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Review Article

Orally Disintegrationg Tablet; A Novel Approches to Enhanced Patient Compliance

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Abstract

Mouth dissolving tablets (MDTs) are an innovative oral dosage form designed to disintegrate rapidly in the mouth without the need for water. These tablets offer significant advantages, including ease of administration, improved patient compliance (particularly for pediatric and geriatric populations), and faster onset of action. MDTs are characterized by their pleasant taste, quick disintegration, and convenience, making them a preferred alternative to traditional tablets and capsules. They are widely used in various therapeutic areas such as pain management, allergy relief, and mental health. Compared to conventional oral dosage forms, MDTs provide enhanced patient experience, though they may have some limitations in terms of cost and formulation challenges. This review highlights the benefits, applications, and patient perspectives on MDTs while comparing them with other dosage forms. Future advancements in MDT technology may further expand their therapeutic potential.

Key words: orodispersible tablets; eletriptan hydrobromide; migraine; direct compression; disintegration time

Introduction

Mouth dissolving tablets are solid dosage forms that quickly break down in the mouth, dissolving into saliva without needing water. The oral cavity is an attractive site for administration due to its ease of use. These tablets have gained popularity over the past decade for their convenience, dissolving quickly in the mouth without chewing or additional water(1). They're known by various names, including fast-dissolving, rapid-melting, and oro-dispersible tablets. According to the European Pharmacopeia, oro-dispersible tablets should disperse in the mouth within three minutes, making them easier to swallow(2). Good mouth dissolving tablets typically dissolve within seconds to a minute. With the high cost of developing new drugs, pharmaceutical companies are focusing on creating more patient-friendly and cost-effective dosage forms for existing medications(3).

Additionally, patients travel with minimal to no water surplus. Limit the effectiveness of oral administration of convectional tablet capsules. A tablet that dissolves in the mouth has a quick onset of action and is quickly absorbed. Furthermore, drug candidates that are formulated as mouth-dissolving tablets and undergo pre-gastric absorption may exhibit high oral bioavailability. It is easy to manufacture and offers precise dosing and good stability. When making mouth-dissolving tablets, synthetic super disintegrants like crospovidone, croscarmellose sodium, sodium starch, glycolate, and others are utilized. This method allows the tablet to dissolve in the tongue and release the medication into the saliva (4). When developing a formulation for such tablets, the appropriate choice of super disintegration and its consistency of performance are crucial factors to consider. By resolving earlier administrative issues and extending patent life, mouth dissolving drug delivery systems have secured a significant place in the market. As soon as the dosage forms come into contact with saliva, even within 60 seconds, they dissolve and disintegrate quickly, releasing the drug (5). It is particularly attractive to bedridden, elderly, and pediatric patients as well as active, busy, and traveling patients who might not have access to water because it does not require water during administration (6).

Dysphagia patients and older adults. One study found that size was the primary cause of swallowing difficulties for 26% of the 1576 patients, followed by shape, surface, and testes 8, 9.Solid dosage forms that can be chewed, dissolved and suspended in water, or rapidly dissolved in the mouth are especially in demand in the pediatric and geriatric markets. (7). These forms can also be used for other patients who would rather have a convenient, easily administered dosage form. Due to the fact that the average lifespan of humans has increased and that it is decreasing with age, Oral tablet administration to patients is a major issue in swallowing

ability and has drawn public attention. The development of oral forms that dissolve or disperse quickly and don't need water to help with swallowing can solve the issue (8). After being put in the mouth, the dosage forms are swallowed normally after being given time to dissolve or spread in the saliva. They are less commonly made to be absorbed as saliva enters the stomach through the esophageal and buccal mucosa. In the latter instance, a drug's bioavailability from fast-dissolving formulations might even surpass that of conventional dosage forms (9),(10).

