Review Article

Orally Disintegrating Films: Innovations, Advancements, and Challenges

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ABSTRACT

The recent trend in pharmaceutical research leans towards the development of innovative patient-friendly dosage forms to improve the efficacy of the currently existing drugs. An outcome of such research efforts is the advent of orally disintegrating films (ODFs), an innovative 'paper-thin' dosage form that rapidly disintegrates and dissolves into the oral cavity. Such a formulation not only facilitates intraoral absorption, thereby bypassing first-pass metabolism and enhancing bioavailability, but also serves as a preferred dosage form for pediatric and geriatric patients who are susceptible to choking. The design and development of ODFs constitute the core of this review article. Formulation design of ODFs inculcate numerous components ranging from disintegrants, taste-masking agents, and film-forming polymers. Various manufacturing techniques, such as hot-melt extrusion, solvent casting, and the rolling method, are employed in the production of ODFs. Innovations in the ODF technology, such as multi-layered and extended-release films, are also highlighted in this review, emphasizing their potential to improve drug bioavailability. Moreover, common challenges encountered during the formulation of ODFs, such as maximizing drug loading without compromising disintegration time, are also effectively addressed. Additionally, insights from recent clinical studies and patented technologies, like VersaFilm™ and Pharmfilm®, are explored. Future trends point to the potential of personalized medicine through innovations like 3D printing and electrospinning, further expanding the therapeutic applications of these dosage forms.

Keywords: Orally disintegrating films, Film forming polymers, Plasticizers, Bioavailability, Solvent casting, Taste masking.

INTRODUCTION

Orally Disintegrating Formulations:

Numerous literature reports highlight the significant advantages and wide-ranging applications of the oral route for drug delivery. The advantages associated with the route include, but are not limited to, safety, convenience, and cost-effectiveness, as the formulations need not be sterile. Moreover, the delivery is non-invasive and often painless. However, a few drawbacks concerning this route include the difficulty in administering the drugs susceptible to first-pass metabolism, thereby compromising bioavailability, and the inability of paediatric and geriatric patients to use this route due to the risk of choking and difficulty in swallowing.[1–3] Various formulation-based strategies have been explored to counter the aforementioned drawbacks, such as adopting taste-masking techniques, developing pro-drugs, and formulating controlled-release and modified release dosage forms. One such strategy is the development of 'Orally disintegrating' or 'Orally dissolving formulations'. Orally disintegrating formulations are designed to rapidly disintegrate upon placement in the oral cavity, releasing the drug, which disperses and dissolves in saliva, followed by absorption through the pharynx, esophagus, and other segments of the gastrointestinal tract. The orally disintegrating formulations are particularly effective for patients experiencing emesis, those that are unconscious, or face difficulty while swallowing, making them particularly beneficial for paediatric or geriatric patients. Moreover, patients suffering from dysphagia or those with limited access to water can also especially benefit from such dosage forms.[4,5]

Some examples of orally disintegrating formulations include: orally disintegrating tablets (ODTs), orally disintegrating films (ODFs), orally dissolving strips etc.[5,6]

Orally Disintegrating/Dissolving Films (ODFs)

ODFs are another prominently explored type of orally disintegrating formulation. These polymeric films are administered orally and rapidly absorb saliva, leading to their quick disintegration and/or dissolution, thereby releasing the active pharmaceutical ingredient (API), which is subsequently absorbed through the buccal mucosa. ODFs have also been commonly referred to as oral films, oral strips, oral wafers, orodispersible films, orosoluble films, dissofilm, buccal soluble film, and transmucosal film. The European Pharmacopoeia, however, introduced 'Orodispersible films' under a chapter on 'Oromucosal preparations'; while 'Mucoadhesive buccal films' were classified under 'Mucoadhesive Preparations'.[7] The first commercial ODF preparation was introduced by Pfizer in 2001 under the name 'Listerine', which was a mouth freshener. The whopping success of this formulation further led to its expansion into other disease areas. The market for ODFs has been exponentially growing since.

