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Overview of mouth dissolving tablet

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ABSTRACT

Mouth dissolving tablets (MDTs) are an important pharmaceutical innovation designed to enhance patient convenience, compliance, and therapeutic effectiveness. These tablets disintegrate or dissolve rapidly in the oral cavity, usually within seconds, without requiring water, making them particularly suitable for pediatrics, geriatric, bedridden, nauseous, and dysphagic patients. The growing demand for user-friendly dosage forms has driven significant progress in MDT technologies, formulation approaches, and quality evaluation techniques.

MDTs are typically formulated using specialized super-disintegrants, hydrophilic excipients, and taste-masking agents to achieve rapid disintegration, acceptable mouthfeel, and patient adherence. Various preparation methods such as direct

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compression, sublimation, spray drying, freeze-drying, and melt granulation have been developed to improve the porosity, dissolution rate, and mechanical strength of tablets. Patented technologies including Zydis®, Orasolv®, and FlashTab® have further advanced the field by offering unique manufacturing processes and improved performance characteristics. The selection of an appropriate technique depends on drug properties, desired onset of action, stability requirements, and cost-effectiveness.

Overall, mouth dissolving tablets represent a promising and patient-centric drug delivery system with expanding applications in modern therapeutics. Continued research in excipient selection, manufacturing technologies, and stability enhancement is expected to further improve the performance of MDTs and support their broader acceptance in the pharmaceutical industry.

KEYWORDS

mouth dissolving tablet, super-disintegrants, taste masking, bioavailability, orodispersible ,

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INTRODUCTION

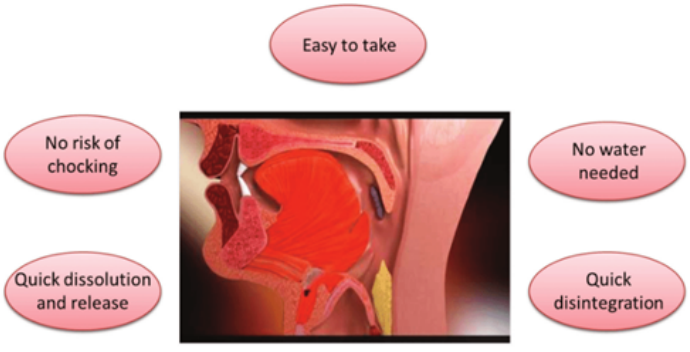
Mouth-disintegrating tablets (MDTs) have emerged as an innovative oral drug delivery system that aligns with the pharmaceutical industry's growing focus on patient-centered formulations. Conventional tablets remain the most widely used dosage form due to their .stability, cost-effectiveness, and ease of manufacturing. However, a significant limitation of traditional tablets is the difficulty some patient groups face in swallowing solid oral medications. This challenge is common among children, elderly individuals, psychiatric patients, and individuals with neurological or physiological dysphagia (1,2). To address these limitations, MDTs were developed as a dosage form that disintegrates or dissolves rapidly in the mouth—typically within 30 seconds—without the need for water (3,4). The background of MDT technology can be traced to early attempts in the 1980s and 1990s to create fast-dissolving dosage forms for emergency drugs such as antihistamines and antiemetics. Initially, lyophilization (freeze-drying) was the predominant technique used due to its ability to create highly porous structures that dissolve quickly (1,6). Although lyophilized MDTs exhibited excellent disintegration characteristics, their high cost, fragile structure, and packaging difficulties led to the exploration of alternative technologies. Over time, advancements in formulation science introduced superdisintegrants, effervescent agents, and mouth-feel enhancers, enabling the production of MDTs using simpler and more cost-effective methods like direct compression, molding, sublimation, and spray drying (2,5,7).

The increasing interest in MDTs also stems from their ability to offer improved pharmacokinetic profiles. Rapid disintegration in the oral cavity can allow partial absorption through the buccal, sublingual, or oropharyngeal mucosa, potentially bypassing first-pass metabolism and

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improving the onset of therapeutic action (8,10). This makes MDTs particularly suitable for drugs used in acute conditions such as pain, allergy, nausea, and cardiovascular emergencies. Additionally, MDTs enhance medication adherence by eliminating the need for water, making them ideal for on-the-go administration and for patients with limited access to potable water (2,7).

