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MOUTH DISSOLVING TABLETS: A PROMISING ALTERNATIVE TO CONVENTIONAL TABLETS

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ABSTRACT

Mouth Dissolving Tablets (MDTs) are advanced oral dosage forms that rapidly break down in the mouth when exposed to saliva, allowing the patient to swallow the medication without water. These tablets have attracted wide interest because they improve convenience, enhance patient adherence, and are especially beneficial for children, elderly individuals, and patients with swallowing difficulties. MDTs provide several advantages, such as faster onset of therapeutic action, the possibility of increased bioavailability for drugs absorbed in the oral cavity, precise dosing, and good stability. Their formulation mainly depends on efficient super disintegrants like cross povidone, croscarmellose sodium, and sodium starch glycolate, which enable quick dispersion on the tongue. The rising preference for user-friendly drug delivery systems and the industry's focus on upgrading existing drugs have further increased the importance of MDTs. Overall, these tablets offer a practical and effective alternative to traditional solid dosage forms, addressing major limitations in oral drug administration.

KEYWORDS: Rapid Disintegration, Mouth Dissolving Tablets, Orally Disintegrating Tablets, Fast Dissolving Tablets & Orodispersible Tablets.

INTRODUCTION

Mouth dissolving tablets (MDTs) are solid dosage forms that rapidly disintegrate and dissolve in the oral cavity on contact with saliva, allowing swallowing without water. They are also known as fast melting, fast dispersing, or orally disintegrating tablets (ODTs). According to the European Pharmacopoeia, MDTs disintegrate within three minutes, usually within a few seconds to one minute.

MDTs are developed to improve patient compliance, especially in pediatric, geriatric, and dysphagic patients, as well as for individuals with limited access to water. They offer advantages such as rapid onset of action, improved bioavailability (due to pre-gastric absorption), accurate dosing, good stability, and ease of administration.

The formulation of MDTs mainly involves the use of superdisintegrants like crospovidone, croscarmellose sodium, and sodium starch glycolate, which enable instant tablet disintegration in the mouth. Due to these benefits and their role in life-cycle management and patient-centric drug delivery, MDTs have gained significant importance in modern pharmaceutical dosage form development.

IDEAL PROPERTIES OF MOUTH DISSOLVING TABLETS (MDTs)

Rapid Disintegration and Dissolution

- MDTs should dissolve or disintegrate in the mouth within a few seconds, generally between 15 seconds to 3 minutes.
- They must provide fast onset of therapeutic action due to rapid disintegration and quick absorption through the oral mucosa.
- Should not require water for administration and should dissolve easily in saliva.

Pleasant Mouth Feel

- MDTs must provide a pleasing mouth feel and pleasant taste to ensure patient compliance.

- Large tablet fragments or gritty textures should be avoided to prevent discomfort.
- Proper particle size reduction and use of sweeteners or flavoring agents enhance mouth feel.

Taste Masking

- Since many drugs have a bitter or unpleasant taste, effective taste masking is essential.
- The formulation should be compatible with taste-masking agents and flavoring excipients without affecting drug stability or disintegration.

Minimal Residue

- After administration, MDTs should leave minimal or no residue in the mouth. This enhances patient acceptability, especially for pediatric and geriatric patients.

Mechanical Strength and Friability

- MDTs should possess sufficient hardness to withstand mechanical shock during manufacturing, packaging, and transportation.
- At the same time, they must be less friable and maintain their integrity even with minimal compression force.

High Drug Loading Capacity

- The formulation should allow high drug loading without compromising the tablet's disintegration property or mouth feel.
- It should also remain compatible with various excipients and flavoring agents.

Stability and Environmental Sensitivity

- MDTs should exhibit low sensitivity to environmental conditions such as temperature and humidity.
- Since some MDTs are hygroscopic, they may require specialized peel-off blister packaging to maintain physical integrity.

Ease of Manufacturing

- MDTs should be compatible with conventional processing and packaging equipment, allowing cost-effective production.
- They should not demand any special manufacturing technology beyond standard tablet compression and coating methods.

Portability and Patient Convenience

- MDTs must be portable, easy to handle, and convenient for patients who may not have immediate access to water (e.g., while traveling).
- They should be economical, easy to store, and simple to administer — promoting better patient compliance.

Patient Compliance

- MDTs are ideal for pediatric, geriatric, and dysphagic patients who face difficulty in swallowing conventional tablets or capsules.
- The combination of rapid action, good mouth feel, and no need for water ensures maximum compliance.