The rapid dissolution of this dosage form can be attributed to the presence of hydrophilic polymers. The size of an ODF extends over an area of 5 to 20 cm^2. The fear of choking associated with ODTs was significantly alleviated with the introduction of ODFs. Moreover, despite extensive instructions of 'do not chew/ do not swallow', numerous incidents of chewing and swallowing of ODTs were reported, which exacerbated adverse effects. The emergence of ODFs relieved the patients of such adverse

effects. ODFs share most of the advantages of ODTs, including rapid disintegration and dissolution, ease of swallowing, no need for water, convenience for pediatric, geriatric, and dysphagic patients, bypassing presystemic metabolism, and higher bioavailability with a rapid onset of action.[8] Some specific advantages of ODFs over ODTs include reduced risk of choking, no expensive lyophilization required, better mechanical strength, and no need for specialized packing systems.[9]

Formulation Components:

A classic ODF consists of an API, a hydrophilic polymer, a plasticizer, a surfactant, a flavoring or sweetening agent, a coloring agent, and a saliva-stimulating agent.[10] Though literature claims that the drug loading in ODFs is restricted to a dose of 15 mg, ODFs can load APIs up to 50% of the unit dose mass. A diverse class of drugs, including antidepressants, antiasthmatics, antiemetics, and vasodilators can be incorporated in these films.[11] A few examples of APIs which have been incorporated in the ODFs include Diphenhydramine, Dextromethorphan, Phenylephrine HCl, Benzocaine/Menthol, Clonazepam, Ondansetron, etc.[12]

The functional characteristics of an ODF, including disintegration time, drug loading, drug release, and mechanical strength, depend upon the type of polymers incorporated. Atleast 45% of the weight of an ODF is composed of polymers, hence the selection of a polymer/ polymeric system is of immense importance. The polymers must be inert, non-toxic, have good wettability and spreading properties, and good tensile strength. Moreover, they must be inexpensive and have a prolonged stability profile. Hydrophilic polymers of natural and/or synthetic origin, used alone or in combination, are preferred in ODF formulations due to their excellent wettability, biocompatibility, and non-toxic nature. Examples of commonly used polymers include but are not restricted to starch, pullulan, pectin, polyvinyl pyrrolidone (PVP), polyvinyl alcohol (PVA), hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), and poly(ε-caprolactone) (PCL).[13]

Maltodextrin is a water-soluble film-forming polymer preferred for people with celiac disease as it is gluten-free. Films formulated with maltodextrin exhibit superior mechanical strength along with improved physical and chemical stability. Some examples of drugs that have been formulated with maltodextrin as a film-forming polymer include Nicotine, Sildenafil, and Diclofenac.[14] Pullulan is another non-toxic, non-immunogenic, biocompatible polymer that possesses high solubility, structural flexibility, and is considered as safe (GRAS status), hence is widely explored for various biomedical applications.[15] The biological source of pullulan is *Aureobasidium pullulans*. Pullulan possesses excellent film-forming properties, resulting in colorless, soluble, non-toxic, tasteless, heat-sealable films that pose a barrier to antioxidants. HPMC is a commonly used semi-synthetic polymer in oral dosage forms due to its non-toxic nature and good film-forming properties.[16] The swelling property of HPMC appreciably influences the release profile of the active ingredient from the films. Another polymer in the same category is hydroxypropyl cellulose (HPC), which offers the additional benefit of a broader solubility profile, allowing the use of multiple solvents based on the solubility characteristics of the drug.[17] Other advantages of HPC include moderate bioadhesion, and reasonable clarity to the cast films. HPC is an ideal film-forming base for ODFs due to its excellent formability and plasticity.[18] In addition to this, it is also used as a solid binder for its magnificent thermoplasticity and water solubility.

