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RECENT ADVANCEMENTS AND FUTURE TRENDS IN FAST DISINTEGRATING DRUG DELIVERY SYSTEM: A FOCUS ON NATURAL SUPERDISINTEGRANTS

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Abstract:

Fast disintegrating tablets (FDTs) represent a significant advancement in oral drug delivery systems, offering rapid disintegration and absorption without the need for water, thereby improving patient compliance. This review provides a comprehensive overview of FDTs, emphasizing their advantages, suitable drug candidates, and formulation strategies. A key focus is placed on natural superdisintegrants as sustainable alternatives to synthetic counterparts. Natural agents like starch, psyllium husk, and aloe vera demonstrate promising efficacy in enhancing tablet disintegration, aligning with the growing demand for eco-friendly excipients. The review further discusses the role of FDA-approved natural polymers and highlights patented technologies such as Zydis®, Orasolv®, and FlashDose® that drive innovation in FDT development. Additionally, various preparation methods—ranging from direct compression to lyophilization—are discussed, addressing their impact on disintegration times and tablet quality. The article also covers regulatory requirements for FDT approval, including stability and taste-masking considerations. Recent advancements, including 3D printing and nanotechnology, are explored as potential game-changers in personalized medicine and FDT manufacturing. Finally, future trends toward the expanded use of natural polymers, smarter FDT designs, and the broader application of these tablets in complex drug therapies.

Keywords: *Fast disintegrating tablets, natural superdisintegrants, oral drug delivery, patented technologies, sustainable polymers*

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INTRODUCTION:

Fast disintegrating tablets (FDTs), also known as orally disintegrating tablets (ODTs) or mouth-dissolving tablets (MDTs), are solid dosage forms that disintegrate or dissolve in the oral cavity, usually within 60 seconds of placement on the tongue. They are designed to release the active pharmaceutical ingredient (API) rapidly into the body, either for immediate therapeutic action or to improve patient compliance [1].

FDTs are particularly advantageous for certain patient populations, including pediatric, geriatric, and psychiatric patients, as well as individuals who have difficulty swallowing traditional tablets or capsules. Over the past decade, FDTs have become increasingly popular in the pharmaceutical industry, and their formulations have expanded to include a variety of drug categories, including over-the-counter medications, prescription drugs, and dietary supplements [2].

Advantages of Fast Disintegrating Tablets (FDTs) [3,4]

1. Improved Patient Compliance

FDTs are ideal for patients who experience difficulty in swallowing (dysphagia), such as children, elderly individuals, or those suffering from neurological conditions like Parkinson's disease. The convenience of taking the medication without water significantly enhances patient adherence.

2. Rapid Onset of Action

Since FDTs disintegrate rapidly in the oral cavity and the active drug is absorbed through the mucosal tissues or the gastrointestinal tract, they provide a faster onset of therapeutic action compared to traditional oral tablets. This is particularly beneficial for drugs intended for conditions requiring immediate relief, such as painkillers, antihistamines, or medications for anxiety.

3. Ease of Administration

No water is needed for ingestion, making FDTs an attractive option for patients on the go or in situations where water might not be readily available, such as during travel.

4. Enhanced Bioavailability

Some drugs, when administered as FDTs, bypass first-pass metabolism in the liver through buccal or sublingual absorption, thereby increasing their bioavailability. This can be especially advantageous for drugs with poor gastrointestinal absorption or high first-pass metabolism.

5. Versatility in Drug Categories

FDTs are used for various therapeutic categories, including analgesics, antihistamines, antipsychotics, antidepressants, anti-inflammatory drugs, and cardiovascular drugs. They are also employed in over-the-counter formulations for conditions such as allergies, colds, and migraines.

Suitable Drugs for FDT Formulation [5,6]

Not all drugs are suitable for FDT formulation. Certain criteria must be met for a drug to be formulated into an FDT:

1. **Dissolution Profile**: Drugs that dissolve or disintegrate rapidly in the oral cavity are ideal candidates. This includes water-soluble drugs or those that exhibit rapid dissolution upon hydration.
2. **Taste Masking**: Many drugs have a bitter taste, which can negatively affect patient compliance. Therefore, the drug must either be inherently tasteless or have effective taste-masking properties when formulated into FDTs.
3. **Dose**: Drugs with low to moderate doses (up to 500 mg) are typically suitable for FDTs. High-dose drugs may not be appropriate, as large tablet sizes could impair disintegration and patient acceptance.
4. **Stability**: Drugs formulated into FDTs must be stable in saliva, as these tablets are exposed to moisture for rapid disintegration.