ADVANTAGE OF MOUTH DISSOLVING TABLETS

- No need for water during administration
- Easy to administer to pediatric, geriatric, psychiatric, bedridden, and dysphagic patients
- Rapid disintegration and onset of action
- Improved bioavailability due to pre-gastric absorption
- Accurate dosing compared to liquid formulations
- Reduced risk of choking or suffocation
- Better patient compliance and convenience for travelers
- Pleasant mouthfeel and improved taste masking
- Solid dosage stability with liquid-like bioavailability
- New business opportunities through product differentiation and lifecycle management

LIMITATION AND DISADVANTAGES

- Hygroscopic nature requiring dry storage
- Limited drug loading capacity
- Fragility and low mechanical strength
- Taste masking challenges for bitter drugs
- Sensitivity to moisture and temperature
- Need for specialized packaging
- Higher production cost for some technologies (e.g., lyophilization)
- Unsuitable for patients with severe dry mouth conditions

MECHANISM OF TABLETS DISINTEGRATION

Tablet disintegration is a critical step in drug release and bioavailability. Several mechanisms contribute to the rapid breakup of MDTs when they come into contact with saliva or aqueous media.

Swelling Mechanism

Swelling is one of the most common mechanisms of tablet disintegration. When disintegrants absorb water, they swell and generate internal stresses that cause the tablet matrix to rupture. Tablets with low porosity experience higher swelling force, whereas highly porous tablets show reduced swelling efficiency. However, excessively high packing density can restrict liquid penetration and slow disintegration. Superdisintegrants enhance this mechanism by rapidly absorbing water, increasing tablet volume, and promoting faster drug release.

Capillary Action (Wicking)

Capillary action is often the initial step in tablet disintegration. When a tablet contacts an aqueous medium, water penetrates through capillary pores and replaces the air trapped within the tablet. This process

weakens intermolecular bonds and breaks the tablet into smaller fragments. Disintegrants that maintain a porous structure and possess low interfacial tension facilitate water uptake and formation of a hydrophilic network around drug particles, accelerating disintegration.

Particle Repulsion Theory

The particle repulsion theory explains disintegration caused by non-swelling disintegrants. According to Guyot-Hermann, electrically charged particles repel each other in the presence of water, leading to tablet breakup. Although water is essential for this mechanism, particle repulsion is considered secondary to capillary action in most formulations.

Heat of Wetting

Some disintegrants release heat upon wetting, resulting in localized stress due to capillary air expansion. This stress contributes to tablet disintegration. However, this mechanism applies only to a limited number of disintegrants and does not adequately explain the behavior of most modern formulations.

Gas Generation

Gas generation is utilized in effervescent MDTs. When bicarbonates or carbonates react with organic acids such as citric or tartaric acid in the presence of moisture, carbon dioxide is produced. The internal pressure generated by the gas causes rapid tablet disintegration. These formulations require strict environmental control during manufacturing due to their sensitivity to humidity and temperature.

Enzymatic Activity

Certain enzymes present in the body act as natural disintegrants by breaking down binders within the tablet matrix. This enzymatic action enhances water uptake, increases granule volume, and promotes tablet disintegration.

Deformation Mechanism

During tablet compression, some particles undergo deformation. When these deformed particles come into contact with water, they return to their original shape, leading to an increase in volume and subsequent tablet breakup. This mechanism is particularly associated with starch-based disintegrants and has gained attention in recent research.

FORMULATION COMPONENTS

Super Disintegrants

Superdisintegrants are a class of high-performance excipients added to tablet formulations to ensure rapid breakdown of the tablet into smaller granules or primary particles upon contact with gastrointestinal fluids. Their high efficiency allows them to be used at low concentrations (typically 1-10% w/w). They primarily act by swelling, wicking (capillary action), or deformation, creating disruptive forces that overcome the inter-particle bonds in the tablet.

- **Mechanism of Action:** Their primary mechanism is rapid and massive swelling upon water absorption, which exerts immense outward pressure, causing the tablet to burst apart. They also create porous channels via wicking, allowing water to penetrate the tablet matrix quickly.
- **Intragranular vs. Extragranular Addition:** Adding a portion intragranularly (within the granules) helps break the granules themselves, while adding extragranularly (between the granules) disrupts the overall tablet structure. A combination of both is often used for maximum efficiency.
- **Critical Concentration:** The concentration is crucial. Below a critical level, disintegration time decreases as concentration increases. Above that critical point, a further increase can lead to higher disintegration times or decreased hardness due to interference with the bonding properties of other excipients.

Examples

- **Synthetic Polymers:** Crospovidone, Croscarmellose Sodium.
- **Natural & Semi-synthetic:** Sodium Starch Glycolate, Microcrystalline Cellulose (e.g., Avicel®, Ac-di-sol®).
- **Cellulose Derivatives:** Sodium Carboxy Methyl Cellulose, Calcium Carboxy Methyl Cellulose.
- **Starch-based:** Modified Corn Starch, Pregelatinized Starch.
- **Novel Agents:** Kyron T-314 (a cation exchange resin).

