



Oro dispersible Films: Recent Trends and Formulation Techniques

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Abstract:

Oro dispersible films (ODFs) are an innovative oral drug delivery system designed to rapidly disintegrate and dissolve in the oral cavity without the need for water. Offering improved patient compliance, especially among paediatric, geriatric, and dysphagic populations, ODFs have gained considerable attention in recent pharmaceutical research. This project explores the fundamental concepts of or dispersible films, focusing on their composition, formulation techniques, evaluation parameters, and recent advancements. Key advantages such as ease of administration, faster onset of action, and enhanced bioavailability are discussed, alongside limitations like drug loading capacity and stability concerns. A detailed literature review highlights previous research trends and market-approved ODF formulations. The study also outlines formulation methodologies involving solvent casting, hot-melt extrusion, and electrospinning, backed by analytical evaluation techniques. Overall, the project emphasizes the growing relevance and potential of ODFs in the development of patient-centric drug delivery solutions.

Keywords: Oro dispersible films, drug delivery, solvent casting, patient compliance, formulation techniques, rapid disintegration

Chapter 1: Introduction

1.1 Overview

Oro dispersible films (ODFs) have emerged as a promising and patient-centric dosage form in modern pharmaceutical technology. Designed to disintegrate rapidly in the oral cavity without the need for water, ODFs are especially beneficial for paediatric, geriatric, and dysphagic patients. This innovative approach bridges the gap between conventional solid oral dosage forms and liquid formulations, offering convenience, compliance, and precision.

The growing interest in ODFs is fuelled by the advancement of polymer science, nanotechnology, and drug delivery strategies. Their thin, flexible structure and ability to incorporate a wide variety of active pharmaceutical ingredients (APIs) make them a versatile platform for systemic or local delivery.

1.2 Historical Background

The concept of fast-dissolving formulations was initially developed in the 1970s to address swallowing difficulties. Early products like fast-dissolving tablets (FDTs) paved the way for the development of films. The first commercial

ODF, Chloraseptic® Sore Throat Relief Strips (containing benzocaine), was introduced in the early 2000s. Since then, numerous ODF-based drugs have been approved and marketed globally.

1.3 Definition and Characteristics

According to the European Pharmacopoeia, ODFs are defined as single or multilayered thin films intended to be placed on the tongue or oral mucosa, where they disintegrate rapidly and release the active substance.

Key characteristics include:

- Rapid disintegration (within seconds)
- No need for water
- Convenient and discrete usage
- High patient compliance
- Good mechanical strength and stability

1.4 Advantages of Oro dispersible Films

Advantage	Details
Patient-friendly	Suitable for children, elderly, and bedridden patients
No water required	Useful in situations where water intake is restricted
Improved bioavailability	Avoids first-pass metabolism in some drugs
Ease of administration	Discrete, portable, and easy to handle
Accurate dosing	Better than syrups or drops for children

1.5 Limitations

- Limited drug loading capacity (usually <30 mg)
- Sensitivity to humidity and temperature
- Challenges in taste masking
- Fragility in packaging and transport

1.6 Composition of Oro dispersible Films

Typical components of ODFs include:

- Film-forming polymers (e.g., HPMC, PVA, pullulan)
- Plasticizers (e.g., glycerol, PEG)
- Active pharmaceutical ingredient (API)
- Sweeteners and flavouring agents
- Surfactants and saliva stimulants

1.7 Mechanism of Action

Upon placement on the tongue, the film absorbs saliva, leading to swelling and disintegration. The API is then either absorbed through the oral

mucosa (buccal, sublingual) or swallowed for gastrointestinal absorption.

1.8 Classification of ODFs

ODFs can be classified based on:

- Layering: Monolayered, bilayer, multilayered
- Purpose: Local vs systemic delivery
- API type: Small molecules, herbal extracts, peptides

1.9 Marketed Products and Commercial Trends

Some commercially available ODFs include:

- Zuplenz® (ondansetron) – antiemetic
- Listerine® PocketPaks – oral hygiene
- Suboxone® (buprenorphine/naloxone) – opioid dependence
- Donepezil ODF – for Alzheimer's disease

With increasing demand and innovation, ODFs are expected to capture a substantial share of the drug delivery market in the coming years.