Recent developments in pharmaceutical technology have further broadened the scope of MDT formulation. Innovations such as 3D printing, co-processed excipients, taste-masking techniques, nanostructure-based carriers, and multifunctional superdisintegrants have significantly improved the mechanical strength, palatability, and stability of these dosage forms (8,9). Moreover, the introduction of regulatory guidelines for orally disintegrating tablets by pharmacopoeias has standardized evaluation parameters such as disintegration time, hardness, friability, and wetting time, strengthening the scientific foundation of MDT development (3,4).



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Need for MDT:

Tablets are the most widely used dosage form today because they are easy to handle, convenient to carry, and simple to manufacture. However, many patients—such as the elderly, individuals with swallowing difficulties, people with weak muscular or nervous systems, and uncooperative patients—often face problems in swallowing conventional tablets. This leads to poor patient compliance. To overcome these issues, Mouth Dissolving Tablets (MDT) or Orally Disintegrating Tablets (ODT) have been developed as an alternative form. These tablets are specially designed to break apart, dissolve, or disperse in saliva within a few seconds. As per the European Pharmacopoeia, an ODT must disintegrate in less than three minutes.

The major formulation technique used in MDTs is the incorporation of superdisintegrants, such as:Cross-linked carboxymethylcellulose (Croscarmellose), Sodium starch glycolate (Primogel, Explotab), Polyvinylpyrrolidone (Polyplasdone). These agents cause the tablet to rapidly break down when placed on the tongue, releasing the drug directly into saliva. This can enhance the bioavailability of many drugs because a portion is absorbed in the oral cavity or upper gastrointestinal tract, lowering the impact of first-pass metabolism compared to regular tablets. Disintegrating agents are commonly added to tablet and capsule formulations to help moisture penetrate the dosage form and allow it to break apart into smaller particles when exposed to dissolution fluids. Ideally, an oral solid dosage form should quickly disperse into its original primary particles. Although many substances have been tested as disintegrants, only a few are extensively used. Traditionally, starch has been the preferred disintegrant in tablet formulations and continues to be widely used. However, starch is not perfect. It usually needs to be added in

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concentrations greater than 5%, which can negatively influence the tablet's compressibility, especially in direct compression methods. In addition, starch used inside granules during wet granulation does not perform as efficiently as dry starch.

In recent years, more advanced disintegrants—known as superdisintegrants—have been developed. These agents are effective even at lower concentrations than starch. Because they occupy less space in a formulation, issues related to flow or compression are minimized. Superdisintegrants are typically grouped into three categories based on their chemical structure.

List of Branded MDTs are available in market

Drug / Combination	**Reason for Ban**	**Notes**
Nimesulide + Paracetamol (dispersible)	No therapeutic justification; safety risk	Part of 14 FDCs banned by Indian government. (mint)
Amoxicillin + Bromhexine	Irrational combination	Listed in the banned FDC list. (India Today)

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Drug / Combination	Reason for Ban	Notes
Pholcodine + Promethazine	Safety concern / lack of justification	From the 2023 banned FDC list. (India Today)
Diphenhydramine HCl + Phenylephrine + Ammonium Chloride	Fixed-dose issue / risk	Part of the banned FDCs. (India Today)
Dextromethorphan + Chlorpheniramine + Phenylephrine (various combos)	Safety and rationality issues	Several of these triple combos are banned. (India Today)

Advantages of Mouth Dissolving Tablets (MDTs)

1. No need for water: MDTs dissolve instantly in the mouth, making them highly convenient for patients who have limited access to water.

2. Improved patient compliance: They are ideal for pediatric, geriatric, bedridden, mentally disabled, and dysphagic patients who face difficulty swallowing conventional tablets.

3. Rapid onset of action: Since the drug dissolves quickly and gets absorbed

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through the oral mucosa, MDTs provide faster therapeutic action.

4. Enhanced bioavailability: Partial or full pre-gastric absorption avoids first-pass metabolism, potentially increasing drug bioavailability.

5. Ease of administration: Suitable for people on the move, travelers, and patients with nausea/vomiting who cannot swallow solid dosage forms.

6. Improved stability: Solid dosage form offers better stability compared to liquid formulations like syrups or suspensions.

7. Better taste and mouthfeel: Formulations often include taste-masking agents, making them more acceptable, especially for children.