Yoshiko et al. investigated the folding endurance (FE) of ODFs prepared using various hydrophilic polymers with a lab-scale endurance testing model, and examined the correlation between FE values and tensile strength (TS) properties. The film's ability to withstand multiple folds is assessed by its folding endurance (FE) value. A FE value greater than 300 indicates that the film possesses good mechanical properties. Film-forming materials used were HPMC, PVA, and HPC. Glycerine was used as a plasticizer, and Acetaminophen was used as a model drug. The FE test of ODFs included 2 methods: a 'manual-folding method' and a 'mandrel method'. Of the various film-forming polymers, HPMC-ODF was found to be more flexible as it stayed intact till 100 folds. The elevated folding endurance (FE) of HPMC films could be due to their extended polymer chain structure. In addition, films composed of HPMC and PVA with plasticizers, but without the API, exhibited tensile strength (TS) in the range of 0.8–2.4 MPa for HPMC and 0.2–0.7 MPa for PVA. It was also noted that while the incorporation of plasticizers lowered the TS and improved the flexibility of the films, it did not enhance the FE of the HPMC-based films. The TS of all three types of films drastically reduced on the addition of insoluble particles. Similarly, loading of Acetaminophen at a higher level resulted in decreased FE number. The method of preparation also influenced the FE number of ODF.[19]

A plasticizer plays an important role in the formulation of films by lowering the glass transition temperature (Tg) of the polymer, which results in films with improved flexibility and less brittleness. Plasticizers enhance flexibility by reducing intermolecular interactions within polymers through the formation of hydrogen bonds between the polymer and the plasticizer. The addition of plasticizers significantly increases the elongation at break, indicating improved film flexibility. Hence, compatibility with the polymers and the solvent systems should be extensively studied when selecting plasticizers.[20] The hydrophilic polymers commonly used in ODFs are usually compatible with plasticizers such as glycerol, low molecular weight grades of PEGs, phthalate derivatives, citrate derivatives, triacetin, and castor oil. Some plasticizers, such as PEG 400 and citric acid esters, are not used due to their incompatibility with other excipients, whereas propylene glycol is not used due to its unpleasant taste.[21] The plasticizer concentration is typically maintained at 0–20% w/w of the dry polymer weight; deviations from this range

may result in compromised film properties, such as breakage, cracking, or poor adhesion.[22] The ability of a plasticizer to increase the flexibility of ODFs mainly depends on its nature and the type of interaction with the polymer.[23] Furthermore, certain APIs can also act as plasticizers. One such example is the formulation of Ibuprofen with Eudragit RS 30D lowered the Tg and resulted in a clear film. Hence, Ibuprofen showed plasticizer activity. [24]

