

Orodispersible Films: Advances in Pharmaceutical Development and Optimization

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ABSTRACT

Orodispersible films (ODFs) are thin polymeric matrices designed to disintegrate or dissolve rapidly in the oral cavity, providing an alternative to conventional oral dosage forms by enabling administration without water and enabling rapid onset of action.

This review synthesizes recent advances in ODF formulation, manufacturing technologies (solvent casting, hot-melt extrusion, electrospinning and printing), performance optimization (disintegration, mechanical strength, content uniformity), and regulatory and commercialization considerations.

Orodispersible films represent a significant advancement in pharmaceutical formulations, bridging the gap between traditional oral dosage forms and modern, patient-centered delivery systems. Their unique properties such as rapid disintegration in the oral cavity, ease of use for patients with swallowing difficulties, and enhanced bioavailability make them particularly appealing in the management of various therapeutic conditions, including pediatric and geriatric populations. The

success of ODFs is not only attributed to their user-friendly nature but also to the continuous evolution of excipient technology and manufacturing processes that enhance their stability, efficacy, and patient compliance.

Keywords: Orodispersible film, solvent casting, hot-melt extrusion, electrospinning, 3D printing, Performance optimization, Patent, Commercialization.

I. INTRODUCTION

Patient-centric drug delivery has driven strong interest in ODFs over the past two decades; these systems are particularly suited for pediatric, geriatric, and dysphagic patients because they avoid swallowing difficulties and often provide improved compliance.¹

The defining quality attributes of ODFs include rapid disintegration (often targeted to <30–60 seconds), adequate mechanical properties for handling and packaging, acceptable taste and mouthfeel, and reproducible content uniformity.²

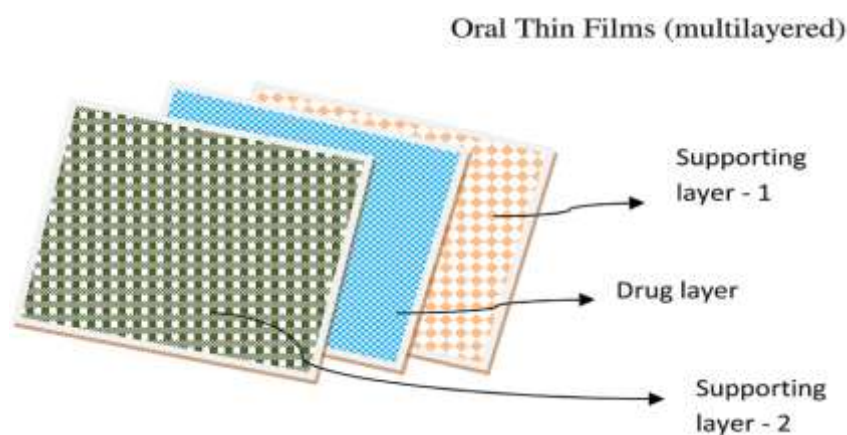


Fig1: Orodispersible film³

Commercial development has been supported by patent activity and continuous manufacturing approaches, but scaling

from laboratory casting methods to industrial processes presents challenges in thickness control, solvent removal, and batch-to-batch uniformity.⁴

Table 1. Comparison of Orodispersible Films with Other Oral Dosage Forms

Parameter	ODFs	Tablets	Capsules
Disintegration	Within 30–60 sec	5–30 min	10–30 min
Need for Water	Not required	Required	Required
Patient Compliance	High	Moderate	Moderate
Manufacturing Complexity	Medium–High	Low	Low–Medium

II. FORMULATION COMPONENTS

Polymers used as film formers are predominantly hydrophilic and include hydroxypropyl methylcellulose (HPMC), pullulan,

polyvinyl alcohol (PVA), sodium alginate, and maltodextrin; polymer selection governs film flexibility, disintegration kinetics, and drug-excipient interactions.⁵

Table 2. Common Excipients in ODFs

Excipient Class	Examples	Function
Polymers	HPMC, Pullulan, PVA, Maltodextrin	Film forming agents
Plasticizers	Glycerol, PEG, Triethyl citrate	Flexibility, elongation
Disintegrants	Crospovidone, Sodium starch glycolate	Rapid breakup
Sweeteners	Sucralose, Aspartame	Taste masking
Solubilizers	Cyclodextrins, Surfactants	Improve solubility