8. Reduced risk of choking: Quick disintegration minimizes the chance of tablets lodging in the throat.

9. Convenient handling and packaging: MDTs can be carried easily and do not require special storage conditions like liquids.

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MATERIALS AND METHODS

Method of Preparation of Mouth Dissolving Tablets (MDTs)

MDTs can be prepared using several technologies, each based on improving tablet porosity, disintegration behavior, or matrix dissolution. Below is a detailed explanation of all major methods:

1. Direct Compression Method

This is the most widely used technique for MDTs because it is simple, cost-effective, and suitable for moisture-sensitive drugs (11,12).

Steps:

1. Selection of Superdisintegrants: Choose fast-acting agents such as croscarmellose sodium, crospovidone, or sodium starch glycolate.

2. Weighing and Sieving: Accurately weigh all ingredients and sieve them through mesh #40 to obtain uniform particle size.

3. Blending: Mix the drug, diluents, superdisintegrants, and other excipients (like sweeteners and flavors) in a blender for uniform distribution.

4. Lubrication: Add lubricants such as magnesium stearate or talc and mix gently to avoid over-lubrication, which may retard disintegration.

5. Compression: Compress the blend into tablets using standard punches on a tablet press with low compression force to maintain porosity.

2. Freeze-Drying or Lyophilization Method

This method creates highly porous and lightweight tablets that dissolve in seconds[1]

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Steps:

1. Preparation of Drug Solution/Suspension: Dissolve or disperse the drug in a water-soluble matrix (e.g., gelatin, mannitol).

2. Molding: Pour the mixture into pre-formed blisters or molds.

3. Freezing: Freeze the molded solution at very low temperature to solidify the structure.

4. Primary Drying (Sublimation): Remove frozen water under vacuum, creating a porous matrix.

5. Secondary Drying: Remove residual moisture to improve tablet stability.

3. Sublimation Method[14]

Volatile substances leave pores after removal, increasing disintegration speed.

Steps:

1. Mixing of Formulation Components: Blend drug with excipients and volatile materials such as camphor, ammonium bicarbonate, or menthol.

2. Compression: Compress the mixture into tablets using low pressure.

3. Sublimation: Expose tablets to a drying chamber or vacuum oven to evaporate volatile components, leaving a porous structure.

4. Tablet Molding Method[12,15]

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Improves mouth feel because molded tablets are usually soft and water-soluble.

Steps:

1. Preparation of a Drug-Excipient Mixture: Wet the powdered mixture with a hydro-alcoholic solvent to form a plastic mass.

2. Molding: Compress the plastic mass inside a mold or blister cavity.

3. Drying: Remove the solvent by air drying/oven drying to solidify tablets.

5. Spray-Drying Method[16]

Produces fast-dissolving porous powders that can be compressed into MDTs.

Steps:

1. Preparation of Liquid Feed: Prepare a solution containing a hydrolyzed gelatin matrix, superdisintegrants, and drug.

2. Spray Drying: Atomize the solution into a hot air chamber to rapidly dry droplets into porous particles.

3. Compression: Compress dried powder into MDTs.

6. Mass Extrusion Method[17]

Used when taste masking is required.

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Steps:

1. Prepare a Soft Mass: Mix the drug with a water-soluble polymer (like PEG) and plasticizer.

2. Extrusion: Pass the mass through an extruder to obtain cylindrical strands.

3. Cutting: Cut strands into uniform segments.

4. Drying: Allow pieces to dry and harden into tablet-like units.

7. Cotton Candy (Flash-Dose) Method[18]

Uses a candy-floss type matrix for extremely fast disintegration.

Steps:

1. Spinning: Melt saccharides (sucrose or polysaccharides) and spin them into floss-like fibers.

2. Blending: Mix the floss matrix with the drug and excipients.

3. Compression: Compress the blend lightly to create MDTs.

8. Nanomelt Technology[19]

Improves dissolution of poorly soluble drugs.

Steps:

1. Preparation of Drug Nanoparticles: Convert the drug into nanosized

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particles using wet milling or precipitation.

2. Mixing: Blend nanoparticles with superdisintegrants and other excipients

3. Compression: Compress into tablets with minimal force.

Ingredients Used in Mouth Dissolving Tablets (MDTs)

MDT formulations require specialized excipients to achieve rapid disintegration, pleasant taste, and stable drug delivery. The major ingredients include[20]:

1. Active Pharmaceutical Ingredient (API)

The therapeutic drug used in the formulation.Should be stable, effective at low dose, and have good solubility or should dissolve quickly after disintegration[21].

