in a solvent, cast, and dried to form films.	Simple, economical, excellent content uniformity, suitable for heat-sensitive drugs	Long drying time, residual solvent concerns	Most commonly used laboratory and commercial oral films

Hot-Melt Extrusion (HME) [29,30]	Drug-polymer mixture is melted and extruded through a die without solvents.	Solvent-free, continuous production, scalable, improved drug dispersion	Not suitable for thermolabile drugs; requires high temperatures	Immediate-release and amorphous solid dispersion films
Semi-Solid Casting	Gel-like mass is cast and dried to produce films.	Suitable for acid-insoluble polymers and high-viscosity systems	Limited industrial application	Controlled-release films
Rolling Method[30]	Drug solution is continuously spread onto a moving substrate and dried.	Continuous manufacturing, uniform thickness	Requires precise process control	Large-scale industrial production
Electrospinning [2,30]	High-voltage electric field generates ultrafine nanofibers that form thin films.	High surface area, rapid dissolution, improved drug solubility	Expensive equipment, scale-up challenges	Poorly soluble drugs, nanofibrous oral films
Inkjet Printing [19,36]	Drug solution is precisely deposited onto preformed films.	Accurate dose personalization, minimal drug wastage	Limited drug loading	Personalized medicine and pediatric formulations
Three-Dimensional (3D) Printing [19,29,36]	Layer-by-layer fabrication of customized oral films.	Precise dose customization, complex geometries, personalized therapy	High equipment cost, evolving regulatory framework	Precision medicine and individualized drug delivery

