IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 4, January 2026
Impact Factor: 7.67

A Review on Formulation Strategies and Evaluation Techniques of Fast Dissolving Drug Delivery Systems

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Abstract: *Fast Dissolving Drug Delivery Systems have emerged as an innovative and patient-friendly approach in modern pharmaceutics, addressing the limitations of conventional oral dosage forms. These systems are designed to disintegrate or dissolve rapidly in the oral cavity without the need for water, making them highly suitable for pediatric, geriatric, and dysphagic patients who experience difficulty in swallowing conventional tablets or capsules. The rapid disintegration leads to quick drug release and absorption, thereby enhancing bioavailability and providing a faster onset of therapeutic action. This review focuses on various formulation strategies employed in the development of FDDDS, including the use of superdisintegrants, sublimation, lyophilization, spray drying, and direct compression methods. Each technique plays a crucial role in improving the porosity, wettability, and dissolution characteristics of the dosage form.*

Additionally, the paper discusses key evaluation parameters such as pre-compression and post-compression characteristics, including hardness, friability, disintegration time, wetting time, and dissolution profile. The review also highlights challenges such as mechanical fragility, moisture sensitivity, and taste masking issues, along with recent advancements like nanotechnology integration, oral thin films, and 3D printing approaches. Overall, FDDDS represents a promising advancement in drug delivery systems, offering improved patient compliance, convenience, and therapeutic efficacy..

Keywords: Fast dissolving drug delivery systems, orally disintegrating tablets, super disintegrants.

I. INTRODUCTION

Fast Dissolving Drug Delivery Systems represent a significant advancement in oral drug delivery technology, designed to overcome the limitations associated with conventional dosage forms such as tablets and capsules. These systems are formulated to disintegrate or dissolve rapidly in the saliva, usually within seconds, without the need for water. The concept of FDDDS is particularly beneficial for special patient populations, including pediatric, geriatric, and psychiatric patients, as well as those suffering from dysphagia or nausea. The rapid dissolution of these dosage forms allows for pre-gastric absorption, which can improve bioavailability and reduce the first-pass metabolism of certain drugs. Furthermore, FDDDS enhances patient compliance due to its ease of administration and improved palatability. Over the past few decades, extensive research has been conducted to develop various formulation techniques that ensure rapid disintegration while maintaining adequate mechanical strength.

These systems are commonly used for drugs requiring rapid onset of action, such as analgesics, antiemetics, and antihypertensives. The growing demand for patient-centric drug delivery systems has led to the development of innovative technologies and excipients that improve the performance of FDDDS. This review aims to provide a comprehensive overview of formulation strategies and evaluation techniques, highlighting their importance in the successful development of fast dissolving dosage forms.

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ADVANTAGES OF FAST DISSOLVING DRUG DELIVERY SYSTEMS

Fast Dissolving Drug Delivery Systems offer numerous advantages over conventional oral dosage forms, making them highly attractive in modern pharmaceutical development. One of the most significant benefits is improved patient compliance, especially among pediatric and geriatric populations who often face difficulty swallowing traditional tablets and capsules. Since FDDDS do not require water for administration, they are particularly useful in situations where water is not readily available, such as during travel or emergencies. Another key advantage is the rapid onset of action, as the drug dissolves quickly in the oral cavity and can be absorbed through the oral mucosa, bypassing the gastrointestinal tract and first-pass metabolism. This leads to enhanced bioavailability and improved therapeutic efficacy for certain drugs. Additionally, FDDDS provide better patient acceptability due to their pleasant taste and mouthfeel, achieved through the use of flavoring agents and sweeteners. These systems also reduce the risk of choking, making them safer for patients with swallowing difficulties. Furthermore, the manufacturing processes of some FDDDS, such as direct compression, are simple and cost-effective, allowing for large-scale production. Overall, the advantages of FDDDS contribute to their growing popularity and widespread application in the pharmaceutical industry.

FORMULATION STRATEGIES OF FDDDS

The formulation of Fast Dissolving Drug Delivery Systems involves various strategies aimed at achieving rapid disintegration and dissolution while maintaining sufficient mechanical strength. One of the most commonly used approaches is the incorporation of superdisintegrants such as crospovidone, croscarmellose sodium, and sodium starch glycolate, which facilitate rapid tablet breakup through swelling and wicking mechanisms. The sublimation technique involves the addition of volatile substances like camphor or ammonium bicarbonate, which are removed after compression, leaving behind a porous structure that enhances water penetration and disintegration. Lyophilization or freeze-drying is another advanced technique that produces highly porous and lightweight tablets with extremely fast dissolution rates, although it is relatively expensive and requires specialized equipment.