Examples of drugs suitable for FDT formulations include: [7,8]

- Analgesics (e.g., ibuprofen, acetaminophen)
- Antihistamines (e.g., loratadine, cetirizine)
- Antipsychotics (e.g., olanzapine, risperidone)
- Anti-epileptics (e.g., clonazepam, lamotrigine)
- Antidepressants (e.g., fluoxetine, escitalopram)
- Proton pump inhibitors (e.g., omeprazole)

Natural Superdisintegrants [9, 10,]

Superdisintegrants play a crucial role in the formulation of FDTs by facilitating the rapid breakdown of the tablet when it comes into contact with saliva. Below is a list of commonly used natural superdisintegrants along with their effective concentrations.

Natural Superdisintegrant	Source	Effective Concentration (%)	Mechanism of Action
Starch	Maize, potato, rice	5-15%	Swelling and capillary action
Psyllium Husk	Seeds of *Plantago ovata*	2-10%	Swelling
Gellan Gum	Fermentation of *Sphingomonas elodea*	0.5-2%	Swelling and gel formation
Aloe Vera Powder	Leaves of *Aloe barbadensis*	1-5%	Swelling and wicking
Fenugreek Seed Mucilage	Seeds of *Trigonella foenum-graecum*	2-10%	Swelling
Guar Gum	Seeds of *Cyamopsis tetragonolobus*	2-10%	Swelling and wicking
Cassia Fistula Gum	Bark of *Cassia fistula* tree	1-5%	Swelling and capillary action
Hibiscus Rosa-Sinensis Mucilage	Leaves and flowers of *Hibiscus rosa-sinensis*	2-10%	Swelling
Chitosan	Exoskeleton of crustaceans	1-5%	Wicking and swelling

Criteria for an Ideal Superdisintegrant [11]

An ideal superdisintegrant should:

- Possess rapid swelling and disintegration properties.
- Be compatible with the drug and other excipients.
- Be chemically inert, non-toxic, and safe for consumption.
- Have good flow properties.
- Be cost-effective and widely available.

Mechanism of Action of Superdisintegrants [12]

The primary mechanisms through which superdisintegrants facilitate tablet disintegration include:

- **Swelling:** Upon contact with saliva, the superdisintegrant swells and breaks the tablet apart. Swelling exerts mechanical pressure on the tablet matrix, leading to disintegration.
- **Capillary Action (Wicking):** Superdisintegrants draw saliva into the pores of the tablet by capillary action, leading to the breakdown of the matrix.
- **Strain Recovery:** Some natural superdisintegrants work by recovering their original shape after being compressed, thus facilitating rapid disintegration when exposed to moisture.
- **Enzymatic Degradation:** Certain natural polymers can be degraded by enzymes present in the body, thereby promoting faster disintegration.

Natural Superdisintegrants used in FDTs

1. Starch [13]

- **Source:** Starch is derived from various plants, including maize, potatoes, and rice.
- **Mechanism:** Starch disintegrates mainly through swelling and wicking. Upon contact with moisture, starch granules swell significantly, leading to rapid tablet disintegration.
- **Advantages:** Starch is widely available, inexpensive, and biocompatible. It also has a long history of safe use in pharmaceutical formulations.
- **Limitations:** Native starch may not have as high disintegration efficiency as some synthetic superdisintegrants, and modifications such as pregelatinization are often used to improve its performance.

2. Plantago Ovata (Psyllium Husk) [14]

- **Source:** Psyllium husk is obtained from the seeds of the Plantago ovata plant.
- **Mechanism:** Psyllium husk acts by swelling in the presence of moisture. It has a high mucilage content, which allows it to absorb water rapidly and expand, leading to the breakup of the tablet matrix.
- **Advantages:** It has excellent swelling properties and is highly biodegradable and non-toxic. It is effective in very small concentrations, making it economical.
- **Limitations:** Psyllium husk may lead to viscous tablet matrices, which can affect the release profile of certain drugs.