2. Superdisintegrants

These are essential for rapid breakup of the tablet within seconds[22].

Common examples:

Croscarmellose sodium (CCS), Sodium starch glycolate (SSG), Crospovidone, Low-substituted hydroxypropyl cellulose (L-HPC)

Function: Promote rapid water uptake and swelling → fast disintegration.

3. Diluent / Filler

Provide bulk and improve mouthfeel. Examples: Mannitol (most preferred due to cooling effect and pleasant taste, Microcrystalline cellulose (MCC), Lactose, Dextrose

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Function: Add volume, improve compressibility, and enhance palatability[23].

4. Binder

Used to maintain tablet integrity while still allowing fast disintegration[24]. Examples:

PVP (Polyvinylpyrrolidone), Starch paste, Hydroxypropyl methylcellulose (HPMC) (low concentration), Pregelatinized starch

5. Lubricants

Reduce friction during tablet compression. Examples: Magnesium stearate, Talc, Sodium stearyl fumarate (preferred for MDTs due to less hydrophobicity) [25]

6. Antiadherents / Glidants

Improve powder flow and prevent sticking to punches. Examples: Colloidal silicon dioxide, Talc

7. Sweeteners

Enhance taste and patient acceptability. Examples: Aspartame, Sucralose, Saccharin sodium, Acesulfame potassium[26]

8. Flavoring Agents

Mask unpleasant drug taste and improve mouthfeel. Examples: Peppermint, Orange, Strawberry, Vanilla

9. Taste-Masking Agents

Used especially when the API is bitter. Examples: Coating materials (Eudragit E-100), Ion-exchange resins (Indion, Tulsion), Cyclodextrins

10. Saliva Stimulating Agents

Enhance saliva production to aid quick disintegration. Examples: Citric acid, Malic acid, Tartaric acid

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11. Wetting Agents / Surfactants

Improve water penetration into the tablet. Examples: Sodium lauryl sulfate (SLS), Poloxamers, Tween 80

12. Coloring Agents

Improve aesthetic appeal of tablets.

Mechanisms of Action of Superdisintegrants

Superdisintegrants facilitate rapid tablet disintegration through multiple physicochemical mechanisms. These mechanisms may act individually or synergistically, depending on the nature of the excipients, formulation composition, and environmental conditions. The major mechanisms involved in tablet disintegration are described below[22,27].

1. Capillary Action (Wicking)

Capillary action is widely recognized as the initial step in tablet disintegration. When the tablet comes into contact with an aqueous medium, water is drawn into the porous network due to capillary forces. The incoming fluid replaces the air trapped within pores, weakens the intermolecular bonds, and causes fragmentation of the tablet matrix. The efficiency of this mechanism depends on the hydrophilicity of excipients, level of porosity, and compression characteristics. A well-developed porous structure and low interfacial tension enable efficient water uptake, thereby promoting rapid disintegration[27].

2. Swelling Mechanism

Many superdisintegrants function by absorbing water and expanding significantly upon hydration. This swelling generates internal pressure within the tablet, ultimately causing the matrix to rupture. While high porosity may reduce the effectiveness of swelling due to lack of structural resistance, excessively dense tablets may inhibit fluid penetration. Thus, an optimal balance in packing density is required to achieve maximum swelling force and effective disintegration[28].

3. Heat of Wetting (Air Expansion)

Certain disintegrants exhibit exothermic wetting behavior. When these materials interact with water, localized heat is released, leading to expansion of entrapped air within the tablet. The resulting increase in internal pressure contributes to matrix disruption. Although this mechanism is limited to

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specific classes of disintegrants, it remains an important supplementary pathway in facilitating disintegration[29].

4. Gas Generation (Effervescence)

Effervescent disintegration occurs when acidic and alkaline components react in the presence of water to produce carbon dioxide. The evolving gas creates pressure within the tablet structure, causing rapid breakup. This mechanism is especially beneficial in fast-dissolving and fast-disintegrating formulations. However, effervescent blends are highly sensitive to humidity and temperature, requiring strict environmental control during processing and storage[30].