In a study related to the interplay between the polymer and plasticizer concentration, and drug loading ability of ODFs, Gailany et al aimed to mechanistically develop and analyse extended-release ODF formulations capable of high drug payload. A single-layered and a multilayered film loaded with Ibuprofen were prepared using the solvent casting method to investigate both fast and extended drug release profiles. Higher polymer concentration yielded films with good physical properties like flexibility, transparency, and ease of peeling. The optimum concentration of plasticizers influenced the film flexibility and disintegration times. The cast films were cut into sizes of 2x2 cm. Ibuprofen, when dissolved in ethanol and incorporated into the polymer solution, led to an increase in drug loading capacity from 12.5% w/w to 56.5% w/w, thereby enhancing the film properties. To enhance the overall Ibuprofen content, the films were cut into 2x3 cm sizes, increasing the surface area and resulting in a higher Ibuprofen content of 20.7 mg per ODF. An almost complete drug release was achieved within the first 5 minutes from these larger films. Formulation of multi-layered extended-release ODFs ensured high drug loading and release of Ibuprofen for a longer period. These films were prepared by a different method wherein the Ibuprofen-containing film-forming dispersion was cast and dried in layers. The ODF was loaded with 62.2 mg of Ibuprofen/film. HPMC was used for bioadhesion of the film to the buccal cavity. The in vitro release studies revealed that Ibuprofen release was sustained, and 80% of the drug content was released within 1 h, making it suitable for developing a formulation requiring local action e.g. aphthous ulcers.[11] In another associated study, Renata et al. incorporated the plant *Cordia verbenacea* in the form of ODFs to enhance the systemic release of active phytoconstituents. The excipients employed for these ODFs included pregelatinized starch and HPMC, sorbitol as a plasticizer, and ethyl alcohol as a solvent. These orally disintegrating films were manufactured by the solvent casting method. It was observed that at a maximum concentration of 0.75mg of flavonoids/ ODF, the disintegration time increased by 48% as compared to the film with the lowest extract concentration (0.25 mg of flavonoids/ ODF). *In vitro* release of flavonoids evaluated that the film with lowest concentration of flavonoids, released about 83% of the active within 90 mins, film containing 0.50 mg of flavonoids/ODF released 75% in the same period, and film loaded with 0.75 mg of flavonoids/ODF released only 60% within 120 mins. Regarding the mechanical properties, an increase in the concentration of *C. verbenacea* extract led to a decrease in tensile strength and an increase in elongation. These results indicated that a decrease in cohesiveness of the matrix and elevated polymer chain mobility is due to the extract that may function as a plasticizer. These evaluations concluded that the concentration of active principle influenced the characteristics of films. Therefore, orally disintegrating films have a high competence for maintaining their pharmacological activity and for the transmission of natural bioactive compounds.[25]

Sweeteners and flavoring agents are inherently added in oral formulations to improve their palatability and patient compliance. The concentration of the sweeteners used in ODFs is maintained at 3-4 %. Commonly used natural sweeteners include sorbitol and mannitol; while synthetic excipients include saccharin, cyclamate, Acesulfame-K, and aspartame.[26] The properties of the loaded API and flexibility of the films are affected to a certain extent upon the addition of a sweetener agent.[27] Vardenafil, a drug used for the treatment of erectile dysfunction, was found to show an increase in solubility and absorption when formulated with a sweetener i.e. Sucralose.[28]

Other miscellaneous excipients used in the preparation of ODFs include saliva-stimulating agents (e.g., maleic acid, ascorbic acid, lactic acid), glidants and lubricants (e.g., colloidal silicas, magnesium stearate, talc, corn starch), and coloring agents.[10,23]

Arwa et al. utilized the 3^3 full-factorial design to develop venlafaxine HCl, an anti-depressant drug in the form of an ODF. The study focused on the optimization of the concentration of film-forming polymer, superdisintegrant, and plasticizer, which were HPMC, sodium starch glycolate (SSG), and glycerol respectively. The effects of these factors on disintegration time, swelling index, and dissolution efficiency at 15 min (DE%15) were assessed using statistical models. The ODFs were developed by the solvent casting method and analysed for film thickness, pH, moisture content, drug content, swelling index, folding endurance, in vitro dissolution, and disintegration. The content of Venlafaxine HCl in the prepared ODFs ranged from 87.04% ± 0.99 to 99.36% ± 0.43. The increase in concentration of HPMC and glycerol led to higher water uptake. A higher folding endurance value associated with greater mechanical strength was a direct result of the plasticizer concentration. Use of citric acid as saliva-stimulating agent resulted in an acidic surface pH. The increased concentration of HPMC prolonged the disintegration time, while the concentration of SSG significantly reduced the disintegration time. Increasing the glycerol concentration upto 1.5% lowered the disintegration time, which was then prolonged following a further increase in glycerol concentration. Increasing the concentration of SSG also increased the swelling index owing to the ability of the superdisintegrants to absorb water. However, at very high concentrations of SSG, the gelling effect can prolong the disintegration time. Concerning dissolution efficiency at 15 min (DE%15) values, the increased HPMC concentration significantly decreased the drug dissolution owing to the formation of a thick gel matrix, while an opposite effect was

seen on increasing plasticizer concentration upto 1.5%. Increasing SSG concentration resulted in insignificant decrease in DE%15.[29]