3. Gellan Gum [15]

- **Source:** Gellan gum is a polysaccharide derived from the bacterium *Sphingomonas elodea*.
- **Mechanism:** Gellan gum disintegrates by swelling and wicking. It forms gels upon contact with water, which contributes to tablet breakdown.
- **Advantages:** Gellan gum is effective at low concentrations and is suitable for formulating both FDTs and controlled-release formulations.
- **Limitations:** It may not provide as fast disintegration as synthetic disintegrants and could require higher concentrations for optimal performance.

4. Aloe Vera Powder [16]

- **Source:** Aloe vera is derived from the leaves of the Aloe barbadensis plant.
- **Mechanism:** Aloe vera powder acts as a superdisintegrant through both swelling and capillary action.
- **Advantages:** Aloe vera is non-toxic, easily available, and has a high water absorption capacity. It also has additional therapeutic properties such as wound healing and anti-inflammatory effects, which may complement certain drug formulations.
- **Limitations:** Limited studies have explored its disintegration efficiency in different tablet matrices.

5. Fenugreek Seed Mucilage [17]

- **Source:** Derived from the seeds of *Trigonella foenum-graecum* (fenugreek).
- **Mechanism:** Fenugreek mucilage exhibits high swelling properties. It absorbs water rapidly, leading to significant swelling and tablet breakup.
- **Advantages:** Fenugreek mucilage is highly biodegradable, cost-effective, and non-toxic. It has excellent gelling properties that contribute to the rapid disintegration of FDTs.
- **Limitations:** The high mucilage content may lead to slower dissolution in some formulations, depending on the drug.

6. Guar Gum [18]

- **Source:** Guar gum is extracted from the seeds of *Cyamopsis tetragonolobus* (cluster bean).
- **Mechanism:** Guar gum acts primarily by swelling and wicking. It has excellent water retention and swelling capabilities, which facilitate rapid disintegration.
- **Advantages:** Guar gum is non-toxic, biodegradable, and cost-effective. It is a versatile excipient used in various pharmaceutical and food applications.
- **Limitations:** Guar gum may result in a slower dissolution rate for certain poorly water-soluble drugs, depending on the tablet formulation.

7. Cassia Fistula Gum [19]

- **Source:** This gum is obtained from the bark of the *Cassia fistula* tree.
- **Mechanism:** Cassia fistula gum disintegrates tablets through swelling and capillary action. It can absorb a large amount of water, leading to tablet breakup.
- **Advantages:** It is biodegradable, non-toxic, and has good swelling properties, making it a suitable alternative to synthetic disintegrants.
- **Limitations:** Limited availability and fewer studies on its applicability across different drug types may restrict its use.

8. Hibiscus Rosa-Sinensis Mucilage [20]

- **Source:** The mucilage is extracted from the leaves and flowers of the hibiscus plant.
- **Mechanism:** Hibiscus mucilage acts by swelling when exposed to moisture. It has high mucilage content, which aids in rapid water absorption and disintegration.
- **Advantages:** Hibiscus mucilage is natural, non-toxic, and cost-effective. Its mucilage also has therapeutic properties that may complement certain drug formulations.
- **Limitations:** Variability in the mucilage yield depending on environmental factors and plant sources may affect its consistency.

9. Chitosan [21]

- **Source:** Chitosan is derived from chitin, which is found in the exoskeletons of crustaceans like shrimp and crabs.
- **Mechanism:** Chitosan acts via wicking and swelling. It absorbs water and swells, causing the tablet to disintegrate.
- **Advantages:** Chitosan is biodegradable, biocompatible, and has additional properties like bioadhesion, which may enhance drug absorption.
- **Limitations:** The variability in chitosan's degree of deacetylation can affect its disintegration efficiency and consistency across formulations.

Advantages of Natural Superdisintegrants [22, 23]

- **Non-toxic and biocompatible**: Natural polymers are generally considered safe and non-toxic, which is a critical factor in pharmaceutical formulations.

- **Biodegradable**: Being biodegradable, these substances pose less environmental risk compared to synthetic polymers.
- **Cost-effective**: Natural superdisintegrants are often less expensive than synthetic options, especially when sourced in bulk from agricultural by-products.
- **Sustainable**: The growing trend toward eco-friendly and sustainable pharmaceutical excipients makes natural superdisintegrants attractive for future development.

