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REVIEW ON MOUTH DISSOLVING TABLET.

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Abstract:

Mouth-dissolving tablets (MDTs), also known as Oro Dispersible Tablets (ODTs), are solid dosage forms that rapidly disintegrate in the oral cavity, typically within one minute, without the need for water. These tablets dissolve or disperse in saliva, enabling faster absorption of the active ingredient. This article reviews the advancements in ODT technology for drug delivery applications. Various techniques used to prepare ODTs include direct compression, freeze-drying, spray drying, tablet molding, sublimation, and mass extrusion. Current formulations aim to achieve rapid disintegration in the mouth, ensuring effective dispersion before swallowing. While ongoing research continues to improve these technologies, further commercialization is needed for broader adoption. In the future, ODTs could be developed for a wide range of therapeutic agents, offering significant benefits in drug delivery.

Keywords:

Mouth Dissolving Tablets, Superdisintegrants, Rapid Disintegration, Bioavailability, Patented Technologies.

Introduction:

The oral route of drug delivery is widely regarded as the most convenient, effective, and costefficient method for administering medications. Its non-invasive nature allows for easy selfadministration, reducing the need for medical professionals and enhancing patient adherence to treatment. Oral drug delivery takes advantage of the gastrointestinal tract's large surface area and rich blood supply, enabling efficient drug absorption. Furthermore, it supports a variety of formulations, including tablets, capsules, and liquids, making it versatile for addressing diverse therapeutic needs. Despite challenges like first-pass metabolism and variable absorption, advancements in drug formulation continue to improve the reliability of oral medications.[1]

Mouth Dissolving Tablets (MDTs), also known as Orally Disintegrating Tablets (ODTs), represent a significant innovation in oral drug delivery. Designed to dissolve rapidly in the mouth without water, MDTs offer a convenient solution for patients who struggle with swallowing traditional tablets, such as children, elderly individuals, and those with medical conditions like dysphagia. The rapid disintegration of MDTs facilitates quicker onset of action by allowing direct absorption through the mucosal lining of the mouth, bypassing the gastrointestinal tract. This feature makes MDTs particularly suitable for acute treatments or emergency situations requiring fast relief.[2]

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MDTs incorporate excipients such as superdisintegrants and flavoring agents, which promote quick disintegration and improve taste, enhancing patient compliance. Their water-free administration makes them ideal for travel or situations where water is inaccessible.[2]

These tablets have applications across various therapeutic areas, including pain management, cardiovascular conditions, infectious diseases, and nutritional supplementation. They provide accurate dosing, improved bioavailability, and enhanced therapeutic outcomes. MDTs also offer flexibility in dosing, making them suitable for individualized treatment plans and both clinical and home-based care settings.[2]

However, MDTs pose challenges in terms of environmental sensitivity, such as humidity and temperature, which can impact their stability and shelf life. Careful formulation, manufacturing processes, and specialized packaging are essential to ensure their integrity and performance.[2]

ADVANTAGES OF MOUTH DISSOLVING TABLETS

1. **Rapid Disintegration and Dissolution**

Mouth Dissolving Tablets (MDTs) disintegrate or dissolve quickly in the mouth without requiring water, offering a convenient and easy-to-administer option, particularly for patients who have difficulty swallowing.

2. **Enhanced Patient Compliance**

MDTs improve medication adherence, especially in pediatric, geriatric, and psychiatric patients who struggle with swallowing solid dosage forms or resist medication due to taste aversion.

3. **Faster Onset of Action**

By dissolving in the oral cavity, MDTs facilitate drug absorption through the oral mucosa, ensuring a quicker onset of action compared to conventional tablets that rely on gastrointestinal transit.

4. **Bypassing First-Pass Metabolism**

MDTs can bypass the first-pass metabolism in the liver, leading to improved bioavailability for certain drugs. This results in more predictable pharmacokinetics and better therapeutic outcomes.

5. **Improved Drug Stability**

Formulations can be designed to protect sensitive active ingredients from degradation by controlling exposure to moisture, oxygen, and light, thereby enhancing drug stability.

6. **Portability and Water-Free Administration**

MDTs are portable and do not require water for administration, making them ideal for situations where water access is limited, such as during travel, outdoor activities, or in emergency settings.

7. **Precise Dosing Flexibility**

MDTs offer flexibility in dose adjustments, enabling tailored formulations based on individual patient needs or clinical requirements.

8. **Taste Masking and Improved Palatability**

Taste-masking agents or flavoring agents can be incorporated into MDTs to mask the unpleasant or bitter taste of certain drugs, improving patient acceptance and compliance.

9. **Reduced Risk of Choking and Aspiration**

MDTs dissolve rapidly in the mouth, minimizing the risk of choking or aspiration compared to traditional tablets or capsules, which is especially beneficial for patients with dysphagia or neurological disorders.[9,4,6]

DISADVANTAGES OF MOUTH DISSOLVING TABLETS

1. **Limited Drug Loading**

MDT formulations have limitations on the amount of active pharmaceutical ingredient (API) they can incorporate. To maintain rapid disintegration and acceptable palatability, high-dose drugs or those with large molecular sizes may pose formulation challenges.

2. **Taste Masking Challenges**

Although taste-masking agents are used to enhance palatability, certain APIs have inherently bitter or unpleasant tastes that are difficult to mask completely. This can impact patient acceptance and compliance, particularly in pediatric and sensitive populations.

3. **Stability Issues**

MDTs are more prone to stability concerns compared to conventional tablets due to their rapid disintegration properties. Exposure to moisture, temperature, and oxygen can cause degradation of the API, compromising product efficacy and reducing shelf life.[9]

4. **Manufacturing Complexity**

The formulation of MDTs requires specialized processes and equipment to achieve optimal disintegration, API uniformity, and mechanical strength. These additional requirements can increase production complexity and costs compared to traditional tablet formulations.