Bulking Agents / Fillers

Bulking agents, or fillers, are inert substances that provide the necessary volume and mass for a tablet to be mechanically robust and easily handled. They are essential for low-dose active pharmaceutical ingredients (APIs) where the amount of drug is too small to form a tablet of practical size. They also act as cost-reducers and can improve the tablet's texture, mouthfeel, and stability.

- **Functionality:** Beyond just adding bulk, they influence critical properties like compressibility, flowability, and density of the powder blend.
- **Solubility Profile:** The choice of filler can be tailored based on the desired drug release. Water-soluble fillers (like sugars) aid in dissolution, while insoluble ones (like dicalcium phosphate) can be used in controlled-release formulations or for moisture-sensitive drugs.
- **Compatibility:** Must be chemically and physically inert, not reacting with the API or other excipients.

Examples

- **Sugar Alcohols (for chewable tablets & good mouthfeel):** Mannitol, Sorbitol, Xylitol, Lactitol.
- **Direct Compression Sugars & Derivatives:** Direct Compressible Lactose (DCL), Starch

Hydrolysate, Polydextrose.
- **Inorganic Salts:** Calcium Carbonate, Calcium Phosphate (Dibasic), Calcium Sulfate.
- **Other Minerals:** Magnesium Carbonate, Magnesium Trisilicate, Aluminum Hydroxide.
- **Starch-based:** Pregelatinized Starch.

Binders

Binders are adhesive materials that impart cohesiveness to the powder blend, ensuring that granules (during wet granulation) and the final tablet have adequate mechanical strength to withstand processing, handling, and packaging without breaking or capping. They form a "glue" that holds the particles together.

- **Application Methods:** Can be added as a dry powder (in dry granulation or direct compression) or as a solution (in wet granulation). The concentration and viscosity of the binder solution are critical parameters.
- **Impact on Dissolution:** While essential for strength, overuse of binders can slow down tablet disintegration and drug dissolution by forming a thick, gelatinous layer or by creating too strong a bond between particles.
- **Natural vs. Synthetic:** Natural binders like starch are cost-effective but can be variable. Synthetic polymers like PVP and HPMC offer more consistent and controllable properties.

Examples
- **Saccharides & Derivatives:** Lactose, Sucrose, Starch, Microcrystalline Cellulose.
- **Cellulose Derivatives:** Hydroxypropyl Cellulose (HPC), Hydroxypropyl Methylcellulose (HPMC), Methyl Cellulose.
- **Sugar Alcohols:** Xylitol, Sorbitol (also provide sweetness and bulk).
- **Proteins:** Gelatin.
- **Synthetic Polymers:** Polyvinylpyrrolidone (PVP/Povidone), Polyvinyl Alcohol (PVA), Polyethylene Glycol (PEG).

Lubricants

Lubricants are essential for preventing the powder blend from sticking to the punches and dies during the high-pressure compression and ejection stages of tablet manufacturing. They reduce inter-particle and particle-metal friction, ensuring a smooth operation and preventing tablet defects like sticking, picking, and excessive wear on tooling.

- **Mechanism:** They act by forming a thin, shear-able film over the particle surfaces and the metal surfaces of the tablet press.
- **Negative Effects:** Most lubricants, especially hydrophobic ones like Magnesium Stearate, are "over-lubricating." If used in excess or mixed for too long, they can weaken tablet strength (reduce hardness) and slow down disintegration and dissolution by creating a water-repellent layer.
- **Glidant Action:** Some, like Talc and Colloidal Silicon Dioxide, also function as glidants, improving the flow of the powder blend by reducing inter-particulate friction.

Examples
- **Metallic Stearates:** Magnesium Stearate, Zinc Stearate, Calcium Stearate.
- **Fatty Acids & Alcohols:** Stearic Acid.
- **Inorganic Minerals:** Talc.
- **Polymers & Waxes:** Polyethylene Glycol (PEG), especially for soluble formulations.
- **Oils:** Liquid Paraffin (mineral oil).
- **Synthetics:** Colloidal Silicon Dioxide (Aerosil®).

Emulsifying / Surface Active Agents (Surfactants)

Surfactants are amphiphilic molecules that reduce surface and interfacial tension. In solid oral dosage forms like tablets, they are primarily used to enhance the wetting of the tablet matrix and the API, thereby accelerating disintegration and dissolution. This is particularly crucial for poorly water-soluble drugs (BCS Class II).

- **Bioavailability Enhancement:** By improving dissolution, they can significantly increase the oral bioavailability of hydrophobic drugs.
- **Stabilizing Role:** In formulations containing immiscible components (e.g., a lipid-based extract), they help stabilize the mixture.
- **Orodispersible Tablets:** They enable the tablet to disintegrate rapidly in the mouth without water by facilitating saliva penetration.