FDA-Approved Natural Polymers in FDT Formulations [24, 25]

The U.S. Food and Drug Administration (FDA) has approved a variety of natural polymers for use in drug formulations, recognizing their safety and efficacy. The following are some FDA-approved natural polymers used in FDTs:

1. **Starch (Maize, Potato)**: Widely used in FDT formulations as a binder and disintegrant. It has FDA approval for use in pharmaceutical formulations and is included in many FDT products.
2. **Pectin**: Derived from citrus fruits, pectin is another FDA-approved natural polymer used as a gelling and disintegrating agent.
3. **Chitosan**: An FDA-approved polymer derived from crustacean shells, chitosan is used for its bioadhesive properties and ability to enhance drug absorption.
4. **Guar Gum**: Derived from the seeds of *Cyamopsis tetragonolobus*, guar gum is FDA-approved for use as a thickener, stabilizer, and disintegrant.

These polymers are considered Generally Recognized As Safe (GRAS) by the FDA and have found applications in a wide range of pharmaceutical and food products.

Preparation Methods for FDTs [26-28]

The choice of preparation method for FDTs depends on factors such as drug stability, taste-masking requirements, and desired disintegration time. Common preparation methods include:

1. Direct Compression

Direct compression is the most widely used method for preparing FDTs. In this process, the drug, disintegrant, and other excipients are mixed and compressed into tablets using standard tableting equipment. This method is simple, cost-effective, and suitable for heat-sensitive drugs, as no heating step is involved.

2. Freeze-Drying (Lyophilization)

In the freeze-drying process, the drug is dissolved or suspended in a solvent, and the mixture is then frozen and lyophilized to remove the solvent, leaving behind a porous tablet that disintegrates rapidly. This method produces tablets with very short disintegration times, but it is more expensive and time-consuming than direct compression.

3. Molding

In the molding process, the drug and excipients are mixed with a solvent and molded into tablets using compression or heat. The solvent is then evaporated, leaving behind a rapidly disintegrating tablet. Molded tablets are typically softer and more porous than compressed tablets.

4. Spray Drying

Spray drying involves spraying a solution of the drug and excipients into a hot chamber, where the solvent evaporates, leaving behind dry particles that can be compressed into tablets. This method is used to create FDTs with good disintegration properties and uniform drug dispersion.

5. Sublimation

Sublimation involves the use of a volatile substance (e.g., camphor) that is added to the tablet formulation and then sublimated, leaving behind pores in the tablet structure. These pores enhance tablet disintegration by allowing saliva to penetrate more easily.

6. Mass Extrusion

In this technique, a mixture of the drug and excipients is softened by heating or solvent addition and then forced through an extruder to form a thin filament. The filament is cut into tablets that disintegrate quickly upon contact with saliva.

Patented Technologies for Fast Disintegrating Tablets

Several patented technologies have been developed for the preparation of FDTs, focusing on improving the disintegration time, taste masking, and overall patient compliance. Some key patented technologies include:

1. Zydis® Technology (Catalent Pharma Solutions) [29]

Zydis® is a freeze-drying (lyophilization) technology used to create fast-disintegrating tablets. The process involves suspending the drug in a solution or suspension, which is then freeze-dried to create a porous structure that dissolves rapidly upon contact with saliva. Zydis® tablets typically disintegrate within a few seconds.

2. Orasolv® and Durasolv® Technologies (Cima Labs) [30]

Orasolv® and Durasolv® are compression-based technologies used to create FDTs. Orasolv® tablets are formulated by incorporating taste-masked drug particles into an effervescent disintegration system, leading to rapid tablet dissolution. Durasolv® is a similar technology but with added durability, allowing

for greater tablet strength and handling during packaging.

3. FlashDose® Technology (Fuisz Technologies Ltd.) [31]

FlashDose® involves the use of a proprietary process called Shearform™, which forms a cotton-candy-like matrix of the drug, excipients, and sweeteners. This matrix rapidly dissolves in the mouth upon contact with saliva, resulting in a fast-disintegrating dosage form.

4. Wowtab® Technology (Yamanouchi Pharmaceutical Co.) [32]

Wowtab® technology involves the use of sugar-based excipients that provide a smooth mouthfeel while promoting rapid disintegration. The technology uses a combination of low and high moldability saccharides to create tablets that are both robust and fast-disintegrating.