5. **Handling and Packaging Challenges**

MDTs tend to be more fragile than conventional tablets due to their porous nature, making them susceptible to damage during handling, transportation, and packaging. Special packaging materials and techniques are often necessary to maintain their integrity.10,3,8

METHOD OF PREPARATION OF MOUTH DISSOLVING TABLETS (MDTs)

1. Direct Compression Method

Direct compression is one of the most widely used methods for preparing MDTs due to its simplicity and cost-effectiveness. The process involves:

- Blending the **active pharmaceutical ingredient (API)** with suitable excipients such as **disintegrants, fillers, binders, lubricants, taste-masking agents, or flavoring agents**.
- Compressing the resulting blend into tablets using a **tablet press**.

Key considerations: Careful selection of excipients is crucial to ensure rapid disintegration and a pleasant mouthfeel for the tablets.[13]

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2. Dry Granulation Method

Dry granulation involves compacting the powder blend into granules without the use of liquid binders. The steps include:

- Compacting the powder blend into granules.
- Milling the granules to achieve the desired **particle size distribution** and **blend uniformity**.
- Compressing the granules into tablets using a **tablet press**.

Advantages: This method is beneficial for moisture-sensitive APIs and eliminates the need for liquid binders.[12]

3. Lyophilization (Freeze-Drying)

Lyophilization is a technique that produces a porous structure to facilitate rapid disintegration. The process includes:

- Preparing a solution containing the **API** and **excipients**.
- Freezing the solution and subjecting it to **sublimation under vacuum**, where the frozen solvent is removed.
- Milling the resulting porous matrix into a fine powder and compressing it into tablets.

Advantages: Lyophilization is suitable for **heat-sensitive APIs** and provides a highly porous matrix for rapid tablet disintegration.[11]**Spray Drying Method**

Spray drying improves powder flowability and compressibility. The steps include:

- Atomizing a solution or suspension of the **API** and **excipients** into fine droplets.
- Drying the droplets using a **hot air stream**, which forms solid particles.
- Blending the dried particles and compressing them into tablets.

Advantages: Spray drying enhances the flowability and uniformity of the powder blend, facilitating easy tablet compression.[15]

4. Hot Melt Extrusion (HME)

Hot melt extrusion involves the following steps:

- Heating a mixture of **polymers, API, and excipients** to an elevated temperature until it melts.
- Extruding the molten mixture through a **die** to form a continuous strand.
- Chopping the extruded strand into granules and compressing them into tablets.

Advantages: HME is suitable for **heat-stable APIs** and offers additional benefits such as **taste masking** and **controlled release**.[14]

5. Sublimation Method

Sublimation is used to create porous structures in the tablets for rapid disintegration. The process involves:

- Adding **volatile solid ingredients** (e.g., urea, ammonium carbonate, ammonium bicarbonate, hexamethylenetetramine, camphor) to the tablet formulation.
- Compressing the mixture into tablets.
- Removing the volatile materials via **sublimation**, leaving behind a porous tablet matrix.

Example Process:

- **Mannitol** is used as the tablet matrix, while **camphor** acts as the subliming material.
- Camphor is vaporized by sublimation in vacuum at **80°C for 30 minutes**, which generates pores in the tablets.

Outcome: Tablets prepared by this method typically disintegrate within **10-20 seconds**.[18]

Ideal Properties of MDTs

1. Disintegration without water in seconds.
2. Acceptable mouthfeel without residue.
3. Stability against humidity and temperature.
4. Robust mechanical strength for handling and packaging.
5. Cost-effective and compatible with current processing equipment.[1,2,5,7]

Formulation Techniques

1 Freeze Drying (Lyophilization)

- Creates porous tablets via sublimation.
- Provides rapid disintegration but is time-consuming and costly.[11]

2 Molding Technology

- Tablets are formed using water-soluble ingredients to improve solubility.
- Produces brittle tablets.[11]

3 Spray Drying

- Produces porous particles for fast dissolution.
- Tablets dissolve in under 20 seconds.[15]

4 Direct Compression

- Simplest and cost-effective method using superdisintegrants like crospovidone and croscarmellose.
- Allows high drug loading but requires optimized disintegrant concentration.[11]

5 Sublimation

- Uses volatile substances like camphor to create a porous structure for rapid disintegration.[14]

6 Melt Granulation and Mass Extrusion

- Meltable binders and solvent systems are used to produce strong tablets.[17]

7 Cotton Candy Process

- Produces amorphous floss-like matrix, improving tablet porosity and disintegration.[3]

8 Nanonization

- Reduces drug particle size to nano level for improved bioavailability.[22]

Quality Control Tests

1. **General Appearance**: Dimensions, color, texture, and markings.
2. **Weight Variation**: Ensures uniform tablet weight within limits.
3. **Hardness**: Determines mechanical strength (tested using Monsanto tester).
4. **Friability**: Measures tablet resistance to abrasion using Roche Friabilator.
5. **Wetting Time**: Assesses time required for the tablet to become wet in water.
6. **Disintegration Test**: Measures the time for tablet breakup in saliva-like conditions.
7. **Water Absorption Ratio**: Quantifies water uptake to evaluate disintegration potential.
8. **In-vitro Dissolution**: Ensures drug release using USP paddle apparatus.[3,4,8,9]

Conclusion

The project successfully demonstrates the development of MDTs as a patient-friendly dosage form with rapid disintegration, improved bioavailability, and enhanced patient compliance. The use of advanced technologies like direct compression and patented systems such as Zydis and OraSolv ensures effective drug delivery. MDTs hold significant potential for further research, especially for pediatric and geriatric populations.[10]

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