



Advancements in Oral Fast Dissolving Drug Delivery Systems: A Comprehensive Review

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Abstract

Nanomedicines have evolved into various forms including dendrimers, nanocrystals, emulsions, liposomes, solid lipid nanoparticles, micelles, and polymeric nanoparticles since their first launch in the market. Widely highlighted benefits of nanomedicines over conventional medicines include superior efficacy, safety, physicochemical properties, and pharmacokinetic/pharmacodynamic profiles of pharmaceutical ingredients. Especially, various kinetic characteristics of nanomedicines in body are further influenced by their formulations. This review provides an updated understanding of nanomedicines with respect to delivery and pharmacokinetics. It describes the process and advantages of the nanomedicines approved by FDA and EMA. New FDA and EMA guidelines will also be discussed. Based on the analysis of recent guidelines and approved nanomedicines, key issues in the future development of nanomedicines will be addressed.

Keywords

Nanomedicines · Pharmacokinetics · Delivery · Guidelines

INTRODUCTION

Oral fast dissolving drug delivery systems (OFDDS) have garnered significant attention in pharmaceutical research and development due to their potential to overcome challenges associated with conventional dosage forms. These innovative formulations offer numerous advantages such as rapid disintegration, enhanced patient compliance, improved bioavailability, and ease of administration, particularly beneficial for pediatric, geriatric, and dysphagic patients. This review aims to provide an overview of OFDDS, including formulation strategies, evaluation methods, and applications in drug delivery¹.

The landscape of pharmaceutical drug delivery has witnessed a paradigm shift with the advent of oral fast dissolving drug delivery systems (OFDDS). These innovative formulations represent a departure from

traditional dosage forms, offering a myriad of advantages that address critical challenges in medication administration. OFDDS are designed to rapidly disintegrate or dissolve in the oral cavity, facilitating swift drug absorption and onset of action. This review endeavors to delve into the realm of OFDDS, exploring their formulation strategies, evaluation methodologies, applications across therapeutic domains, as well as the challenges and prospects that define this burgeoning field².

Traditional oral dosage forms, such as tablets and capsules, often pose hurdles in medication adherence, especially among certain patient populations. Children, elderly individuals, and patients with swallowing difficulties encounter difficulties in ingesting conventional solid dosage forms, leading to issues of compliance and efficacy. In emergency situations, where immediate drug

action is imperative, the delayed onset of conventional formulations can prove to be detrimental. Additionally, concerns regarding gastrointestinal irritation, variability in absorption, and first-pass metabolism further underscore the limitations of traditional oral delivery systems³.

In response to these challenges, OFDDS have emerged as a game-changing solution, offering rapid drug dissolution or disintegration within the oral cavity. By leveraging innovative formulation techniques and excipients, these dosage forms ensure rapid absorption through the oral mucosa, bypassing the gastrointestinal tract and hepatic first-pass metabolism. The result is enhanced bioavailability, predictable pharmacokinetics, and improved patient compliance. Moreover, the convenience and ease of administration offered by OFDDS make them particularly well-suited for pediatric, geriatric, and dysphagic patients, as well as individuals with nausea or vomiting tendencies.

The formulation of OFDDS involves a meticulous selection of excipients and manufacturing techniques tailored to achieve rapid disintegration and dissolution kinetics. Superdisintegrants, such as croscopovidone and croscarmellose sodium, act as key facilitators of disintegration, ensuring rapid breakdown of the dosage form upon contact with saliva. Water-soluble polymers, including hydroxypropyl cellulose and polyvinylpyrrolidone, serve as binders to impart mechanical strength and cohesiveness to the formulation. Various dosage forms, such as orally disintegrating tablets (ODTs), oral films, and powders, are fabricated using techniques like direct compression, freeze-drying, or spray-drying.