5. FlashTab® Technology (Prographarm) [33]

FlashTab® combines the use of a traditional tablet compression technique with superdisintegrants to create tablets that disintegrate in the mouth within 1 to 2 minutes.

Regulatory Requirements for Fast Disintegrating Tablets [34-38]

The regulatory approval process for FDTs follows the same general principles as for other pharmaceutical dosage forms, with additional considerations for disintegration time, taste masking, and patient compliance. Key regulatory requirements include:

1. Disintegration Time

According to the U.S. Pharmacopeia (USP) and European Pharmacopoeia (EP), FDTs must disintegrate within 30 seconds to 3 minutes, depending on the specific formulation. The disintegration time is a critical quality attribute for FDTs and is often tested using specialized equipment.

2. Stability

FDTs must be stable under a variety of conditions, including temperature, humidity, and light exposure. Stability testing is performed to ensure that the drug remains effective and that the tablet retains its disintegration properties over time.

3. Taste Masking

Taste masking is an essential consideration for FDTs, particularly for bitter drugs. Regulatory authorities require evidence that the taste of the drug is adequately masked to ensure patient compliance.

4. Bioavailability

For drugs intended to be absorbed through the oral mucosa, bioavailability studies are required to demonstrate that the drug reaches therapeutic levels in the bloodstream. These studies may include pharmacokinetic and pharmacodynamic assessments.

5. Packaging

FDTs are typically more sensitive to moisture and mechanical stress than traditional tablets, so appropriate packaging is essential to protect the tablets during storage and transportation. Regulatory authorities may require packaging stability data to ensure product integrity.

Recent Advancements in FDT Technology [39-43]

Recent advancements in FDT technology have focused on improving patient compliance, expanding the range of suitable drugs, and enhancing tablet disintegration properties. Some key advancements include:

1. Nanotechnology in FDTs

Nanoparticle-based formulations have been explored to enhance the bioavailability of poorly water-soluble drugs. Nanoparticles can improve drug dissolution and absorption, making them ideal for inclusion in FDTs.

2. 3D Printing of FDTs

The use of 3D printing technology has gained attention for its ability to create highly personalized FDTs with precise dosing and complex structures. This technology allows for the incorporation of multiple APIs into a single tablet and can be tailored to the specific needs of individual patients.

3. Smart FDTs

Smart FDTs are being developed with the incorporation of sensors or microchips that can monitor drug release, patient adherence, or physiological parameters. These advanced tablets have the potential to improve patient outcomes by providing real-time feedback to healthcare providers.

Future Trends in FDT Development [44-46]

The future of FDTs lies in the continued development of natural superdisintegrants, advanced drug delivery systems, and personalized medicine. Key trends include:

1. Increased Use of Natural Superdisintegrants

As the demand for eco-friendly and sustainable pharmaceutical products grows, the use of natural superdisintegrants is expected to increase. Researchers are exploring new sources of natural polymers, such as marine algae and plant-derived polysaccharides, to replace synthetic excipients.

2. Personalized FDTs

With the advent of precision medicine, FDTs may be tailored to individual patient needs, offering personalized dosing, drug combinations, and release profiles. Advances in 3D printing and nanotechnology will play a crucial role in achieving this level of customization.

3. Expansion of Therapeutic Categories

FDTs are currently used for a limited range of therapeutic categories, but their application is expected to expand to include more complex drugs, such as biologics, vaccines, and cancer therapies. This expansion will require new formulation strategies and technologies to ensure the stability and efficacy of these drugs in FDT form.

4. Smart and Connected FDTs

The integration of digital health technologies with FDTs, such as sensors that monitor drug adherence or physiological responses, has the potential to revolutionize patient care. These smart FDTs could provide real-time data to healthcare providers, allowing for more personalized and responsive treatment plans.

CONCLUSION:

Fast disintegrating tablets (FDTs) have emerged as a versatile and patient-friendly dosage form, offering numerous advantages in terms of ease of administration, rapid onset of action, and improved patient compliance. The use of natural superdisintegrants in FDT formulations provides a sustainable and eco-friendly alternative to synthetic excipients, aligning with the growing demand for green pharmaceutical products. While FDTs are widely used in the treatment of various conditions, recent advancements in nanotechnology, 3D printing, and personalized medicine are expected to expand their application to more complex therapeutic categories. As research continues, FDTs will likely play an increasingly important role in the future of drug delivery systems.

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