Examples
- **Anionic:** Sodium Lauryl Sulfate (SLS) / Sodium Dodecyl Sulfate.
- **Non-ionic:** Polyoxyethylene Sorbitan Fatty Acid Esters (Polysorbates / Tweens®), Sorbitan Esters (Spans®).
- **Natural:** Lecithin (from soy or egg).
- **Specialty Esters:** Propylene Glycol Esters, Sucrose Esters, Polyoxyethylene Stearate.

Flavouring Agents (Flavours)

Flavours are critical for masking the unpleasant, bitter, or metallic taste of APIs, thereby improving patient acceptability and compliance, especially in paediatric, geriatric, and orodispersible formulations.

- **Selection Strategy:** The choice of flavour is strategic and based on the taste profile of the API.
- **Synergy with Sweeteners:** Flavours are almost always used in combination with sweeteners and sometimes with taste-masking agents for a synergistic effect.
- **Thermal & Chemical Stability:** Must be stable during processing (e.g., drying, compression) and throughout the product's shelf life without reacting with other components.

Examples

- **For Bitter APIs:** Peppermint Oil, Cherry, Anise Oil, Chocolate, Citrus flavours (Orange, Lemon).
- **For Savory/Salty Products:** Peach, Apricot, Liquorice, Butterscotch, Caramel.
- **For Sour Products:** Raspberry, Liquorice, Wild Cherry.
- **To Counteract Excessive Sweetness:** Vanilla, Cream.
- **For a Cooling Sensation:** Menthol, Peppermint.

Sweeteners

Sweeteners are incorporated to impart a pleasant sweet taste, directly counteracting the bitterness of the API and improving palatability.

- **High-Intensity vs. Bulk:** High-intensity sweeteners (Aspartame, Sucralose) provide sweetness at very low concentrations and are calorie-free. Bulk sweeteners (Sorbitol, Xylitol) provide both sweetness and volume (acting as fillers) and often have a pleasant cooling sensation in the mouth.
- **Stability:** Some artificial sweeteners, like Aspartame, can degrade upon exposure to moisture and heat, which must be considered during formulation and storage.
- **Regulatory Status:** The choice depends on regional regulatory approvals and the target market (e.g., sugar-free products).

Examples

- **Artificial (High-Intensity):** Aspartame, Sucralose, Acesulfame Potassium (Ace-K), Saccharin.
- **Natural (High-Intensity):** Stevia (Steviol Glycosides).
- **Sugar Alcohols (Bulk):** Sorbitol, Xylitol, Mannitol, Maltitol.

Anti-adherents & Antistatic Agents

These excipients prevent the granulated powder from sticking to the punch faces and die walls, a phenomenon known as 'sticking' or 'picking'. This is crucial for maintaining a clean, sharp engraving on the tablet and for ensuring a smooth production run.

- **Difference from Lubricants:** While lubricants primarily reduce friction during ejection, anti-adherents specifically prevent adhesion to the metal surfaces. Many substances (e.g., Magnesium Stearate, Talc) perform both functions.
- **Antistatic Role:** Some, like Colloidal Silicon Dioxide, help dissipate static charge, which can otherwise cause powder segregation and poor flow.
- **Critical for Problematic Formulations:** Essential for formulations that are sticky, hygroscopic, or have a low melting point.

Examples

- **Commonly Used:** Magnesium Stearate, Talc, Colloidal Silicon Dioxide (Aerosil®).
- **Specialized:** Precipitated Silica.
- **Starch-derived:** Maltodextrins.
- **Cyclodextrins:** Beta Cyclodextrin (also used for complexation and taste-masking).

Colours

Colours are added to pharmaceutical dosage forms for identification, brand recognition, product differentiation, and aesthetic appeal. They can also improve patient compliance by making the medicine more visually acceptable.

- **Natural vs. Synthetic:** Colours can be derived from natural sources (e.g., Turmeric, Beetroot) or be synthetically produced. Synthetic dyes are more intense and stable but require regulatory approval.
- **Uniformity:** It is critical to ensure uniform colour distribution during the blending process to avoid mottled or marbled tablets.
- **Stability:** The colour must be stable and not fade or change when exposed to light, moisture, or other excipients/APIs over time.

Examples

- **Water-soluble Dyes:** Sunset Yellow FCF, Amaranth, Erythrosine.
- **Lake Pigments:** These are insoluble complexes of dyes with a substrate (like alumina) and are preferred for coating and formulations that might cause dye migration. E.g., Allura Red AC Lake, Indigo Carmine Lake.
- **Iron Oxides:** Red Iron Oxide, Yellow Iron Oxide, Black Iron Oxide (used in film coatings and are very light-stable).
- **Natural Colourants:** Titanium Dioxide (white), Caramel, Chlorophyll (green).