Spray drying is used to produce porous powders with improved dissolution characteristics by incorporating carriers such as gelatin and mannitol. Direct compression is the simplest and most economical method, widely used in the pharmaceutical industry due to its ease of processing and scalability. Each of these formulation strategies has its own advantages and limitations, and the selection of an appropriate method depends on the physicochemical properties of the drug and the desired product characteristics.

EXCIPIENTS USED IN FDDDS

Excipients play a fundamental and multifunctional role in the formulation of Fast Dissolving Drug Delivery Systems, as they directly influence critical parameters such as disintegration time, dissolution rate, mechanical strength, mouthfeel, and overall patient acceptability. Unlike conventional tablets, FDDDS require a delicate balance between rapid disintegration and sufficient structural integrity, which is achieved through the careful selection and optimization of excipients. Among all categories, superdisintegrants are the most essential components, as they facilitate the rapid breakup of the dosage form upon contact with saliva. Commonly used superdisintegrants include crospovidone, croscarmellose sodium, and sodium starch glycolate, which act through mechanisms such as swelling, wicking, and deformation recovery. These agents significantly reduce disintegration time and enhance drug release profiles. Fillers or diluents, such as mannitol, lactose, and microcrystalline cellulose, are incorporated to provide bulk to the formulation and improve mouthfeel. Mannitol is particularly preferred in FDDDS due to its pleasant cooling sensation and non-hygroscopic nature, which contributes to improved patient compliance.

Binders are another important class of excipients used to impart mechanical strength and cohesion to the tablet matrix, ensuring that the dosage form can withstand handling, packaging, and transportation. Common binders include polyvinylpyrrolidone (PVP), hydroxypropyl methylcellulose, and natural gums. However, their concentration must be carefully controlled, as excessive binding can delay disintegration. Lubricants such as magnesium stearate and talc are

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added to reduce friction during the compression process and prevent sticking of the tablet to punches and dies. While lubricants are necessary for manufacturing efficiency, their hydrophobic nature can negatively affect wettability and dissolution if used in high concentrations. Therefore, their optimization is critical in FDDDS formulations.

In addition to these, sweeteners and flavoring agents are incorporated to mask the unpleasant taste of active pharmaceutical ingredients, as the drug is released directly in the oral cavity. Artificial sweeteners such as aspartame and saccharin, along with natural flavors like peppermint, orange, or vanilla, enhance palatability and improve patient acceptance, especially among pediatric populations. Saliva stimulating agents, such as citric acid, may also be included to promote faster disintegration by increasing saliva production. Furthermore, surfactants like sodium lauryl sulfate are sometimes added to enhance wettability and solubility of poorly water-soluble drugs, thereby improving dissolution rates. In some advanced formulations, co-processed excipients and novel materials such as natural polymers and nanomaterials are used to achieve superior performance.

Overall, excipients are not merely inactive ingredients but are critical determinants of the success of FDDDS. Their appropriate selection and synergistic combination enable the development of dosage forms that are not only effective and stable but also patient-friendly. Continuous research in excipient technology is further enhancing the efficiency and applicability of fast dissolving drug delivery systems in modern pharmaceutics.

Category	Examples	Function
Superdisintegrants	Crospovidone, CCS, SSG	Rapid disintegration
Fillers	Mannitol, lactose	Improve mouthfeel
Binders	PVP, HPMC	Provide mechanical strength
Lubricants	Magnesium stearate	Reduce friction
Sweeteners/Flavors	Aspartame, menthol	Enhance taste

Excipients play a crucial role in the formulation of Fast Dissolving Drug Delivery Systems, as they significantly influence the disintegration, dissolution, mechanical strength, and overall performance of the dosage form. Superdisintegrants are the most important class of excipients used in FDDDS, as they promote rapid tablet disintegration by swelling upon contact with saliva and facilitating water penetration into the tablet matrix. Commonly used superdisintegrants include crospovidone, croscarmellose sodium, and sodium starch glycolate. Fillers such as mannitol and lactose are used to increase the bulk of the tablet and improve mouthfeel, with mannitol being particularly preferred due to its cooling sensation and pleasant taste. Binders like polyvinylpyrrolidone and hydroxypropyl methylcellulose are used to provide mechanical strength and ensure the integrity of the tablet during handling and transportation. Lubricants such as magnesium stearate reduce friction during tablet compression and prevent sticking to the punches and dies. Additionally, sweeteners and flavoring agents are incorporated to enhance the palatability of the dosage form, which is essential for patient acceptance. The selection and optimization of excipients are critical in achieving the desired balance between rapid disintegration and adequate mechanical strength in FDDDS.