Carvalho et al aimed to develop an ODF composed of HPMC and Guar Gum (GG) loaded with essential oil of *Plectranthus amboinicus* L. optimized by design of experiments using Statistica® software. A 2^4 factorial design was utilized for the development of ODF, wherein the concentrations of HPMC, GG, and drying temperatures were optimized, and the films were assessed for their appearance and disintegration. The ANOVA was used to analyze independent variables. Samples with a high GG content showed the longest disintegration time (average 3661.1s) due to the formation of a polymeric mesh that delayed disintegration. Samples containing higher HPMC concentration (6%w/w) showed increased disintegration time, whereas samples containing 3% HPMC disintegrated rapidly. The film with a composition of 1% GG and 3% HPMC, dried at a temperature of 50°C, was considered as an optimal choice for further investigations. The presence of an additional plasticizer in some formulations showed improved physical and mechanical resistance.[16]

Manufacturing of ODFs

ODFs are commonly manufactured using methods like 'Solvent casting', 'Hot melt extrusion (HME)', 'Solid dispersion extrusion', 'Rolling method', etc. Of these, solvent casting and HME are more commonly preferred. The solvent casting method involves preparing a clear solution of the API, excipients, including polymers and plasticizers, in a common solvent. This solution is dried slowly and under controlled conditions, leaving a uniform, transparent film behind. Vacuum is sometimes applied to remove the entrapped air from the solution, ensuring homogeneity of the film. A teflon plate or petridish is used as the mould. The film is then cut into desired dimensions. Critical processing parameters involved in the solvent casting method include drying temperature and viscosity of the solution. The residual solvent in the film must be restricted and assessed. Large-scale manufacturing involves the use of rollers for pouring the solution on a base, which is then dried. Challenges in the solvent casting method include ensuring uniformity in both film thickness and drug dispersion throughout the film.[5] Pezik et al. aimed to incorporate an antihypertensive drug, Amlodipine besylate (ADB), in pullulan-based ODFs by the solvent casting method using different plasticizers and superdisintegrants. Coloring agents and sweeteners used were FD&C Green and aspartame, respectively. The formulation containing propylene glycol as a plasticizer and crospovidone as a superdisintegrant exhibited desirable morphological and mechanical properties, with disintegration times of 51.3 seconds and 28.8 seconds as determined by the petri plate and drop plate methods, respectively. 78.1% of ADB dissolved within 20 mins, and no toxic effects were seen in cell culture studies on Caco-2 cells. In addition to this, permeability studies of the optimized formulation showed very similar intestinal permeability to that of crude ADB. Solvent casting was thus found to be a feasible method for the formulation of ODFs.[30]

Panraksa et al. aimed to develop an ODF for Phenytoin, a poorly soluble antiepileptic drug, by employing a cosolvent solubilization technique to achieve drug amorphization. Formulations were prepared using the solvent casting method, with polymers, such as PVA and high methoxyl pectin (HMP). The developed ODFs were then characterized for their surface and mechanical properties, and solid-state evaluation was performed using DSC, XRD analysis, and *in vitro* release profile. The formulation comprising 1%w/w of PVA, 0.04%w/w SSG with PEG 400, glycerine, and water as cosolvents had satisfactory properties. The film had a smooth, clear surface with a pH of 7.47. The film disintegrated within 1.44 min. The transformation of Phenytoin present in the film from pure crystalline to a partial amorphous state was confirmed by solid-state analysis. The film incorporating a cosolvent exhibited faster dissolution compared to the formulation without a cosolvent. This indicated that the addition of cosolvents enhanced the solubility and accelerated the dissolution of the poorly soluble API. Incorporating a cosolvent system also improved the flexibility of films by reducing drug crystallinity. However, the cosolvent system failed from the standpoint of disintegration time, as it took a longer time for disintegration than the one without a cosolvent system.[31]