In the subsequent sections of this review, we delve deeper into the formulation strategies employed in OFDDS, elucidate the evaluation methodologies used to assess their quality and performance, explore their diverse applications across therapeutic domains, and delineate the challenges and future prospects that lie ahead in this dynamic field of drug delivery. Overall, the advent of OFDDS heralds a new era in pharmaceutical science, poised to revolutionize medication delivery and improve patient outcomes in diverse clinical settings.

Formulation Strategies⁴

Formulating OFDDS involves the selection of suitable excipients and techniques to achieve rapid disintegration and dissolution in the oral cavity. Superdisintegrants play a crucial role in facilitating quick disintegration, with commonly used excipients including croscopovidone, croscarmellose sodium, and sodium starch glycolate. Additionally, water-soluble polymers like hydroxypropyl cellulose and

polyvinylpyrrolidone are employed as binders to enhance the mechanical strength of the dosage form. Techniques such as direct compression, freeze-drying, and spray-drying are utilized to produce orally disintegrating tablets (ODTs), oral films, and powders.

Formulating oral fast dissolving drug delivery systems (OFDDS) requires a comprehensive understanding of the physicochemical properties of the drug and the excipients employed, as well as the desired pharmacokinetic profile and patient preferences. Several key formulation strategies are employed to develop OFDDS that exhibit rapid disintegration, enhanced dissolution, and optimal bioavailability. These strategies encompass the selection of excipients, choice of dosage form, and utilization of innovative manufacturing techniques.

1. Excipient Selection⁵:

- **Superdisintegrants:** Superdisintegrants play a pivotal role in promoting rapid disintegration of the dosage form upon contact with saliva. Commonly used superdisintegrants include croscopovidone, croscarmellose sodium, and sodium starch glycolate. These excipients swell rapidly, creating channels within the tablet matrix and facilitating the ingress of saliva, thereby accelerating disintegration.
- **Binders:** Binders are employed to impart mechanical strength and cohesiveness to the formulation, ensuring tablet integrity prior to administration. Hydrophilic polymers such as hydroxypropyl cellulose and polyvinylpyrrolidone serve as effective binders, enhancing the robustness of orally disintegrating tablets (ODTs) and oral films.
- **Fillers:** Fillers are used to increase the bulk volume of the formulation and facilitate uniform distribution of the active pharmaceutical ingredient (API). Common fillers include mannitol, lactose, and microcrystalline cellulose, which contribute to the overall compactness and flow properties of the dosage form.

2. Choice of Dosage Form:

- **Orally Disintegrating Tablets (ODTs):** ODTs represent one of the most widely utilized OFDDS due to their convenience, ease of administration, and rapid disintegration properties. ODTs are typically formulated using a blend of superdisintegrants, binders, and fillers, which are compressed into tablets using conventional tableting equipment or specialized compression techniques.

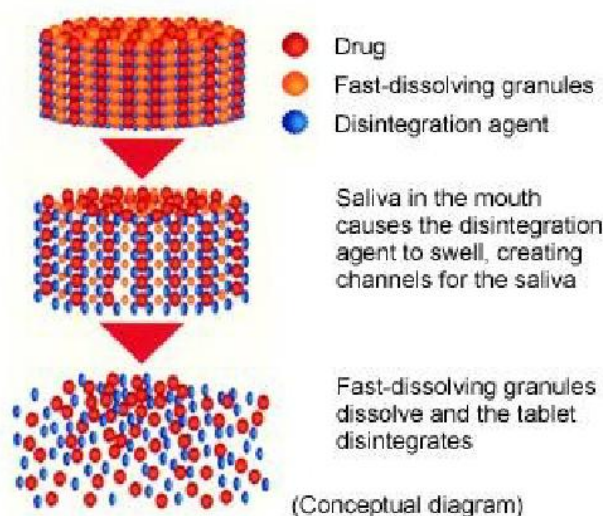


Figure 01: Orally Disintegrating Tablets (ODTs)⁶

- **Oral Films:** Oral films offer an alternative dosage form characterized by thin, flexible sheets that rapidly dissolve upon contact with saliva. These films are composed of water-soluble polymers, plasticizers, and API, which

are cast or extruded into thin films using solvent casting or hot-melt extrusion techniques. Oral films are particularly well-suited for pediatric and geriatric populations, as well as individuals with swallowing difficulties⁷.