❖ CHALLENGES IN MDT DEVELOPMENT

Despite their advantages, MDTs present several formulation and manufacturing challenges.

Taste Masking

Most active pharmaceutical ingredients are bitter or unpleasant in taste. Since MDTs dissolve in the oral cavity, taste masking is essential for patient compliance. Common approaches include coating drug particles, granulation with sweeteners and flavors, polymer coating, spray drying, and direct blending for low-dose or tasteless drugs.

Mechanical Strength versus Disintegration Time

MDTs must balance rapid disintegration with sufficient mechanical strength. Tablets are often made porous or compressed with low force, which can result in friability and handling difficulties. Specialized packaging such as peel-off blisters is frequently required. Only a few technologies, such as WowTab and DuraSolv, provide

adequate hardness for multi-dose bottle packaging.

Hygroscopicity Issues
Many MDTs are hygroscopic and sensitive to moisture, leading to loss of physical integrity and reduced stability. Understanding the hygroscopic nature of drugs and excipients is crucial for formulation development and appropriate packaging selection.

❖ MANUFACTURE TECHNIQUES FOR MOUTH DISSOLVING TABLETS

Freeze Drying (Lyophilization)
Freeze drying involves freezing the formulation followed by sublimation of water under reduced pressure. This process produces highly porous tablets with rapid disintegration, improved dissolution, and enhanced bioavailability. It is particularly suitable for heat-sensitive drugs, although the tablets are fragile and require specialized packaging.

Tablet Molding
Tablet molding is performed using either solvent molding or heat molding techniques. In solvent molding, a hydroalcoholic solvent is used to moisten the powder blend, followed by low-pressure compression and air drying. Heat molding involves preparing a suspension with agar or sugars, which is poured into molds, solidified, and dried under vacuum. Molded tablets exhibit high porosity but low mechanical strength, which can be improved using binders.

Direct Compression
Direct compression is the simplest and most economical method for MDT preparation. It involves blending the drug with excipients and compressing the mixture directly. Superdisintegrants are commonly used to achieve rapid disintegration. Sugar-based excipients such as mannitol, sorbitol, maltose, and xylitol are preferred for their high solubility and pleasant mouthfeel. A major limitation of this method is the hygroscopic nature of some excipients.

Spray Drying
Spray drying produces porous powders that disintegrate rapidly. Formulations typically include gelatin as a matrix former, mannitol as a bulking agent, and superdisintegrants such as sodium starch glycolate. The resulting tablets usually disintegrate within 20 seconds in aqueous media.

Sublimation
In the sublimation technique, volatile substances such as camphor, urea, or ammonium bicarbonate are incorporated into tablets and later removed by heating or vacuum. The removal of these substances leaves behind pores that facilitate rapid disintegration. Tablets prepared by this method exhibit good mechanical strength and fast dissolution.

❖ PATENTED TECHNOLOGIES FOR MOUTH DISSOLVING TABLETS

Zydis Technology
Zydis technology is based on freeze drying of a drug within a water-soluble matrix, commonly gelatin. The tablets are extremely porous, light, and rapidly disintegrate upon contact with saliva. Zydis products are self-preserving due to low residual moisture and are packaged in blister packs to protect from humidity. This technology is suitable for low-dose drugs but has limitations with highly water-soluble drugs.

Ora Solv Technology
OraSolv technology utilizes direct compression at low pressure and incorporates effervescent agents for rapid disintegration and improved mouthfeel. Although the tablets dissolve quickly, they have low mechanical strength and require specialized packaging.

Durasolv Technology
Durasolv is an advanced version of orasolv technology, offering improved mechanical strength through higher compaction forces. Tablets produced using this method can be packaged conventionally but are limited to low-dose drugs due to high compression pressures.

Wow tab Technology
Wowtab technology, meaning "Without Water," uses a combination of low- and high-moldability saccharides to achieve both hardness and rapid dissolution. These tablets are more stable than Zydis and orasolv tablets and are suitable for both bottle and blister packaging.

Flash Dose Technology
Flash dose technology employs a shear-form matrix known as floss, produced using flash thermal processing. This technology was first commercialized in products such as Nurofen Meltlet.

Flash tab Technology
Flashtab technology produces tablets containing drug microcrystals using conventional tableting equipment. It offers rapid disintegration while maintaining good mechanical strength.

Frosta Technology
Frosta technology uses standard wet granulation and tableting equipment to produce fast-melting tablets. These tablets exhibit low friability, good stability, and rapid dissolution without the need for specialized machinery.

Pharma burst Technology
Pharmaburst is a ready-to-use excipient system designed to simplify the development of quick-dissolving tablets. It enables rapid formulation with minimal processing complexity.