Chapter 2: Formulation Techniques of Oro dispersible Films

The formulation of or dispersible films (ODFs) requires careful consideration of film-forming agents, active pharmaceutical ingredients (APIs), plasticizers, and other excipients to ensure mechanical strength, rapid disintegration, and patient acceptability. Various techniques have been explored for the preparation of ODFs, each with its own advantages and limitations. This chapter provides an overview of the most widely used formulation methods.

2.1 Solvent Casting Method

The solvent casting technique is the most commonly employed method for preparing ODFs. It involves dissolving the polymer and drug in a suitable solvent, followed by casting the solution onto a flat surface and drying it to form a thin film. The dried film is then cut into desired sizes.

Steps Involved:

1. Dissolution of API and excipients in a volatile solvent.
2. Homogenization to ensure uniform dispersion.
3. Casting of the solution on a film applicator.
4. Drying at a controlled temperature.

5. Cutting and packaging.

Advantages: Uniform thickness and drug distribution.

Limitations: Residual solvent issues and long drying time [20].

2.2 Hot Melt Extrusion (HME)

Hot melt extrusion involves the mixing of API and polymer at elevated temperatures, followed

by extrusion through a die to form a film. This solvent-free method is suitable for heat-stable drugs.

Advantages: Solvent-free, continuous process.

Limitations: Not suitable for thermolabile drugs; high energy input [21].

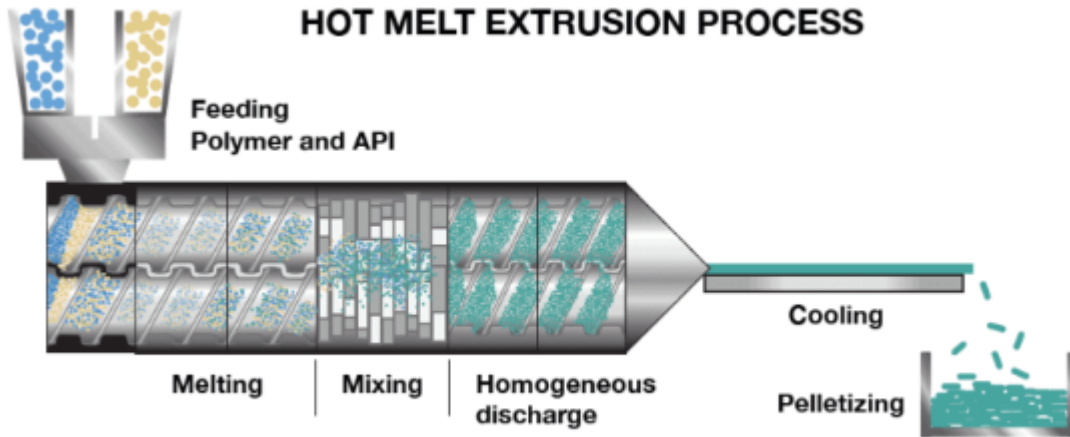


Fig 1

2.3 Semisolid Casting Method

In this technique, a semisolid mass is prepared containing water-soluble polymers and then cast into films. It is an adaptation of the solvent

casting method and is often used when the drug has poor solubility.

Advantages: Suitable for poorly soluble drugs.

Limitations: Requires precise temperature and viscosity control [22].