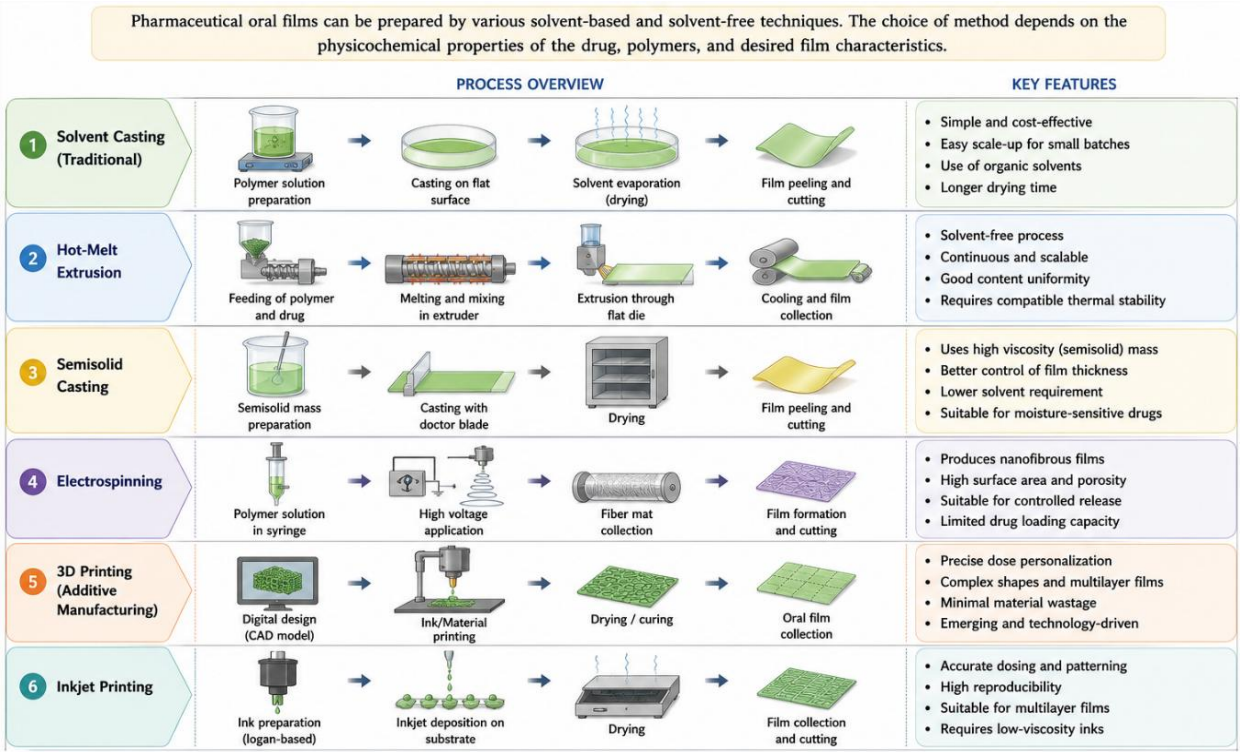

Figure 3. Schematic Illustration of Manufacturing Techniques for Pharmaceutical Oral Films.

VI. PARAMETERS FOR EVALUATION OF PHARMACEUTICAL ORAL FILMS[13,21,24]

Pharmaceutical oral films are physicochemically, mechanically and pharmaceutically evaluated to determine their quality, safety and therapeutic efficacy. These factors are consistency, patient acceptance, stability of the formulation and the distribution of the medicine across the shelf life of the product. Especially for commercial production, there should be standardized evaluation procedures to assure repeatability and regulatory compliance. The selection of assessment methods relies on the desired application, polymer composition, and medication release profile.

Table 8. Evaluation Parameters of Pharmaceutical Oral Films [13,21]

Evaluation Parameter	**Purpose**	**Method/Instrument**	**Expected Outcome**
Appearance	Assess colour, transparency, smoothness, and surface defects	Visual inspection	Uniform, smooth, defect-free film
Thickness	Ensure dose uniformity	Digital micrometer	Uniform thickness throughout the film
Weight variation	Assess formulation uniformity	Analytical balance	Minimal weight variation
Surface pH	Determine mucosal compatibility	Digital pH meter after surface wetting	Approximately neutral (pH 6.5–7.5)
Folding endurance	Evaluate flexibility and mechanical durability	Repeated folding until breakage	High folding endurance without cracking
Tensile strength	Determine mechanical strength	Texture analyzer/Universal testing machine	Adequate tensile strength for handling
Percent elongation	Measure elasticity	Texture analyzer	High elasticity without rupture
Disintegration time	Assess rate of film disintegration	Simulated saliva medium	Rapid disintegration for immediate-release films
In vitro dissolution	Evaluate drug release profile	USP dissolution apparatus	Desired drug release characteristics
Drug content uniformity	Ensure accurate drug distribution	UV-Visible spectroscopy/HPLC	Drug content within pharmacopeial limits
Moisture content	Evaluate residual moisture	Desiccator/Hot air oven	Low residual moisture for improved stability
Moisture uptake	Assess hygroscopicity	Stability chamber	Minimal moisture absorption
Swelling index	Evaluate hydration behaviour	Gravimetric method	Controlled swelling depending on application
Transparency	Assess optical clarity	UV-Visible spectrophotometer	High transparency for patient acceptance
Stability studies	Determine long-term formulation stability	ICH stability conditions	No significant changes in quality attributes

VII. PHARMACEUTICAL ORAL FILMS FOR THERAPEUTIC USE

The unique properties of pharmaceutical oral films, including as fast breakdown, convenience of administration, and enhanced patient compliance, have resulted in their application across a broad spectrum of therapeutic fields. POFs may enable local or systemic drug delivery depending on the place of injection and the formulation approach. The fact that they don't need water is particularly useful for juvenile, geriatric, dysphagic and immobile patients.