Plasticizers such as glycerol, polyethylene glycol (PEG), and triethyl citrate are added to reduce brittleness and improve elongation; however, plasticizer level must be optimized because excessive amounts can increase tackiness and slow disintegration.⁶

Disintegrants (e.g., cross-linked polyvinylpyrrolidone, sodium starch glycolate) or superdisintegrants are incorporated to accelerate wetting and breakup of the film matrix upon contact with saliva.⁷

Other excipients include sweeteners (sucralose, aspartame), flavors, colorants, and permeation enhancers or solubilizing agents (cyclodextrins, surfactants) used to improve

palatability and bioavailability of poorly soluble APIs.⁸

APIs with poor water solubility or high dose requirements present formulation challenges; strategies include loading as nanosuspensions, solid dispersions, or complexation with ion-exchange resins to balance dose, dissolution and mouthfeel.⁹

III. MANUFACTURING TECHNOLOGIES

There are several **manufacturing methods** for preparing ODFs, each with its own advantages and applications depending on the drug and formulation requirements.

Table 3. Common Manufacturing Methods for Orodispersible Films:

Method	Advantages	Limitations	Applications
Solvent Casting	Simple, lab friendly	Residual solvents	Prototype development
Hot-Melt Extrusion	Continuous, solvent-free	Heat sensitive APIs unsuitable	Scale-up
Electrospinning	Nanofibers, ultrafast dissolution	Low throughput	Poorly soluble APIs
3D Printing	Personalized dosing	Regulatory unfamiliarity	Tailored therapies

A. Solvent Casting Method (Most Common)

Process Overview:

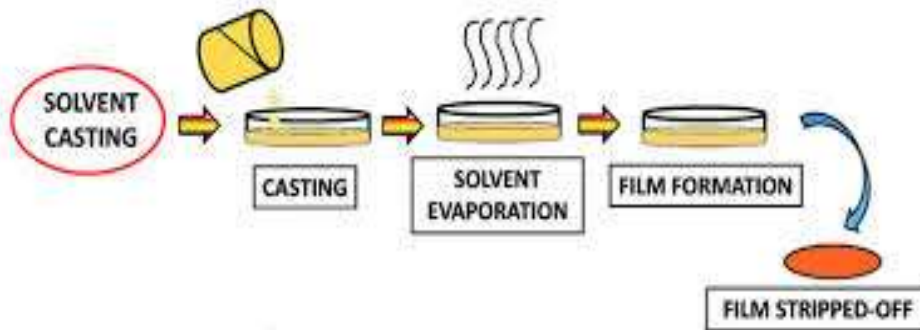


Fig2: solvent casting method ¹⁰

Drug and excipients (polymers, plasticizers, etc.) are dissolved or dispersed in a suitable solvent. The solution is cast onto a flat surface (usually a Teflon plate or stainless-steel plate). The solvent is evaporated under controlled conditions (e.g., heat, air). The dry film is peeled off and cut into desired sizes.

Advantages:

Uniform thickness and drug content.
Good film clarity and flexibility.

Limitations:

Solvent handling and removal can be problematic.
Not suitable for heat- or moisture-sensitive drugs.¹¹

B. Hot-Melt Extrusion

Process Overview:

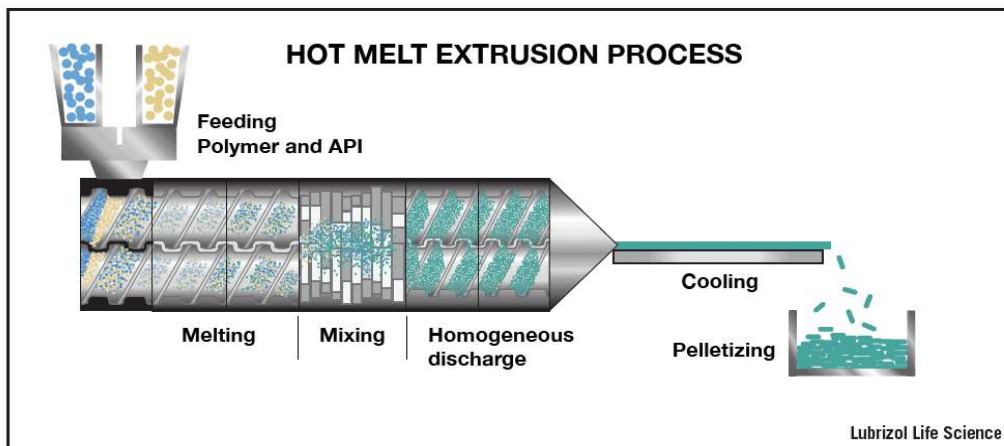


Fig3:Hot melt extrusion process ¹²

Drug and polymers are melted and mixed using an extruder. The molten mass is shaped into a film through a flat die. The film is cooled and cut into units.

Advantages:

Solvent-free process.
Suitable for poorly water-soluble drugs.
Continuous manufacturing.

Limitations:

High temperatures may degrade thermolabile drugs.
Requires specialized equipment.¹³

C. Electrospinning
Process Overview:

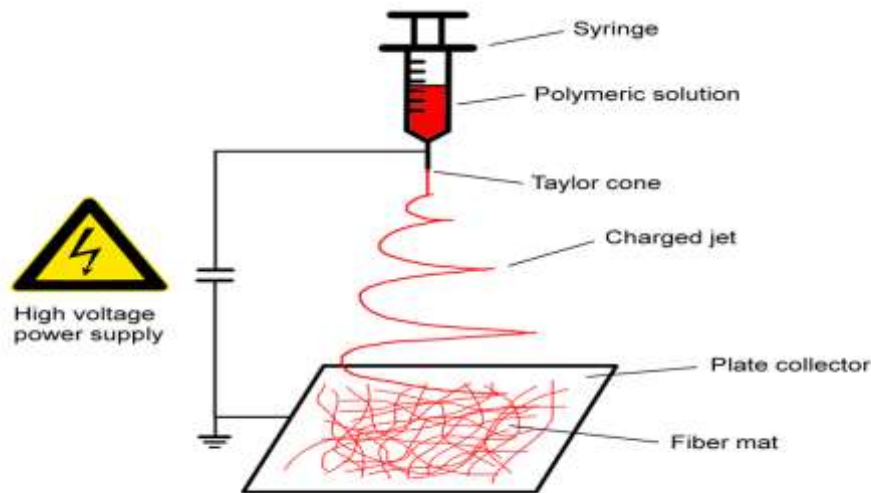


Fig4: Scheme of basic electrospinning setup¹⁴

A drug-loaded polymer solution is placed in a syringe.
 High voltage is applied to form a charged jet (Taylor cone).
 The jet travels to a grounded collector, and solvent evaporates mid-air.
 Solid nanofibers deposit as a non-woven film, which is then cut.

Advantages:

Produces ultra-fast dissolving nanofiber films.
 Enhances solubility and bioavailability.
 Suitable for thermolabile drugs (low-temperature process).

Limitations:

Not yet scalable for large-scale production.
 Sensitive to processing conditions (humidity, voltage, etc.).
 Requires specialized high-voltage equipment.¹⁵