Ideal Characteristics of Mouth Dissolving Tablet

- It shouldn't need water or any other liquid to function.
- It feels good in your mouth.
- Be portable without worrying about fragility and compatible with taste masking.
- The recipients' wet ability should be high.
- After taking the tablet, there shouldn't be any residue in the mouth.
- It is less affected by environmental factors like temperature and humidity.
- The drug is absorbed from the pre-gastric route more quickly.
- The equipment used for processing and packaging is inexpensive.
- Permit a high drug loading (11).

Advantages of Mouth Dissolving Tablet over traditional oral dosage forms

- *Faster Drug Absorption and Quicker Effects* - Since MDTs disintegrate quickly in saliva, the drug is absorbed rapidly through the oral mucosa or stomach. Some medications bypass liver metabolism, leading to a faster onset of action useful for emergencies like heart pain or migraines.
- *No Water Required for Administration* - These tablets are ideal for people who struggle with swallowing, such as children, elderly patients, or those with dysphagia. They are also convenient when water isn't easily accessible .
- *Improved Drug Bioavailability* - Some drugs break down in the stomach or lose potency due to liver metabolism. MDTs that dissolve in the mouth can avoid first-pass metabolism, increasing the drug's effectiveness.
- *Flexible Use for Different Treatments* -MDTs are useful for,Emergency drugs (e.g., nitroglycerin for angina), Nausea/vomiting cases (where swallowing is hard), Psychiatric medications (for patients who resist treatment) (12).

Therapeutic Application

Therpetic Category	Drug	Advantages
Neurological	Risperidone, Olanzapine, Clonazepam	Improves compliance in resistant patients, rapid absorption [13]
Cardiovascular	Nitroglycerin, Nifedipine	Immediate action in angina anc
Pain /Fever	Paracetamol, Tramadol	Quick migraine relief, pediatric-friendly [14]
Allergy	Fexofenadine, Levocetirizine	Rapid relief, no water needed
Gastrointestinal	Ondansetron, Lansoprazole	Effective for chemo-induced nausea
Endocrine	Voglibose, Metformin	Controls postprandial glucose [15]

Table 1: Therapeutic Application Of MDS

Mouth-dissolving tablets have become increasingly valuable in managing modern health challenges. For Long COVID symptoms like brain fog and fatigue, fluvoxamine and montelukast ODTs offer rapid relief while bypassing swallowing difficulties (16). In pediatric ADHD, methylphenidate and guanfacine ODT It improve compliance without choking risks. Post-stroke patients with dysphagia benefit from donepezil and clopidogrel ODTs, ensuring neuroprotection despite swallowing impairments. For dementia-related agitation, risperidone and memantine ODTs reduce medication refusal while providing rapid calming effects (17) . In chemotherapy-induced nausea, olanzapine and aprepitant ODTs are critical when vomiting prevents pill. Migraine sufferers rely on rimegepant and zolmitriptan ODTs (e.g., Nurtec®) for fast relief during nausea Even diabetes management leverages voglibose and metformin ODTs to control post-meal spikes These innovations highlight MDTs' role in enhancing compliance, speed, and accessibility in modern therapy (18) .

MDS Comparison with other Dosage Form

Pharmaceutical dosage forms have evolved significantly to improve patient compliance and therapeutic efficacy. Among these advancements, mouth-dissolving tablets (MDTs), also known as orodispersible tablets (ODTs), represent a notable innovation over conventional tablets. Unlike traditional tablets that require water for swallowing, MDTs are designed to rapidly disintegrate in the oral cavity, releasing their active ingredients quickly., typically within seconds, making them particularly advantageous for pediatric, geriatric, and dysphagic patients. This comparison highlights the key differences between these two dosage forms in terms of administration, formulation, patient suitability, and clinical applications. The following table provides a detailed side-by-side analysis of their distinct characteristics (19)