Moreover, improvements in formulation technology in the last several years have extended their applicability to the administration of biologics, vaccines and customized medications.[31,33]

Table 9. Therapeutic Applications of Pharmaceutical Oral Films [31,33,34]

Therapeutic Area	Representative Drug(s)	Commercial Product(s)	Clinical Significance
Nausea and vomiting	Ondansetron	Zuplenz®	Rapid antiemetic therapy
Breakthrough cancer pain	Fentanyl	Onsolis®	Rapid pain relief
Chronic pain	Buprenorphine	Belbuca®	Sustained pain management
Opioid dependence	Buprenorphine + Naloxone	Suboxone®	Opioid substitution therapy
Parkinson's disease	Apomorphine	Kynmobi®	Rapid management of "OFF" episodes
Amyotrophic lateral sclerosis (ALS)	Riluzole	Exservan®	Improved administration in dysphagic patients
Migraine	Rizatriptan, Sumatriptan	Investigational formulations	Rapid symptomatic relief
Allergic disorders	Cetirizine, Levocetirizine	Investigational formulations	Fast onset of antihistaminic action
Oral fungal infections	Miconazole	Investigational oral films	Localized antifungal therapy
Pediatric drug delivery	Paracetamol, Vitamins	Investigational formulations	Improved compliance and dose convenience
Nutraceutical delivery	Vitamins, Probiotics	Investigational formulations	Patient-friendly supplementation
Personalized medicine	Patient-specific APIs	3D-printed formulations	Individualized dosing

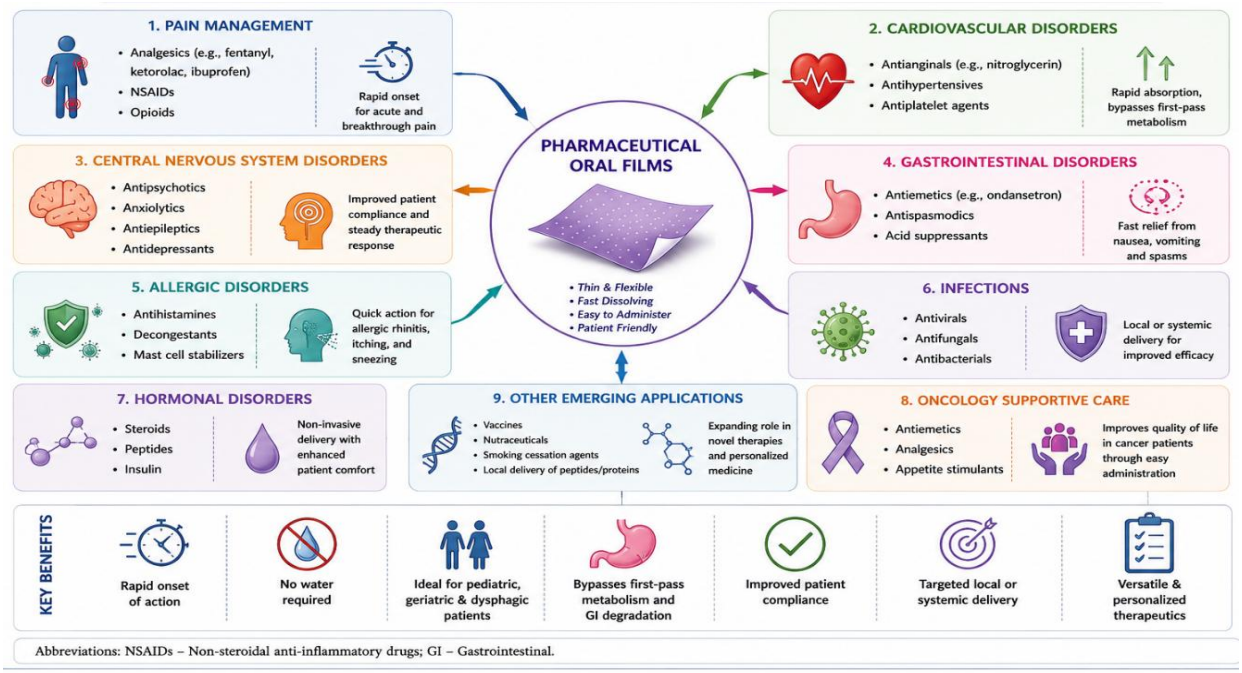

Figure 4. Therapeutic Applications of Pharmaceutical Oral Films Across Different Disease Conditions