D. 3D Printing(Inkjet Printing)
Process Overview:

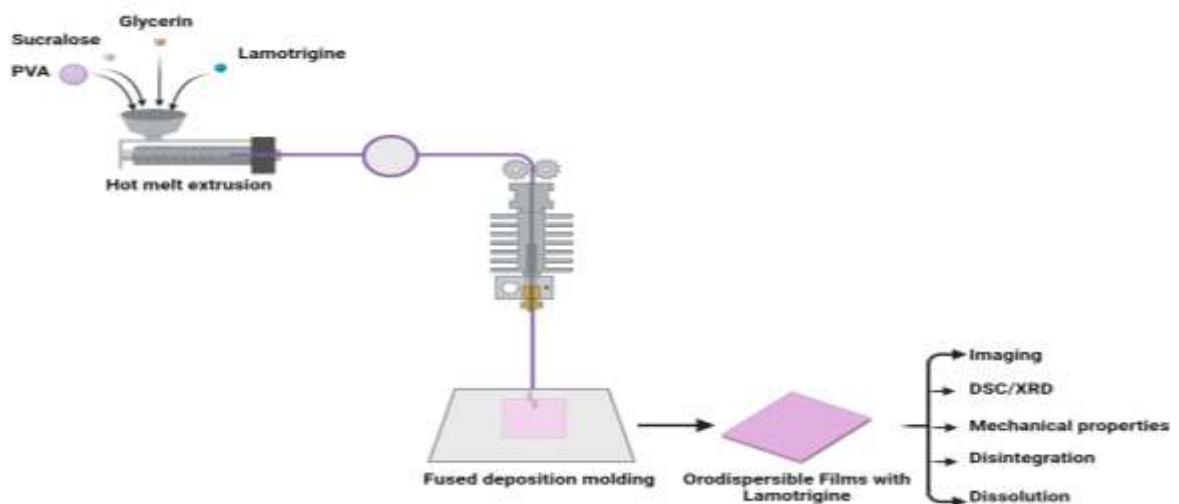


Fig5: 3D printed Orodispersible film¹⁶

A drug-loaded ink (solution or suspension) is prepared.

The ink is printed in precise micro-droplets onto a substrate (usually a pre-formed film or edible base). Multiple passes or patterns can control dose and release.

The printed film is dried and cut into individual units.

Advantages:

Highly precise and customizable dosing.

Suitable for personalized medicine and low-dose drugs.

Minimal material waste.

Limitations:

Limited to low-viscosity inks.

May require compatible substrates.

Still developing for large-scale pharma use.¹⁷

IV. PERFORMANCE OPTIMIZATION

Disintegration time is controlled by polymer hydrophilicity, film thickness, incorporation of disintegrants, and porosity; optimization via design-of-experiments (DoE) is common to balance rapid disintegration with mechanical integrity.¹⁸

Mechanical properties (tensile strength, percent elongation, folding endurance) are critical for handling and packaging. These are typically improved by plasticizers but can be negatively impacted if disintegration enhancers are overused.¹⁹

Content uniformity is vital for dose accuracy, particularly for potent APIs; manufacturing controls focus on thorough mixing, precise casting or extrusion, and in-process monitoring to limit variability.²⁰

Strategies to enhance solubility and bioavailability in ODFs include incorporation of drug nanoparticles, solid dispersions, cyclodextrin complexes, and lipid-based carriers; several studies demonstrated improved dissolution rates and in vivo performance after such incorporations.²¹

Taste masking remains a central aspect of acceptability: approaches include complexation (resins, cyclodextrins), coating of drug particles, use of bitter blockers and flavorants, and selection of excipients that reduce API exposure to taste buds during disintegration.²²

V. EVALUATION AND CHARACTERIZATION

Standard quality tests for ODFs include thickness and weight uniformity, folding endurance, tensile strength and elongation, surface pH, moisture content, and disintegration time measured in simulated saliva.²³

Dissolution testing adapted to thin films uses small-volume apparatus and simulated saliva or dissolution media chosen to mimic buccal or oral cavity conditions; release kinetics are modeled to predict in vivo uptake.²⁴

Solid-state characterization (X-ray powder diffraction, DSC, FTIR, Raman mapping) is used to evaluate crystallinity, API-excipient interactions, and the success of amorphization strategies such as solid dispersions.²⁵

Advanced imaging (SEM) and particle-size analysis confirm distribution of nanoparticles or drug crystals within the film matrix, which is correlated with release and mechanical behavior.²⁶

VI. APPLICATIONS AND CASE STUDIES

Applications of Orodispersible Films (ODFs)

Orodispersible films (ODFs) represent a versatile and patient-friendly drug delivery platform, offering rapid disintegration in the oral cavity without the need for water, which enhances compliance particularly for pediatric, geriatric, and dysphagic patients. As detailed in the reviewed article, ODFs can be formulated for either local or systemic absorption, leveraging the buccal mucosa's rich capillary network and large surface area (approximately 170 cm²) for efficient drug uptake via paracellular and transcellular pathways. This makes them suitable for a broad spectrum of therapeutic applications, from chemical drugs to vaccines, probiotics, and herbal extracts, addressing limitations of traditional oral forms like low bioavailability and swallowing difficulties.²⁷