Approaches	Mouth-Dissolving Tablet	Traditional Tablet	Capsule	Liquid (Syrup/Suspension)
Administration	Dissolves in mouth (no water needed)	Swallowed with water	Swallowed with water	Pre-measured oral ingestion
Disintegration	10-60 seconds	5-30 minutes (in GI tract)	10–20 mins (GI tract)	Immediate (pre-dissolved)
Absorption Speed	Fast (potential buccal absorption)	Moderate	Moderate	Fastest
Patient Suitability	Ideal for dysphagia, children, elderly	Not suitable for dysphagia	May be opened (for some types)	Best for pediatrics
Taste Masking	Must be well-flavored	Coating masks taste	Shell masks taste	Easily flavored
Dosing Precision	Precise	Precise	High	Variable (measuring needed)
Stability	=Moisture-sensitive (needs special packaging)	Stable	Humidity-sensitive	Short shelf life (often refrigerated)
Examples	Zofran ODT, Maxalt MLT	Tylenol tablets	Advil capsules	Children's Tylenol liquid

Table no 2: Difference between MDS, Tablet, Capsule, liquids

Limitations of Mouth Dissolving Tablet:

• ***Mechanical strength:*** Mouth-dissolving tablets often have compromised mechanical strength.

• ***Hygroscopicity:*** Many mouth-dissolving tablets are hygroscopic, requiring special packaging to maintain their integrity.

• ***Brittleness and friability:*** These tablets are typically brittle and prone to damage due to their porous nature and low compression force (20).

• ***Packaging challenges:*** Specialized packaging, such as peel-off blister packs, may be necessary to protect the tablets.

• *Formulation challenges:* Developing mouth-dissolving tablets for potent or odor-unpleasant medications can be difficult, requiring careful consideration during formulation (21).

Problems with Existing Oral Dosage form:

• Patients with tremors may struggle with liquids and powders due to difficulty swallowing.

• Dysphagia can cause solid dosage forms like tablets and capsules to adhere to the esophagus, potentially leading to ulcers, and is particularly problematic for elderly patients and young children (22).

• Liquid medications in multidose containers can lead to inconsistent dosing.

• Some patients may experience irritation from buccal or sublingual formulations, making them unappealing (23).

• Parenteral formulations, while effective, are often the most expensive and uncomfortable option, making cost a significant factor (24).

Technologies for Mouth Dissolving Tablets:

Conventional Technologies:

• ***Freeze Drying:*** Lyophilization, or freeze-drying, is a process that removes water from a product by freezing and then reducing the surrounding pressure to allow the frozen water to sublimate (change directly from a solid to a gas) without going through the liquid phase (25). This technique is particularly useful for preserving heat-sensitive pharmaceuticals and biological materials. The resulting product is highly porous, with a large surface area, which enables rapid dissolution, improved absorption, and enhanced bioavailability (26) .

• ***Tablet Molding:*** The solvent method and the heat method are the two types of molding processes. In order to create a wetted mass (compression molding), the powder blend is moistened with a hydro-alcoholic solvent and then compressed at low pressures in molded plates(27). The solvent is eliminated below by air-drying (27). The resulting tablets are small and light. The porous structure of the compressed tablets speeds up dissolution. A suspension containing a drug, agar, or sugar (such as lactose or mannitol) is made before the heat molding process begins (28).

• ***Direct Compression:*** Direct compression is a straightforward and cost-effective method for producing mouth-dispersing tablets (29). The drug mixture and excipients are compressed without prior treatment, often incorporating super disintegrants to enhance disintegration and dissolution rates. Optimizing disintegrant concentration is crucial, as it inversely affects disintegration time up to a critical concentration point (30). Beyond this point, further increases in disintegrant concentration do not significantly impact disintegration time. However, hygroscopicity can be a limitation (31). Alternatively, sugar-based excipients like fructose, dextrose, and others (such as xylitol, mannitol, and sorbitol) can be used, offering pleasant mouthfeel and high aqueous solubility(32).