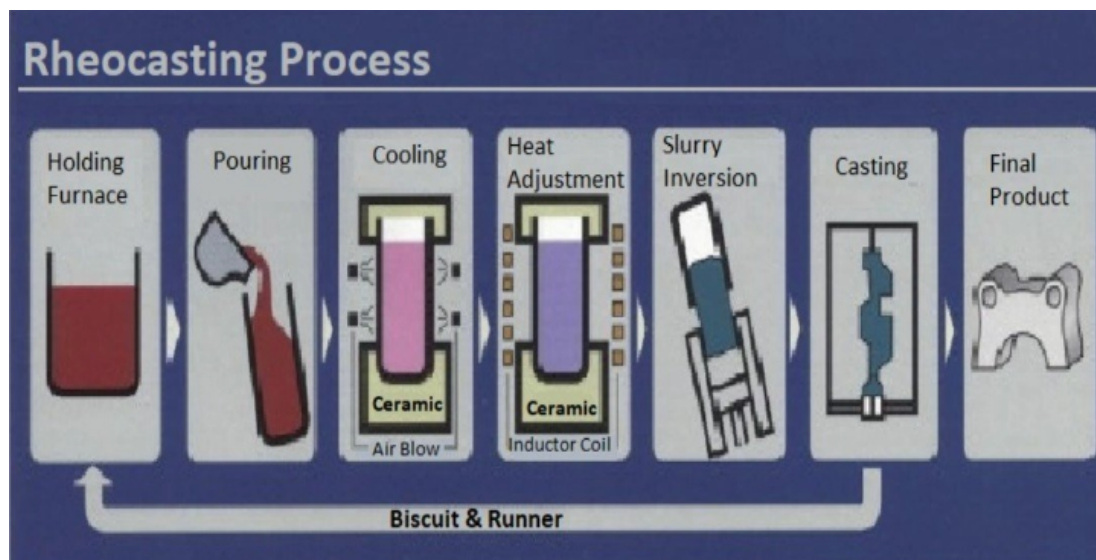


Fig 2

2.4 Electrospinning Technique

Electrospinning is a novel method used for fabricating nanofiber-based ODFs. A polymer solution is exposed to a high-voltage electric field, which causes the formation of nanofibers deposited on a collector.

Advantages: High surface area, enhanced solubility, rapid drug release.

Limitations: Equipment cost, scalability issues [23].

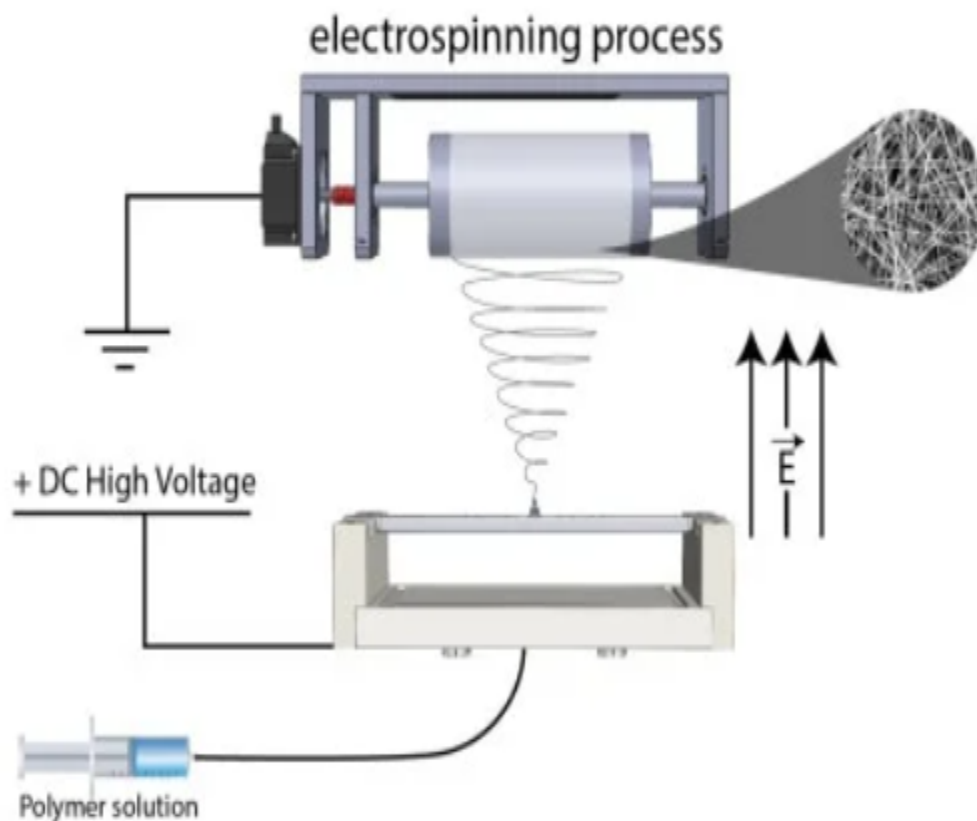


Fig 3:

2.5 3D Printing Technology

Recent developments have enabled the use of 3D printing to produce ODFs with precise drug loading and complex geometries. Inkjet and fused deposition modeling (FDM) are two common 3D printing methods explored.