One primary application is in oral **inflammation management**. Common conditions such as oral ulcers, erosive lesions, mucositis, and stomatitis affect up to 20% of the general population and are exacerbated by chemotherapy or radiation therapy, leading to epithelial cell damage and increased infection risk. ODFs provide a protective layer over wound sites, preventing secondary infections and irritation while delivering high local drug concentrations. Unlike gels, ointments, or sprays which suffer from poor bioadhesion, saliva dilution, and imprecise dosing.²⁸

In **cardiovascular diseases**, which cause 17.9 million global deaths annually according to the World Health Organization, ODFs facilitate rapid systemic absorption to ensure quick onset of action. Drugs targeting heart and blood vessel disorders benefit from ODFs' ability to bypass first-pass metabolism via buccal delivery or gastrointestinal tract absorption post-swallowing, making them ideal for conditions requiring frequent dosing without water. The article highlights ODFs' role in improving bioavailability for potent, low-dose agents, such as those used in hypertension or arrhythmia management.²⁹

Pulmonary diseases benefit from ODFs' potential for localized or systemic delivery, such as IvyFilm (16 mg ivy leaves extract) for productive cough relief, aiding expectoration without gastrointestinal degradation.³⁰

ODFs have been developed for a wide range of therapeutic areas including analgesics, antiemetics, antipsychotics, cardiovascular agents, and pediatric vaccines or nutraceuticals; the fast onset and ease of use make them attractive for many indications.

Case studies demonstrate practical solutions: rosuvastatin loaded as a solid dispersion in films improved dissolution and potential bioavailability; nitrendipine nanoparticulate films improved dissolution and provided rapid release.

Taste-masked donepezil resin-complex films showed modified release while improving palatability, illustrating how ion-exchange resins can be effective for bitter CNS drugs.³¹

VII. REGULATORY, PATENTS AND COMMERCIALIZATION

Patent activity for ODF manufacturing and device innovations has been extensive, covering casting methods, specialized substrates, multilayer designs, and printing technologies; intellectual property considerations shape development strategies. From a regulatory standpoint, ODFs must meet standard impurity, stability, residual solvent, packaging, and biocompatibility requirements; regulators also expect justification for novel excipients and manufacturing methods.³²

Commercial adoption has been gradual: while some ODF products have reached the market, challenges in large-scale continuous manufacturing and long-term stability explain the cautious industrial uptake.³³

VIII. CHALLENGES AND FUTURE DIRECTIONS

Key challenges include achieving high-dose loading without compromising disintegration, ensuring long-term moisture stability, achieving content uniformity at scale, and taste masking for bitter APIs. Future directions emphasize personalized medicine (3D printing), hybrid manufacturing (HME + printing), novel polymers with tunable disintegration and mucoadhesion, and integration of nanotechnology for solubility enhancement.³⁴

Regulatory harmonization and development of standardized testing protocols (for disintegration and dissolution specific to films) will facilitate technology transfer and commercialization.³⁵

IX. CONCLUSION

Continued innovation in the formulation and manufacturing processes of orodispersible films will be critical in addressing the evolving needs of healthcare practitioners and patients alike. The potential for integrating personalized medicine approaches, where ODFs can be tailored to match individual patient profiles and therapeutic regimens, presents an exciting opportunity for improving treatment outcomes. Nonetheless, it is essential for researchers, manufacturers, and regulatory bodies to work collaboratively to ensure that advancements in ODF technology are matched with thorough safety assessments and effective commercialization strategies.

Orodispersible films stand at the forefront of pharmaceutical innovation, combining patient-centric benefits with the potential for manufacturing flexibility. Their future success will rely on ongoing research, development of novel technologies, and the establishment of robust regulatory frameworks to support both their safety and efficacy. As the landscape of drug delivery continues to evolve, ODFs will undoubtedly play an increasingly important role in enhancing patient adherence and therapeutic effectiveness across a wide array of indications. With sustained commitment from the pharmaceutical community, the promise of orodispersible films can be fully realized, transforming how medications are delivered and experienced by patients around the world.