5. Enzymatic Action

In the gastrointestinal tract, naturally occurring enzymes may degrade or weaken certain formulation binders, contributing to tablet disintegration. While this mechanism is not predominant in most modern superdisintegrants, it may enhance disintegration in formulations containing natural polymers or starch-based materials[31].

6. Particle–Particle Repulsive Forces

The particle repulsion theory, proposed by Guyot-Hermann, suggests that repulsive electrostatic forces can drive tablet disintegration. Upon wetting, particles may acquire charges that cause them to repel one another, leading to disruption of the matrix. This mechanism can be particularly relevant in non-swelling disintegrants, although it is generally considered secondary to wicking and swelling[27].

7. Deformation Recovery

During tablet compression, certain disintegrant particles undergo deformation. When exposed to water, these particles tend to recover their original shape, expanding within the tablet matrix. This recovery process generates mechanical stress, which promotes breakup. Modified starches and some synthetic disintegrants exhibit enhanced deformation-recovery behavior, making this a meaningful mechanism in specific formulations[28].

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Characterization of Mouth-Dissolving Tablets (MDTs)

Evaluation of mouth-dissolving tablets (MDTs) is essential to ensure their performance, patient acceptability, and regulatory compliance. Since these formulations are designed to disintegrate rapidly in the oral cavity without water, both mechanical and performance-based parameters must be assessed carefully.

1. Appearance and Physical Parameters[3,4,32]

a. General Appearance: MDTs are visually inspected for color, shape, texture, surface finish, and presence of defects such as cracks or chipping. Consistency in appearance ensures batch uniformity and consumer acceptability.

b. Tablet Thickness and Diameter: A digital vernier caliper is used to measure thickness and diameter. These dimensions affect packaging, tablet integrity, and uniformity of dosage units.

c. Weight Variation: Twenty tablets are weighed individually, and the average weight is calculated. Variations must fall within limits as per pharmacopeial standards. This ensures dose accuracy and uniform distribution of ingredients.

2. Mechanical Strength Tests[33]

Though MDTs are designed to be soft for rapid disintegration, they must still withstand handling.

a. Hardness Test: Hardness is measured using a Monsanto or Pfizer hardness tester. An optimal balance is required: too hard may delay disintegration, while too soft may cause breakage.

b. Friability Test: Friability using the Roche friabilator determines the tablet's ability to resist abrasion during handling. Weight loss below 1% is generally acceptable.

3. Performance-Based Evaluation[34]

a. Wetting Time: Wetting time indicates how quickly saliva penetrates the tablet. A tablet is placed on filter paper soaked with water; the time required for complete wetting is recorded. Faster wetting correlates with rapid disintegration.

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b. Water Absorption Ratio: This evaluates the tablet's ability to absorb water, which directly influences disintegration behavior. The ratio is calculated by comparing tablet weight before and after wetting.

c. In-Vitro Disintegration Time[32,35]: MDTs should disintegrate typically within 30 seconds or as per pharmacopoeia limits. Disintegration is tested in distilled water at 37 ± 0.5°C using the USP disintegration apparatus. Rapid disintegration is a key indicator of MDT performance.

d. In-Vitro Dissolution Studies: Dissolution testing evaluates drug release profiles. Using USP Apparatus II (paddle method), samples are withdrawn at set intervals to determine the percentage of drug released. Rapid dissolution ensures bioavailability.

4. Organoleptic Evaluation[36]:

Since MDTs dissolve in the mouth, taste, mouthfeel, and aftertaste are crucial. A trained volunteer panel evaluates sweetness, bitterness, grittiness, and overall acceptability, especially for pediatric and geriatric populations.

5. Drug Content Uniformity

Drug content is measured by crushing tablets and analyzing the drug concentration using UV-spectrophotometry or HPLC. Content should lie within 90–110% of the labeled claim.

6. Moisture Uptake Studies

Due to their porous and hygroscopic nature, MDTs may absorb moisture. Stability chambers with controlled humidity (usually 75% RH) are used to determine moisture uptake and its effect on mechanical strength and disintegration.

7. Stability Studies

Stability testing under accelerated conditions (40°C ± 2°C / 75% RH ± 5%) helps determine changes in appearance, drug content, hardness, dissolution time, and behavior. These results predict the shelf life of MDTs[37].