Advantages: Personalized medicine and controlled release profiles.

Limitations: Costly equipment, regulatory challenges [24].

2.6 Freeze-Drying Technique

In freeze-drying (lyophilization), a drug-polymer solution is frozen and then dried under vacuum. Though more commonly used for or

dispersible tablets, this method has also been adapted for film formulations.

Advantages: Suitable for thermolabile drugs.

Limitations: Time-consuming and expensive [25].

2.7 Spray Drying and Coating Techniques

Spray drying involves atomizing a liquid mixture into a hot air chamber, resulting in the rapid formation of dry particles that are subsequently compressed or coated into thin films.

Advantages: Rapid drying and scalability.

Limitations: Risk of thermal degradation of APIs [26].



Fig 4:

2.8 Comparative Summary of Formulation Techniques

Technique	Advantages	Limitations
Solvent Casting	Uniform film, simple process	Residual solvent, long drying time
Hot Melt Extrusion	Solvent-free, continuous	Not suitable for heat-sensitive drugs
Semisolid Casting	Better for poorly soluble drugs	Needs viscosity and temp. control
Electrospinning	Nanofibers, fast dissolution	High cost, scale-up issues
3D Printing	Personalized films, accurate dosing	Equipment cost, complex regulation
Freeze Drying	Good for sensitive drugs	Cost-intensive, time-consuming
Spray Drying	Fast drying, scalable	Risk of API degradation due to heat

Chapter 3: Evaluation Parameters of Oro dispersible Films

The successful formulation of or dispersible films (ODFs) demands rigorous evaluation to ensure their safety, efficacy, stability, and patient compliance. This chapter outlines the key parameters and standard methods employed to evaluate ODFs.

3.1 Thickness and Uniformity

Thickness of the film is measured using a micrometre screw gauge or digital vernier calliper at different points. Uniform thickness ensures consistent drug content and mechanical strength [27].

3.2 Weight Variation

Films are weighed individually, and the mean and standard deviation are calculated. Minimal

variation indicates uniform drug distribution [28].

3.3 Folding Endurance

Folding endurance is tested by repeatedly folding a film at the same place until it breaks. High endurance suggests good flexibility and resistance to physical stress [29].

3.4 Tensile Strength and Elongation

Mechanical properties such as tensile strength, percent elongation, and Young's modulus are measured using a texture analyser or universal testing machine. These parameters indicate the film's robustness and elasticity [30].

3.5 Disintegration Time

The disintegration time is the period required for the film to break apart in the oral cavity without the need for water. It is typically tested by

placing the film in a Petri dish containing phosphate buffer or simulated saliva [31].

3.6 In Vitro Dissolution Study

Dissolution profiles are studied using USP Type I (basket) or Type II (paddle) apparatus. The medium may include simulated saliva or phosphate buffer. Rapid drug release is characteristic of a well-formulated ODF [32].

3.7 Drug Content Uniformity

Drug content is determined by dissolving a film in a suitable solvent followed by spectrophotometric or chromatographic analysis. The results should comply with pharmacopeial limits [33].

3.8 Surface pH

The surface pH is measured by placing the film in contact with distilled water and using a pH meter. A near-neutral pH is essential to avoid mucosal irritation [34].

3.9 Swelling Index

Swelling behaviour of the film is determined by immersing it in a medium and calculating the weight gain over time. This reflects hydration properties and mucoadhesive potential [35].

3.10 Stability Studies

Stability testing is conducted under ICH-recommended conditions (temperature and humidity) to assess drug content, disintegration time, and physical appearance over time [36].

Table: Key Evaluation Parameters and Their Significance

Parameter	Method	Significance
Thickness	Micrometre, calliper	Uniformity and consistency
Folding Endurance	Manual folding	Flexibility and resistance
Disintegration Time	In vitro in Petri dish	Speed of oral disintegration
Drug Content	UV/Vis or HPLC analysis	Dosage accuracy
Surface pH	pH meter	Safety and comfort in oral cavity
Tensile Strength	Texture analyser	Mechanical robustness
Swelling Index	Weight gain method	Mucoadhesive potential
Stability	ICH-guided storage	Shelf life and reliability

Chapter 4: Recent Advances and Future Trends in Oro dispersible Films

The domain of or dispersible films (ODFs) continues to evolve with emerging technologies and innovations that promise to improve drug delivery efficiency, expand therapeutic applications, and enhance patient compliance. This chapter discusses recent advances and highlights future trends that are likely to shape the next generation of ODFs.