Ora quick and Dispersible Technologies
Oraquick technology uses solvent-free taste-masked

microspheres to achieve rapid disintegration and good mouthfeel. Dispersible tablet technology enhances dissolution rates of poorly soluble drugs through the use of organic acids and superdisintegrants.

EVALUATION PARAMETERS

(a) Pre-compression Parameters

Before compressing the powder blend into tablets, it is essential to evaluate the physicochemical and flow properties of the powder mixture. These **pre-compression parameters** ensure that the powder possesses adequate flowability, compressibility, and uniformity, which are crucial for producing tablets of consistent weight and mechanical strength. Poor flow or packing characteristics can lead to issues like weight variation, capping, lamination, or non-uniform drug content in the final product.

Angle of Repose (θ)

The *angle of repose* is one of the most important indicators of powder flowability. It is defined as the maximum angle formed between the surface of a heap of powder and the horizontal plane. When powder is allowed to flow freely through a funnel, it forms a conical pile, and the height (h) and radius (r) of this heap are measured. The angle of repose is calculated using the formula.

Angle of repose: $\theta = \tan^{-1}(h/r)$

- **h** = Height of the powder heap
- **r** = Radius of the powder base
- **θ (theta)** = Angle formed by powder slope, shows powder flow property

The flow property of a powder blend is classified based on the value of θ: a smaller angle indicates better flow. Powders with an angle of repose below 25° exhibit excellent flow, 25–30° indicate good flow, 30–34° show passable flow, while values greater than 34° suggest poor flow characteristics. The test is particularly useful in predicting whether the blend will uniformly fill tablet dies during compression, which is essential for producing tablets with consistent weight.

Bulk Density and Tapped Density

These parameters reflect how the powder particles pack under different conditions.

- **Bulk Density (ρ_β)** is the mass of powder divided by the bulk volume it occupies before tapping.
- **Tapped Density (ρ□)** represents the mass of the same powder after being mechanically tapped or vibrated to minimize the void spaces.
- **Bulk density:** Bulk density (ρb) = W / Vb
- **W** = Weight of powder
- **Vb** = Bulk volume (untapped volume)

Hausner's Ratio (HR)

Hausner's ratio is another measure of inter-particle friction and powder flow, calculated as:**Hausner's Ratio:** HR = ρt / ρb

- **ρt** = Tapped density
- **ρb** = Bulk density

Moisture Content (Loss on Drying)

Moisture in the powder blend can affect both flow and compressibility. Excessive moisture causes sticking or picking during compression, whereas too little moisture can make tablets brittle. The **moisture content** is determined using a moisture analyzer or by the *Loss on Drying (LOD)* method, where the sample is dried at 105°C until a constant weight is achieved. The percentage of weight loss indicates the moisture level. For MDT formulations, an ideal moisture content is typically less than 5%. Controlled moisture ensures smooth compression and stability of hygroscopic components such as superdisintegrants and sweeteners.

Particle Size and Size Distribution

Particle size directly influences flow, compressibility, and the disintegration behavior of MDTs. Finer particles tend to have poor flow but promote faster disintegration and dissolution, while larger particles improve flow but may slow dissolution. An optimal particle size distribution, often achieved by sieving or granulation, ensures uniformity and consistent tablet properties. Particle size can be measured using sieve analysis, microscopy, or laser diffraction methods.

Blend Uniformity (Drug Content in Blend)

Uniform distribution of the active pharmaceutical ingredient (API) in the powder mixture is critical for dose uniformity in the final tablets. A representative sample of the powder blend is analyzed spectrophotometrically to confirm that the drug content is within 95–105% of the intended value. Proper blending time, equipment speed, and sequence of addition of excipients play a key role in achieving blend uniformity.

(B) Post-compression Parameters

Once the powder blend is compressed into tablets, the finished product must undergo several **post-compression evaluation tests** to ensure it meets all required quality attributes. These tests assess the **physical integrity, mechanical strength, uniformity, disintegration, and drug release performance** of the tablets. In the case of *Mouth Dissolving Tablets (MDTs)*, the evaluation focuses especially on rapid disintegration and patient acceptability.

Post-compression parameters are essential for maintaining batch-to-batch uniformity, ensuring compliance with pharmacopoeial specifications (as per IP, BP, and USP), and verifying that the tablet formulation performs as intended in the oral cavity and gastrointestinal tract.

General Appearance

The general appearance of a tablet reflects its **visual quality and acceptability**. Each batch is examined for **shape, size, color, surface texture, odour, and taste**.

Uniformity in appearance is vital for consumer confidence and identification. Tablets should be free from cracks, chipping, mottling, or capping.