Figure 02: Oral Films⁸

• **Powders:**

Fast dissolving powders consist of finely milled particles that disperse rapidly in saliva, allowing for quick absorption of the drug through the oral mucosa. These powders can be administered directly onto the tongue or mixed with a small volume of water prior to ingestion. Powders offer flexibility in dosing and can be customized to accommodate varying drug concentrations and patient preferences.

3. **Manufacturing Techniques⁹:**

• **Direct Compression:**

Direct compression is a commonly employed manufacturing technique for ODTs, involving the blending of API, excipients, and lubricants followed by compression into tablets using high-speed tableting equipment. This method offers simplicity, cost-effectiveness, and scalability, making it ideal for large-scale production of OFDDS.

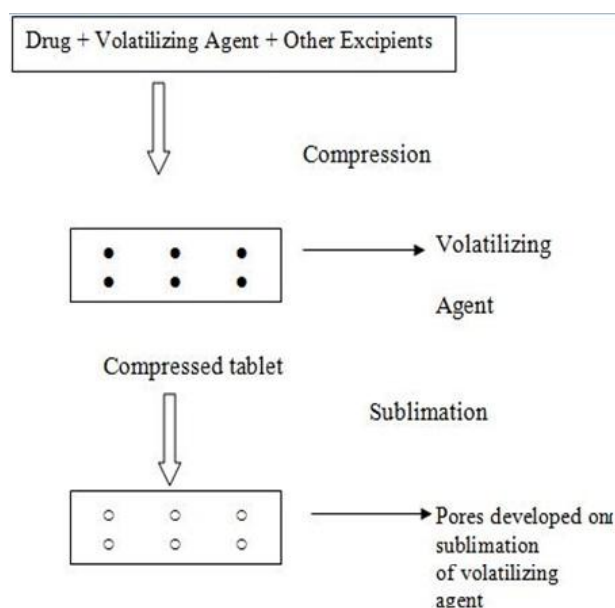


Figure 03: Schematic diagram of sublimation techniques for preparing fast dissolving tablets⁹

• **Freeze-Drying:**

Freeze-drying, also known as lyophilization, is utilized to produce orally disintegrating powders or lyophilized ODTs. This process involves freezing the formulation followed by sublimation of ice under vacuum conditions, resulting in a porous matrix with enhanced disintegration properties. Freeze-drying preserves the integrity of heat-sensitive drugs and allows for precise control over the formulation composition.

• **Spray-Drying:**

Spray-drying entails atomizing a liquid formulation into droplets, which are subsequently dried using hot air to yield fine particles or powders. This technique is particularly suitable for formulating oral films and powders, as it enables rapid drying of the formulation and uniform distribution of the API and excipients.

EVALUATION METHODS¹⁰

Several parameters are evaluated to assess the quality and performance of OFDDS. Physicochemical properties, including disintegration time, dissolution rate, content uniformity, and physical appearance, are analysed to ensure the formulation's effectiveness. Mechanical properties such as hardness and friability are assessed to evaluate the dosage form's robustness. Palatability studies are conducted to determine the taste, mouthfeel, and overall acceptability of the formulation. Stability studies and bioavailability assessments are essential to understand the long-term stability and pharmacokinetic profile of OFDDS.

The evaluation of oral fast dissolving drug delivery systems (OFDDS) encompasses a comprehensive

assessment of various physicochemical, mechanical, and biopharmaceutical properties to ensure their quality, performance, and suitability for clinical use. Several evaluation methods are employed to characterize OFDDS and elucidate their dissolution behavior, disintegration kinetics, mechanical strength, and palatability. These evaluation methods play a crucial role in guiding formulation optimization and ensuring compliance with regulatory standards.