4.1 Nano formulation and Nanotechnology Integration

Recent studies have focused on incorporating nanoparticles, liposomes, and solid lipid nanoparticles into ODFs to improve drug solubility, stability, and bioavailability. These nano-ODFs are particularly promising for

poorly water-soluble and macromolecular drugs [37].

4.2 3D Printing and Personalized Films

Additive manufacturing techniques, such as 3D printing, are being utilized to fabricate ODFs with customized doses and release profiles. Inkjet and fused deposition modeling allow for precision drug loading and patient-specific therapy [38].

4.3 Smart Films and Responsive Materials

Smart ODFs, capable of responding to stimuli such as pH, temperature, or enzymes, are being explored. These films offer site-specific and time-controlled release, potentially useful in targeted drug delivery [39].

4.4 Electrospun Nanofibers and Biopolymer Films

Electrospinning has enabled the creation of nanofibrous ODFs with larger surface area and enhanced drug dissolution. Researchers are also shifting toward biodegradable and sustainable polymers like chitosan and alginate [40].

4.5 Herbal and Nutraceutical ODFs

There is growing interest in herbal ODFs, which incorporate natural extracts such as curcumin, tulsi, and ashwagandha. These provide systemic benefits with minimal side effects and appeal to consumers seeking plant-based therapies [41].

4.6 Multi-Layer and Bilayer Films

Advanced formulations now include bilayer or multilayer ODFs to separate incompatible drugs or to provide immediate and sustained release in a single dosage form. This enhances versatility and therapeutic efficacy [42].

4.7 Regulatory and Commercial Outlook

With increasing market acceptance, regulatory agencies have begun to define quality control parameters specific to ODFs. Recent approvals and market launches signal commercial viability, especially in paediatrics, geriatrics, and CNS therapy segments [43].

Table: Recent Innovations and Their Impacts on ODF Development

Innovation	Impact on ODFs
Nanoparticles	Enhanced bioavailability and solubility
3D Printing	Personalized dosing and complex formulations
Smart Films	Targeted and stimuli-responsive delivery
Herbal Formulations	Natural, safer therapeutic options
Electrospun Nanofibers	Increased surface area and rapid disintegration
Biodegradable Polymers	Sustainable and patient-friendly materials
Multi-layer Films	Combination and controlled drug delivery

Future Directions

- AI and machine learning for predictive formulation modeling.
- Microneedle-ODF hybrids for transmucosal and transdermal therapies.
- Digital health integration through smart packaging and compliance sensors.

Chapter 5: Conclusion

Oro dispersible films (ODFs) have emerged as a significant advancement in drug delivery systems, offering rapid disintegration, ease of administration, and improved patient compliance. This project comprehensively explored the multifaceted aspects of ODFs, including their introduction, literature background, formulation techniques, evaluation parameters, and emerging trends.

Through the review of historical and recent research, it is evident that ODFs present a versatile platform for delivering various classes of drugs, particularly for populations with swallowing difficulties such as paediatrics, geriatrics, and psychiatric patients. The formulation techniques, ranging from solvent casting to modern 3D printing and electrospinning, have evolved to accommodate a

wide range of active pharmaceutical ingredients (APIs) and ensure precise dosing, taste masking, and improved bioavailability.

Rigorous evaluation of ODFs across mechanical, physicochemical, and biopharmaceutical parameters is crucial to ensure their safety and efficacy. Modern analytical methods and standardized testing protocols have contributed to enhancing the reproducibility and commercial scalability of these formulations.

Recent innovations such as nano formulations, herbal ODFs, multilayer systems, and stimuli-responsive films have widened the horizon of ODF applications. The integration of technologies like 3D printing and AI-based formulation design is likely to revolutionize personalized medicine further.

In conclusion, ODFs stand at the intersection of patient-centric design and pharmaceutical innovation. With continued research, technological integration, and regulatory support, ODFs are expected to become a mainstream dosage form in the near future, transforming therapeutic approaches across several medical fields.

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