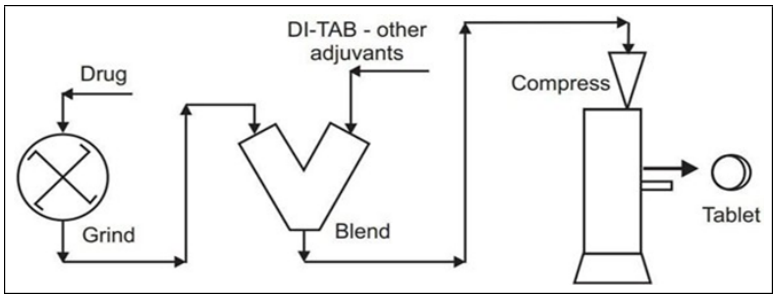

Figure 1: Process of drying compression technology

• ***Spray Drying:*** Spray-drying is used to create mouth-dissolving tablets by formulating a mixture containing a bulking agent like mannitol, a disintegrant such as sodium starch glycolate or croscarmellose, and a matrix-supporting agent like gelatin (33). Adding an acid (e.g., citric acid) and an alkali (e.g., sodium bicarbonate) enhances disintegration and dissolution. The mixture is then spray-dried to produce a porous powder, which is compressed into tablets that disintegrate rapidly (in under 20 seconds) in aqueous media. (34).

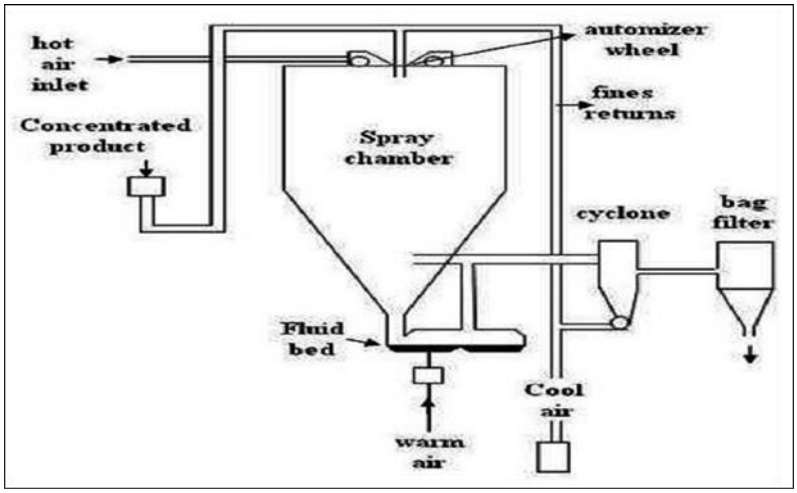

Figure 2: Process Spray drying technology

• ***Sublimation:*** The sublimation technique for fast-dissolving tablets involves incorporating a volatile substance into the formulation, which is then removed through sublimation, creating pores that facilitate rapid disintegration in saliva. Substances like camphor, naphthalene, and urea can be used to create porous tablets with good mechanical strength. By removing the volatile component, the resulting tablets exhibit improved dissolution properties. This technique allows for the creation of tablets with tailored porosity and mechanical strength, enhancing their fast-dissolving characteristics. (37).