1. **Physicochemical Evaluation¹¹:**

- **Disintegration Time:** The disintegration time of OFDDS is determined using disintegration testers such as the USP disintegration apparatus. The time taken for complete disintegration of the dosage form in simulated saliva or water is recorded to assess the rapidity of disintegration and oral absorption.
- **Dissolution Rate:** The dissolution rate of OFDDS is evaluated using dissolution testers, including USP apparatus 2 (paddle method) or apparatus 4 (flow-through cell method). The release of the drug from the dosage form is monitored over time, and the dissolution profile is analysed to determine the rate and extent of drug release.
- **Content Uniformity:** Content uniformity testing ensures the uniform distribution of the active pharmaceutical ingredient (API) within the dosage form. Multiple samples are assayed for API content using validated analytical methods, and the results are compared to assess the consistency of drug content.
- **Physical Appearance:** The physical appearance of OFDDS, including colour, shape, size, and surface texture, is visually inspected to ensure uniformity and integrity

of the dosage form. Any deviations from the desired specifications are noted and addressed accordingly.

2. Mechanical Evaluation¹²:

- **Hardness:** Tablet hardness testing is conducted using a tablet hardness tester to assess the mechanical strength and resistance to crushing of OFDDS. The force required to fracture the tablet is measured, and the hardness value is compared to predefined specifications to ensure adequate tablet integrity.
- **Friability:** Friability testing evaluates the tendency of OFDDS to undergo abrasion or breakage during handling and transportation. Tablets are subjected to repeated tumbling in a friabilator, and the percentage weight loss is calculated to assess friability. Low friability values indicate good tablet robustness and resistance to mechanical stress.

3. Palatability Evaluation¹³:

- **Sensory Evaluation:** Sensory evaluation is conducted to assess the taste, mouthfeel, and overall palatability of OFDDS. Trained panelists or volunteers evaluate the taste attributes using standardized taste panels or sensory testing protocols. Feedback from panelists is solicited to identify any taste masking issues or formulation-related taste aversions.
- **Patient Acceptability:** Patient acceptability studies involve administering OFDDS to target patient populations and soliciting feedback on ease of administration, taste preference, and overall satisfaction. Patient preferences and experiences provide valuable insights into formulation optimization and patient-centred drug design.

Table 1: Challenges in formulation of FDTs¹⁴

Challenges	Description
Mechanical strength and disintegration time	MDTs are formulated to obtain disintegration time usually less than a minute. While doing so, maintaining a good mechanical strength is a prime challenge. Many MDTs are fragile and there are many chances that such fragile tablet will break during packing, transport, or handling by the patients. It is very natural that increasing the mechanical strength will delay the disintegration time.
Taste masking	Many drugs are bitter in taste. So effective taste masking of the bitter drugs must be done so that the taste of the drug is not felt in the oral cavity.
Mouth feel	Tablet should not disintegrate into larger particles in the oral cavity. The particles generated after disintegration of the Tablet should be as small as possible. Tablet should leave minimal or no residue in mouth after oral administration.
Sensitivity to environment	Tablet generally should exhibit low sensitivity to environment conditions such as humidity and temperature as most of the materials used in a Tablet are meant to dissolve in minimum quantity of water.
Palatability	As most drugs are unpalatable, tablets should contain the medicament in a taste-masked form.
Mechanical strength	In order to allow ODTs to disintegrate in the oral cavity, they are made of either very porous and soft-molded matrices or

Hygroscopic property	compressed into tablets with very low compression force, which makes the tablets friable and/or brittle, difficult to handle, and often requiring specialized peel-off blister packing that may add to the cost. Several orally disintegrating dosage forms are hygroscopic and cannot maintain physical integrity under normal conditions of temperature and humidity. Hence, they need protection from humidity which calls for specialized product packaging.
Aqueous solubility	Water-soluble drugs pose various formulation challenges because they form eutectic mixtures, which result in freezing-point depression and the formation of a glassy solid that may collapse upon drying because of loss of supporting structure during the sublimation process.
Size of tablet	It has been reported that the easiest size of tablet to swallow is 7-8 mm while the easiest size to handle was one larger than 8 mm.
Fast Disintegration	FDTs should disintegrate in the mouth without additional water or with a very small amount (e.g., 1–2 mL) of water.