VIII. RECENT ADVANCES IN ORAL FILMS FOR PHARMACEUTICAL APPLICATIONS

The area of pharmaceutical oral film has expanded significantly over the past decade, spurred by improvements in material science, pharmaceutical engineering, and precision medicine. Current research is focused on addressing the traditional constraints of oral films, including low drug-loading capacity, poor permeability, limited durability, and difficulty in large-scale manufacture. The incorporation of innovative

excipients, nanotechnology-based drug delivery methods, sophisticated formulation techniques and digital production processes has greatly expanded the therapeutic potential of pharmaceutical oral films.

One of the most important discoveries is the application of nanotechnology for the formulation of oral films. Nanocarriers such as polymeric nanoparticles, solid lipid nanoparticles, nanostructured lipid carriers, nanoemulsions, liposomes and nanocrystals have been successfully incorporated in oral films to improve the solubility, permeability, stability and oral bioavailability of poorly water-soluble drugs. These technologies also provide regulated medication release and targeted distribution, while reducing dose-related side effects. The coupling of nanotechnology with oral film technology has emerged as a viable technique for the delivery of anticancer drugs, peptides, vaccines and other problematic medicinal compounds.[20,25-27,32]

Another significant development is the use of three-dimensional (3D) printing in the manufacture of pharmaceutical oral films. 3D printing provides exact control over the size of the film, drug loading, shape and release properties, which is not possible by conventional production processes. This technology enables customized therapy by tailoring a patient's dosage according to age, body weight, severity of disease or pharmacogenetic profile. Different printing processes are being explored for the manufacture of personalized oral films with improved therapeutic effectiveness, including fused deposition modeling, semi-solid extrusion, and inkjet printing.[19,29,36]

Formulation development and production optimization are being progressively investigated using Artificial Intelligence (AI) and Machine Learning (ML) to speed them. Predictive computational models can be employed to aid excipient selection, optimization of crucial formulation factors, prediction of drug release kinetics, and quality-by-design (QbD) implementation. The combination of process analytical technology (PAT) with artificial intelligence (AI) is projected to enhance production efficiency, save development time, and support regulatory compliance via real-time monitoring of processes.[4,25-27,36]

Recently, there has been a research trend towards the development of multifunctional oral films that can combine numerous treatment techniques in a single dose form. These include multilayer films for sequential drug release, mucoadhesive systems for longer residence duration, stimuli-responsive polymers for site-specific drug release and hybrid formulations with nanoparticles or amorphous solid dispersions. Such advancements have widened the application of pharmaceutical oral films beyond the traditional immediate-release formulations to complex drug delivery platforms for individualized therapy and precision medicine.