EVALUATION TECHNIQUES OF FDDDS

Parameter	Description
Hardness	Strength of tablet
Friability	Resistance to abrasion
Disintegration Time	Time to dissolve in mouth
Wetting Time	Time to absorb moisture
Dissolution Test	Drug release rate

The evaluation of Fast Dissolving Drug Delivery Systems is essential to ensure their quality, performance, and compliance with pharmacopeial standards. Various pre-compression and post-compression parameters are assessed during the development of FDDDS. Pre-compression parameters include angle of repose, bulk density, tapped density, and compressibility index, which provide information about the flow properties of the powder blend. Post-compression parameters are more critical, as they directly affect the performance of the final dosage form. Hardness testing is

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performed to determine the mechanical strength of the tablet, ensuring it can withstand handling and transportation without breaking. Friability testing evaluates the tablet's resistance to abrasion and mechanical stress. Disintegration time is one of the most important parameters for FDDDS, as it measures the time required for the tablet to break down into smaller particles in the oral cavity.

Wetting time is another important parameter that indicates how quickly the tablet absorbs saliva, which is directly related to its disintegration behavior. Dissolution testing is conducted to determine the rate and extent of drug release from the dosage form, which is critical for assessing its therapeutic efficacy. Additionally, drug content uniformity ensures that each tablet contains the correct amount of active pharmaceutical ingredient. Stability studies are also performed to evaluate the effect of environmental conditions such as temperature and humidity on the product's shelf life. These evaluation techniques collectively ensure the quality and effectiveness of FDDDS.

CHALLENGES AND LIMITATIONS

Despite their numerous advantages, Fast Dissolving Drug Delivery Systems face several challenges and limitations that must be addressed during formulation and development. One of the primary challenges is maintaining sufficient mechanical strength while achieving rapid disintegration, as highly porous tablets tend to be fragile and prone to breakage during handling and transportation. Another significant issue is moisture sensitivity, as FDDDS are designed to dissolve quickly in the presence of saliva, making them highly susceptible to degradation in humid environments. This necessitates the use of specialized packaging materials such as blister packs with desiccants to ensure product stability. Taste masking is another critical challenge, especially for drugs with a bitter or unpleasant taste, as the drug is released directly in the oral cavity.

Various techniques such as coating, complexation, and the use of flavoring agents are employed to overcome this issue. Additionally, FDDDS have limited drug loading capacity, making them unsuitable for drugs that require high doses. The cost of manufacturing can also be a concern, particularly for advanced techniques such as lyophilization and spray drying, which require specialized equipment and processes. Furthermore, regulatory challenges and the need for stringent quality control measures add to the complexity of developing FDDDS. Addressing these challenges is essential for the successful commercialization and widespread adoption of fast dissolving drug delivery systems.

II. CONCLUSION

Fast Dissolving Drug Delivery Systems represent a revolutionary advancement in the field of pharmaceutical sciences, offering a patient-friendly alternative to conventional oral dosage forms. Their ability to disintegrate rapidly in the oral cavity without the need for water makes them highly suitable for a wide range of patient populations, including pediatric, geriatric, and dysphagic individuals. The use of various formulation strategies such as superdisintegrants, sublimation, lyophilization, and direct compression has enabled the development of efficient and effective FDDDS with improved bioavailability and rapid onset of action. Evaluation techniques play a crucial role in ensuring the quality, safety, and performance of these systems, with parameters such as disintegration time, dissolution rate, and mechanical strength being of utmost importance.

Despite the challenges associated with mechanical fragility, moisture sensitivity, and taste masking, ongoing research and technological advancements are continuously improving the design and functionality of FDDDS. Innovations such as nanotechnology, oral thin films, and 3D printing are expected to further enhance the capabilities of these systems. In conclusion, FDDDS hold great potential in improving patient compliance and therapeutic outcomes, making them an important area of research and development in modern pharmaceutics.

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