HME has recently gained prominence in the pharmaceutical industry as a preferred method for manufacturing transdermal, transmucosal dosage forms, sustained release tablets, granules, etc. ODFs are manufactured using the HME method by shaping a mixture of API and polymers into films via heating. Compared to solvent casting, the HME method offers advantages such as fewer processing steps, no need for the use of solvent/ water, minimum product wastage, suitability for scale-up, feasibility for drugs susceptible to moisture, and potential for solubility enhancement of hydrophobic drugs. In the HME method, the API and other excipients are dry-blended, followed by their melting and extrusion through a hot-melt extruder. The extruded films are allowed to cool and then cut into the desired dimensions. The success of the process depends upon process parameters including temperature, speed, feeding rate, and pressure conditions. The HME process is, however, unsuitable for thermosensitive drugs and requires costly and specialized equipment.[32]

The rolling method includes the preparation of a mixture of the drug, film-forming polymer, excipients, and solvents termed as "master batch". This is then loaded onto a roller drum, rolled, and dried without external currents and heat using a controlled bottom drying approach where the amount of master batch is predetermined. Once completely dry, the obtained film is cut to the desired shape and size. The metering roller controls the thickness of the films and the commonly used solvent system is water or a hydroalcoholic system.[10] Other methods for manufacturing of ODFs include semi-solid casting that incorporates a

combination of hydrophilic and hydrophobic polymer and solid dispersion extrusion wherein solid dispersion of the APIs are dissolved in a suitable solvent and incorporated into polyols, such as melted PEG. 3D Printing technique has also been employed in recent years to overcome the challenges associated with conventional manufacturing techniques. A Fused Deposition Modeling (FDM) 3D printer is used to produce film of uniform weight and content. The challenge associated with 3D printing includes the instability of taste masking agents which form a separate layer during the manufacturing process.[33]

Electrospinning technique is one of the simplest and versatile techniques used to produce nano- and micro-sized fibers and particles. Electrospinning enhances wettability, porosity, and surface area, which makes it a suitable method for manufacturing ODFs. Birer et al. developed an ODF to improve the solubility and bioavailability of Telmisartan (TEL), an antihypertensive BCS Class II drug. The polymeric solution of Polyvinylpyrrolidone (PVP) K 90 and L -Arginine (alkalizing agent) was prepared in various organic solvent combinations like chloroform, ethanol, methanol, and water. Solutions were electrospun using a NE100 nano-spinner. Assay results indicated a drug loading in the range of 98.5% to 102% in all the solvent combinations. The optimized formulation comprising PVP:TEL:L-Arginine;10:1:0.5 showed disintegration in less than 30 seconds, unlike the formulation composed of PVP:TEL:L-Arginine;10:1:0, which retained its solid state and did not undergo disintegration at all. All the developed formulations could release the complete dose of the drug within 5 minutes, while drug release from the physical mixtures was in the range of 33% to 78%. The drug release from the optimized formulation was found to be much faster than the marketed product (Micardis®). The optimized nanofibers exhibited tensile strength and elongation at break values of 7.6 ± 1.2 MPa and 19.6 ± 2.5%, respectively. This justifies the potential of electrospinning as a rapidly developing method for the development of ODFs.[34] Table 1 enlists a few patented platform technologies for the development of ODFs.