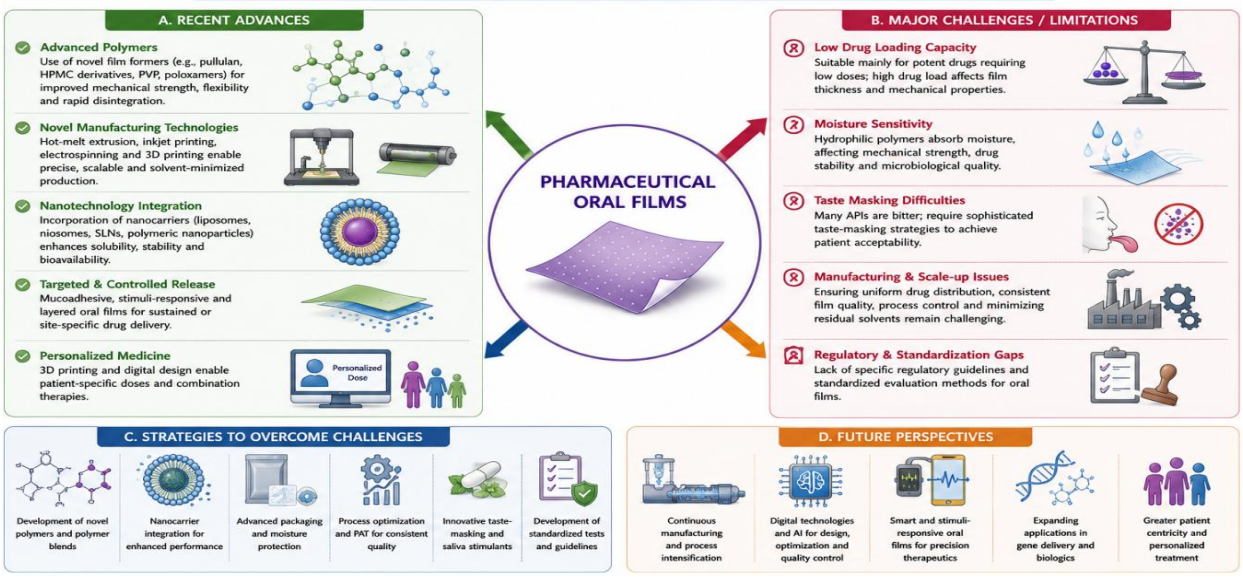

Figure 5. Recent Advances in Pharmaceutical Oral Films: Integration of Nanotechnology, 3D Printing, Artificial Intelligence, Personalized Medicine, and Multifunctional Drug Delivery Systems.

IX. FUTURE OUTLOOK AND CHALLENGES

Despite the advances in formulation design and production technology, the commercialization of pharmaceutical oral films has been limited due to scientific and industrial obstacles. The comparatively modest drug loading capacity limits their use to powerful medications requiring low dosages . The homogeneity of content is more difficult to maintain as the drug concentration increases . Moreover, the hygroscopic property of the typically employed hydrophilic polymers requires appropriate packaging to avoid the breakdown of the films by moisture during storage and shipping.[3,2228,31]

Despite the potential for commercial manufacture and scale-up, process parameters such as drying temperatures, residual solvent content, film thickness, and mechanical qualities must be managed closely to assure uniformity from batch to batch. Regulatory advice for pharmaceutical oral films is continually developing, which creates further obstacles for quality evaluation, production validation, and product clearance. Further harmonization of regulatory criteria and the development of uniform evaluation processes will allow larger industrial deployment of this technology.

Future research will focus on developing biodegradable and sustainable polymers, solvent-free manufacturing techniques, multifunctional drug delivery systems and digital pharmaceutical production. The combination of nanotechnology, artificial intelligence, continuous manufacturing and 3D printing is expected to improve further formulation design, production efficiency and individualized medicine delivery. Also, the application of oral films for biologics, vaccines, gene therapies, and combination medication therapy may greatly extend their clinical relevance. Academic, industrial and regulatory bodies will need to work collaboratively to transform these promising technologies into commercially viable pharmaceutical treatments that meet unmet clinical requirements .[19,29,34,36,37]

X. CONCLUSION

Pharmaceutical oral films are a novel, patient-centric drug delivery platform that efficiently overcomes a number of drawbacks of traditional oral dose forms. Their simplicity of injection, quick release of medication, increased patient compliance and capacity to boost bioavailability have made them an attractive choice for local and systemic drug delivery. Advances in formulation science, polymer technology, and manufacturing techniques have facilitated the production of oral films with improved mechanical qualities, controlled drug release, and greater therapeutic efficacy.

The recent advances of nanotechnology, artificial intelligence and three-dimensional printing have further broadened the reach of pharmaceutical oral films towards the customized medicine and precision medication delivery. However, for future commercialization, major issues remain the drug-loading capacity, moisture sensitivity, large-scale production and regulatory uniformity. Continued multidisciplinary research incorporating new materials, pharmaceutical engineering and digital manufacturing technologies would be expected to hasten the development of next generation oral film formulations with enhanced efficacy, safety and patient acceptance. Thus, pharmaceutical oral films are expected to play a more prominent part in the design of new drug delivery systems.

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