- **Shape and size** are influenced by punch design and compression settings.
- **Color** is often due to coloring agents and must remain consistent across batches.
- **Surface texture** should be smooth to provide pleasant mouthfeel for MDTs.
- **Odour and taste** are particularly critical for MDTs since they disintegrate in the mouth; thus, sweeteners and flavoring agents are used to mask unpleasant drug taste.

Size, Shape, and Thickness

These parameters are measured using **a vernier caliper or micrometer screw gauge**. Uniform size and thickness are important for proper tablet packaging, handling, and mechanical stability.

- **Thickness** depends on the die fill and compression force. It should remain consistent (±5% variation) among tablets in a batch.
- Deviations in thickness may indicate variations in granule flow, compressibility, or improper adjustment of the compression machine.

In MDTs, a uniform and moderate thickness ensures both rapid disintegration and adequate strength.

Uniformity of Weight (Weight Variation Test)

This test ensures that tablets contain a uniform quantity of the powder blend, leading to consistent drug content.

Method: Twenty tablets are selected randomly and weighed individually. The average weight is calculated, and the percentage deviation of each tablet from the average is determined using the formula:

Weight variation (% deviation): % deviation = [(Wi − Wavg) / Wavg] × 100

where WiW_iWi is the individual tablet weight and WavgW_{avg}Wavg is the average weight.

- **Wi** = Individual tablet weight
- **Wavg** = Average weight of tablets

Hardness (Crushing Strength)

The **hardness** or **crushing strength** of a tablet measures the force required to break it diametrically. It reflects the tablet's mechanical integrity during handling, packaging, and transportation.

Hardness is measured using instruments such as the **Monsanto hardness tester**, **Pfizer tester**, or **Digital hardness tester**. The typical range for MDTs is **2–4 kg/cm²**, which provides sufficient strength while still allowing rapid disintegration in the mouth.

A balance between hardness and disintegration is crucial — higher hardness may delay disintegration, while low hardness may cause breakage and friability.

Friability

Friability measures the tablet's **resistance to abrasion or breakage** during handling and transport. The test is performed using a **Roche Friabilator**, where a sample of tablets (usually 20 tablets) is rotated at 25 rpm for 4 minutes (100 revolutions).

After testing, tablets are dedusted and reweighed. The percentage weight loss is calculated using the formula.

Friability: % Friability = [(Wi − Wf) / Wi] × 100

- **Wi** = Initial total weight of tablets
- **Wf** = Final weight after friabilator test

A friability value of **less than 1%** is considered acceptable. For MDTs, friability must be minimized to prevent chipping, as these tablets are often softer due to the inclusion of superdisintegrants and low compression forces.

Disintegration Time

This test determines the **time required for a tablet to break down into smaller fragments** under specified conditions. For MDTs, it simulates the rapid disintegration process in the oral cavity.

The test is carried out using a **disintegration test apparatus** with six glass tubes containing distilled water maintained at **37 ± 2°C**. The time taken for complete disintegration of the tablet, without any palpable core, is recorded.

According to the **European Pharmacopoeia**, the disintegration time for MDTs should be **less than 3 minutes**, while for high-performance formulations it may be within 30 seconds. The use of effective superdisintegrants like crospovidone and sodium starch glycolate ensures this rapid disintegration.

Wetting Time

The **wetting time** indirectly measures the time required for water to penetrate the tablet matrix, which is critical for the disintegration process.

Method: A tablet is placed on a folded tissue paper in a Petri dish containing a small volume of water (usually 5 ml) with a water-soluble dye. The time required for the water to reach the upper surface of the tablet (indicated by dye coloration) is recorded as wetting time.

A shorter wetting time implies faster water uptake and quicker disintegration. Ideal wetting time for MDTs ranges between **10–30 seconds**.

Water Absorption Ratio (R)

The **water absorption ratio** quantifies the ability of a tablet to absorb moisture, which affects disintegration behavior.

Water absorption ratio: R = [(Wa − Wb) / Wb] × 100

- **Wb** = Weight before wetting
- **Wa** = Weight after wetting

In-vitro Dispersion Time
This simple test measures the time required for a tablet to completely disperse in a small volume of liquid (usually 50 ml of water) maintained at 37°C. The endpoint is when no solid residue remains. For high-quality MDTs, the dispersion time should be **below 30 seconds**.

Content Uniformity Test
This test ensures **dose consistency** among individual tablets. Ten tablets are randomly selected, powdered, and analyzed for drug content using spectrophotometric or chromatographic methods (e.g., UV or HPLC).

According to pharmacopoeial standards, the individual content of each tablet should be within **85–115%** of the label claim, and the relative standard deviation (RSD) should not exceed **6%**.

Content uniformity ensures that each tablet delivers the intended therapeutic dose, especially important in low-dose drugs and MDT formulations.