Factors Affecting Moisture Sensitivity in Mouth-Dissolving Tablets

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1. Water-Soluble Excipients:

Mouth-dissolving tablets usually include ingredients like superdisintegrants and water-soluble polymers that promote fast breakup and dissolution in the mouth. Because these substances naturally attract and absorb moisture, the tablets can easily take up water from the surroundings, which may weaken their structure.

2. Hygroscopic Materials:

Some of the excipients and active pharmaceutical ingredients (APIs) used in these tablets are hygroscopic. This means they tend to absorb moisture from the environment. When this happens, the physical properties of the tablet—such as hardness, flexibility, and overall durability—can change, potentially affecting tablet performance.

3. Storage Conditions:

To prevent moisture absorption, mouth-dissolving tablets must be kept under proper storage conditions. Poor storage practices—such as keeping the tablets in high humidity or using inadequate packaging—can increase moisture uptake, leading to faster deterioration of the tablet quality.

4. Stability Issues:

Moisture exposure can negatively affect the stability of certain drugs within the tablet. This may result in reduced drug potency or unwanted chemical changes. Such modifications may impact the medication’s safety, reliability, and therapeutic effectiveness.

To reduce the impact of moisture, manufacturers may use special moisture-proof packaging and ensure proper storage methods. Additionally, optimizing the formulation and choosing moisture-resistant excipients can significantly improve the stability of mouth-dissolving tablets.

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RESULTS

From the reviewed studies, it is clear that Mouth Dissolving Tablets (MDTs) are a convenient and effective dosage form, especially for patients who have difficulty swallowing conventional tablets. MDTs formulated with commonly used superdisintegrants such as croscarmellose sodium, sodium starch glycolate, and crospovidone were found to disintegrate very quickly in the mouth, usually within a few seconds, while still maintaining sufficient strength for handling.

The results also show that the method of preparation plays an important role in tablet performance. The direct compression method was found to be simple, economical, and suitable for large-scale production. On the other hand, advanced techniques like freeze-drying and sublimation produced tablets with very fast disintegration due to their porous structure, although these methods involve higher cost and special handling. Other techniques such as spray drying, molding, and mass extrusion helped improve drug release and taste masking.

Evaluation tests including wetting time, disintegration time, dissolution studies, hardness, friability, and drug content uniformity confirmed that properly formulated MDTs meet pharmacopeial standards. Most formulations showed acceptable hardness, low friability, uniform drug content, and rapid drug release, indicating good quality and stability.

Overall, the results suggest that MDTs provide faster onset of action, better patient comfort, and improved compliance compared to conventional tablets, making them a promising and patient-friendly oral drug delivery system.

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DISCUSSION

Mouth Dissolving Tablets (MDTs) offer a significant advantage in patient convenience due to their ability to disintegrate rapidly in the oral cavity without water (1,11,22). The reviewed studies show that the type and concentration of superdisintegrants strongly influence tablet performance. Different manufacturing methods also impact tablet quality. While direct compression is simple and economical, techniques such as sublimation and lyophilization create highly porous tablets with very fast disintegration but higher production costs (6,13.14). Taste masking remains crucial for patient acceptability, especially in pediatric and geriatric populations.

Evaluation parameters—including disintegration time, wetting time, and dissolution profile—indicate that optimized MDTs typically disintegrate within a few seconds and provide rapid drug release. Overall, MDTs remain a promising dosage form that improves compliance, enhances onset of action, and benefits patients with swallowing difficulties (32,34,35).

CONCLUSION

Mouth Dissolving Tablets (MDTs) represent an effective and patient-friendly oral drug delivery system designed to disintegrate rapidly in the mouth without the need for water. The formulation studies suggest that selecting appropriate superdisintegrants, optimizing their concentration, and choosing a suitable manufacturing technique are crucial for achieving fast disintegration, good mechanical strength, and acceptable taste. MDTs significantly improve patient compliance, especially in populations with swallowing difficulties, and offer quicker onset of action compared to conventional tablets. Overall, MDT technology continues to play a vital role in developing convenient, efficient, and patient-centered pharmaceutical dosage forms

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ABBREVIATIONS

MDT- mouth dissolving tablet

ODT- Orally disintegrating tablet

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CONFLICT OF INTERESTS

The author declare not conflict of interest

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