Table 2: Some drugs formulated as FDTs.¹⁵

Therapeutic Category	Drugs
Anti-fungal	Griseofulvin, Miconazole
Anti-bacterial	Doxycycline, Erythromycin, Rifampicin, Tetracycline
Anti-Malarial	Chloroquine, Amodiaquine
Anti-hypertensive	Amlodipine, Nifedipine, Prazosin
Ant-Thyroid	Carbimazole
Analgesic/Anti-inflammatory	Ibuprofen, Mefenamic acid, Piroxicam
Anticancer	Acyclovir
Antiemetic	Ondansetron

4. Stability Studies^{16,17}:

- **Accelerated Stability Testing:** Accelerated stability studies are conducted under accelerated conditions (e.g., elevated temperature and humidity) to assess the physical and chemical stability of OFDDS over time. Samples are periodically analyzed for changes in drug content, dissolution profile, and physical appearance to predict long-term stability and shelf-life.
- **Real-Time Stability Testing:** Real-time stability studies involve storing OFDDS under ambient conditions and monitoring their stability over an extended period. Samples are analysed at predefined time intervals to assess any changes in physicochemical

properties and ensure compliance with regulatory stability requirements.

5. In Vitro/In Vivo Correlation (IVIVC)^{18, 19}:

- **In Vitro Dissolution vs. In Vivo Performance:** IVIVC studies establish a correlation between in vitro dissolution profiles and in vivo performance of OFDDS. Pharmacokinetic studies in humans or animal models are conducted to evaluate the bioavailability, onset of action, and pharmacokinetic profile of OFDDS and correlate these findings with in vitro dissolution data. By employing these comprehensive evaluation methods, pharmaceutical scientists can gain valuable insights into the performance, quality, and acceptability of OFDDS, facilitating

formulation optimization and ensuring their efficacy and safety for clinical use.

APPLICATIONS^{20, 21, 22}

OFDDS find applications across various therapeutic areas, including analgesics, anti-allergic, antiemetics, antipsychotics, and cardiovascular drugs. These formulations offer significant benefits in emergency

situations, where immediate drug action is required, and in patients with swallowing difficulties or nausea. Paediatric and geriatric populations benefit from the ease of administration and improved compliance offered by OFDDS. Additionally, fast dissolving formulations can be tailored for personalized medicine, enabling precise dosing and drug delivery.

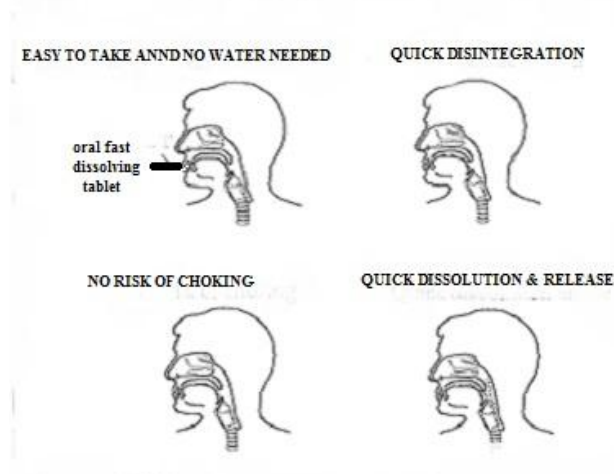


Figure 03: Advantages of FDT²³

Oral fast dissolving drug delivery systems (OFDDS) have found diverse applications across a wide range of therapeutic areas, offering numerous advantages over conventional dosage forms. These innovative formulations are particularly well-suited for patient populations with specific needs, emergency situations, and scenarios where ease of administration and rapid onset of action are paramount. The applications of OFDDS span various therapeutic domains, including but not limited to^{23, 24}:

1. Pediatrics:

- OFDDS offer a convenient and child-friendly alternative to conventional tablets and capsules for pediatric patients who may have difficulty swallowing solid dosage forms.
- The rapid disintegration and palatable taste of OFDDS enhance compliance and facilitate accurate dosing in pediatric populations, thereby improving treatment outcomes.