REFERENCES

- [1]. Ferlak J., Guzenda W., Osmałek T. Orodispersible Films—Current State of

- the Art, Limitations, Advances and Future Perspectives. *Pharmaceutics*. 2023;15(2):361. <https://doi.org/10.3390/pharmaceutics15020361>
- [2]. Jacob S., Boddu S.H.S., Bhandare R., Ahmad S.S., Nair A.B. Orodispersible Films: Current Innovations and Emerging Trends. *Pharmaceutics*. 2023;15(12):2753. <https://doi.org/10.3390/pharmaceutics15122753>
- [3]. Maram Suresh Gupta, Tegginamath Pramod Kumar, Devegowda Vishakante Gowda Orodispersible Thin Film: A new patient-centered innovation, *Journal of Drug Delivery Science and Technology*, Volume 59, October 2020, 101843
- [4]. Gupta M.S., Gowda D.V., Kumar T.P., Rosenholm J.M. A Comprehensive Review of Patented Technologies to Fabricate Orodispersible Films, 2022;14(4):820, <https://doi.org/10.3390/pharmaceutics14040820>
- [5]. Musazzi U.M., Selmin F., Cilurzo F. Trends in the Production Methods of Orodispersible Films. *Int J Pharm*. 2020;576:119243. <https://doi.org/10.1016/j.ijpharm.2019.119243>
- [6]. Palezi S.C., Silva S., Santos J. Oral Disintegration Films: Applications and Production Technologies. *Pharmaceutics*. 2022;14(8):1582. <https://doi.org/10.3390/pharmaceutics14081582>
- [7]. Salawi A., Alhowyan A.A., Ahmed M.M. An Insight into Preparatory Methods and Characterization of Orodispersible Films. *Pharmaceutics*. 2022;14(7):844. <https://doi.org/10.3390/pharmaceutics14070844>
- [8]. Łyszczarz E., Kurek M., Sosnowska K., Sznitowska M. Electrospinning vs. Casting and 3D Printing Methods for Orodispersible Films. *Pharmaceutics*. 2021;13(8):1122. <https://doi.org/10.3390/pharmaceutics13081122>
- [9]. Asatiani N., Kaminska I., Dobrzynski P. Electrospun HPMC/PEO-blend Orodispersible Films for Rapid Drug Delivery. *Cellulose*. 2023;30:5457–5471. <https://doi.org/10.1007/s10570-023-05137-4>
- [10]. Reuther M., Brandl M., Schubert M.A. Orodispersible Films Prepared by Hot-Melt Extrusion versus Solvent Casting: A Comparative Study. *Int J Pharm*. 2024;648:123456. <https://doi.org/10.1016/j.ijpharm.2024.123456>
- [11]. Borbolla-Jiménez FV, Peña-Corona SI, Farah SJ, Jiménez-Valdés MT, Pineda-Pérez E, Romero-Montero A, et al. Films for wound healing fabricated using a solvent casting technique. *Pharmaceutics*. 2023;15(7):1914.
- [12]. Bala R., Khanna S., Pawar P. Polymers in Fast Dissolving Oral Films: A Review. *Asian J Pharm Clin Res*. 2013;6(1):18–23.
- [13]. Lubrizol Life Science, www.lubrizol.com/industries/healthcare
- [14]. Karki S., Kim H., Na S.J., Shin D., Jo K., Lee J. Thin Films as an Emerging Platform for Drug Delivery. *Asian J Pharm Sci*. 2016;11(5):559–574. <https://doi.org/10.1016/j.ajps.2016.05.004>
- [15]. Teo and Ramakrishna, published by IOP Publishing. *Nanotechnology*, Vol: R89-R106 Year: 2006.
- [16]. Cilurzo F., Musazzi U.M., Franzé S., Selmin F. Polymer Selection for Orodispersible Films: Influence on Mechanical and Dissolution Properties. *Eur J Pharm Biopharm*. 2018;132:103–112. <https://doi.org/10.1016/j.ejpb.2018.09.004>
- [17]. Arafat B, Qinna N, Cieszynska M, Forbes RT, Alhnan MA *Journal Name: International Journal of Pharmaceutics, Volume: 590 Article Number: 119906 Year: 2020 DOI:10.1016/j.ijpharm.2020.119906, https://www.sciencedirect.com/science/article/pii/S0378517320306723*
- [18]. Zaki R.M., Kassem M.A., Mohsen A.M. Fabrication and Characterization of Orodispersible Films Loaded with Solid Dispersion to Enhance Rosuvastatin Calcium Bioavailability. *Saudi Pharm J*. 2022;31(1):135–146. <https://doi.org/10.1016/j.jsps.2022.11.012>
- [19]. Gandhi S., Pandey V., Kaul C.L., Panchagnula R. Nanoparticulate Oral Fast Dissolving Film of Nitrendipine for