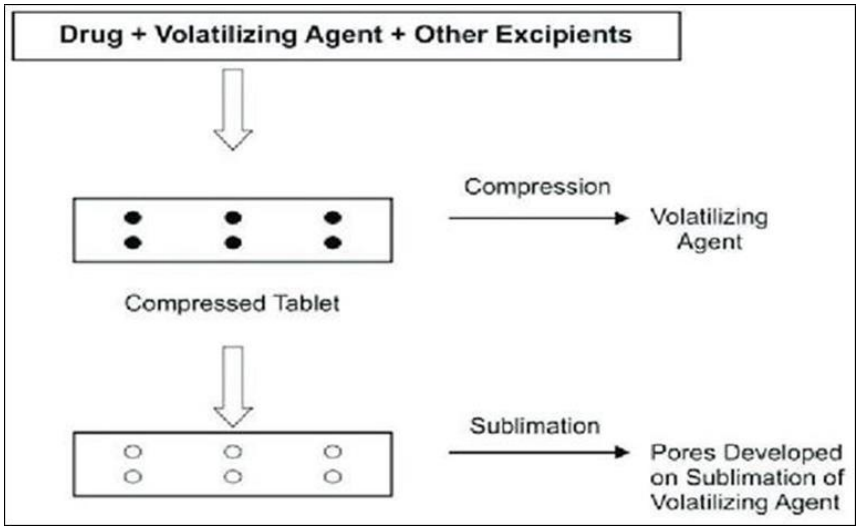

Figure 3: Steps involved in sublimation technology

Patented Technologies:

• Zydis Technologies: Zydis technology, developed by R P Scherer (Cardinal Health), involves freeze-drying a drug in a water-soluble matrix, typically gelatin. This process creates a light, fragile, and highly porous tablet that dissolves rapidly upon contact with saliva. The low water content in the final product inhibits microbial growth, providing self-preservation. Ideal candidates for Zydis formulation are drugs with fine particles, stable aqueous suspensions, and relatively low water solubility. The high limit for drug loading for water-soluble medications is extremely low (about 60 mg). Water-soluble drugs' primary issue is the creation of a eutectic mixture, which lowers the freezing point and produces glossy solids when frozen, causing the supporting structure to collapse during sublimation. Using a solvent mixture of water-soluble polyethylene glycol and methanol, the active blend was softened. Then, the softened mass was expelled through a syringe or extruder to divide a cylinder of the product into uniform segments using a heated blade to create tablets. Additionally, granules of bitter-tasting medications can be coated with the dried cylinder to cover their bitter flavor(40).

• **Orasolv Technologies:** The first fast-dissolving formulation developed in the CIMA lab. To reduce oral disintegration and dissolution time, tablets are made by direct compression with a lower compression force. One example of a slightly effervescent tablet that dissolves quickly in the mouth is Orasolv technology (41).Because of the action of effervescent agents, the active medications are taste-masked and dispersed in saliva. It gives the patient a pleasing feeling in their mouth. Orasolv technology's primary drawback is its lower mechanical strength. The manufactured tablets must be packed in a specially made pack because they are soft and brittle(42).

• **Durasolv Technologies:** Durasolv, a second-generation fast-dissolving tablet technology from CIMA, boasts enhanced mechanical strength due to its high compaction tableting process. This results in efficient and cost-effective production(43). However, the high compaction pressure may limit its suitability for formulations with high active ingredient doses. Durasolv is currently utilized in products such as Zorlip and Nulev, showcasing its potential in fast-dissolving tablet applications (44).

• **Wowtab Technologies:** The Wowtab technology, developed by Yamanouchi, enables the creation of intrabuccal soluble tablets that dissolve quickly without water. This technology combines granules with varying moldability properties - high and low - to achieve a balance between tablet hardness and rapid dissolution. By blending active ingredients with low-moldability saccharides and granulating with high-moldability saccharides, tablets can be compressed to meet specific requirements. The unique combination of properties allows for efficient tablet formulation(46).

Conclusion

Mouth dissolving tablets (MDTs) represent a significant advancement in drug delivery, offering numerous benefits such as rapid disintegration, improved patient compliance, and enhanced convenience. Their ability to dissolve quickly in the mouth without water makes them particularly useful for children, elderly patients, and individuals with swallowing difficulties. MDTs are successfully employed in various therapeutic fields, including pain relief, allergy treatment, and mental health, providing an effective alternative to traditional tablets and capsules. While they may come with slight drawbacks such as formulation complexity or higher costs, their advantages often outweigh these limitations. Overall, MDTs are a highly recommended dosage form for patients seeking ease of use and faster drug absorption. As technology progresses, further innovations in MDTs are expected to enhance their efficacy and accessibility, solidifying their role in modern medicine.

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