2. Geriatrics:

- Elderly patients often experience swallowing difficulties, reduced salivary flow, and impaired hand-eye coordination, making conventional dosage forms challenging to administer.
- OFDDS provide a solution for geriatric patients by offering a user-friendly dosage

form that dissolves rapidly in the mouth, eliminating the need for water and minimizing the risk of choking or aspiration.

3. Emergency Medicine:

- In emergency situations, such as anaphylaxis, acute pain, or seizures, rapid drug administration is critical for timely intervention and improved patient outcomes.
- OFDDS enable swift drug delivery and absorption, bypassing the gastrointestinal tract and achieving rapid onset of action, making them invaluable in emergency medicine settings.

4. Psychiatry and Neurology:

- Patients with psychiatric and neurological disorders, such as schizophrenia, bipolar disorder, and Parkinson's disease, may have trouble swallowing or may require immediate relief from symptoms.
- OFDDS offer a convenient and discreet method of drug administration, allowing patients to self-administer medication without the need for water or additional assistance.

5. Palliative Care:

- Palliative care patients, particularly those with advanced cancer or end-stage diseases, may experience nausea,

- vomiting, or dysphagia, which can compromise oral medication intake.
 - OFDDS provide a non-invasive and effective means of drug delivery, offering rapid relief from symptoms and enhancing patient comfort and quality of life in palliative care settings.
6. **Travel Medicine:**
- Travelers may encounter situations where access to clean water for swallowing conventional tablets or capsules is limited or unavailable.
 - OFDDS offer a convenient and portable dosage form that can be easily carried and administered without the need for water, making them ideal for travelers seeking medication convenience and compliance during trips.
7. **Nutraceuticals and Dietary Supplements:**
- Nutraceuticals and dietary supplements, such as vitamins, minerals, and herbal extracts, are often consumed for health maintenance and disease prevention.
 - OFDDS provide an innovative and palatable delivery platform for nutraceuticals, allowing for rapid absorption and enhanced bioavailability of active ingredients.
8. **Veterinary Medicine:**
- Administration of oral medications to companion animals and livestock can be challenging due to reluctance or difficulty in swallowing solid dosage forms.
 - OFDDS offer a convenient and palatable option for administering medications to animals, facilitating compliance and ensuring accurate dosing in veterinary medicine.

Challenges and Future Perspectives^{23, 24}

Despite their numerous advantages, OFDDS face challenges related to formulation stability, taste masking, and regulatory approval. Overcoming these challenges requires innovative formulation approaches and advanced technologies. Future research directions include the development of multifunctional excipients, incorporation of taste-masking agents, and the utilization of nanotechnology for targeted drug delivery. Furthermore, exploring alternative manufacturing methods and conducting comprehensive

pharmacokinetic studies will enhance the clinical utility of OFDDS.

CHALLENGES^{25, 26}

While oral fast dissolving drug delivery systems (OFDDS) offer numerous advantages, they also present several challenges that must be addressed to realize their full potential in pharmaceutical applications:

1. **Formulation Stability:** Maintaining the stability of OFDDS poses a significant challenge, particularly for moisture-sensitive drugs and formulations containing hygroscopic excipients. Strategies to prevent physical and chemical degradation during storage, such as moisture barrier packaging and the use of stabilizing agents, are essential to ensure formulation stability.
2. **Taste Masking:** Many active pharmaceutical ingredients (APIs) exhibit unpleasant taste characteristics, which can negatively impact patient acceptability and compliance. Taste masking strategies, such as the incorporation of flavoring agents, sweeteners, and encapsulation techniques, are necessary to enhance palatability and improve patient adherence to OFDDS.
3. **Regulatory Approval:** The regulatory approval process for OFDDS may be complex, requiring comprehensive data on formulation stability, safety, efficacy, and bioequivalence compared to conventional dosage forms. Meeting regulatory requirements necessitates extensive preclinical and clinical studies, as well as compliance with Good Manufacturing Practices (GMP) and other regulatory standards.
4. **Scalability and Manufacturing Costs:** Scaling up the production of OFDDS from laboratory-scale to commercial-scale manufacturing presents technical and economic challenges. Optimizing manufacturing processes, selecting cost-effective excipients, and minimizing production costs while maintaining product quality are critical considerations for successful commercialization.
5. **Biopharmaceutical Variability:** Variability in physiological factors, such as saliva composition, oral pH, and saliva flow rate, can influence the dissolution and absorption kinetics of OFDDS. Understanding and controlling these biopharmaceutical factors are essential for predicting drug

bioavailability and ensuring consistent therapeutic outcomes.

FUTURE PERSPECTIVES

Despite the challenges, the future of OFDDS holds promise for addressing unmet needs in drug delivery and improving patient care. Several avenues for future research and development include:

1. **Advanced Formulation Technologies:** Continued innovation in formulation technologies, such as nanotechnology, microencapsulation, and 3D printing, can enable the development of next-generation OFDDS with enhanced stability, controlled release, and targeted drug delivery capabilities.
2. **Personalized Medicine:** Tailoring OFDDS to individual patient characteristics, such as age, genetic factors, and disease state, holds potential for personalized medicine. Customized formulations optimized for patient-specific needs can improve treatment efficacy, minimize adverse effects, and enhance patient satisfaction.
3. **Multifunctional Excipients:** The design and utilization of multifunctional excipients with properties such as taste masking, mucoadhesion, and controlled release offer opportunities to overcome formulation challenges and enhance the performance of OFDDS.
4. **Patient-Centric Design:** Emphasizing patient preferences and usability in the design of OFDDS can improve medication adherence and health outcomes. User-friendly packaging, dosage forms tailored to specific patient populations, and patient-centered clinical trials are essential for optimizing patient acceptance and compliance.
5. **Digital Health Technologies:** Integration of digital health technologies, such as smart packaging, mobile applications, and electronic monitoring devices, can enhance medication adherence and patient engagement with OFDDS. Real-time feedback and personalized medication reminders can support patient self-management and improve treatment outcomes^{27, 28}.

CONCLUSION

Oral fast dissolving drug delivery systems (OFDDS) represent a transformative approach to drug delivery, offering rapid disintegration, enhanced

bioavailability, and improved patient compliance compared to conventional dosage forms. Through innovative formulation strategies, comprehensive evaluation methods, and targeted applications, OFDDS have emerged as a cornerstone of modern pharmaceutical science.

In this review, we have explored the formulation strategies employed in OFDDS, encompassing the selection of excipients, choice of dosage forms, and utilization of advanced manufacturing techniques. The evaluation methods discussed have highlighted the importance of assessing physicochemical properties, mechanical characteristics, palatability, and stability to ensure the quality and performance of OFDDS.

The applications of OFDDS across diverse therapeutic areas underscore their versatility and clinical utility in addressing unmet medical needs. From pediatrics to geriatrics, emergency medicine to palliative care, OFDDS offer tailored solutions for patient populations with specific requirements, enhancing medication adherence, and improving treatment outcomes.

While challenges such as formulation stability, taste masking, and regulatory approval persist, the future of OFDDS is promising. Continued research and development efforts, coupled with advances in formulation technologies and personalized medicine, hold the potential to overcome these challenges and unlock new opportunities for innovation in drug delivery.

In conclusion, OFDDS represent a cornerstone of pharmaceutical innovation, poised to revolutionize oral drug delivery, and improve patient care. By addressing formulation challenges, leveraging advanced technologies, and prioritizing patient needs, OFDDS pave the way for a future where medications are not only effective but also convenient, accessible, and patient-centric. As research in oral drug delivery continues to evolve, the potential of OFDDS to transform healthcare remains boundless.

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