In-vitro Dissolution Study
The dissolution study evaluates **the rate and extent of drug release** from the Mouth Dissolving Tablets. It predicts the tablet's performance *in vivo*.
Apparatus: USP Type II (Paddle) Dissolution apparatus
Medium: 900 ml of pH 6.8 phosphate buffer (or other relevant media)
Rotation Speed: 50 rpm
Temperature: 37 ± 0.5°C
Samples are withdrawn at specific intervals (e.g., 1, 3, 5, 10, 15 min), filtered, and analyzed spectrophotometrically to calculate cumulative % drug release. For most MDTs, at least **85% of the drug should be released within 15 minutes**, demonstrating rapid dissolution and potential for faster onset of action.

Surface pH
To ensure the tablet does not irritate the oral mucosa, the surface pH of MDTs is measured. Tablets are allowed to swell in 5 ml of distilled water for 2 hours, and the pH is measured using a pH meter.

The ideal surface pH should be **close to neutral (6.5–7.5)**, ensuring patient comfort and preventing mucosal irritation.

Taste Evaluation of MDT (Mouth Dissolving Tablet)
Taste evaluation is the process of assessing the palatability of a mouth-dissolving tablet to ensure that it has an acceptable or pleasant taste for the patient.

Methods of Evaluation.
1. Panel Testing (Human Taste Panel)
A group of 5–10 healthy volunteers is selected.
Each volunteer places the tablet or formulation on the tongue.

The taste is rated using a numerical or descriptive scale (e.g., very good, good, acceptable, bad).

2. Electronic Tongue (E-tongue)
An analytical instrument that detects and quantifies taste-masking efficiency using sensor arrays.
Provides objective and reproducible results.

3. In-vitro Taste Evaluation
The formulation is dissolved in simulated saliva.
The drug concentration released is analyzed by UV spectroscopy to estimate bitterness level.

TASTE MASKING METHODS FOR MDTs
Taste masking is essential to ensure patient acceptability of MDTs. Several techniques are employed depending on the drug properties.

Granulation and Particle Size Reduction
Drugs may be granulated using wet granulation or roller compaction with excipients such as sweeteners and flavors. Repeated sieving through fine meshes helps reduce particle size, minimizing direct contact of the drug with taste buds.

Coating Techniques
Drug particles can be coated directly or after granulation with suitable polymers. Polymer coating prevents the release of the bitter drug in the oral cavity while allowing release in the gastrointestinal tract.

Direct Blending
For tasteless drugs or drugs administered in very low doses, direct blending into a fast-disintegrating matrix is a simple and effective approach.

Adjustment
Many drugs exhibit reduced solubility at pH values different from that of saliva (approximately pH 5.9). Alkalizing agents such as sodium bicarbonate, sodium carbonate, sodium hydroxide, or calcium carbonate are added to modify the microenvironmental pH, thereby reducing bitterness. In some cases, bitterness can be effectively masked using sweeteners alone when pH adjustment is applied.

REGULATORY AND MARKET ASPECTS
FDA and ICH Guidelines
According to USFDA guidelines, MDTs should disintegrate within approximately 30 seconds, weigh less than 500 mg, and dissolve rapidly after administration. Patient acceptability, including taste, mouthfeel, and dosing convenience, is also emphasized. ICH guidelines recommend accelerated stability testing at controlled temperature and humidity conditions, with evaluation of parameters such as hardness, friability, dissolution, and disintegration.

Market Overview
Several MDT products are commercially available,

reflecting growing market acceptance. These products address patient-centric needs and offer improved convenience compared to conventional tablets.

STABILITY AND PACKING CONSIDERATION

Stability Concerns

Moisture can degrade drug stability by reducing potency, altering chemical composition, and promoting microbial growth. Such degradation affects the safety and efficacy of MDTs.

Packaging Solutions

To address moisture sensitivity, manufacturers employ moisture-barrier packaging materials and optimize formulations using moisture-resistant excipients. Proper storage conditions and protective packaging are essential to extend shelf life.

Shelf-Life Limitations

The hygroscopic nature of MDTs often results in a limited shelf life. Continuous monitoring of stability parameters and appropriate packaging strategies are necessary to ensure product quality throughout its intended lifespan.

FUTURE PROSPECTIVE

The future of MDTs is promising due to growing demand among pediatric and geriatric populations. Advances in excipients, taste masking, superdisintegrants, and packaging technologies will expand applications. MDTs may increasingly be used for personalized medicine, over-the-counter products, vitamins, and drugs with low bioavailability or high first-pass metabolism.

CONCLUSION

Mouth dissolving tablets represent an important advancement in oral drug delivery systems. Their performance relies on multiple disintegration mechanisms, careful formulation design, effective taste masking, and robust packaging. Despite challenges related to mechanical strength and moisture sensitivity, adherence to regulatory guidelines and advances in formulation technologies continue to support the successful development and commercialization of MDTs.

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