- Enhanced Bioavailability. AAPS PharmSciTech. 2021;22(6):218. <https://doi.org/10.1208/s12249-021-02100-z>
- [20]. Kathpalia H., Gupte A. An Overview of the Recent Advances in Orodispersible Films. *Int J Pharm Sci Res.* 2022;13(3):879–896. [https://doi.org/10.13040/IJPSR.0975-8232.13\(3\).879-96](https://doi.org/10.13040/IJPSR.0975-8232.13(3).879-96)
- [21]. Irfan M., Rabel S., Bukhtar Q., Qadir M.I., Jabeen F., Khan A. Oral Thin Films: A New Frontier in Drug Delivery System and Dosage Form Design. *J Appl Pharm Sci.* 2016;6(6):184–191. <https://doi.org/10.7324/JAPS.2016.60629>
- [22]. Polonini H.C., da Silva A.D., Oliveira C.S. Compatibility Assessment of Novel Orodispersible Film Formulations. *J Pers Med.* 2023;13(11):1565. <https://doi.org/10.3390/jpm13111565>
- [23]. Dixit R.P., Puthli S.P. Oral Strip Technology: Overview and Future Potential. *J Control Release.* 2009;139(2):94–107. <https://doi.org/10.1016/j.jconrel.2009.06.014>
- [24]. Peh K.K., Wong C.F. Polymeric Films as Vehicle for Buccal Delivery: Swelling, Mechanical, and Mucoadhesive Properties. *J Pharm Pharm Sci.* 1999;2(2):53–61.
- [25]. Preis M., Knop K., Breitreutz J. Mechanical Strength Test for Orodispersible and Buccal Films: Development and Validation. *Int J Pharm.* 2014;461(1-2):22–29. <https://doi.org/10.1016/j.ijpharm.2013.11.009>
- [26]. Hoffmann E.M., Breitenbach A., Breitreutz J. Advances in ODF Characterization and Performance Testing. *Eur J Pharm Biopharm.* 2011;78(1):151–160. <https://doi.org/10.1016/j.ejpb.2011.01.005>
- [27]. Karki S., Kim H., Na S.J., Shin D., Jo K., Lee J. Thin Films as an Emerging Platform for Drug Delivery. *Asian J Pharm Sci.* 2016; 11(5): 559–574.
- [28]. Sudhakar Y., Kuotsu K., Bandyopadhyay A.K. Buccal Bioadhesive Drug Delivery — A Promising Option for Orally Less Efficient Drugs. *J Control Release.* 2006; 114(1): 15–40.
- [29]. Musazzi U.M., Selmin F., Cilurzo F. Trends in the Production Methods of Orodispersible Films. *Int J Pharm.* 2020;576:119243.
- [30]. Palezi S.C., Silva S., Santos J. Oral Disintegration Films: Applications and Production Technologies. *Pharmaceutics.* 2022;14(8):1582.
- [31]. Zaki R.M., Kassem M.A., Mohsen A.M. Fabrication and Characterization of Orodispersible Films Loaded with Solid Dispersion to Enhance Rosuvastatin Calcium Bioavailability. *Saudi Pharm J.* 2022;31(1):135–146.
- [32]. Irfan M., Jabeen F., Ahmed R. Stability and Evaluation Parameters of Orodispersible Films: A Review. *Curr Drug Deliv.* 2020;17(2):105–113. <https://doi.org/10.2174/1567201816666191205112814>
- [33]. Choudhary D.R., Patel V.A., Patel H.V., Kundawala A.J. Development and Evaluation of Fast-Dissolving Film of Levocetirizine Dihydrochloride. *Int J PharmTech Res.* 2011;3(1):178–187.
- [34]. Karki S., Kim H., Lee J. Formulation Variables Influencing Film Characteristics and Disintegration. *Asian J Pharm Sci.* 2016;11(5):559–574. <https://doi.org/10.1016/j.ajps.2016.05.004>
- [35]. Rowe R.C., Sheskey P., Quinn M. Handbook of Pharmaceutical Excipients. 8th ed. Pharmaceutical Press; 2017.