Table 1: Patented technologies for the development of ODFs

Name of the Technology	Owner	Process Involved	Advantages/ Characteristics	Drugs Incorporated	References
Pharmfilm®	MonoSol	Solvent casting method	Rapid dissolution and drug absorption	Ondansetron	[35]
VersaFilm™	IntelGenx Technologies Corp.	Solvent casting method	Fast disintegration, immediate onset of action	Rizatriptan	[36]
Thinsol™	BioEnvelop	Solvent casting or Hot melt extrusion	Fast dissolving film, suitable for thermolabile drugs	Tropicamide	[37]
SmartFilm®	Seoul Pharma co Ltd	Solvent casting method	high loading dose capacity, unique taste masking technology	Sildenafil citrate	[38]
BEMA®	BioDelivery Sciences International	Laminated Film Technology (Advanced solvent casting)	bioerodible mucoadhesive, drug delivery technology	Fentanyl	[39]

Evaluation of ODFs

The evaluation parameters for orally disintegrating films mainly comprises organoleptic evaluation followed by the evaluation of mechanical properties such as thickness test which is crucial to assess the dose accuracy of film. TS which is the maximum stress applied to a film until it breaks and dryness or tack test which is performed to determine ability of a film to get adhere to a surface are also evaluated. Percentage elongation which primarily depends upon the quantity of plasticizer used is measured. Increased amount of plasticizer results into enhanced elongation of strip and tear resistance which is the maximum force required to tear the film is also assessed.[40] Evaluation of swelling property included degree of swelling, transparency determined by UV-spectrophotometer carried out at 600 nm wavelength, and contact angle measured using a goniometer. The disintegration time measured using the official apparatus ranged from 5 to 30 secs. Apart from these in vitro tests, surface pH determination by wetting the film using distilled water.[41] pH measurement is significant, so is the measurement of moisture uptake and moisture loss that determines hygroscopicity of film are also evaluated. The taste masking efficiency can also be evaluated with the help of electronic tongue.[42]

Challenges associated with orally disintegrating films and future prospects

Innovation is the foundation of the pharmaceutical industry, driving the continuous need to discover new methods for formulation, development, and production. Enhancing or optimizing existing techniques plays a crucial role in advancing pharmaceutical formulations, ultimately shaping a better future for healthcare. This trend is evident in the

development of various dosage forms, including oral dissolvable films (ODFs). The numerous pending patent applications and already granted patents highlight the promising future of ODFs. Their progress as a pharmaceutical formulation is undeniable, underscoring their growing significance in the industry. Although orally disintegrating Formulations (ODFs) have many advantages, there are still several unresolved issues that limit their widespread use. The future of ODFs is two-fold: Large-scale manufacturing to make them widely available and Personalized therapy to tailor treatments to patients. Both approaches have limitations that must be addressed. Currently, large-scale manufacturing is dominated by Solvent Casting Method, but 3D printing could emerge as an important technology for personalized therapies in hospitals and pharmacies.[43] Concerns about stability, shelf life, and environmental impact. One approach is to encapsulate the high-load active substance in nanoparticles and embed them in an adhesive polymeric material.[44] Research is focusing on nanoparticle-based films and exploring functionalized approaches to improve diffusion through the oral mucosa and facilitate systemic targeting of actives. Patient noncompliance is often attributed to the unpleasant taste of the drug. Partial taste masking can be achieved using complexing, cooling, and sweetening agents. Despite the challenges, ODFs have tremendous potential, especially for pediatric and geriatric patients; ODFs can improve patient compliance and are attractive for drug repurposing. ODFs are promising because they are easy to administer, have a rapid onset of action, and are suitable for acute and chronic diseases. Multilayer and sustained-release ODFs, together with 3D printing, expand the potential of oral dissolution formulations and enable patient-specific and personalized therapy.

CONCLUSION

Orally disintegrating films are novel dosage forms that emphasize improving pharmaceutical oral drug delivery systems for paediatric, geriatric, and dysphagic patients, dealing with the difficulty in swallowing conventional dosage forms. These formulations are more favorable due to their ability to bypass the hepatic metabolism while limiting the use of water and providing rapid disintegration. The thin film characteristics of orally disintegrating films also enhance the mechanical stability, providing a rapid drug release. ODFs are widely accessible for hypertension, acidity, allergy, etc. Their significant taste-masking property is the reason for its current success and acceptance in the worldwide market**.**

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